



# Oregon

Kate Brown, Governor

## Alcohol and Drug Policy Commission

201 High St SE  
c/o OTIS Suite 500  
Salem, OR 97301  
503-757-0989

December 20, 2021

Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer Street NE  
Salem, OR 97301

Dear Ms. Hatfield:

The Alcohol and Drug Policy Commission (ADPC) is an independent state agency created by the Oregon Legislature in 2009 to improve the effectiveness of substance use prevention, treatment, and recovery support services for all Oregonians. Last year, ADPC completed a Statewide Strategic Plan for Substance Use Services, which was approved by the Governor and the Legislature and is now Oregon's Strategic Plan for Substance Use Services. After reviewing the Policy Concept Papers for Oregon's 1115 Waiver, I'm pleased to see there are several proposals which align with strategies or activities in the Strategic Plan and, if approved, will positively impact the work of ADPC. Among these proposals are:

Waive federal rule preventing a person in custody from accessing Medicaid benefits. Currently, individuals who are justice-involved are not eligible for Medicaid coverage while in custody. Upon release these individuals can enroll or re-enroll for Medicaid coverage, but that can often be a two-week process. At the same time, many providers will not place someone on a waiting list until that person has proof of health insurance. This results in justice-involved people frequently waiting long periods of time to connect with a provider even though this same population of people experiences higher rates of behavioral health conditions. For these reasons and more, the Strategic Plan calls for ensuring a continuum of care for justice-involved people before, during, and post incarceration (Strategic Plan Objective 3.a.6). Waiving the federal rule mentioned above aligns very well with the Strategic Plan.

Waive eligibility rules so that Youth with Special Health Care Needs are covered up to age 26. It is not entirely clear from the Policy Concept Papers if Youth with Special Health Care Needs includes youth with behavioral health conditions, but if not I strongly urge you to include behavioral health in this group. Youth with substance use conditions frequently have contact with multiple systems, including juvenile justice and child welfare, which makes the transition into young adulthood even more challenging. Additionally, young adults are a population of concern in the Strategic Plan—it is estimated that almost ten percent of adults in Oregon have a substance use disorder, but when looking specifically at young adults age 18 to 25 the number jumps to 18 percent. Actions we can take that ease the transition into adulthood and offer support to young adults will help Oregon make progress on the Strategic Plan.

Waive federal covered services rules so that Oregon Health Plan members experiencing major life transitions can have social supports. People who are homeless, exiting the criminal justice system, or transitioning in and out of foster care (which includes aging out of Child Welfare) frequently have inconsistent access to medical care and support services. These populations of people also have higher rates of substance use disorders. Providing supports such as housing, transportation, food, and employment services to these and other Oregonians facing major life transitions will help reduce emergency room visits and criminal justice involvement. And for those who also have a substance use condition, providing these supports will help them maintain a treatment or recovery plan. The Strategic Plan highlights the need for an array of supports, such as the ones listed above, for those in treatment or recovery (Strategic Plan Objective 4.b.3). This proposal to provide social supports to Oregon Health Plan members facing major life transitions is in alignment with the Strategic Plan.

Waive federal covered services rules so that Oregon Health Plan members can use more types of providers. The Centers for Medicare and Medicaid Services (CMS), as well as the Substance Abuse and Mental Health Services Administration (SAMHSA), recognize that peer-delivered services are an effective way to support people in treatment, recovery, and more. Yet, today, we are not able to use Medicaid funds to pay for peer services outside of a treatment plan. I have voiced my concern multiple times about this situation because treatment and recovery are equally important parts of the substance use continuum of care, as is prevention, harm reduction, and other points along the continuum. Waiving federal rules so that Oregon Health Plan members have access to peers and other traditional health workers outside of a treatment plan is directly on point with the Strategic Plan, which calls for increasing access to Peer Mentors and Recovery Support Specialists (Strategic Plan Objective 4.a.4).

Thank you for this opportunity to submit comments regarding Oregon's 1115 Waiver application. I believe there are several opportunities through the waiver to advance Oregon's Strategic Plan, and I look forward to working with you and your colleagues on any next steps.

Sincerely,



Reginald C. Richardson, Ph.D., LCSW, ACSW  
Director

## BOARD OF DIRECTORS

Chair: Keren Brown Wilson  
Vice-Chair: Tony Leineweber  
Treasurer: Mark Stevenson  
Secretary: Tina Castañares  
Peggy Brey  
Kristen Connor  
Mary Jaeger  
Marvin Kaiser  
Paul Lumley  
Marcus Mundy  
Julie Reynolds  
Kimberly Solis

## EMERITUS BOARD MEMBERS

Martha Pelaez  
Janet Sehon  
Gary Withers

## COUNCIL OF ADVISORS

Connie Baldwin  
Richard Browdie  
Michael DeShane  
Mauro Hernandez  
Robert Hudson  
Marshall Kapp  
Nichole Maher  
Susan Reinhard  
Steven Vick

December 21, 2021

[1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Team Members:

AGE+ is an Oregon nonprofit focused on successful and equitable aging for all Oregonians by empowering communities, linking generations and stimulating innovation to make longer life an opportunity, not a burden.

AGE+ supports the Oregon Health Authority's efforts to improve health equity through the 1115 Waiver Renewal. Specifically:

1. We support the vision of an equity-centered system of health. Specifically, we agree revamping Oregon's metrics program so that equity is the primary organizing principle is an essential step in addressing historical mistakes. To achieve this, we support the value of offering communities significantly more say in spending decisions and identifying care and health supports they want, specifically by redistributing funds and decision-making power. We support a more person-centered system of health that aim to improve health and not just medical care.
2. One of our programs, Ties That Bind, supports grandparents and kin who step up to provide homes for children of parents who may be incarcerated, in treatment, or otherwise unable to parent. Providing this care is costly to individuals, but provide significant cost savings to DHS because the children do not enter foster care.
  - a. The kin caregivers need more support. We support the proposed Coordinated Transition Support package to assist families during these destabilizing transitions.
  - b. Many children in grandfamilies have suffered trauma. We support extending OHP Eligibility to every child at the point of diagnosis of behavioral health needs.
3. Because we work in rural places, we are concerned about the impact of the demographic shift that will soon see a majority of rural Oregon counties where residents 65+ top 25% of population. To ensure that these Oregonians are not left behind:
  - a. We support peer-based and Community Health Workers as local, strength-based solution to providing support to older adults.
  - b. We support improved rural access to behavioral health support.
  - c. We support expanded Medicaid support for housing, social supports and pre-treatment services for members with complex needs.

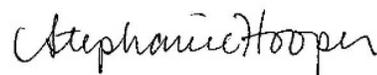
On behalf of Oregon's older adults, and especially on behalf of those historically marginalized communities, AGE+ applauds the creative thinking and fundamental hard work behind the 1115 Demonstration. Your work continues, and honors, the tradition of innovation and leadership of which Oregonians can be proud.

If we can further contribute to the success of the Waiver, we stand ready to help.

With respect,



Keren Brown Wilson, CEO



Stephanie Hooper, President

## Hatfield Michelle M

---

**From:** Alisha Morton <alisha.morton@multco.us>  
**Sent:** Thursday, December 2, 2021 8:18 AM  
**To:** 1115 Waiver Renewal  
**Subject:** Improving Health Outcomes by Streamlining Life and Coverage Transitions

You don't often get email from alisha.morton@multco.us. [Learn why this is important](#)

**Think twice** before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Hello-

My name is Alisha Morton, I am a Corrections Counselor and OHP Eligibility Specialist with Multnomah County Department of Community Justice. I have been supporting clients transitioning out of prison and jail for the last six years and a big part of their transition is obtaining health insurance for their multiple medical needs. I believe we are fortunate in our state to have someone within the Department of Corrections that signs people up for OHP before their release AND in Multnomah County we have a person that signs clients up for OHP before their release from jail and then you have me, once they are released who helps sign them up if they didn't get signed up prior to release, helps them with any issues they may be having with their OHP and helps them get connected to a PCP. I wish that every county in the state was able to have this kind of support for their justice involved clients.

Even though we have this support for justice involved clients there is still a gap that creates barriers and obstacles and that is the suspension or discontinuation of their benefits while in custody. I recently worked with a

mental health client who's behavior completely decompensated when he was released because he did not have the capability to walk from the jail to the local APD office to get his OHP turned back on again to get into the mental health crisis facility that he needed. Instead he traveled to Eugene and was eventually arrested and brought back to Multnomah County and placed in custody. Another example is for our very high acuity mental health clients the facilities in our community that work with this very particular and vulnerable population do not accept Open Card so it is imperative that once they are released that they are already enrolled into a CCO so they can be immediately accepted into these appropriate programs. When this doesn't happen it becomes very challenging to keep the clients and the community safe.

I am very pleased that the waiver includes providing a limited OHP benefit and CCO enrollments for OHP members in jail or a local corrections facility, including those awaiting adjudication. Thank you for adding to this to the waiver and I can't stress enough how much this will help the vulnerable clients that I work with on a daily basis.

If you have any questions for me on the matter please do not hesitate to reach out.

Alisha Morton

--

*Alisha Morton, BA, MPA*

Corrections Counselor

Dept. of Community Justice/ARC

Desk Phone: 503-988-8482

Work Cell: 971-533-4670



Friday, January 7, 2022

To: Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301  
[1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

From: AllCare Health  
1701 NE 7<sup>th</sup> St  
Grants Pass, OR 97526  
[josh.balloch@allcarehealth.com](mailto:josh.balloch@allcarehealth.com)

AllCare Health Public Comments Regarding the Draft 1115 Medicaid Waiver:

AllCare Health is pleased to support the general goals outlined in the Draft 1115 Medicaid Waiver. We support increasing access to coverage, creating better continuity of care and coordination for members experiencing transitions, improving financial flexibilities to address community health needs, constructing upstream health metrics and increasing community voices & accountability to address health inequities.

Overall, while we have a few operational and implementation concerns, we think the Draft 1115 Medicaid Waiver proposal is moving in the right direction on four out of the five goals. Below we provide some general comments and concerns.

**Increasing access to coverage:**

AllCare very much supports creating opportunities to increase health insurance coverage for Oregon health plan (OHP) members. Expanding eligibility and redetermination timelines will help ensure continuity of care for OHP members across the state. Evidence from Oregon and nationwide shows keeping continuity of care between providers and members improves health outcomes for members and reduces overall costs.

Our concern is, even if we maintain a 3.4% rate of growth for OHP, increasing the number of OHP members will greatly increase Oregon's share of Medicaid payments. In this waiver, we don't see a path to sustainably fund this increase in state matching dollars. As health care providers, we see the long-term value in making these investments in Medicaid, but we fear future state governments may not share this commitment. In order to maintain continuity of care for OHP members, we must have stable and reliable funding. We ask that the OHA outline a long term funding strategy through the waiver to fund this increase in state Medicaid obligation.

**Creating better continuity of care and coordination for members experiencing transitions:**

AllCare Health very much supports these efforts and applauds the Waiver's concept to break down silos in the different healthcare delivery settings. Tearing down barriers between delivery systems through



better coordination and clearer funding structures will close gaps in the system for members. The result will be better care for members and reduced gaps in care and duplicative services.

We do have concerns about the implementation of strategies proposed in the Draft 1115 Medicaid Waiver. Following establishment of CCOs in 2012, it took significant time and effort to break implementation barriers between mental, physical, and oral health. Equally difficult conversations are likely to occur if Oregon is successful in getting its waiver requests. CCOs and other stakeholders must have time and flexibility to make new integrated systems work. We request this flexibility be factored into any implementation plan.

**Improving financial flexibilities to address community health needs:**

AllCare Health has been a champion of financial flexibility for CCOs making upstream investments in health. Simply put, the current rate-setting procedures penalize CCOs for making such investments. And yet, even with those penalties, CCOs have spent millions of dollars investing in non-medical health-related support. Some of this has been captured by the OHA by considering Community Health Investments, but many other impactful upstream health investments are discounted as mere “administrative” expenditures. This needlessly discourages such investments.

We support the general concepts of creating flexibility and surety in CCO budgets. There are, however, key shortcomings in implementation of HB 3353 as outlined in the Draft Waiver. The Waiver is largely silent on the requirements funding must meet in order to be counted toward the 3% investment (*2021: HB 3335 Section 2 (3)*). The legislature contemplated the importance of these safeguards that create accountability for CCOs and the communities we serve. Those safeguards should be included as a focus of the waiver.

Including the 3% upstream health investment as medical expenditures for rate calculation, as outlined in HB 3353, is fundamental to our health system’s continued success. It is vitally important to the viability of the CCO model and moves Oregon even farther ahead as a Medicaid innovator.

**Constructing upstream health metrics**

AllCare Health supports the concept of applying CCO incentive metrics to encourage CCOs to make more upstream health investments. This is a system that is proven to work, and we would warn against significant changes to the current structure of the metrics-setting process. There could be significant unintended consequences. The Waiver should also make clear that these metrics are focused on a small amount of high value upstream investments. “Metric fatigue” is a concern, and Oregon Providers (and now Community Based Organizations) must focus the majority of their time on providing care.

**Increasing community voices & accountability to addresses health inequities**

AllCare Health and the AllCare Community Advisory Councils have made our concerns clear about the current proposed policies proposed in the Draft 1115 waiver. We have attached our comment letters to this email.

To be clear, AllCare is strongly supportive of incorporating more diverse voices and promoting community accountability to ensure that health needs of all people are being met. Our concern is that equity silos can create divergent efforts that are unsustainable in a “grant-based” system. This is



antithetical to the legislative intent of HB 3353. Quite simply, the program outlined in the current Draft Waiver does not shift power to the community as the legislature intended, rather it shifts power from local communities to the OHA.

It is our experience that the leading issue with sustainable equity investments in the community has been the fact that CCOs have never had a true global budget. These investments are strongly supported by our Community Advisory Councils, our CCO Board of Governors, and locally based organizations.

Our request is that you make the following meaningful changes to Oregon's 1115 Waiver Request:

- 1.) Follow the bi-partisan concepts laid out in HB 3353 as written and supported by more than 80% of the legislature.
- 2.) Before the Waiver Request is finalized, invite public comment, so stakeholders, especially Community Advisory Councils, can help ensure any waiver changes are in keeping with the intent of HB 3353 and avoid unintended consequences for OHP members.
- 3.) Make clear that the identified 3% of investments in health equity and SDOH-E be recognized as Medical Expenditures. This identification is crucial to make these investments sustainable.
- 4.) Make clear a request for full federal funding of these important upstream investments.

While we and our community have significant concerns about some implementation concepts in the waiver, four out of the five major pillars of the draft waiver are consistent with the Coordinated Care Model. We thank you for considering our recommended changes to the Draft 1115 Medicaid Waiver. We hope that as you consider these changes, robust community feedback will help refine the final waiver to benefit all Oregonians. AllCare Health stands ready and willing to help in that effort.

Sincerely,

AllCare Health



Thursday, December 9<sup>th</sup>, 2021

To: Oregon Health Policy Board  
Attention: David Bangsberg MSc, MD, MPH  
C/O: Tara Chetock, Oregon Health Authority  
[tara.a.chetock@dhsosha.state.or.us](mailto:tara.a.chetock@dhsosha.state.or.us)

From: Josh Balloch  
AllCare Health  
1701 NE 7<sup>th</sup> St  
Grants Pass, OR 97526  
[josh.balloch@allcarehealth.com](mailto:josh.balloch@allcarehealth.com)

Written public comment to the Oregon Health Policy Board for the December 7<sup>th</sup> 2021 meeting --  
RE: Draft Application for the 1115 Medicaid Waiver

Chair Bangsberg and members of the Oregon Health Policy Board,

AllCare Health is currently reviewing the 157-page publically available waiver application, and will be submitting formal comments soon. However, before those comments are completed, I wish to raise concern about this draft waiver's failure to comply with legislative direction, as outlined in HB 3353.

In 2020, when Oregon faced a massive budget shortfall because of the COVID pandemic, likely resulting in hundreds of millions of dollars taken from the Medicaid delivery system, many of us realized the impending negative impact on Oregon Health Plan members and providers. To minimize this impact, a strategy was created to use the 1115 Oregon Medicaid Waiver to leverage more federal dollars being directed into the Oregon Medicaid System. By allowing Coordinated Care Organizations to spend 3% of their funding on health equity improvements and upstream Social Determinants of Health investments, we could then provide significant health improvements for OHP members and the community as a whole. This strategy required that those funds count as "medical expenditures", ensuring the sustainability of those investments.

In late 2020, a coalition comprised of local equity groups, providers, Community Advisory Councils, and legislators, established a consensus that created House Bill 3353 (*Reference:* <https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB3353>). HB 3353 outlines a blue print for the 1115 Oregon Medicaid Wavier request in 2022, giving the Oregon Medicaid System more flexibility on spending Medicaid dollars. More importantly, it created local accountability for CCOs investing in the delivery system, in a way that meaningfully serves members and the communities as a whole.

During the 2021 session, the collation was focused on attaining comprehensive bi-partisan and bi-cameral support for HB 3353. The bill had four chief sponsors (Two Democrats and Two Republicans) and 22 regular sponsors (12 House Democrats; 6 House Republicans; 3 Senate Democrats and 1 Senate Republican). The broad legislative support resulted in the bill passing overwhelmingly (57-0 in the House; 19-10 in the Senate). This is the similar to the broad support enjoyed by the legislation that created the CCOs in 2011/2012.



This bi-partisan legislative support gives added credibility to Oregon's waiver request and demonstrates that funding and flexibility for Medicaid is a non-partisan core issue in Oregon. This is significant when Oregon is again seeking to be a national trailblazer for Medicaid.

Unfortunately, the Oregon Health Authority's Draft Waiver Proposal fails to match the language or the intent of HB 3353. The bill explicitly says CCOs are to "spend" their global budgets on specific investments. (*Reference: Section 2(1)(a) of HB 3353*). Instead, the OHA's draft application, in direct contravention of legislative intent, tells CCOs to give money to a newly formed third party that would "grant out" funds without CCO accountability.

The OHA's draft waiver request seemingly ignores the legislative directive to cause CCOs, at the local level, to be responsible for engaging the whole community in making health investments. (*Reference Section 2(3)(a) & (b) of HB 3353*). The waiver request also rejects the legislators' bi-partisan intent for accountability, by allowing a siloed, third party equity entity to make funding decisions. HB 3353 clearly states that expenditures "be approved by the coordinated care organization's community advisory council."

Another concerning aspect of the draft waiver is the misunderstanding of HB 3353's general operation. The bill specifically and intentionally outlines that unless the OHA can insure CMS will include the 3% expenditures as medical expenses **AND** is fully funded by the increased federal reimbursement, then the CCOs can "spend up to" 3%. Legislators made clear it is not a "shall spend", unless specific requirements are met (*Reference: Section 4 of HB 3353*).

Many of the accountability measures that were included in HB 3353, aimed at ensuring that community voices were present during the creation of spending strategies in an effort to hold both CCOs and the OHA accountable, were not included in the 1115 Draft Waiver. The bill states that in order for these dollars to be counted as this 3%, they have to be part of "a plan developed in collaboration with, or directed by, members of organizations or organizations that serve local priority populations that are underserved in communities served by the coordinated care organization." In short, the plan the CCOs use for investments (i.e. Community Health Improvement Plan or Health Equity Plan) must include voices from priority and underserved populations within the service region, in the development of that plan. (*Reference: Section 2(3)(a) of HB 3353*). Within HB 3353, there is clear direction that these investments must demonstrate "practice-based or community-based evidence", giving CCOs the flexibility they need in order to find innovative solutions in partnership with new community organizations, likely to serve smaller populations among the underserved communities. These requirements were included in the Bill as part of the discussion with RHECs and should apply to the full 3%, but the Draft Waiver only applies this to the third party equity silos. (*Reference: Section 2(3)(b) of HB 3353*).

There are many other conflicts between the current draft waiver proposal and HB 3353. This letter is only intended to highlight the most urgent concerns about the draft 1115 proposal, which I and other members of the coalition wish to bring to your attention.

The Oregon Health Policy Board must be informed of these concerns, as failure to follow both the language and intent of HB 3353 will create significant issues and unnecessary confusion. The lack of



alignment between the waiver and HB 3353, which is referenced many times in the waiver, will generate uncertainty when the Centers for Medicare and Medicaid (CMS) review Oregon's request. Confusion at CMS will make it difficult to obtain the flexible and sustainable funding Oregon needs to address health inequities by 2030. Failure to follow the language and intent of HB 3353 also disenfranchises partners, such as regional health equity commissions and community advisor councils, which supported and helped pass the bill. Importantly, creating a third party equity silo, will very likely fail to win the endorsement from many of HB 3353's bi-partisan supporters. Divisions in the federal Oregon Congressional delegation could create a reason for CMS to label the waiver as "partisan" and to reject it.

Many community members in our region are thoroughly disappointed about the current direction of this waiver. Concerns about third party equity silo concepts have been shared with the OHA many times, yet meaningful changes have not been made.

To be clear, AllCare is extremely supportive of incorporating more diverse voices and having community accountability to ensure that health needs of all people are being met. Our concern is that these third party equity silos create bifurcated efforts that are unsustainable in a "grant-based" system.

Based on our experience, the number one issue with a CCO's ability to support sustainable equity investments within the community, is the lack of a true global budget; not an absence of desire by our Community Advisory Councils, our CCO Board of Governors, or any of the locally-based organizations with whom we partner.

Our request to you, the Oregon Health Policy Board, is that you ask the OHA to make meaningful changes to Oregon's 1115 Waiver Request, in the following areas:

- 1.) Removal of the third party equity silos, replaced with bi-partisan concepts laid out in HB 3353, as written and supported by over 80% of the legislature.
- 2.) Make clearer the request that the identified 3% of investments in health equity and SDOH be recognized as Medical expenditures. This is key to making these investments sustainable.
- 3.) Make clearer a request for full federal funding of these important upstream investments.

HB 3353 was a significant bi-partisan accomplishment during a contentious legislative session. It is important that the negotiated cooperation of the stakeholders and legislators and their significant achievement is not squandered in this application to the Federal Government. Thank you for you considering this sincere request for the changes necessary for the waiver application to appropriately reflect House Bill 3353 and the will of the People of Oregon.

If you would like to discuss this further please feel free to call me anytime (503-508-5868).

Sincerely,

Josh Balloch  
AllCare Health  
Vice-President of Health Policy



Connected for Life

January 7, 2021

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Deputy Director Hittle:

The American Diabetes Association (ADA) appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

I am writing on behalf of the ADA, the nation's largest voluntary health organization concerned with the health of people with diabetes. An estimated 34 million Americans and nearly 457,447 Oregonians have diabetes, a chronic illness that requires continuing medical care and ongoing patient self-management to prevent acute complications and reduce the risk of long-term complications, such as blindness, amputation, kidney failure, heart attack, and stroke.

The ADA is committed to ensuring that Oregon's Medicaid program provides quality and affordable healthcare coverage. The American Diabetes Association appreciates the focus that the Oregon Health Program has placed on equitable access to healthcare in the 1115 Demonstration Waiver. In addition, Oregon's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

The ADA offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Program.

#### *Continuous Eligibility*

ADA supports the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>i</sup> Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>ii</sup> Continuous eligibility will help reduce these negative health outcomes.

#### *Closed Formulary*

ADA is concerned by the proposal to transition to a closed formulary for adult beneficiaries. Diseases present differently in different patients. Prescription drugs have different indications, different mechanisms of action and different side effects, depending on the person's diagnosis and comorbidities. A closed formulary limits the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to the state. Yet people with diabetes may need to rely on a broad range of medications, as well as various technologies for administering insulin and



Connected **for Life**

monitoring glucose levels, in order to support proper diabetes management and avoid adverse outcomes.

Our organization is disappointed that Oregon's proposal does not even include an appeals process for patients to access non-formulary medications. However, even an appeals process

or exemptions for certain classes drugs would not eliminate the barriers to care that patients would face with a closed formulary.

Additionally, Oregon's proposal to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through FDA's accelerated approval processes, will also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new treatments have been approved through an accelerated approval process that benefit patients. All patients enrolled in Oregon's Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life.

The ADA requests that the Oregon Health Program remove these requests and provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

#### *Retroactive Coverage*

The ADA is concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. Eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as Diabetes, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>iii</sup> Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>iv</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb



Connected **for Life**

uncompensated care costs. The ADA opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

Thank you for the opportunity to provide comments. If you have questions or would like to discuss this issue, please contact me at 1-800-676-4065 x 7207 or [lkeller@diabetes.org](mailto:lkeller@diabetes.org).

Sincerely,

A handwritten signature in black ink that reads "Laura Keller".

Laura Keller  
Managing Director Advocacy

---

<sup>i</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/center-for-children-and-families/gaps-in-coverage-a-look-at-child-health-insurance-trends)

<sup>ii</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>iii</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at:

<https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>iv</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)



1/4/22

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Deputy Director Hittle:

The American Heart Association (AHA) appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

The AHA represents over 100 million patients with cardiovascular disease (CVD) including many who rely on Medicaid as their primary source of care. Nationally, about 1 in 10 adults with Medicaid coverage are estimated to have cardiovascular disease, with 6 in 10 having multiple chronic conditions.<sup>1</sup> Because low-income populations are disproportionately affected by CVD—with these adults reporting higher rates of heart disease, hypertension, and stroke—Medicaid serves as the coverage backbone for the healthcare services these individuals need.

The AHA is committed to ensuring that Oregon's Medicaid program provides quality and affordable healthcare coverage and appreciates the focus that the Oregon Health Program has placed on equitable access to healthcare through the 1115 Demonstration Waiver. In addition, Oregon's request to provide multi-year continuous enrollment for children under six, continuous eligibility for all beneficiaries ages six and over, and extended benefits to incarcerated individuals pre-release will help to eliminate gaps in coverage. Our organization is supportive of Oregon's efforts to improve the continuity of care for individuals with serious and chronic health conditions. Unfortunately, this waiver contains a few areas that may undermine access to care for patients with cardiovascular disease. The AHA would like to offer the following comments on the proposed five-year extension of the "Oregon Health Plan" 1115 demonstration.

### ***Multi-year Continuous Eligibility***

The AHA enthusiastically supports Oregon's request for continuous eligibility for all Medicaid beneficiaries. Continuous eligibility reduces gaps in coverage which prevents patients from accessing the care that they need. It also increases equitable access to care, as studies show children of color are more likely to be affected by gaps in coverage.<sup>2</sup> Research has also shown individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>3</sup> Continuous eligibility will help reduce these negative health outcomes.

### ***Closed Formulary***

The AHA is concerned by the proposal to transition to a closed formulary for adult beneficiaries. Chronic conditions such as cardiovascular disease and uncontrolled hypertension present differently in different patients. Prescription drugs have different indicators and mechanisms of action and side effects depending on the person's diagnosis and comorbidities. A closed formulary limits the provider's ability to prescribe pharmaceutical interventions for optimal patient treatment and management of disease.

### ***Retroactive Coverage***

The AHA would like to encourage Oregon to reevaluate this waiver’s proposal as it relates to retroactive eligibility for coverage and recommends removal of limitations for all Medicaid beneficiaries. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common for individuals to be unaware they are eligible for Medicaid until a medical event or diagnosis occurs—this is especially true for pregnant people. Eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as cardiovascular disease, to begin treatment without being burdened by medical debt prior to their official eligibility determination. Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor’s office or pharmacy.

### ***Waiver of Early and Periodic Screening, Diagnostic and Treatment***

Oregon is the only state with an EPSDT waiver. In every other state, under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called “Early and Periodic Screening, Diagnostic and Treatment” (EPSDT) to ensure that they receive “age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting.” Many conditions diagnosable during childhood can have lifelong cardiovascular impacts, and we are concerned there is not enough evidence to show that exclusion of coverage for EPSDT services supports the health of patients across their lifetime. Therefore, we encourage Oregon to strongly reconsider this.

### ***Investments in Social Determinants of Health Services and Community Capacity***

The AHA applauds Oregon’s proposal to expand non-medical services to address the needs of the “whole person” and provide transitional care to tackle health equity challenges experienced by Medicaid beneficiaries. This forward-thinking approach to help high-risk populations access critical supports needed to improve health conditions and address social determinants of health advances the objectives of the state’s Medicaid program.

We stand ready to partner with you to further expand care for Medicaid recipients and to offer our continued guidance and support as you review ways to implement additional actions to protect vulnerable populations. If you have questions or would like to discuss further, please contact **Christina Bodamer, Oregon Director of Government Relations** at [Christina.Bodamer@heart.org](mailto:Christina.Bodamer@heart.org).

Thank you for the opportunity to provide comments.

Christina Bodamer

---

<sup>1</sup> Chapel, JM, Ritchey MD, Zhang D, Wang G. Prevalence and medical costs of chronic diseases among adult Medicaid beneficiaries. 2017; 53(6):S143-S154. [https://www.ajpmonline.org/article/S0749-3797\(17\)30426-9/fulltext](https://www.ajpmonline.org/article/S0749-3797(17)30426-9/fulltext)

<sup>2</sup> Osorio, Aubrianna. Alker, Joan, “Gaps in Coverage: A Look at Child Health Insurance Trends”, Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/health-policy/institute/publications/gaps-in-coverage-a-look-at-child-health-insurance-trends)

<sup>3</sup><https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.



January 6, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Deputy Director Hittle:

The American Lung Association appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

The American Lung Association is the oldest voluntary public health association in the United States, currently representing the more than 36 million Americans living with lung diseases, including more than 577,000 Oregonians. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education, and advocacy.

The American Lung Association is committed to ensuring that Oregon's Medicaid program provides quality and affordable healthcare coverage. The American Lung Association appreciates the focus the Oregon Health Program has placed on equitable access to healthcare in the 1115 Demonstration Waiver. In addition, Oregon's request to provide multi-year continuous enrollment for children under six and two-year continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver also contains multiple proposals that undermine access to care for patients with lung disease. The American Lung Association is deeply concerned with the proposed closed formulary for adult beneficiaries, which will make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries and to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one, as both proposals will significantly jeopardize access to care for patients we represent.

The American Lung Association offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Program:

*Continuous Eligibility*

The American Lung Association supports the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>1</sup> Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have

more emergency department visits.<sup>2</sup> For example, patients with asthma may struggle to maintain control over their symptoms without regular doctor's visits and prescription refills, leading to more frequent asthma attacks. Continuous eligibility will help reduce these negative health outcomes for all patients.

#### *Closed Formulary*

The American Lung Association is concerned by the proposal to transition to a closed formulary for adult beneficiaries. Diseases present differently in different patients. Prescription drugs have different indications, different mechanisms of action and different side effects, depending on the person's diagnosis and comorbidities. A closed formulary limits the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to the state.

The Lung Association is disappointed that Oregon's proposal does not even include an appeals process for patients to access non-formulary medications. However, even an appeals process or exemptions for certain classes of drugs would not eliminate the barriers to care patients would face with a closed formulary. Appeals processes can cost patients important time while waiting for the medication that they need to be approved. Patients may also be forced to spend months on the trial and failure of a formulary-preferred drug before being able to access the prescription they need. Barriers like these to medication access can ultimately have negative outcomes for patients' health.

Additionally, Oregon's proposal to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through the Food and Drug Administration's (FDA) accelerated approval processes, will also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new treatments have been approved through an accelerated approval process that benefit patients. In particular, patients with lung cancer would be unable to access potentially life-saving treatments as research continues to advance and promising new drugs are receiving accelerated approval from the FDA. All patients enrolled in Oregon's Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life.

The American Lung Association requests that the Oregon Health Program remove these requests and provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

#### *Retroactive Coverage*

The American Lung Association is concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind, and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. While waiting for their application to be approved, eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete. This can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as lung cancer, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical

costs with the elimination of retroactive eligibility.<sup>3</sup> Without retroactive eligibility, Medicaid enrollees could face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care because of the waiver.<sup>4</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. The American Lung Association opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

#### *EPSDT Benefit and Prioritized Service List*

The American Lung Association is opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). The purpose of the EPSDT benefit is to ensure that children receive appropriate healthcare, however, the limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services. Many of the services that have not been prioritized are for serious and concerning conditions. These limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued elimination of the EPSDT benefit is a step in the opposite direction. For example, children of color are enrolled in Medicaid at disproportionately higher rates<sup>5</sup> and as mentioned before, are also more likely to be affected by gaps in coverage.<sup>6</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit.

The American Lung Association urges the state to remove restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit. We also urge the state to remove the prioritized list to ensure all patients are able to receive the care they need to manage their health conditions.

#### *Coverage for Individuals who are Incarcerated and Institutionalized*

The American Lung Association has questions about the proposed continuous coverage for incarcerated and institutionalized individuals. While the American Lung Association supports transition-related benefits as this would fill a care gap and increase health equity, it is not entirely clear what services for incarcerated individuals will be funded through Medicaid. The state should explain how it will invest any savings in community-based services to keep individuals out of the justice system and develop more concrete guidelines on how the proposed Medicaid coverage will meaningfully impact care for the justice-involved population.

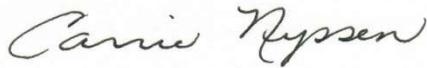
#### *Additional Services*

The Lung Association appreciates the demonstration's focus on health-related social needs. As the state moves forward with this proposal, it is critical that these services are supplementing, not supplanting, services currently provided under the state plan. We urge the state to develop rates based on all state

plan services and supplement those rates by adding health-related social needs services to ensure patients can access all of the care that they need.

Thank you for the opportunity to provide comments.

Sincerely,



Carrie Nyssen  
Senior Director, Advocacy in Oregon  
American Lung Association

---

<sup>1</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/health-policy-institute/publications/gaps-in-coverage-a-look-at-child-health-insurance-trends)

<sup>2</sup><https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>3</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>4</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>5</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. EPSDT-At-Risk-Final.pdf (georgetown.edu)

<sup>6</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/health-policy-institute/publications/gaps-in-coverage-a-look-at-child-health-insurance-trends)



**January 7, 2022**

**To: OHA 1115 Waiver Renewal Team**

**Re: 1115 Waiver Renewal Comments**

**From: Association of Oregon Community Mental Health Programs**

---

These comments are submitted on behalf of the Association of Oregon Community Mental Health Programs (AOCMHP), representing all 32 CMHPs across the state, who have responsibilities for local behavioral health system management and services, from community-wide prevention to acute, forensic and crisis services delivery and coordination.

First, we agree with maximizing OHP Coverage in all categories listed in the draft 1115 waiver renewal.

Second, we agree on key benefit changes for populations who are transitioning from institutional care and incarceration, and from houselessness to residential treatment or supported housing. We also support key investments in social determinants of health to help people recover and thrive in their own communities.

In addition to Housing Supports, Food Assistance, Education Supports, Employment Supports, Health Related Transportation, and Climate Supports, we would like outreach and engagement, or pre-treatment services, to be included in the allowable service array. Outreach and engagement are essential to build trust and rapport with marginalized individuals who may not be willing to engage in other services for some time. Outreach and engagement serve as a bridge to the initial SDOH services, which hopefully lead to mental health and substance use treatment down the road. As mentioned in the draft waiver renewal, outreach and engagement could be paid through the flexible use of health-related services funds and meet the criteria for improving care delivery and overall health and well-being.

We highly value the focus on peer support services for various transitional services and support the wide expansion of peer support reimbursement. We would also add qualified mental health associates (QMHA) as a provider type to assist people during transitions, including outreach and engagement.

Our third comment is to express enthusiastic support for allowing people in custody to access or retain Medicaid benefits, including youth in the juvenile corrections system for the duration

of their involvement, adults in prison or jail up to 90 days pre-release, and adults within 90 days of discharge from the Oregon State Hospital. These are all policies we have been advocating for at the federal level for years. Maybe it will take states, through waivers, to demonstrate to the federal government that allowing people to retain their Medicaid benefits to access the care they need immediately will result in better health outcomes and lower costs.

Our fourth comment is to emphasize the need for behavioral health investment and incentives to enable the public behavioral health system to retain and recruit its workforce. As mentioned in the waiver renewal draft, one of the CCO 2.0 priorities was to improve the behavioral health system. However, it was noted that the “distribution of spending within Oregon’s health care system (e.g., the amounts split between physical, behavioral, and oral health) remains largely the same, indicating spending is following historical habits and market power, rather than a true shift in focus to population health.”

The public behavioral health system has always served many of the most marginalized people, who have been disproportionately impacted by the COVID-19 pandemic and climate disasters. The public behavioral health system, together with social service agencies, provides upstream services and are first responders to help community members in distress and to stay safe. We know upstream care prevents poor health outcomes and high cost care later. Therefore, we would like to see flexibility in moving funding from medical to behavioral health and social services, without impacting the 3.4% cost growth threshold. If the public behavioral health system were able to receive more Medicaid investments, coupled with state general funds and other funds, we will be able to retain and recruit a more sustainable and diverse workforce with living wages.

On behalf of our AOCMHP membership, I want to express our appreciation for OHA’s Medicaid program innovation and dedication to improving health outcomes and striving for health equity. Thank you for this opportunity to provide comments on the 1115 waiver renewal draft and we look forward to working with you as system partners to implement the 2022-2027 waiver.

Sincerely,

A handwritten signature in cursive script that reads "Cheryl L. Ramirez".

Cherryl L Ramirez  
Executive Director, AOCMHP



January 7, 2022

To: Health Policy and Analytics Medicaid Waiver Renewal Team, Oregon Health Authority  
Subject: 2022 OHA Medicaid Waiver Renewal Feedback

APANO, PCUN, and Family Forward have recently come together as a newly formed coalition to create an effective health justice advocacy campaign across our three diverse organizations. The communities we collectively organize - mothers, caregivers, refugees, farmworkers and immigrants - have always lacked reliable access to health care and mental health care services. During this time, as a result of increasing hate crimes and incidents of racial violence, the COVID-19 pandemic, and the economic recession, we are seeing our communities' elevated need for mental health care support services.

We are submitting this testimony to express our coalition's support, concerns, and encourage adjustments for the following proposed changes in the Oregon Medicaid Waiver application.

- 1) We support the Oregon Health Authority's (OHA) decision to continue allowing people to self-attest their income when applying for Oregon Health Plan (OHP). This is not only helpful to increasing access during a public emergency but also in general for vulnerable individuals.
- 2) We support OHA's proposal to expedite OHA enrollment for SNAP recipients. This is an efficient way for state agencies to work together and help promote two kinds of critical social services. **We recommend that individuals be notified of the opportunity in different ways, including a phone call, email, mailed letter, and through word of mouth from community based organizations. The notification should be available in multiple languages to ensure that as many Oregonians as possible are aware of their eligibility for OHP enrollment.**
- 3) We support continuous enrollment for children until age 6 and two-year continuous eligibility for 6 and up. This is especially important for families who are disproportionately impacted by existing conditions and public emergencies.
- 4) We strongly support OHA's request to waive the federal rule which prevents a person in custody from accessing Medicaid benefits. We also support the request for a federal match to support coverage for individuals in custody, and **encourage the OHA to expand this proposal to include access for individuals prior to reentry to set the stage for coordination of care and connection to health care and other services in the community.**



Our coalition echoes OHA's comments that people of color are over-represented in the criminal justice system, which means that they are also most vulnerable to gaps in healthcare coverage while transitioning from custody. Many women in Oregon who enter the prison system are also mothers and caregivers who heavily rely on medical and mental health care from OHP.

- 5) We strongly support identifying Housing, Transportation, Food assistance, Employment Supports, and Exposure to Climate Events as the five areas of SDOH (social determinants of health) and providing additional assistance during those life transitions.

**We urge the OHA to include an additional area which includes becoming a new parent as a life transition.** We suggest adding this area so that the OHA can provide additional assistance and access for new parents including, but not limited to, health coverage for a new baby, Temporary Assistance for Needy Families (TANF), and child care subsidies.

**Additionally, we strongly encourage adding child care services as a benefit/social support under the OHA's proposed changes to Employment Supports.** For mothers and caregivers, lack of affordable and accessible child care is a significant obstacle to entering and re-entering the workforce. This language could read "Child care services for a parent/guardian/any individual who has official caretaking duties for a child".

- 6) **Under the "Exposure to Climate Events" section within the five SDOH, we recommend adding technology assistance for learning for students/kids, as well as wifi hotspots for students/workers to access important services and learning.** Technology and access to the internet continue to be barriers for impacted families before, during and after public emergencies such as extreme climate events.
- 7) Our coalition also strongly supports OHA's proposal to expand the infrastructure needed to support access to services using providers outside of the medical model. We believe that it is important for OHP members to receive care from providers within their own communities regardless of location/whether they are "in-network". Receiving care from community health workers, personal health navigators, peer wellness and support specialists and doulas will ensure trust between provider/patient, and allow for culturally responsive services for OHP members.

**We encourage OHA to take it one step further and explore other types of non-traditional community care/healing work that federal requirements may not allow, and titles that are not considered to be Traditional Health Workers (TIW).**



- 8) **We have concerns about the OHA seeking a commercial-style closed formulary approach** to reach agreement with pharmaceutical companies. We are uncertain on what this could mean for access to prescription drugs particularly for those with behavioral and mental health needs, disabilities and other chronic conditions.
  
- 9) Lastly, we are pleased to see continued funding and investments going towards community based organizations (CBOs) and community investment collaboratives (CICs). **We highly recommend that these investments also go towards CBOs who are currently working on retention of the behavioral health workforce, (especially BIPOC providers) as a method of capacity building that OHA mentions.**

The Oregon Medicaid Waiver process is a new area of policy change/renewal that we, as a coalition committed to furthering health equity, have appreciated learning more about through our research. This process is foundational to the work we are doing increasing access for most impacted communities.

Thank you for your consideration of our feedback.

Sincerely,

Lisa Kwon, Policy Manager, Family Forward Oregon

Coua Xiong, Interim Advocacy and Civic Engagement Director, APANO

January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301  
Submitted via email to [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Re: Comments on the Oregon's 1115 Demonstration Waiver for the Oregon Health Program

Dear Deputy Director Hittle:

The Arthritis Foundation appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program. Arthritis is an umbrella term to describe more than 100 types of diseases related to the bones and joints. This chronic disease is America's number one cause of disability and is expected to conservatively impact nearly 80 million Americans by 2040. By any measure, arthritis is an urgent national priority that remains underappreciated in the spheres of federal public health research and medical innovation. While life-changing medicines have undoubtedly transformed the lives of people with arthritis, many challenges remain, from high out-of-pocket costs to continuous administrative burdens, all on top of managing their disease symptoms.

The Arthritis Foundation supports a holistic approach to care for people with arthritis, with the understanding that people with this chronic disease often rely on multiple care providers to manage their symptoms, ranging from primary care physicians to rheumatologists, orthopedic surgeons to physical therapists. We advocate for patient-centered care that recognizes the importance of patient access to multiple providers and services, and the importance of self-management for forms of the disease like osteoarthritis (OA) that have no disease-modifying therapeutics.

The Arthritis Foundation is committed to ensuring that Oregon's Medicaid program provides quality and affordable healthcare coverage. The Arthritis Foundation appreciates the focus that the Oregon Health Program has placed on equitable access to healthcare in the 1115 Demonstration Waiver. In addition, Oregon's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver request contains multiple proposals that undermine access to care for patients with arthritis. We are concerned with the proposed closed formulary for adult beneficiaries, which would make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries and to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one, as both proposals will significantly jeopardize access to care for patients we represent.

The Arthritis Foundation offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Program.

### *Continuous Eligibility*

The Arthritis Foundation supports the request for continuous enrollment for children aged 0-5 (until their sixth birthday) and two-year continuous eligibility for beneficiaries over the age of five. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need, especially for children of color, as studies show they are more likely to experience coverage gaps.<sup>1</sup> Research also shows that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>2</sup> Specifically for arthritis patients, the previously mentioned delays in care can lead to joint damage and joint destruction and other negative health outcomes. In addition, the Centers for Medicare & Medicaid Services has addressed the importance of continuous coverage by stating that "eliminating the cycling on and off of coverage during the year reduces state time and money wasted on unnecessary paperwork and preventable care needs."<sup>3</sup> Continuous eligibility will help reduce these negative health outcomes and administrative burden issues.

### *Closed Formulary*

We are concerned by the proposal to transition to a closed formulary for adult beneficiaries. Diseases present differently in different patients, and it is often difficult to know which treatment will work best for any given patient. In fact, our surveys among rheumatoid arthritis patients show that patients cycle through an average of 2.5 medications before they find one that works for them. Prescription drugs have different indications, different mechanisms of action and different side effects, depending on the person's diagnosis and comorbidities. A closed formulary limits the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to the state.

Our organization is disappointed that Oregon's proposal does not include an appeals process for patients to access non-formulary medications. However, even an appeals process or exemption for certain classes of drugs would not eliminate the barriers to care patients would face with a closed formulary. Arthritis patients will often report that their medications can become less effective over time and they have to work with their health care provider to find a new medication that works for them. A closed formulary will restrict an arthritis patient's ability to find medications that work best for them.

Additionally, Oregon's proposal to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through FDA's accelerated approval processes, will also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new treatments that benefit patients have been approved through an accelerated approval process. Patients with chronic diseases like arthritis need uninterrupted access to their treatments to maintain their health and this proposal could impede their ability to access the best treatment for them, potentially leading to negative health outcomes. All patients enrolled in Oregon's Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life.

---

<sup>1</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families (georgetown.edu)

<sup>2</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>3</sup> <https://www.medicare.gov/medicaid/enrollment-strategies/continuous-eligibility-medicare-and-chip-coverage/index.html>

The Arthritis Foundation requests that the Oregon Health Program remove these requests and provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

#### *Retroactive Coverage*

The Arthritis Foundation is concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. Eligible applicants may also delay necessary health care until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as arthritis, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>4</sup> Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>5</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. We oppose the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

#### *EPSDT Benefit*

The Arthritis Foundation is opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). The purpose of the EPSDT benefit is to ensure that children receive appropriate healthcare. However, the limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services. Many of the services that have not been prioritized are for serious and concerning conditions, and these limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. For example, children

---

<sup>4</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/11115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>5</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

of color are enrolled in Medicaid at disproportionately higher rates<sup>6</sup> and as mentioned before, are also more likely to be affected by gaps in coverage.<sup>7</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit.

The Arthritis Foundation supports the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

Again, thank you for the opportunity to comment on your state's 1115 Demonstration Waiver for the Oregon Health Program and we look forward to future opportunities to engage with you. Please contact me at [ahyde@arthritis.org](mailto:ahyde@arthritis.org) with any questions or if we can provide additional information.

Sincerely,



Anna Hyde  
Vice President, Advocacy and Access  
Arthritis Foundation

---

<sup>6</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. EPSDT-At-Risk-Final.pdf (georgetown.edu)

<sup>7</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families (georgetown.edu)



ASSOCIATION FOR CLINICAL ONCOLOGY

January 7, 2022

Director Patrick Allen  
Oregon Health Authority  
Attn: Michelle Hatfield  
500 Summer St. NE, 5<sup>th</sup> Floor, E65  
Salem, OR 97301

Dear Director Allen,

The Association for Clinical Oncology (ASCO) is writing to express concerns with certain provisions of the [Oregon Health Plan 1115 Demonstration Waiver Application for Renewal](#) put forth by the Oregon Health Authority (OHA). Specifically, the proposed closed formulary may prevent Oregon Health Plan (OHP) patients with cancer from getting the best treatment.

ASCO is a national organization representing physicians who care for people with cancer. With nearly 45,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality cancer care.

The proposal to implement a restrictive formulary, in some instances with only one drug per therapeutic class, is a significant concern for continued access and potential health outcomes for OHP cancer patients. We are encouraged by the mitigation strategies to address unintended consequences, but the policies outlined in this proposal could delay care, prevent access to the most appropriate treatment for a patient's disease, and jeopardize chances of a successful outcome.

Prescription drugs have different indications, different mechanisms of action, and different side effects, depending on the diagnosis and comorbidities of an individual patient. While we acknowledge some of the best cancer drugs have a high cost, restricting OHP's drug benefits to such a tightly restricted formulary would limit the ability of providers to make the best medical decisions for the care of their patients. Cancer patients represent a special population that should be largely exempt from regulations intended to restrict access or limit doses, in recognition of the unique nature of the disease, its treatment, and potentially life-long sequelae. Cancer is a heterogeneous disease, with some forms experiencing high rates of mortality and others having an indolent biology extending over many years. Patients suffering from chronic, life-threatening conditions need a guarantee of access to the appropriate prescription drugs critical to treating their disease.

ASCO applauds the Oregon Health Authority's efforts in working to deliver greater access to care for the state's most vulnerable patients. If you have questions or would like assistance on any issue involving the care of individuals with cancer, please contact Aaron Segel at ASCO at [aaron.segel@asco.org](mailto:aaron.segel@asco.org).

Sincerely,

A handwritten signature in black ink, appearing to read "H. Burris III", with a horizontal flourish extending to the right.

Howard A. Burris III, MD, FACP, FASCO  
Chair of the Board  
Association for Clinical Oncology



Christian Moller-Andersen, Executive Director, A Smile for Kids  
Comments on OHA's Application for Renewal and Amendment of 1115 Waiver  
Submitted on 12/31/21 via the OHA public comment portal:  
[https://mslc.qualtrics.com/jfe/form/SV\\_7O1XVYN2bJqvd8G](https://mslc.qualtrics.com/jfe/form/SV_7O1XVYN2bJqvd8G)

**It is time to address the orthodontia inequity in Oregon's Medicaid program.** Oregon's current 1115 Medicaid waiver waives the federal requirements under the Early and Periodic Screening, Diagnostic and Testing (EPSDT) benefit for services listed below line 471 on the prioritized list of health services. Oregon's draft Application for Renewal and Amendment of the 1115 Waiver, dated 12-1-2021, proposes to continue to *"Restrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one."* (See pages 42, 147, and 156.)

As treatment of handicapping malocclusion is listed at line 618 of the current prioritized list, well below the line 471 cut off, the Oregon Health Plan (OHP) is proposing to continue to severely restrict children's access to medically necessary orthodontia services. Currently these services are covered by the OHP only when related to the treatment of cleft lip, cleft palate, or another craniofacial anomaly. Oregon is unique in the country in this respect. As required by EPSDT, all other state Medicaid programs cover children's orthodontia when necessary to correct or ameliorate medical conditions such as severe malocclusion. This coverage is required under federal law (unless waived) and enumerated in the Centers for Medicare & Medicaid Services' EPSDT Guidelines. It is time for Oregon to join every other state in offering this coverage.

**In this 1115 renewal, the Oregon Health Authority (OHA) should cease waiving EPSDT coverage for non-prioritized services.** As noted above, the waiver renewal application includes a request to continue the waiver of EPSDT requirements such that treatment needs identified during an EPSDT screening that are not consistent with the prioritized list of health services for children over age one would not be covered. We believe that continuing this waiver is unnecessary for OHA to meet its stated goals. Federal Medicaid law already provides all the tools a state needs to ensure that services are covered only when medically necessary. This gives states the necessary discretion to design an individualized benefit that also meets State fiscal goals. Forty-nine states and the District of Columbia have demonstrated that it is possible to craft coverage guidelines for children's orthodontia, along with individual medical necessity determination protocols, that ensure provision of the service only to children who need it. We stand ready to help Oregon do the same.

**Providing medically necessary orthodontia services to children covered through the Oregon Health Plan will advance health equity.** Severe malocclusion is a life-altering condition. It interferes with eating, speaking, sleeping, smiling, and normal social relating. It can affect both the physical and the social/emotional development of children. Its impacts can be felt over a lifetime in the loss of achievements in education, possibilities in employment, and a reduction in overall health and wellness, including mental health. The remedy for severe malocclusion – orthodontia – is well-established but only readily available to middle- and upper-income children. It is not currently available to low-income children in Oregon except through the very limited resources of A Smile for Kids (ASK), a charity that is able to serve fewer than 100 children each year. A failure to address severe malocclusion can combine with other social determinants of health to interfere with a child’s ability to access a healthy and successful life trajectory, leading to greater dependency and higher health care costs over a lifetime. Addressing this coverage gap is an essential part of Oregon’s aim, in this renewal package, to create more equity in health care and in health outcomes.

**Example:**

Oscar (name changed) entered the ASK orthodontic program when he was 13 years old in seventh grade. He suffered from a handicapping malocclusion, which led to teasing and bullying by peers. Oscar had a hard time with eating, speaking and drinking, and endured pain in his mouth due to the malocclusion. All of these challenges were exacerbated by the relentless teasing. He grew up in a family of eight with an annual household income of \$28,000. Both parents were undocumented immigrants, so work and income options were limited for them.

Under current OHP coverage and the limitations in the proposed renewal of the Medicaid Waiver, the State of Oregon is telling kids like Oliver that his need for braces is not important enough and that he’ll simply have to get used to it and somehow make it through despite this massive barrier. Before and after photos below:



Although the direct correlation is difficult to prove scientifically, Oscar went on to complete the orthodontic treatment funded by ASK, improved his grades in school, graduated high school and is now sophomore at private university in Oregon with a full four-year academic scholarship, majoring in political science. Oscar wants to be an attorney.

When asked to identify obstacles when growing up, Oscar provided the following answer: *"My teeth were definitely one of 2 obstacles. The other obstacle being limited financial resources. Having braces gave me the confidence to take my education and its opportunities to the next level. I don't think I would be where I am now if I had not had the braces."*

**To successfully meet its purpose, a new orthodontia benefit will need to be adequately funded and pay reasonable rates to providers.** Because orthodontia for children would be a new benefit in the OHP, when computing the base rate in the global budget OHA will need to go beyond the proposed 5-year look back at utilization and spending. OHA will need to estimate what amount it will pay for a course of orthodontic treatment and how many children will be approved for the service in the first year, and then incorporate those figures into the global budget computation. Further, when computing the projected future trend of the base rate, OHA would need to incorporate an assumption of gradually increasing utilization of the benefit. This approach will ensure that Coordinated Care Organizations (CCOs) are not caught short financially as the new orthodontia coverage eventually reaches more eligible children in Oregon.

**Lastly, OHA will need to design and implement a meaningful reporting and accountability structure to ensure that all affected children, including those in Tribal communities, can equitably access high quality orthodontic care in locations convenient to where they live.** This will help guard against inappropriate underutilization of the orthodontia benefit and outright denials of medically necessary care by CCOs. CCOs should, at the very least, be actively monitored to see that they are effectively implementing the new benefit. Ideally, they could be incentivized to ensure that affected children are being screened, referred, diagnosed, and served appropriately. Both member and provider satisfaction should regularly be assessed and reported. CCOs should be required to report data on utilization of, and satisfaction with, the orthodontic benefit, stratified by subpopulation so any gaps can be identified and addressed.

**Specific impacts and measures that are affected by orthodontic treatment** include an increase in middle- and high-school grades after orthodontic treatment, increased self-esteem as self-reported and as reported by third party professionals, higher community involvement, higher graduation rates, increased social interactions with peers, improved oral health/hygiene, and assignment of dental home for the child and rest of family.

**In conclusion, we urge OHA to include in its Application for Renewal and Amendment of the 1115 Waiver:**

- **An explicit withdrawal of the request to limit EPSDT treatment services to those on the prioritized list of health care services;**
- **A statement that OHA will begin to provide coverage for treatment for medically necessary orthodontia in children, i.e., fixed, and removable appliances and associated surgical procedures for handicapping malocclusion;**
- **An indication that OHA will incorporate in the global budget base rate, and in the projected future trending of the base rate, a reasonable provider rate and an expectation of a gradually increasing number of orthodontia cases over the five (5) year duration of the waiver; and**
- **An indication that the CCO accountability structure will include the necessary data collection and reporting requirements, stratified by subpopulation, to ensure that all affected children are being equitably served by the orthodontia benefit.**

Respectfully submitted,

Christian Moller-Andersen, Executive Director  
A Smile for Kids  
446 SW 7<sup>th</sup> Street  
Redmond OR 97756  
Phone: 541-280-4214  
Email: [cma@asmileforkids.org](mailto:cma@asmileforkids.org)



**BY ELECTRONIC DELIVERY**

January 7, 2022

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**RE: Application for Renewal and Amendment Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

The Biotechnology Innovation Organization (BIO) and Oregon Bioscience Association (OR Bio) appreciate the opportunity to comment on the Oregon Health Authority's (OHA) proposed renewal and amendment of its Section 1115 waiver, which among other things, would be a waiver of compliance with essential provisions of §1927 of the Social Security Act (SSA). We urge the State to abandon this attempt and work with biopharmaceutical manufacturers, patient groups, and other key stakeholders to accomplish the goals of stability and predictability in the Medicaid pharmacy budget without jeopardizing patient access and care.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. OR Bio, a state affiliate of BIO, represents biotech companies throughout Oregon developing critical lifesaving drugs, advanced health-care technologies, and cutting-edge medical devices. OR Bio supports Oregon's bioscience community through networking, educational programs, enterprise support, advocacy, and the enhancement of research collaboration.

Our organizations represent thousands of large and small biotech companies throughout the country—including in Oregon. Our members span from those engaging in foundational research, to entrepreneurs, to major manufacturers and developers of therapies, cures, and devices. Our collective members develop medical products and technologies to treat patients afflicted with serious diseases, delay the onset of these diseases, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

The focus of our comment's centers on the OHA's request to waive §1927 of the SSA in order to adopt a "commercial-style" closed formulary for adults, leaving

many Medicaid beneficiaries with only one drug per formulary class, as well as its proposal to deny access to drugs approved via an accelerated pathway which will restrict access to drugs that address serious or life-threatening diseases with limited or no treatment options. The Centers for Medicare and Medicaid Services (CMS) has already soundly rejected previous such approaches because of its violation of Section 1927. To predictably manage drug expenditures, we recommend that Oregon focus on alternative, innovative payment strategies based on the value that balance patient care and positive health outcomes against the needs and limitations of the state's finite resources.

We support the OHA's purported goal of ameliorating disparities in the health care system but are deeply concerned that the policies being proposed in this waiver renewal and amendment application will have the opposite effect and instead exacerbate the inequities engrained in our health system. One of the primary tenets of BIO's own health equity agenda serves to promote health equity through:

- The enhancement of clinical trial diversity by partnering with contract research organizations and minority-serving institutions;
- Promotion of access to vaccines and therapeutics for uninsured and underserved populations, especially related to COVID-19; and
- Fostering enhanced nutritional, environmental, and mental wellness opportunities in economically disadvantaged communities.

We do agree that the state should leave in place an open formulary for children, a vulnerable patient group that already faces narrowed treatment options and for whom we must ensure access to medically necessary care, including therapies approved via accelerated pathways, where applicable.

Our specific comments on the OHA's Section 1115 Waiver Renewal and Amendment Application with respect to the proposal to waive §1902(a)(54) of the SSA, insofar as it incorporates §1927 are summarized as follows:

- **A closed formulary hinders access and jeopardizes the quality of care of the most vulnerable patients, especially those with rare, life-threatening diseases;**
- **Denial of access to drugs approved through one of FDA's expedited programs (accelerated approval) harms the most vulnerable patients;**
- **A closed formulary violates Section 1927 of the SSA, and Section 1115 of the SSA does not permit such a waiver; and**
- **Oregon could achieve better financial predictability in its pharmacy program by using its Preferred Drug List. Another option is to align payment to value through alternative payment mechanisms that emphasize value and outcomes.**

Our more detailed comments are outlined on the following pages:

## **A Closed Formulary Hinders Access and Jeopardizes the Quality of Care of the Most Vulnerable Patients**

We have grave concerns that a waiver of compliance with SSA § 1927's coverage requirements would harm patient health by restricting access to medically necessary drugs. Consequently, in covering as few as one drug per therapeutic class, Oregon would seriously jeopardize the health of many patients, which will exacerbate growing inequities in access to health care. This is contrary to the application's purported goal: "to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon."<sup>1</sup>

Studies show that restricting access to drugs through closed formularies results in non-adherence or poor adherence to prescribed medication regimens, worsened health outcomes and hospitalizations, not to mention other costs to the state such as additional costs to the state correctional system.<sup>2,3,4,5</sup> One study found a causal relationship between formulary restrictions of schizophrenia drugs and increased incarcerations.<sup>6</sup> For many therapeutic classes, such a culling of select drugs from overall drug classes would leave some Medicaid beneficiaries in a far worse position. Providing access to a wide variety of drug agents remains the cornerstone to improved patient care and health outcomes since one formulary agent may not produce the intended therapeutic outcome across all patient types. Also, side effect profiles can vary across patient subgroups, and a closed formulary design may lead to therapy discontinuation due to side effects. These concerns are even more heightened as science and innovation move toward personalized medicine, particularly in rare and chronic diseases. Below we highlight only a few examples in which a closed formulary is detrimental to patients.

**Example: Epilepsy.** Despite the availability of a variety of drug treatments for epilepsy, approximately 30% to 40% of all epilepsy patients still do not have the ability to adequately manage their seizures,<sup>7</sup> and those patients who are able to manage their condition often must take up to three to five drugs at a time to

---

<sup>1</sup> Application for Renewal and Amendment: Oregon Health Plan Section 1115 Demonstration Waiver, Oregon Health Authority.

<sup>2</sup> Happe LE, Clark D, Holliday E, Young T. A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. *J. Managed Care Spec Pharm.* 2014;20(7):677-84. <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2014.20.7.677> Accessed: December 10, 2021.

<sup>3</sup> Zullig, LL, Bosworth, H, "Engaging patients to optimize medication adherence." NEJM Catalyst, May 14, 2017. <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0489> Accessed: December 10, 2021.

<sup>4</sup> Seth A. Seabury, et al., "Formulary restrictions on atypical antipsychotics: impact on costs for patients with schizophrenia and bipolar disorder in Medicaid," 20 AM. J. MANAGED CARE e52 (2014). <https://www.ajmc.com/view/formulary-restrictions-on-atypical-antipsychotics-impact-on-costs-for-patients-with-schizophrenia-and-bipolar-disorder-in-medicaid> Accessed: December 10, 2021.

<sup>5</sup> Yujin Park, et al., "The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systemic Literature Review," *Journal of Managed Care Pharmacy.* 2017 Aug; 23(8):893-901. <https://www.jmcp.org/doi/10.18553/jmcp.2017.23.8.893> Accessed: December 10, 2021.

<sup>6</sup> Seabury, et al., Formulary Restrictions on atypical antipsychotics, 2014.

<sup>7</sup> NIH Epilepsy Data: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Epilepsies-and-Seizures-Hope-Through>. Accessed: December 9, 2021.

control their seizures. According to the Centers for Disease Control and Prevention (CDC), there are roughly 42,900 people in Oregon suffering from epilepsy, 5,400 of which are children.<sup>8</sup> For those on Medicaid, once these children reach 18 years of age, they would be subject to the closed formularies, potentially destabilizing their care. If the Oregon Health Plan were to limit coverage to a single drug in a therapeutic class, many epilepsy patients would be left without adequate therapy to manage their condition leading to costly acute care episodes and hospitalizations. Of additional concern, because epilepsy is more prevalent in Hispanic than non-Hispanic individuals, a closed formulary is likely to increase the health inequities that are already prevalent in this population.<sup>9</sup>

**Example: Chronic Respiratory Diseases.** Furthermore, access to necessary medications for appropriate care is especially important for adults and children with chronic conditions such as chronic lower respiratory disease, which often requires multiple medications to treat. This disease, which includes chronic obstructive pulmonary disease (COPD) and asthma is the fourth leading cause of death in the United States, with over 160,000 deaths in 2016.<sup>10</sup> According to the CDC, approximately 369,735 Oregon adults (11.1%)<sup>11</sup> were affected by asthma, while another 229,000 (6.9%) of Oregonians were affected by COPD.<sup>12</sup> According to the Oregon Asthma Leadership Plan 2014-2019, at least 7% of children in Oregon are affected by Asthma.<sup>13</sup> Again, these children would age into the Oregon Health Plan and be subject to a destabilizing closed formulary. Furthermore, the same report indicates that those on the Oregon Health Plan are disproportionately affected by Asthma.<sup>14</sup> Given the prevalence of COPD and asthma in Oregon and the fact that the State has one of the highest rates of Asthma in the country,<sup>15</sup> a drug formulary should accommodate standard medical science, accept treatment guidelines, and support new innovations to safeguard the medication needs of the State's population. A commercial style closed formulary design with one drug per class policy would not ensure patient access to current and innovative therapies for the appropriate treatment of respiratory diseases. It would further exacerbate health inequities in the State. According to the American Lung Association, African Americans and Native Americans have a higher prevalence of Asthma than other racial backgrounds. In fact, African Americans are 42% more likely to have Asthma than whites.<sup>16</sup>

---

<sup>8</sup> <https://www.cdc.gov/epilepsy/data/index.html> Accessed: December 9, 2021.

<sup>9</sup> <https://www.epilepsy.com/start-here/about-epilepsy-basics/who-gets-epilepsy>

<sup>10</sup> CDC 2017 Most recent Asthma Data: [https://www.cdc.gov/asthma/most\\_recent\\_data.htm](https://www.cdc.gov/asthma/most_recent_data.htm) Accessed: December 10, 2021.

<sup>11</sup> Id.

<sup>12</sup> American Lung Association, 2018. <https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/data-tables/copd-prevalence-rates-by-state-gender> Accessed: January 1, 2022.

<sup>13</sup> *Oregon Asthma Leadership Plan 2014-2019*, Oregon Health Authority. <https://www.oregon.gov/oha/PH/DISEASES/CONDITIONS/CHRONIC/DISEASE/ASTHMA/Documents/alplan.pdf>. Accessed: December 10, 2021.

<sup>14</sup> Id.

<sup>15</sup> American Lung Association, 2018. <https://www.lung.org/research/trends-in-lung-disease/asthma-trends-brief/current-demographics> Accessed: December 29, 2021

<sup>16</sup> Id.

**Example: HIV.** This is also true for people living with HIV. HIV treatments are not one-size-fits-all, and anti-retroviral therapy (ART) options may not be easily substituted for all patients. Health care providers work closely with patients to select treatment with great specificity for each patient. Patients may respond differently to the same ART. People living with HIV rely on open formularies because the effective treatment of HIV is highly individualized and accounts for a wide variety of factors. In fact, the HHS clinical treatment guidelines<sup>17</sup> state that,

*"Selection of a regimen should be individualized based on virologic efficacy, potential adverse effects, childbearing potential and use of effective contraception, pill burden, dosing frequency, drug-drug interaction potential, comorbid conditions, cost, access, and resistance test results. . ."*<sup>18</sup>

The guidelines also recognize that "[i]t is important to consider the patient's daily schedule; patient tolerance of pill number, size and frequency; and any issues affecting absorption."<sup>19</sup> Medical challenges for people living with HIV also include an increased risk for, and prevalence of, comorbidities that require additional drug treatment such as depression and substance use disorders,<sup>20</sup> as well as cardiovascular disease, hepatic and renal disease, osteoporosis, metabolic disorders, hypertension, hyperlipidemia, and endocrine disease and several non-AIDS-defining cancers.<sup>21,22,23,24</sup> In addition, HIV impacts people of all ages and demographics, including children, adolescents, adults, women, men, etc. However, different HIV medicines may be more appropriate for different patient types. For example, not all treatment regimens are appropriate for pediatrics, pregnant mothers, or patients with resistance. For context, some drugs have low dose options available for younger/lower weight children; some drugs are not recommended for women of childbearing potential; patients with resistance to a certain class of HIV drugs would need to use drugs from a different class(es) to suppress their HIV. Accordingly, we must focus on maintaining access to all ART instead of limiting the number of HIV medicines. Closing the Oregon Health Plan formulary would restrict access to high-quality treatment for many people living with HIV at a time when ART can lower viral load to undetectable levels. This means that the virus is suppressed to levels that cannot be detected in blood tests and cannot be transmitted to others. Therefore, maintaining patient access to ART

---

<sup>17</sup> DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, 2021.

<https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed December 10, 2021.

<sup>18</sup> Id.

<sup>19</sup> Id.

<sup>20</sup> CDC, Medical Monitoring Project, United States, 2013 Cycle (June 2013–May 2014)

<sup>21</sup> Gallant, Joel, Priscilla Y Hsue, Sanatan Shreay, Nicole Meyer; Comorbidities Among US Patients with Prevalent HIV Infection—A Trend Analysis, *The Journal of Infectious Diseases*, Volume 216, Issue 12, 19 December 2017, Pages 1525–1533, <https://doi.org/10.1093/infdis/jix518> Accessed: December 10, 2021.

<sup>22</sup> Rodriguez-Penney, Alan T. et al. "Co-Morbidities in Persons Infected with HIV: Increased Burden with Older Age and Negative Effects on Health-Related Quality of Life." *AIDS Patient Care and STDs* 27.1 (2013): 5–16. PMC. Web. 21 June 2018. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3545369/> Accessed: December 10, 2021.

<sup>23</sup> Joint HHS, CMCS, HRSA, and CDC Informational Bulletin, Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries, p. 9 (December 1, 2016), <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf>. Accessed December 10, 2021.

<sup>24</sup> Gallant, Joel, et al., December 19, 2017, <https://doi.org/10.1093/infdis/jix518>

options that are most clinically appropriate based on patients' individual factors is critical not just for the health of people living with HIV but also for the prevention of HIV for those at risk. The types of short-sighted policies, such as a closed formulary, can have poor public health consequences, increase health disparities, and can result in increased costs elsewhere in the budget.

**Example: rare genetic diseases.** Rare diseases can affect multiple organ systems and present with severe symptoms. The US Pharmacopeia (USP) category for genetic diseases lists many therapies that are the only therapy available for a particular disease state. Restricting access to only one, sole drug within a USP category (note: there are no "classes" offered for genetic disease, only "categories") would severely limit access to medically necessary therapy for patients with rare genetic diseases, a population that makes up some of the state's most vulnerable patients, who already experience incredibly limited treatment options.

Moreover, the State's assertion that a "closed formulary" would offer Medicaid beneficiaries coverage comparable to that of Medicare Part D beneficiaries is inaccurate. Unlike many Oregon Health Plan beneficiaries, Medicare Part D beneficiaries have a choice among multiple coverage options, with transparency into the drugs included on any individual formulary and protections against mid-year formulary changes. As a result, Medicare Part D beneficiaries can choose the formulary that best suits their medical needs with reasonable certainty that they will have such coverage over the next year. And, if their needs change, they can choose a new Part D plan during the annual open enrollment period. Furthermore, as the application notes, Medicare Part D formularies have two drugs per class, yet the State intends to limit coverage to just one drug per class. In addition, the Part D program has an exception and reconsideration process that provides access to off-formulary therapies, as well as six protected classes of drugs, for which Part D plans must include all, or substantially all, drugs in the class on-formulary — namely, the classes of anti-convulsants, anti-depressants, anti-psychotics, anti-neoplastics (oncology), immunosuppressants, and anti-retrovirals (HIV/AIDS). The OHA has described no such protections in its draft Waiver Application.

It is likewise the case that patients who obtain coverage through the health insurance exchanges can choose plans with a formulary best suited to their individual needs and can also change their plan during the annual open enrollment period as their health care needs change. In addition, these patients would have access to an exceptions process to obtain their medically necessary medications.

The Health Equity Committee, a subcommittee of the Oregon Health Policy Board (OHPB) was tasked with coordinating and developing policy that proactively promotes the eradication of health disparities and the achievement of health equity for all people in Oregon and the state has a goal of "eliminating health inequities by 2030."<sup>25</sup> This is an admirable goal for the state, one with which we support.

---

<sup>25</sup> Oregon Health Policy Board, Health Equity Committee, <https://www.oregon.gov/oha/OEI/Pages/Health-Equity-Committee.aspx> (Accessed: January 1, 2022).

However, we are concerned that the proposed closed formulary is incongruent with this policy.

Individuals with rare diseases tend to report common concerns that result from being underserved, such as a long road to diagnosis, limited treatment options, and a need for research to better understand their medical condition.<sup>26</sup> Additionally, rare diseases are disproportionately prevalent among some racial and ethnic minority groups. These patients may also face greater disease burden, earlier age of disease onset, and/or complex sets of comorbidities that limit the safety and effectiveness of older treatment options.

Rather than making progress toward Oregon's goal of eradicating health disparities, this draft Waiver Application's proposed closed formulary would likely create additional health disparities for rare disease patients, especially those who are also part of racial and/or ethnic minority groups. As part of two underserved populations, these individuals face substantial burdens which can cause economic hardship, difficulty accessing care, and poorer health outcomes for themselves and their caregivers. Without the ability to have coverage of a medicine that may not be included in the proposed closed formulary, these issues will be accentuated, and could result in poor health outcomes and increased costs of care, rather than achieving the state's goals of "eliminating health disparities and the achievement of health equity for all people in Oregon."

The suggestion that the Oregon Health Plan would maintain a high quality of care – while denying access to many medically necessary drugs – seems highly unlikely. The State did not even specify in its proposal whether patients might have access to an exceptions process or appeals process. Whether or not there is an exceptions process or appeals process, there are likely to be delays in treatment for thousands of Oregonians. Delays in access to treatment have been shown to lead to worsened patient outcomes. A recent study assessing time to treatment initiation (TTI) for cancer patients showed that increased TTI was associated with worsened overall survival for stages I and II breast, lung, renal, and pancreas cancers, and stage II colorectal cancers.<sup>27</sup>

Today, meaningful therapies for people living with rare diseases are only available for 5% of more than 7,000 rare diseases, and the overall economic burden of just 379 rare diseases – including all direct medical costs as well as indirect nonmedical costs – is estimated at \$966 billion.<sup>28</sup> If the Oregon Health Plan succeeds in adopting its proposed closed formulary in Medicaid, patients will continue to struggle for access to high-quality health care and may delay care or forgo important aspects of life (e.g., getting married, buying a home, starting a family). This will be an especially acute problem for rare disease patients, for whom multiple

---

<sup>26</sup> "Barriers to Rare Disease Diagnosis, Care and Treatment: A 30-Year Comparative Analysis," *NORD Rare Insights*, NORD, November 19, 2020.

<sup>27</sup> Khorana AA, Tullio K, Elson P, et al. Increase in time to initiating cancer therapy and association with worsened survival in curative settings: A U.S. analysis of common solid tumors. *Journal of Clinical Oncology* 2017 35:15\_suppl, 6557-6557. [https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15\\_suppl.6557](https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.6557) Accessed: December 10, 2021.

<sup>28</sup> "The National Economic Burden of Rare Disease Study," Every life Foundation and National Health Council. 2021.

therapeutic options for treatment rarely exist. Furthermore, the accelerated approval pathway is a mechanism for expediting innovative treatments for patients with rare diseases too challenging to study using a traditional pathway, without compromising FDA's stringent, science-based approval standards. By denying access to new therapies approved through this pathway, Oregon could make it nearly impossible for rare disease patients who sometimes wait years to access a transformative medicine for their condition – concerns that we further detail in the following section.

Lastly, it is important to note that OHA currently lacks authority to enforce prior authorization for non-preferred drugs. Oregon has a long history of protecting access to needed medicines while also allowing OHA to manage utilization and cost through prior authorization. These protections were originally established in 1977 and were later developed as part of the Oregon Health Plan's Practitioner-Managed Prescription Drug Program (PMPDP).<sup>29</sup> Stakeholders negotiated changes to the PMPDP in 2009, allowing OHA limited prior authorization capabilities but prohibiting prior authorization criteria or requirements for unreviewed classes of drugs, mental health drugs, or refills of immunosuppressants and drugs to treat HIV/AIDS, cancer, or seizures.<sup>30</sup> These changes preserved the long-standing "prescriber prevails" protections allowing a provider to prescribe medicines subject to PA requirements.

Due to the ongoing attempts to appropriately balance access and costs, the Oregon Legislature has not granted OHA permanent authority to establish and enforce prior authorization requirements. After portions of statutory authority establishing the PMPDP sunset in early 2018, the Legislature has declined to re-implement that authority.<sup>31</sup> OHA supported legislation in 2021 to re-institute prior authorization authority, with the historic provider and patient protections, but that effort failed to pass, continuing to leave OHA without statutory authority to enforce prior authorization requirements for non-listed drugs.<sup>32</sup> Even if CMS were to authorize a closed formulary as part of a Section 1115 Demonstration Waiver, the OHA would still need explicit authority under state law to require prior authorization for those drugs not listed on the formulary.

### **Denial of Access to Drugs Approved through FDA's Accelerated Approval Pathway Harms the Most Vulnerable Patients**

The State proposes that it should have the ability to exclude drugs approved through FDA's accelerated approval process from its formulary because they have limited or inadequate clinical efficacy.<sup>33</sup> CMS notes in *State Release 185* that these drugs must be covered by the Medicaid program if there is a signed Medicaid

---

<sup>29</sup> See ORS 414.325, enacted in 1977 and ORS 414.334 "Oregon Practitioner Managed Prescription Drug Program," enacted in 2001.

<sup>30</sup> See HB 2126 of 2009, which created ORS 414.337

<sup>31</sup> Portions of ORS 414.337 expired on January 2, 2018. See also HB 2678 of 2019.

<sup>32</sup> See SB 848 of 2021.

<sup>33</sup> Oregon Health Plan Section 1115 Waiver Renewal and Amendment.

National Rebate Agreement, but it also reaffirms that these drugs go through the same rigorous approval as drugs through the traditional approval process. *State Release 185* notes,

“Section 506(c) of the FDCA allows the FDA to grant accelerated approval to a drug for a serious or life-threatening disease or condition. Part of the criteria for accelerated approval under section 506(c) is a demonstrated effect on either:

- “a. A surrogate endpoint that is reasonably likely to predict a clinical benefit, taking into account severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments, or
- b. A clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

“Drugs granted accelerated approval by FDA under the process described in 506(c) of the FDCA are approved under section 505(c) of the FDCA and **must meet the same statutory evidentiary standards for safety and effectiveness as those granted traditional approvals.** See section 506(e)(2) of the FDCA. Thus, as noted above, at the time a product is granted accelerated approval, FDA has based such an approval on a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint other than survival or irreversible morbidity.”<sup>34</sup>

The FDA, the scientific community, and Congress<sup>35</sup> have all deemed surrogate endpoints as an appropriate marker of clinical efficacy for serious and life-threatening diseases and conditions for which there are no other meaningful alternatives. In the case of diseases that take course over a long period of time (e.g., nephrology disease or respiratory disease), surrogate endpoints are critical because without the pathway for researchers to feasibly study the ultimate, long-term impact on clinical outcomes through clinical trials it would require years, or even decades, of study, denying seriously ill patients medicines during the long wait. Additionally, the pathway is a lifeline for patients who have severe life-threatening diseases, including those with rare diseases, cancers, or HIV/AIDS. By attempting to limit Medicaid beneficiaries’ access to therapies for which only surrogate endpoints have been reported, Oregon would deprive patients of access to important therapy options approved by the FDA as safe and efficacious.

For nearly 30 years, FDA and Congress have both been clear in affirming that accelerated approval does not dilute or otherwise compromise FDA’s approval standards. FDA similarly responded to concerns that the accelerated approval

---

<sup>34</sup> *State Release 185*, CMS, June 27, 2018. (Emphasis added.)

<sup>35</sup> *Food Drug Administration Safety and Innovation Act*, §901.

process was inconsistent with the substantial evidence requirement of section 505(d) of the Food, Drug, and Cosmetic Act (21 U.S.C. § 355(d)):

“Approval under this rule requires ... that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. This judgment does not represent either a ‘lower standard’ or one inconsistent with section 505(d) of the act, but rather an assessment about whether different types of data show that the same statutory standard has been met.”<sup>36</sup>

The State appears to suggest that Oregon can determine the safety and clinical efficacy of a drug in a manner superior to that of the FDA, which is considered the worldwide gold standard in the review and efficacy of drugs. The State is attempting to thwart the goals of the Federal Food, Drug and Cosmetic Act (FDCA), which tasks the FDA with applying its expertise to speed the development of medicines for serious diseases while maintaining its rigorous approval standards. Furthermore, this new type of decision-making outside the FDA could lead to unequal treatment access for patients already dealing with serious, life-threatening diseases. As explained in the extensive findings and sense of Congress provisions of the *Food Drug Administration Safety and Innovation Act*, §901:

“[FDA] serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is one element of the Nation’s strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.”

As specified by Congress, the FDA may consider the use of accelerated approval to

“a product for a serious or life-threatening disease or condition . . . upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.”<sup>37</sup>

We also believe the State makes an erroneous misinterpretation of the 21<sup>st</sup> Century Cures Act, incorrectly stating, “the 21<sup>st</sup> Century Cures Act was intended to expedite the drug approval process by reducing the level of evidence required for drugs to reach the market and allowing doctors, patients, and payers to decide whether to purchase them.”<sup>38</sup> Drugs approved through the accelerated approval pathway are subject to a demanding standard of review —demonstration of “substantial

---

<sup>36</sup> 57 Fed. Reg. at 58944.

<sup>37</sup> 21 U.S.C. § 356(a)(1).

<sup>38</sup> Oregon Health Plan Section 1115 Waiver Renewal and Amendment Application.

evidence” of effectiveness.<sup>39</sup> In fact, studies have found that certain drugs reviewed under the accelerated approval processes have offered greater medical gains than drugs reviewed through the FDA’s traditional, lengthier process.<sup>40</sup> Importantly, for drugs granted accelerated approval, post-approval confirmatory trials or studies are required as part of the regulatory process to verify and describe the anticipated clinical benefit.<sup>41</sup> If the confirmatory trial fails to verify the benefit, the FDA has the authority to withdraw approval and has done so when needed.<sup>42</sup>

We strongly object to the exclusion of such categories of drugs in Medicaid not just because the statute and regulations demand it, but because these drugs must go through the same rigorous clinical review as other drugs. These drugs provide treatment for unmet medical needs, and most patients have limited or no current treatment options available to them. If the State excludes accelerated approval drugs from coverage, these patients will no longer have any treatment options.

For patients with rare diseases, this policy would have a devastating impact. Of the 7,000 rare diseases that exist, only 5% have treatment options available. Many of these patients have waited years for treatments only to not be able to access it, however, a patient living next door that has commercial insurance likely can. This would greatly exacerbate inequities in the State. In addition, exclusion from coverage removes a strong incentive for biopharmaceutical companies to research and develop these important innovative therapies, further exacerbating the inequities that are inherent in rare disease patients. In addition, studies have shown that accelerated approval drugs have accounted for less than 1% of Medicaid pharmacy costs between 2007 and 2018.<sup>43</sup> It would be deeply troubling to deny care to rare and chronic disease patients, who have few or no treatments, simply to gain a negligible financial impact.

Furthermore, studies have found that certain therapies reviewed under expedited programs, including the accelerated approval pathway, have offered greater medical gains than drugs reviewed through the FDA’s traditional, lengthier process.<sup>44</sup> A further consideration is that this approval pathway was created principally in response to the HIV/AIDS crisis of the 1980s as well as in response to calls that cancer drugs were not being developed quickly enough. We have seen the trajectory of those diseases change remarkably due, in large part, to the therapies developed under this FDA accelerated approval pathway. Should the State decide

---

<sup>39</sup> 21 U.S.C § 355(d)(5).

<sup>40</sup> Chambers, et al., *Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved by Conventional Process*, Health Affairs Vol. 36, No. 8, 2017.

<sup>41</sup> FDA. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics. May 2014.

<sup>42</sup> FDA. Delivering Promising New Medicines Without Sacrificing Safety and Efficacy. FDA Voices: Perspectives from FDA Leadership and Experts. August 2019.

<sup>43</sup> Thorpe, Kenneth E., Ph. D, and Douglas Holtz-Eakin, Ph.D., “Limiting Medicaid Access to Accelerated Approval Drugs: Costs and Consequences,” *American Journal of Managed Care*, March 30, 2021. Accessed: December 30, 2021. <https://www.ajmc.com/view/limiting-medicare-access-to-accelerated-approval-drugs-costs-and-consequences>

<sup>44</sup> Chambers, et al., *Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved by Conventional Process*, Health Affairs Vol. 36, No. 8, 2017.

not to cover these drugs until their FDA-required confirmatory studies are complete, then it will jeopardize the incentives for the research and development of these treatments, once again leaving these vulnerable patients with few, if any, options.

In the waiver renewal and amendment application, the State also appears to indicate its intention to restrict coverage for accelerated approval drugs and beyond, which would functionally exclude most drugs from coverage because the FDA's drug approval framework does not require evidence of "incremental benefit" over existing therapies to demonstrate safety and efficacy. This concept is deeply troubling as it fundamentally undermines the FDA's ability to evaluate and approve a safe and efficacious drug for the US public, leaving the general public questioning whether their own medical therapies are really safe and effective.

### **The Closed Formulary Violates Section 1927 and Section 1115 Does Not Permit Such a Waiver.**

The OHA stated intent is to waive §1927 of the SSA to adopt a "commercial-style" closed formulary and circumvent the formulary requirements of §1927(d)(4). The waiver amendment application also suggests the Oregon Health Plan would utilize the "new flexibility" it seeks under the waiver to deny access to new innovative drugs approved through the FDA accelerated approval process, because "they have not yet demonstrated actual clinical benefit and have been studied in clinical trials using only surrogate endpoints." Accelerated approval is reserved for drugs that address serious or life-threatening diseases with limited or no treatment options and, *importantly*, are proven safe and effective by the same rigorous evidentiary standards used by the FDA to approve all other medicines.<sup>45</sup>

The Medicaid rebate provisions of the SSA represent a carefully balanced compromise made by Congress to ensure the Government has access to the lowest available price for covered outpatient prescription medicines – via a statutorily mandated rebate – while also ensuring that manufacturers' products would be accessible to Medicaid recipients if medically necessary and subject to statutorily defined access restrictions.

[Section 1927] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs **must cover all covered outpatient drugs**, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.<sup>46</sup>

---

<sup>45</sup> 21 U.S.C. §356(e)(2).

<sup>46</sup> 78 Fed. Reg. 4594, 4631 (Jan. 22, 2013). (Emphasis Added)

The Medicaid program is guaranteed a manufacturer's "best price," as defined in the statute, and in addition, receives an inflationary rebate to protect states from price increases that rise above the consumer price index.

In 2017, the Commonwealth of Massachusetts proposed a plan to reform its Medicaid pharmacy program to waive §1902(a)(54) of the SSA, insofar as it incorporates §1927, in an attempt to circumvent the Medicaid drug formulary requirements of §1927(d)(4). It proposed a closed formulary with at least one drug per class, with the intent to exclude drugs approved through the FDA's accelerated approval process. Both policies were firmly rejected by CMS, indicating that a state cannot simply opt out of §1927 and not provide access to "covered outpatient drugs" for which a manufacturer has a signed National Rebate Agreement.<sup>47</sup> The same day that CMS responded to the Massachusetts waiver amendment, the agency issued "State Release No. 185," which underscored the fact that drugs approved through the FDA's expedited approval processes "must be covered by state Medicaid programs, if the drug meets the definition of "covered outpatient drug" as found in Section 1927 of the Social Security Act"<sup>48</sup> and the Manufacturer has a signed Medicaid National Rebate agreement.<sup>49</sup>

Given the nearly identical components of the Oregon and Massachusetts proposals, we urge the State to abandon this attempt and work with manufacturers and CMS on other alternatives, which are discussed later in this letter.

Furthermore, the Medicaid bargain is a favorable one for state Medicaid programs, because states can already negotiate rebates higher than what is statutorily mandated, it is dubious that states can negotiate better rebates by opting out of the statute. According to the Georgetown University Health Policy Institute, "Medicaid obtains rebates that are far larger than those in Medicare Part D and in private insurance."<sup>50</sup> According to the June 2021 Report to Congress, the Medicaid and CHIP Payment and Access Commission noted that the Medicaid program received \$37.1 billion in rebates from pharmaceutical manufacturers in 2019.<sup>51</sup> This resulted in a net reduction in pharmacy spending of 55.6%.<sup>52</sup> The Medicare Part D

---

<sup>47</sup> CMS letter to Asst. Secretary Tsai, MassHealth, June 27, 2018.

<sup>48</sup> CMS State Release No. 185, June 27, 2018.

<sup>49</sup>Tennessee also sought and obtained approval for a Section 1115 demonstration, which includes authority to implement a commercial style closed drug formulary, with certain exceptions. CMS letter to Dir. Stephen Smith, TennCare, January 8, 2021. Following an Administrative Procedures Act (APA) challenge to CMS' decision, CMS issued and opened a new comment period regarding the Tennessee demonstration and will issue a decision with respect to whether it will make any changes to its approval of the TennCare III demonstration. CMS letter to Dir. Stephen Smith, TennCare, August 10, 2021. The Massachusetts and Oregon proposed plans are distinct from the TennCare waiver, which was tied to a block grant. However, BIO has concerns that the TennCare demonstration also presents risks for Medicaid beneficiaries who rely on prescription drugs to treat acute conditions or manage chronic health needs.

<sup>50</sup> "How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs," Issue Brief, Georgetown University Health Policy Institute, January 2019.

<sup>51</sup> Report to Congress, MACPAC, June 2021. <https://www.macpac.gov/wp-content/uploads/2021/06/June-2021-Report-to-Congress-on-Medicaid-and-CHIP.pdf> Accessed: December 9, 2021.

<sup>52</sup> BIO Calculation from: MACPAC Report to Congress 2021.

program only received 26.5% in rebates in 2020.<sup>53</sup> In short, the Medicaid Drug Rebate Program works to achieve both the intended goals, ensuring patient access to much-needed medicines at the lowest prices in the commercial marketplace.

### **The Proposed Waiver Amendment Does Not Further the Objectives of the Medicaid Program and Therefore is Not Authorized by SSA § 1115**

Under SSA § 1115(a), a state’s proposed waiver must set forth an “experimental, pilot, or demonstration project,” that, in the judgment of the Secretary, is “likely to assist in promoting the objectives of title XIX [i.e., the Medicaid program].”<sup>54</sup> A waiver of compliance with SSA § 1927 would fail to satisfy these criteria.

In the first instance, the State has not specified a research proposition that it seeks to test to improve patient care for Medicaid enrollees. It proposes only to cut costs by restricting coverage of covered outpatient drugs that it would otherwise be required to cover under SSA § 1927. As the Court of Appeals for the Ninth Circuit has emphasized, “[SSA § 1115] was not enacted to enable states to save money or to evade federal requirements, but to test out new ideas and ways of dealing with the problems of Medicaid recipients”<sup>55</sup>...such “[a] simple benefits cut, which might save money but has no research or experimental goal, would not satisfy th[e] criteria [of] ha[ving] a research or demonstration value.”<sup>56</sup> SSA § 1115 demonstration projects must test innovative approaches aimed at furthering the objectives of the Medicaid program, for example, by enhancing the quality of care or promoting efficient administration. A demonstration project may not operate as a mere benefit cut with no actual experimental value.

Additionally, a waiver of compliance with SSA § 1927 would fail to promote the objectives of title XIX, which was enacted by Congress to provide medical care to the needy and medically needy.<sup>57</sup> By denying access to otherwise-covered and potentially life-saving therapies, the State would do precisely the opposite – strip away medical care for the needy and medically needy, exacerbating health disparities in the process. Such a waiver would also fail to promote Congress’s clear objectives in enacting SSA § 1927 in particular – indeed, it would contradict these objectives. Congress enacted SSA § 1927 in order to guarantee that “[s]tates that elect to offer prescription drugs ... cover all the products of any manufacturer that agrees to provide price rebates.”<sup>58</sup> If CMS were to approve a waiver of compliance that enables a state to avoid its drug coverage obligations under SSA § 1927, the agency would undermine the primary objective of SSA § 1927, as stated by

---

<sup>53</sup> 2021 Annual Report of the Board of Trustees of the Federal Hospital Insurance and the Federal Supplementary Insurance Trust Funds, 2021.

<sup>54</sup> SSA § 1115(a).

<sup>55</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

<sup>56</sup> *Id.*

<sup>57</sup> Staff of H. Comm. on Ways and Means, 89th Cong., Summary of Major Provisions of H. R. 6675, The “Social Security Amendments of 1965” 1 (Comm. Print 1965).

<sup>58</sup> *Id.*

Congress itself. On top of this, the State would fail to ensure that “Medicaid beneficiaries have access to the same range of drugs that the private patients or their physicians enjoy,” as intended by Congress.<sup>59</sup> CMS confirmed this understanding in its June 27, 2019, letter to the Commonwealth of Massachusetts that rejected the nearly identical closed formulary proposal.

**Oregon can achieve better financial predictability in its pharmacy program by using its Preferred Drug List (PDL). Oregon can also align payment to value through alternative payment mechanisms that emphasize value and outcomes.**

We believe that Oregon would be better served by utilizing its PDL to manage drug costs and enacting a permanent structure for enforcing prior authorization. Lack of explicit statutory authority and a permanent, predictable system for patients, providers, and others have hindered effective implementation. As described above, Medicaid programs already obtain rebates that are far larger than those in Medicare Part D and in private insurance. Oregon could negotiate further, supplemental Medicaid rebates from manufacturers as a condition of product placement on the PDL.

Oregon’s current proposal also does not take advantage of potential structures to align the State’s payment for medicines with the value they deliver to patients and the Medicaid program. The State could seek a State Plan Amendment or waiver amendment that would allow the State the flexibility to negotiate voluntary alternative payment models that emphasize value, quality, and health outcomes. The success of the voluntary, innovative contracting approaches such as those approved in Oklahoma, Michigan, Colorado, Washington, and several more states have the potential to demonstrate beneficial outcomes, stability, and predictability in the financing, and continued future innovation.

- For example, some contracts are strictly linked to outcomes. If a drug does not produce certain metrics, such as a reduction in hospitalizations by patients using the drug, the manufacturer would receive a reduced payment or no payment.
- Other examples such as an amortized payment contract, or pay-over-time, would allow for the drug to be delivered up front for the patient and then the state would stretch out the payment over a set period of payments, with payments that could be tied to a health outcome (referred to as milestone payments); or alternatively, the subscription model in which manufacturers partner with states to agree upon pricing to treat a larger number of patients. These options can provide more predictable, value-driven financing for the appropriate disease states.

---

<sup>59</sup> H. Rep. No. 101-881, at 96-97 (1990).

Furthermore, we expect the new regulation due to take effect on July 1, 2022, permitting manufacturers to report multiple best prices, could increase the options states and manufacturers will have to enter into these novel agreements.

We strongly support innovative, voluntary negotiation between states and biopharmaceutical companies, which will, in turn, help ensure patient access to necessary therapies. We believe that value-, outcomes- or indication-based arrangements, and alternative payment models, can all have merits to both states and biopharmaceutical companies. BIO and Oregon Bio look forward to working with OHA to help the State understand the variety of arrangements that exist and flexibility they can provide to ensure new models can be advanced as health care evolves, and new medications are developed.

\*\*\*

Thank you for the opportunity to submit comments on the OHA's Section 1115 Demonstration Waiver Renewal and Amendment application. BIO and Oregon Bio strongly urge the state to work with all stakeholders including the biopharmaceutical industry to ensure new policies do not severely jeopardize patient access to care, given our belief that OHA can achieve its objectives without any waiver of §1927.

Should you have any questions, please do not hesitate to contact me at (202) 962-9200 or at [jgeisser@bio.org](mailto:jgeisser@bio.org).

Sincerely,

/s/  
Jack Geisser  
Sr. Director, Healthcare Policy,  
Medicaid, & State Initiatives  
The Biotechnology Innovation Organization



Chief Executive Officer  
Oregon Bioscience Association

January 7, 2022

Oregon Health Authority  
500 Summer Street, NE, E-20  
Salem, OR 97301

Re: 1115 Waiver

Dear Oregon Health Authority:

The vision of the Oregon 2022-2027 1115 Demonstration Waiver, meaningful progress towards health equity and a more equitable health system, offers opportunity to improve and strengthen the work accomplished in earlier waivers (CCO 1.0 and CCO 2.0), specifically:

- removing health barriers impacting the life success of Oregonians,
- expanding coverage to new populations,
- improving quality care coordination with an equity lens,
- enhancing overall health outcomes for all Oregon Health Plan Members,
- managing health care costs within an equitable funding system,
- increasing local participation and accountability.

Capitol Dental Care supports the vision of the Waiver and looks forward to being an active participant in the discussions and innovative solutions for implementation of the waiver and concept papers. We believe that the best desired result will be to strengthen and expand upon the original goals of Oregon's coordinated care model, with added focus to attain health equity for all Oregonians.

To achieve success with the proposed waiver goals and reach health equity for all Oregonians, we will need to have discussions to address several issues that will adversely impact our ability to be successful in implementing these proposals, specifically 1) Healthcare workforce; and 2) Health IT infrastructure. While these are not specifically mentioned in the waiver application, we do believe that they are key to our ability to meet the vision of the waiver.

Oregon has had a critical shortage of health care workforce across all provider types and settings, including dental. These shortages have only been and will continue to be exacerbated by the COVID pandemic, which has prompted additional issues of compassion fatigue, moral fatigue and attrition among the current healthcare workforce. Without a collective discussion and development of statewide strategies to address the healthcare workforce, including addressing burnout, retention and equitable recruitment, reaching the vision of this waiver will be compromised.

Further, quality care coordination, including referrals across both the health care system and social services agencies, will not be as successful as desired without an improved and expanded IT infrastructure. Supporting, enhancing and prioritizing the work of the Health Information Technology Oversight Committee is critical to the transformation of truly coordinated care delivery to provide an

ongoing quality member experience. It will also support and enhance the health and social services workforces in their efforts to provide the best care coordination.

### **Dental Specific Comments**

As a Dental Care Organization, we feel that several comments about oral health are important. We are excited to see that our recommendation from our July, 2021 comments on the Waiver Concept Papers to *“Consistently recognize the importance of oral health in the overall health of Oregonians”* was noted and the Waiver Application does include more consistent references to oral health as part of the Oregon Health Plan benefits along with physical and behavioral health. Oral health is critical for attainment of overall individual and population health in an equity-focused system and it is a key component in evaluating and addressing social determinants of health (SDOH).

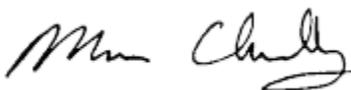
We are very supportive of the following strategies, and believe oral health has a key role in being successful in accomplishing them:

- 1) “Proposed Change 3.2 Improving Health Outcomes by Streamlining Life and Coverage Transitions, Strategy 1: Obtain expenditure authority to allow people in custody to access Medicaid benefits,”
- 2) “Proposed Change 3.2 Improving Health Outcomes by Streamlining Life and Coverage Transitions, “Strategy 3: Provide a defined set of SDOH services based on transition-related criteria to support vulnerable populations in need during transitions,” and
- 3) Section IV, Benefits and Cost Sharing; Social Determinants of Health Support Services, specifically Housing and Employment

While the references #1 and #2 above are about the Oregon Health Plan coverages, which do include dental care, it is important to understand that the oral health benefits are critical, not only for the individual’s immediate care and overall health, but these oral health benefits are also critical to referenced SDOH services in #3 above. Studies have shown that when an individual has a healthy mouth and smile, their confidence increases and their ability to have success in school, improved social interactions, and in obtaining housing and employment are enhanced, and prevents regressive outcomes in their health and overall well-being.

Capitol Dental Care supports the waiver application and looks forward to collaborating with OHA, our CCO partners and other interested parties in the implementation of the vision of meaningful progress towards health equity and a more equitable healthcare system. We appreciate the opportunity to provide comments and consideration of them. Thank you!

Sincerely,



Manu Chaudhry, MS, DDS  
President  
Capitol Dental Care, Inc.



## CareOregon Comments on Oregon's 2022-2027 1115 Waiver Draft Application

For over 25 years CareOregon has served Oregon Health Plan members and currently manages benefits for over 500,000 Oregonians through ownership of Columbia Pacific Coordinated Care Organization (CCO) and Jackson Care Connect, our partnership within Health Share of Oregon, and tribal care coordination. Together, we deeply share the Oregon Health Authority's commitment to erasing health disparities by 2030 and appreciate the direction in which the draft application and waiver concepts take us to achieve that goal.

It is in this context that we still have remaining questions regarding the health equity investment strategy and the implementation of Community Investment Collaboratives. We support the intention behind these concepts because of the deep connection we have developed over ten years of implementing the coordinated care model within the Portland Metro area, the North Coast, and Southern Oregon. This work has allowed us to successfully forge partnerships and gain understanding of our communities' needs, while learning how best to work collaboratively to meet these needs. Furthermore, critical structures strengthening the feedback loop between CCOs and the communities we serve, such as, Consumer Advisory Councils (CACs), Comprehensive Behavioral Health Plans (CBHPs), and Community Health Improvement Plans (CHPs), are built into the foundation of the CCO model and continue to be advanced by the CCO 2.0 contract. Our primary questions regarding the health equity investment strategy continue to be: 1) how to prevent the potential for siloed and parallel investments in community infrastructure; 2) how CICs will be integrated into the existing community-based contractual components of the CCO model; and 3) what will accountability for outcomes look like given 1% of CCO budgets will be directed towards CICs for infrastructure?

With a commitment to addressing health equity head-on, we believe that progress can be made by building on our existing transformation successes. To achieve this, we look forward to continued dialogue on how to best implement the final approved waiver, leveraging our successes while continually improving how we meaningfully collaborate with the communities we serve on health equity investments.

Regarding changes to the global budget, we support OHA's strategy of moving the coordinated care model to a global budget that is more stable and sustainable. A predictable budget forecast, that remains flexible to account for unexpected budget trends or population changes, will help CCOs better plan operations while aligning activity with cost control. A global budget will also alleviate the administrative burden that accompanies annual rate development. While overall supportive of the larger concept, we do caution the removal of the requirement for actuarially sound rates, a longstanding mechanism to protect CCOs from insolvency. We believe actuarially sound rates are necessary to have a financially stable system for the long term.

As stewards of public funds, we appreciate the innovation and inclusion of strategies to help the system address rising pharmacy costs through adoption of an evidence-based commercial-style formulary. We believe the following changes (underlined) help make clear our goal of supporting CCO members' access to FDA accelerated pathway approved pharmaceuticals that demonstrate clinical effectiveness within existing FDA timeframes:



## Changes to Prescription Drug Benefits

### *Ability to define a preferred drug list for pharmacy benefits*

Oregon seeks the ability to more closely manage pharmacy costs in its Medicaid program, through a two-part strategy:

#### *A. Adopt a commercial-style limited formulary approach*

Taking a limited formulary approach for adult members, including at least a single drug with standard FDA approval per therapeutic class, would enable OHA and CCOs to negotiate more favorable rebate agreements with pharmaceutical manufacturer partners. Oregon would keep an open formulary for children. For each therapeutic class, manufacturers could be offered an essentially guaranteed volume in exchange for a larger rebate. Currently, OHA and CCOs have limited ability to explore and enact such agreements with manufacturers, given the requirement to cover all drugs in the Medicaid rebate program. OHA would create a collaborative process that includes CCOs to select drugs for the closed formulary.

In recent years, the majority of commercial pharmacy benefit managers (PBMs) have adopted such closed formularies, which allow them to customize their drug offerings based on clinical efficacy and cost considerations. As an example, for 2021 CVS Health excluded from its formulary 57 additional products—some because a less expensive, medically equivalent drug had become available and some because the drugs were hyperinflationary, having dramatically increased in price without clear justification. Medicare Part D commercial plans are also permitted to employ such closed formularies (as authorized under 42 CFR 423.120) with at least two drugs per therapeutic class. Medicare Part D plans may also include just a single drug per class if only one drug is available, or if only two drugs are available, but one drug is clinically superior. Given that Medicare and other commercial plans are permitted to adopt closed formularies, we believe Oregon should have the same flexibility for Medicaid. As such, we request a formulary that is driven by clinical evidence and lowest net cost to best serve Oregon Health Plan members.

#### *B. Allow exclusion of drugs with limited or inadequate evidence of clinical efficacy*

Many drugs coming to market through the FDA's accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints. Oregon seeks the ability to use its own rigorous review process to determine coverage for drugs previously granted accelerated approval, but that have not confirmed benefit with conversion to full FDA approval in the expected time interval. Through this process, the state could incentivize drug sponsors to complete their regulatory obligations to demonstrate clinical benefit as laid out by the FDA upon approval. This will allow Oregon to avoid exorbitant spending on high-cost drugs marketed to treat conditions that have yet to demonstrate a clinical benefit despite ample time to do so. Many stakeholders agree that national policy changes are necessary to ensure proper oversight after approval of accelerated pathway drugs based on surrogate endpoints. Current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be covered without being fully clinically proven and despite drug manufacturers not meeting obligations set forth as a condition of accelerated approval.

To that end, Oregon proposes to build on the success of the Prioritized List of Services and limit the coverage of drugs approved through the accelerated pathway without traditional approval. Under this proposal, Oregon would utilize the timelines set out in the FDA approval letter and review confirmation

of benefit data in peer reviewed literature or clinicaltrials.gov. Applying the FDA developed guidance and timetables ensures a universal standard, clinically feasibility, and drug sponsor agreement.

New drugs approved under the FDA's accelerated approval pathway tend to be specialty medications that represent a significant portion of pharmacy expenditures. As such, it is our responsibility to ensure we are following through with the promise of expedited approval pathways. In addition, re-formulations of older, existing drugs that provide no incremental clinical benefit might be labeled non-formulary as well. While commercial payers can exercise discretion to exclude drugs from their formularies in certain situations, OHA and CCOs currently do not have this ability.

CareOregon appreciates the Oregon Health Authority's partnership in serving our Oregon Health Plan members through its commitment to advancing our state's unique coordinated care model. We are particularly supportive of all efforts to expand Continuous Eligibility for those eligible for OHP, as we know that this will add stability and improve the continuity of care for the population that we serve. Given the many details yet to be determined as implementation of the final approved waiver takes shape, we look forward to continuous engagement in the 1115 waiver process as we partner in achieving an equity-centered system of health.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stefan Shearer', written in a cursive style.

Stefan Shearer, MPA:HA  
Public Policy & Regulatory Affairs Specialist  
CareOregon



December 28, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Ms. Hatfield,

The Caring Ambassadors Program is a national, nonprofit advocacy organization based in Oregon City, Oregon. Caring Ambassadors has been empowering patients to be advocates for their health since 1997. Caring Ambassadors Program greatly appreciates the work you and state agencies are doing to reach the goals of the Oregon Health Authority, improve lifelong health, increase access to quality care and affordable care. Thank you for the opportunity to comment on the proposed 1115 Waiver.

Caring Ambassadors applaud the inclusion of expanded access to peer-delivered services. We have witnessed the vital services peers provide to people in recovery.

We respectfully ask that you withdraw the following aspects of the waiver.

*Strategy 3: Increase predictability of costs and ensure value for spending through closer management of pharmacy costs by adopting commercial-style closed formularies and by excluding drugs with limited or inadequate evidence of clinical efficacy.*

*a) Adopt a commercial-style closed formulary approach*

Drug formularies should encourage the proper use of resources while not restricting or adversely delaying medically necessary care. The Medicaid formulary should not be about treating populations but treating one person at a time. Delaying access to the most effective treatment for an individual can impact health status, quality of life, education, and employment. Such delay may also result in higher costs to the patient and the system if emergency care or hospitalization is needed, at odds with the cost savings intent. In addition, having a single drug per therapeutic class may cause non-medical switching. For patients with multiple comorbidities on multiple medications, this switching can be extremely harmful. For infectious diseases, like hepatitis C, hepatitis B or HIV, this can cause drug resistance. For patients with cancer, this can be deadly. Oregon's stated goal of "Protect member access, quality, and health equity" will not be reached if OHP members are limited in access to FDA-approved drugs and physicians' prescribing choice is taken out of their hands.

*OHA would create a collaborative process that includes CCOs to select drugs for the closed formulary.*

What would this collaborative process look entail? Will patient outcomes be considered? Will you include patients living with these conditions in the process? Closed formularies are not transparent nor equitable.

*b) Allow exclusion of drugs with limited or inadequate evidence of clinical efficacy*

*New drugs approved under the FDA's accelerated approval pathway can be particularly costly and would be ideal for more rigorous evaluation of coverage and potential labeling as non-formulary where appropriate.*

In 2013, the FDA granted Sovaldi Priority Review and Breakthrough Therapy designation for the treatment of hepatitis C. Since 2014, DAA's have CURED thousands of Oregonians. Yet in 2021, the P & T committee recent drug class review on Direct-Acting Antivirals for hepatitis C states, "There is insufficient direct evidence from randomized controlled trials (RCTs) that DAA therapy improves long term clinical outcomes". These FDA-approved drugs eliminate the virus in more than 90% of those studied. Patients are cured of the cancer-causing hepatitis C virus. **Would these drugs still not be available for people on OHP? If you move forward with this approach, what other breakthrough cures will be denied to people on the Oregon Health Plan?**

Our other area of concern is in *Section II. Waiver Authority*.

*Restrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one.*

Caring Ambassadors encourages OHA to remove the waiver authority. Oregon touts the passing of Senate Bill 558, also known as Cover All Kids. OHA has launched a campaign; OHP now covers me! However, you do not "Cover All Kids" if you continue this authority. This waiver authority is discriminatory against children with disabilities and their families that rely on the state for their health care.

Thank you for your time and consideration of our concerns regarding the application for renewal and amendment to the Oregon Health Plan 1115 Demonstration Waiver.

Sincerely,



Lorren Sandt  
Executive Director



January 3, 2022

To whom it may concern:

I am writing on behalf of Cascade AIDS Project (CAP) and the undersigned organizations to submit public comment on Oregon's draft 1115 Medicaid Demonstration Waiver application.

Founded in 1985 as a grassroots response to the AIDS crisis, CAP is now the oldest and largest HIV-services provider in Oregon. We and our allies are deeply concerned by the proposal in Oregon's draft application to adopt a closed formulary approach, and **we urge the state to commit in the application to maintaining open access to HIV treatment medications.**

Although we understand the reasons for adopting a closed formulary, this approach is not appropriate for HIV treatment medications, for a number of reasons:

- (1) HIV is a highly individual disease. Different people living with HIV have different treatment needs based on their specific medical history and the resistance(s) to medication that may have developed in their bodies. As a result, people living with HIV and their healthcare providers need maximum flexibility to select an HIV treatment regimen that is right for them.
- (2) HIV disproportionately impacts people who are also experiencing challenges such as homelessness, mental illness, and/or substance-use disorder. Members of this population may need simpler, more manageable HIV treatment regimens (e.g., single-tablet regimens) to remain adherent to their medications, but closed formularies can restrict access to those regimens by not factoring social determinants of health into decision-making on coverage.
- (3) Utilization-management techniques used in a closed-formulary approach, such as prior-authorization requirements, can cause abandonment of treatment, especially for those already at risk of falling out of care. For people living with HIV, in particular, the consequences can be disastrous: Medication non-adherence can lead not only to poor health outcomes, but also to permanent resistance to a drug or entire class of drugs.
- (4) People who are living with HIV and in successful treatment cannot transmit the virus through sex. However, if people fall out of care, as utilization management can cause them to do, they can spread HIV to their sexual partners. Adherence is, therefore, a public-health issue as well as an individual one.

**Chief Executive Officer**

Tyler TerMeer, PhD

**Board of Directors**

**President**

Karol Collymore  
Nike

**Vice President**

William E. Spigner  
Nike

**Secretary**

Miguel Villarreal  
Kaiser Permanente

**Treasurer**

Edwin Kietzman  
Smart Foodservice  
Warehouse Stores

**Member at Large**

Kris Young  
Nike

**Tracy A. Curtis**

Wells Fargo Bank

**Eric Garcia**

Multnomah County

**Daniel Guilfoyle**

Native American Youth &  
Family Center (NAYA)

**Andy Jamison-LeGere**

OnPoint Community Credit  
Union

**Jordan Olson**

Community Volunteer

**Rhodes Perry**

Rhodes Perry Consulting, LLC

t > 503 223 5907

f > 503 223 6437

capnw.org

520 Northwest Davis Street, Suite 215 Portland, Oregon 97209

For all these reasons, it is considered best practice to ensure access to HIV treatment medications, even within a closed-formulary approach. This is why **antiretrovirals are designated as a drug class “of clinical concern” within Medicare Part D, requiring Part D plans to cover all drugs within that class** (rather than only two or more drugs, as for most classes). It’s also why the federal agencies responsible for ending the HIV epidemic direct states to “design their prescription drug formularies to minimize potential barriers presented by utilization management techniques so that Medicaid...beneficiaries can readily access all [HIV] regimens.”<sup>1</sup> Several states, including California, Colorado, and Illinois, have gone so far as to codify in statute protections from utilization-management techniques for Medicaid members living with HIV.

Oregon currently includes all U.S. Food and Drug Administration-approved HIV drugs on its Preferred Drug List, and the above-average health outcomes of Oregonians living with HIV reflects such public policies. Ensuring access to HIV treatment medications bolsters not just Oregon’s efforts to end the HIV epidemic, but the state’s commitment to eliminating health inequities as well, because Black, Latinx, and Indigenous Oregonians are more likely to be living with HIV, and more likely to experience poor HIV health outcomes (e.g., viral non-suppression). We hope that Oregon will remain aligned with best practice and the state’s own strategic goals by **committing in its 1115 waiver application to maintain open access to HIV treatment medications.**

Sincerely,

Jonathan Frochtz wajg  
Public Policy & Grants Manager, CAP



<sup>1</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf>

## Public comment

### Draft Application of Oregon Health Plan 1115 Demonstration Waiver

January 3, 2022

Submitted by: Joshua K. Graves, MBA, QMHA,  
Catholic Community Services, CEO

Please accept the following as a public comment to the Oregon Health Plan 1115 Demonstration Waiver:

The world health organization created the social determinants of health framework in 2003. Social determinants apply more broadly than within the scope of healthcare. Social factors are critical for all community enterprises, including education, business, and government. Everyone needs stable and productive social systems. The Application needs to be more specific about creating reproducible and sustainable improvement in social determinants.

Healthcare cannot solve the social determinants issue because social systems are too big, different, and outside the scope of healthcare's already formidable and vital mission. But it can catalyze real change, as noted in the Application's Health Equity Plan. Its best hope is to support effective **local** systems development.

Getting this right will be difficult for healthcare because the social fundamentals lie outside its core experience and expertise. Community Advisory Councils (CAC) provide input and support for health plan decisions, but operational management of human services is appropriately outside any previous or proposed scope of operation.

The people working in human services are top-notch, and the people they serve have needs that those who are not directly providing social services cannot understand. Additionally, the current system's approach and tools do not match the nature of the growing problem. A radical local human service transformation is needed. CCO investment and support of systemic change will create more long-term value than picking a single issue to support or distributing smaller amounts across the community. A fresh perspective and innovative ideas will help everyone move forward.

Growing more effective **local** human service systems will deliver more value for healthcare by recruiting other stakeholders such as housing, education, and business. This growth will also be a catalyst for increased governmental coordination resulting in more efficient and effective service delivery.

Another catalyst of change for Oregon would be supporting a private, nonprofit, organization **Medicaid Match** as part of the 1115 waiver. Currently, states receiving Medicaid funds must provide a certain amount of matching funds. State policy should allow nationally accredited and

state-licensed private social service agencies to use charitable donations as Medicaid matching funds. This match would increase the available federal money and enable providers to enhance mental health services for the children, youth, and families. The current 1115 draft waiver references similar opportunities in Items 3,4,5. Innovative concepts such as this are reportedly included in waivers in other states, so the preliminary concept work should be easy to replicate. Policy recommendations should allow charitable donations as a source for Medicaid matching funds.

In looking at solutions, this is an opportunity to shift the paradigm. We can put new knowledge to work, restoring the core of society. Each community would have its solution and contract with healthcare and other stakeholders to deliver incremental improvement in social determinants. This value-based contracting would include measures based on new social determinant codes and billing sets from HL7<sup>i</sup>.

A better human service system would be local and connected to each person, family, or neighborhood through a local Traditional Health Worker (CHW or Peer Support Specialist). These THW's need community-level coordination support. A core component would be the integrating infrastructure designed for the dynamic reality of human services.

In the ideal scenario, a better human service system would be coordination-based like healthcare but implemented as an adaptive network that includes the client. In the same way, social media tracks behavior and network topology, we can learn and improve our solutions through understanding **local** complex system dynamics. This additional information is an avenue for data science to teach us more about our communities.

An improved human service system would have a **local** mutual benefit organization to support shared goals and performance. This organization is not a financially driven IPA but an outcome-driven platform of mutual support. This structure would enable concerted action on behalf of providers and those they serve.

Change is needed. Today, we seek to improve complex adaptive problems with complicated rigid solutions. We are trying to understand issues emerging from the dynamics of human behavior using static population-based data. We need to move away from the older top-down systems approach and embrace today's systems theory when dealing with complex and adaptive environments. The current path cannot take us where we need to go.

This Application is hopeful because it opens the door to improving the foundational systems supporting society.

---

<sup>i</sup> <https://vsac.nlm.nih.gov/> Value sets can support value-based reimbursement by tracking client state



## In response to the Oregon Health Authority's draft application for the next §1115 Medicaid Demonstration Waiver

The §1115 Medicaid Demonstration Waiver offers an opportunity to innovate, improve, and strengthen the care members of the Oregon Health Plan (OHP) receive across the delivery system and coordinated care model. For these reasons, we focused our collective efforts on the principles below throughout the waiver application development process over the past year.

### **CCO OREGON FRAMING FOR THE §1115 MEDICAID DEMONSTRATION WAIVER RENEWAL**

1. Continue progress towards a true global budget that is flexible and allows for community-defined infrastructure development with improved health and social outcomes while maintaining a 3.4% rate of growth for CCOs.
2. Diminish regulatory barriers to delivery and payment innovation and maximize health system cost savings and federal investments in health and social services.
3. Further Oregon's health transformation goals, including new payment models, expanded coverage access, eliminating health disparities, and the quadruple aim.
4. Increase local accountability ensuring program goals and implementation are community-based, optimize existing systems, and center the elimination of health disparities.
5. Strengthen the coordinated care model, support the goals of CCO 2.0, and set a stage for growth towards CCO 3.0.

These principles were included in our [May 2021 public comment](#) to the Oregon Health Policy Board (OHPB). This comment also recommended additions to the Oregon Health Authority's (OHA's) initial ideas for the §1115 Medicaid Demonstration Waiver renewal. We offered further [public comment in July 2021](#) to the OHPB after OHA posted the first draft of the waiver renewal concept papers. In review of the OHA's revised concept papers released in early November 2021 and the draft waiver renewal application posted on December 1, 2021, we appreciate the incorporation of many of our earlier suggestions; these include developing care coordination or targeted coverage for those OHP members that are justice-involved including the pre-adjudication phase or placed at the Oregon State Hospital or Oregon Youth Authority as well as improved access to peer support with less barriers, such as the federal treatment plan requirements.

Moreover, we appreciate the overall direction of the draft application and proposed waiver concepts. We agree that maintaining and/or expanding coverage or care coordination for targeted populations and specifically those facing transitions where they may currently lose their continuity of care, supports, or coverage should be a priority. For these concepts to succeed, there are system challenges outside of the §1115 Medicaid Demonstration Waiver

that must be considered, such as a plan to fund the state's portion of the expansions and new programs in the short and long terms. Looking to the Triple Aim, we must ensure sustained funding and thereby program continuity to improve member experience and overall population health while maintaining a reasonable rate of cost growth.

The concepts in the §1115 Medicaid Demonstration Waiver renewal and other proposed expansions in coverage and care will impact our workforce at a time when we are already experiencing devastating burnout, retention, and recruitment challenges across the delivery system. We call upon the state to launch a coordinated effort with stakeholder input from all regions of Oregon to address the workforce crisis across all provider types and settings. We realize this may not be in the actual waiver application but request a statewide, streamlined public forum to begin now so Oregon may prepare for the implementation of the waiver concepts and other programs that will increase or expand access to care and coverage.

Similarly, expansions in care and coverage will be most successful with improved infrastructure elements, such as Health and Community Information Exchanges. Connect Oregon and similar platforms, which CCOs and community-based organizations have been developing in partnership for years, are critical in urban and rural communities as we continue to transform the delivery of care to ensure referrals, warm handoffs, a quality member experience, and making the best use of the already stretched health and social service workforce. We believe this work is critical to guarantee that the proposed coverage expansions lead to the delivery of successful and sustainable whole person quality care and will engage with the Health Information Technology Oversight Committee's work over the next year(s) to scale this work across Oregon.

As our previous comments from [May 2021](#) and [July 2021](#) reflect, we support the intentions behind the proposed health equity investment strategies and have questions about how they will be operationalized, align with existing processes and contract expectations, and include accountability for outcomes and optimized spending. CCOs and coordinated care partners are committed to working with historically underserved populations to better identify systemic health disparities and leverage the coordinated care model to amplify the community role in financial decision-making. We acknowledge that the voices of those with lived experience are essential to guiding our work. We understand that we must center the perspectives of those impacted by institutionalized racism, colonialism, sexism, ableism, and heteronormativity to ensure we eradicate all remnants of such perspectives in our health delivery system from frontline workers to system partners and from the state agency to our federal partners. We know these conversations may be challenging and that they are necessary.

Our goal is to better integrate our work with local communities as opposed to work apart from it. Regional networks and partnerships developed across the coordinated care model leverage

the role of the CCO as the hub or convener with a focus on local decision making and accountability. With CCOs as the hub, provider, community-based partners, and OHP member voices are engaged in identifying and choosing regionally developed strategies to improve overall health and address disparities through the CCO Community Advisory Councils (CACs), Boards, and the development of systems and strategies, such as the Community Health Improvement Plans (CHPs), Health Equity Plans (HEPs), and Comprehensive Behavioral Health Plans (CBHPs).

OHA's draft §1115 Medicaid Demonstration Waiver application identifies two primary sources of funding for the health equity investment strategy; these investments include 1% from CCO budgets. Questions remain about which entities(y) will be accountable for the outcomes of these funds, including how they may be reflected in various CCO deliverables and metrics and how the 1% would be calculated. Further, many details are yet to be defined to ensure the proposed health equity investment strategy is integrated with the existing coordinated care model and contracting expectations (i.e., the CHP, HEP, and CBHP) to avoid duplication at the patient, provider, and payer level and prevent the creation of new funding or programmatic silos. We also need to understand how the voice and work of the CACs and other existing community-based committees will be integrated. Moreover, it is important that OHA partner with other state agencies, such as those administering housing, education, and criminal justice, to maximize all opportunities for funding and the elimination of barriers to care, services, and supports.

Lastly, we appreciate the inclusion of strategies to address the impact of pharmacy costs on Medicaid spending in Oregon. Below are suggested adjustments (in blue) to the pharmacy strategies as presented on pages 76 and 77 of OHA's [draft application](#). Our goal is to support the FDA's accelerated pathway for innovative drugs and ensure these drugs move to full evidence-based FDA approval on the expected timeline.

### **Changes to Prescription Drug Benefits**

#### *Ability to define a preferred drug list for pharmacy benefits*

Oregon seeks the ability to more closely manage pharmacy costs in its Medicaid program, through a two-part strategy:

##### *A. Adopt a commercial-style **evidence-based** formulary approach*

Taking an **evidence-based, limited** formulary approach for adult members, including at least a single drug **with standard FDA approval** per therapeutic class, would enable OHA and CCOs to negotiate more favorable rebate agreements with **pharmaceutical** manufacturer **partners**. Oregon would keep an open formulary for children. For each therapeutic class, manufacturers could be

offered an essentially guaranteed volume in exchange for a larger rebate. Currently, OHA and CCOs have limited ability to explore and enact such agreements with manufacturers, given the requirement to cover all drugs in the Medicaid rebate program. OHA would create a collaborative process that includes CCOs to select drugs for the evidence-based formulary.

In recent years, the majority of commercial pharmacy benefit managers (PBMs) have adopted such limited formularies, which allow them to customize their drug offerings based on clinical efficacy and cost considerations. As an example, for 2021 CVS Health excluded from its formulary 57 additional products—some because a less expensive, medically equivalent drug had become available and some because the drugs were hyperinflationary, having dramatically increased in price without clear justification. Medicare Part D commercial plans are also permitted to employ such evidence-based, limited formularies (as authorized under 42 CFR 423.120) with at least two drugs per therapeutic class. Medicare Part D plans may also include just a single drug per class if only one drug is available, or if only two drugs are available, but one drug is clinically superior. Given that Medicare and other commercial plans are permitted to adopt evidence-based, limited formularies, we believe Oregon should have the same flexibility for Medicaid. As such, we request a formulary that is driven by clinical evidence and lowest net cost to best serve Oregon Health Plan members.

*B. Allow exclusion of drugs with limited or inadequate evidence of clinical efficacy*

Many drugs coming to market through the FDA's accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints. Oregon seeks the ability to use its own rigorous review process to determine coverage for drugs previously granted accelerated approval, but that have not confirmed benefit with conversion to full FDA approval in the expected time interval. Through this process, the state could incentivize drug sponsors to complete their regulatory obligations to demonstrate clinical benefit as laid out by the FDA upon approval. This will allow Oregon to avoid exorbitant spending on high-cost drugs marketed to treat conditions that have yet to demonstrate a clinical benefit despite ample time to do so. Many stakeholders agree that national policy changes are necessary to ensure proper oversight after approval of accelerated pathway drugs based on surrogate endpoints. Current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be covered without being fully clinically proven and despite drug manufacturers not meeting obligations set forth as a condition of accelerated approval.

To that end, Oregon proposes to limit the coverage of drugs approved through the accelerated pathway without traditional approval. Under this proposal,

Oregon would utilize the timelines set out in the FDA approval letter and review confirmation of benefit data in peer reviewed literature or clinicaltrials.gov. Applying the FDA developed guidance and timetables ensures a universal standard, clinically feasibility, and drug sponsor agreement.

New drugs approved under the FDA’s accelerated approval pathway **tend to be specialty medications that represent a significant portion of pharmacy expenditures. As such, it is our responsibility to ensure we are following through with the promise of expedited approval pathways.** In addition, re-formulations of older, existing drugs that provide no incremental clinical benefit might be labeled non-formulary as well. While commercial payers can exercise discretion to exclude drugs from their formularies in **certain** situations, OHA and CCOs currently do not have this ability.

In closing, the sustained success of many of the proposed concepts in the draft §1115 Medicaid Demonstration Waiver application will rest in implementation and operational specifics. We know many of these elements are yet to be determined and understand that the submission of the application is the start of the process. We look forward to partnering with the OHA, regional and system partners, providers, and advocates on next steps and those details that will ensure success. We expect organizations represented here may also submit individual comments presenting similar and additional ideas, concerns, or questions. We appreciate your consideration of our comments and look forward to next steps. Thank you for your work.



## Public comment

### Draft Application of Oregon Health Plan 1115 Demonstration Waiver

January 3, 2022

Authors: *Joshua K. Graves, MBA, QMHA*, Catholic Community Services, CEO, Fostering Hope Program, *Chris Barber MSN, ANP*, Director of Community Integration, Curandi Human Service Network, *Michael D. Rohwer MD*, Founder Curandi Human Service Network.

Please accept the following as a public comment to the Oregon Health Plan 1115 Demonstration Waiver:

The world health organization created the social determinants of health framework in 2003. Social determinants apply more broadly than within the scope of healthcare. Social factors are critical for all community enterprises, including education, business, and government. Everyone needs stable and productive social systems. The Application needs to be more specific about creating reproducible and sustainable improvement in social determinants.

Healthcare cannot solve the social determinants issue because social systems are too big, different, and outside the scope of healthcare's already formidable and vital mission. But it can catalyze real change, as noted in the Application's Health Equity Plan. Its best hope is to support effective **local** systems development.

Getting this right will be difficult for healthcare because the social fundamentals lie outside its core experience and expertise. Community Advisory Councils (CAC) provide input and support for health plan decisions, but operational management of human services is appropriately outside any previous or proposed scope of operation.

The people working in human services are top-notch, and the people they serve have needs that those who are not directly providing social services cannot understand. Additionally, the current system's approach and tools do not match the nature of the growing problem. A radical local human service transformation is needed. CCO investment and support of systemic change will create more long-term value than picking a single issue to support or distributing smaller amounts across the community. A fresh perspective and innovative ideas will help everyone move forward.

Growing more effective **local** human service systems will deliver more value for healthcare by recruiting other stakeholders such as housing, education, and business. This growth will also be a catalyst for increased governmental coordination resulting in more efficient and effective service delivery.

Another catalyst of change for Oregon would be supporting a private, nonprofit, organization **Medicaid Match** as part of the 1115 waiver. Currently, states receiving Medicaid funds must

provide a certain amount of matching funds. State policy should allow nationally accredited and state-licensed private social service agencies to use charitable donations as Medicaid matching funds. This match would increase the available federal money and enable providers to enhance mental health services for the children, youth, and families. The current 1115 draft waiver references similar opportunities in Items 3,4,5. Innovative concepts such as this are reportedly included in waivers in other states, so the preliminary concept work should be easy to replicate. Policy recommendations should allow charitable donations as a source for Medicaid matching funds.

In looking at solutions, this is an opportunity to shift the paradigm. We can put new knowledge to work, restoring the core of society. Each community would have its solution and contract with healthcare and other stakeholders to deliver incremental improvement in social determinants. This value-based contracting would include measures based on new social determinant codes and billing sets from HL7<sup>i</sup>.

A better human service system would be local and connected to each person, family, or neighborhood through a local Traditional Health Worker (CHW or Peer Support Specialist). These THW's need community-level coordination support. A core component would be the integrating infrastructure designed for the dynamic reality of human services.

In the ideal scenario, a better human service system would be coordination-based like healthcare but implemented as an adaptive network that includes the client. In the same way, social media tracks behavior and network topology, we can learn and improve our solutions through understanding **local** complex system dynamics. This additional information is an avenue for data science to teach us more about our communities.

An improved human service system would have a **local** mutual benefit organization to support shared goals and performance. This organization is not a financially driven IPA but an outcome-driven platform of mutual support. This structure would enable concerted action on behalf of providers and those they serve.

Change is needed. Today, we seek to improve complex adaptive problems with complicated rigid solutions. We are trying to understand issues emerging from the dynamics of human behavior using static population-based data. We need to move away from the older top-down systems approach and embrace today's systems theory when dealing with complex and adaptive environments. The current path cannot take us where we need to go.

This Application is hopeful because it opens the door to improving the foundational systems supporting society.

*This approach is supported by Catholic Community Services of the Mid-Willamette Valley and the Curandi Human Service Network.*

---

<sup>i</sup> <https://vsac.nlm.nih.gov/> Value sets can support value-based reimbursement by tracking client state



January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

**Re: Oregon Health Plan 1115 Demonstration Waiver**

Dear Deputy Director Hittle,

Thank you for the opportunity to comment on Oregon's Section 1115 Demonstration Waiver. On behalf of people with cystic fibrosis (CF) living in Oregon, we write to express our serious concerns with this waiver application. While we commend the state for its focus on health equity and inclusion of multi-year continuous eligibility in this application, we have serious concerns that several other proposals could create barriers to access care for people with cystic fibrosis (CF). Specifically, our comments below focus on the requests to adopt a commercial-style closed drug formulary, implement an internal review process to evaluate new drugs for clinical effectiveness, and eliminate retroactive coverage for nearly all beneficiaries.

Cystic fibrosis is a life-threatening genetic disease that affects more than 35,000 children and adults in the United States, including nearly 500 in Oregon. Roughly a third of adults and children living with CF in the state rely on Oregon Health Plan (OHP) for some or all of their health care coverage. Through careful, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. In addition to advances in care, recently approved genetically-targeted drugs that address the underlying cause of CF are available for patients with specific genetic profiles and have contributed to the increases in life expectancy. This milestone reflects over 50 years of hard work to improve CF treatments, develop evidence-based standards of care, and encourage adherence to a lifetime of chronic care. However, despite immense progress in recent decades, there is still critical work to be done to ensure that all those living with the disease have access to effective therapies and, ultimately, a cure.

Given the vital role Medicaid plays in helping this patient population access essential specialized care, we urge Oregon to consider the needs of people living with CF as the state seeks changes to OHP. Within Oregon's' 1115 demonstration request, we are particularly concerned with the following provisions:

**Adopt a commercial-style “closed formulary”**

Oregon seeks to waive the requirement that Medicaid provide at least some coverage for all FDA-approved drugs and instead implement a commercial-style closed formulary to include at least one drug available per therapeutic class. The CF Foundation recognizes the reality that growth in drug costs contributes to the increasing strain on state budgets. However, we are concerned that the adoption of a closed formulary could create barriers to accessing necessary, life-saving treatments.

Treatments for CF are finite and not interchangeable; more than one drug per class is necessary in some therapeutic areas such as CFTR modulators, inhaled antibiotics, and pancreatic enzymes. For example, inhaled antibiotics are an important part of the CF care regimen. Because the type of antibiotic, the dosage, and the length of time to take the drug all vary from person to person—and the fact that some people become resistant to antibiotics over time—it is critical that people with CF have access to all available inhaled antibiotics designed specifically for CF.

Similarly, access to all CFTR modulators, the only class of CF therapies to address the underlying cause of the disease, is necessary due to the highly individualized nature of cystic fibrosis. Ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), tezacaftor/ivacaftor (Symdeko®), and elexacaftor/ivacaftor/tezacaftor (Trikafta®) are FDA-approved therapies that improve the function of CFTR protein for individuals with specific mutations in the CFTR gene. Different CFTR mutations cause different defects in the protein; therefore, genetically targeted modulators are effective only in people with specific mutations, and multiple therapies are needed within the same class to ensure everyone has access. Individual treatment regimens for CF are best determined between a patient and their CF care team.

This application also states that there will be pharmacy protections so that the adoption of a commercial-style formulary does not negatively impact members' access to safe, effective drugs. However, we are alarmed that the waiver does not outline what these pharmacy protections will be, nor does it include an exception process or any other mechanism for patients to access medically necessary drugs that are not on the formulary. This proposal lacks clear detail and fails to specify exactly how this process will work or how the state would ensure patient access. Oregon should articulate a clearly defined exceptions process, including a timeline for decisions that protects patients from delays. The state should also ensure that this exceptions process does not create an undue burden for providers.

#### **Exclude drugs with limited or inadequate evidence of clinical efficacy from the formulary**

Oregon requests the authority to use its own review process, in partnership with the Coordinated Care Organizations (CCOs), to determine whether drugs are covered by OHP. The state maintains that many drugs coming to market through FDA's accelerated approval pathways have not yet demonstrated clinical benefit. However, this waiver could apply more broadly to any drug, with the state noting that it will prioritize any new drugs (not just accelerated approval drugs) as well as re-formulations of existing drugs.

Furthermore, the state's plan to adopt a closed formulary must include more specificity and transparency. This waiver application states that Oregon would use its "own rigorous review process" to develop the OHP formulary but does not provide any information about how coverage decisions would be made, how the state would ensure transparency around this process, or how it would result in timely access to therapies for members. Should the state receive approval for its commercial-style formulary, it must provide a clearly defined and transparent review process, with opportunities for public review and comment, including significant input from experts, such as CF clinicians.

#### **Remove retroactive eligibility**

We are also concerned with this waiver's request to extend the elimination of retroactive coverage for almost all beneficiaries. Retroactive eligibility helps adults living with CF in Oregon who rely on Medicaid avoid gaps in coverage and costly medical bills. Cystic fibrosis care and treatments are costly, even with coverage, and retroactive eligibility helps protect against additional out-of-pocket costs.

According to a survey conducted by George Washington University of 1,800 people living with CF and their families, over 70 percent indicated that paying for health care has caused financial problems such as being contacted by a collection agency, having to file for bankruptcy, experiencing difficulty paying for basics like rent and utilities, or having to take a second job to make ends meet. And while nearly 75 percent received some form of financial assistance in 2019 to pay for their care, almost half reported still having problems paying for at least one medication or service in that same year.<sup>1</sup> Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as cystic fibrosis, to begin treatment without being burdened by medical debt prior to their official eligibility determination.

\*\*\*\*\*

The Cystic Fibrosis Foundation appreciates the opportunity to provide input on these important policy changes. We look forward to working with the state of Oregon to ensure access to high-quality, specialized CF care and improve the lives of all with cystic fibrosis. Please contact Sage Rosenthal, State Policy Sr. Coordinator, at [srosenthal@cff.org](mailto:srosenthal@cff.org) or (301) 841-2631 with any questions or comments.

Sincerely,

**Mary B. Dwight**

Chief Policy & Advocacy Officer  
Senior Vice President, Policy & Advocacy  
Cystic Fibrosis Foundation

**Aaron Trimble, MD**

Director, Adult CF Care Center  
Oregon Health Sciences University  
Portland, OR 97239

**Mike Powers, MD**

Director, Pediatric CF Care Center  
Oregon Health Sciences University  
Portland, OR 97239

---

<sup>1</sup> Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Cost, coverage, and the underuse of medications among people with CF" (2020). Health Policy and Management Issue Briefs. Paper 57. [https://hsrc.himmelfarb.gwu.edu/sphhs\\_policy\\_briefs/57](https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/57)



December 16, 2021

TO: Oregon Health Policy Board and Oregon Health Authority  
FROM: Children's Institute  
RE: Investing in Children and Families to Improve Health Equity in Oregon's Next 1115 Medicaid Waiver

Dear Oregon Health Policy Board and Oregon Health Authority,

Children's Institute is a statewide research, policy, and advocacy organization working to ensure all young children in Oregon have the opportunity to thrive. We work in partnership with families, schools, and community organizations to improve health and learning outcomes for children.

We are excited to see a strong focus on children and families in the final policy concepts that the Oregon Health Authority (OHA) has developed for Oregon's next 1115 Medicaid Waiver. We believe that investing in young children, starting prenatally, is a crucial strategy for impacting the upstream determinants of health. By improving health care coverage, access, and service quality for children and their families, and through addressing the needs and barriers faced by communities furthest from opportunity, we can make significant progress toward eliminating health disparities and achieving health equity in Oregon.

We offer the below input, informed by our work in early childhood systems, early learning programs, and policy advocacy and reflective of feedback from many early childhood partners across the state committed to ensuring every Oregon family has the resources and supports needed to help children thrive from the start.

1. We strongly support ensuring continuous eligibility for children from birth through age 5 and two-year continuous enrollment for all Oregon Health Plan members ages 6 and up. Reducing barriers to coverage and reducing the burden of annual reenrollment will help families stay healthy and ensure children have consistent access to coverage during this important developmental period.
2. We are disappointed to see that Oregon proposes to continue waiving three-month retroactive coverage for pregnant women and children, along with other Medicaid beneficiaries. Retroactive coverage provides a critical protection to families against the financial burden of medical debt. If Oregon continues to waive retroactive coverage families will remain at risk of the added and unnecessary financial burden of costs incurred from needed medical services provided in the three months prior to enrolling in Medicaid.
3. We believe the time is overdue for Oregon to stop waiving Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. [EPSDT](#) is Medicaid's comprehensive and guaranteed pediatric benefit, ensuring all children from birth to age 21 receive all preventive, dental, mental health and specialty services that their doctor or other medical professional deems necessary. Oregon has previously been allowed to waive its provision of the EPSDT benefit, the full impacts of which are unknown since there is no mechanism to track and resolve issues with children's access to medically necessary services. Moving forward Oregon must reinstate the EPSDT benefit and establish



accountability mechanisms so that children have equitable access to timely prevention and treatment services for their healthy development.

4. We agree that supporting families' health and social needs through important life transitions is vital. Research shows that community health workers (CHWs), doulas, home visitors, and peer navigators are highly effective at supporting families during the prenatal and postpartum period and throughout early childhood, including for families experiencing developmental disabilities or special health care needs and navigating the foster care system. These interventions, particularly if they are culturally specific and representative, often achieve better health outcomes for families than the health care system can achieve on its own. We encourage OHA and CCOs to intentionally invest in this workforce so that more families get the trusted and responsive health care and navigation support they need.

This focus area presents an opportunity to align with the federal Build Back Better investment package, which includes proposed funding to support women and children throughout the perinatal period. Build Back Better would require all states provide 12 months of Medicaid coverage for postpartum women, offer states additional Medicaid funds to create "maternal health homes" as team-based care hubs for women and children, and provide new funding to grow and diversify the perinatal workforce, including expanding doula training programs. Oregon's early investments in these strategies could lay a strong foundation for future federal support, so we encourage OHA to double down on prioritizing and resourcing this work.

5. While behavioral health is named as a priority, we believe Oregon's next waiver needs to have a deeper focus on the behavioral health needs of children. The American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association have [declared a national emergency in child and adolescent mental health](#). Of the recommendations included in the declaration, several are ripe for advancement through Oregon's waiver:
  - Accelerate adoption of effective and financially sustainable models of integrated mental health care in primary care pediatrics, including clinical strategies and models for payment.
  - Fully fund comprehensive, community-based and at times community-developed systems of care that connect families in need of behavioral health services and supports for their child with culturally relevant evidence-based interventions in their home, community, or school.
  - Promote and pay for trauma-informed care services including those that are culturally specific and community-based to support relational health and family resilience.
  - Accelerate strategies to address longstanding workforce challenges in child mental health, including innovative training programs, grow-your-own initiatives, loan repayment, and intensified efforts to recruit underrepresented populations into mental health professions.

Young children face unique and persistent challenges accessing services that promote social-emotional health and treat behavioral health challenges. Oregon will continue to lack workforce and service capacity and families will continue to suffer unless we intentionally name, resource, and prioritize these services for young children and their families.



6. We are encouraged to see how this waiver lifts up community and consumer engagement, particularly in the redesign of the CCO metrics program and in the formation and implementation of community investment collaboratives. Through our multi-year effort to recommend and develop CCO incentive metrics for the health aspects of kindergarten readiness, as well as our work engaging with community partners and families in early childhood advocacy, we have learned that engagement is most effective when it is 1) built on a foundation and community trust, 2) adequately resourced (e.g., paying parents as consultants, dedicating sufficient staff support for engagement), 3) designed with clear roles and responsibilities for a specific scope of work, 4) multimodal to offer a variety of engagement opportunities at multiple stages, and 5) flexible to allow for continuous improvement as feedback is gathered about what is working and what is not.

In order to advance Oregon's vision for healthy children, families, and communities, we also encourage OHA to consider ways to align CCO contracts, policy guidance, and resources with the spending priorities outlined in this waiver application.

Thank you for considering this input as you move forward to finalize the waiver application and enter into negotiations with the Centers for Medicaid and Medicare Services. We would be happy to connect if you have questions, reactions, or would like further details.

Sincerely,

Elena Rivera, MPH on behalf of **Children's Institute**  
Senior Health Policy and Program Advisor  
[elena@childinst.org](mailto:elena@childinst.org)



# The Oregon Coalition of Local Health Officials

December 16<sup>th</sup>, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301  
[1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Re: Oregon Health Authority's 1115 Medicaid Waiver 2022-2027 Renewal Application

To Whom It May Concern:

The Oregon Coalition of Local Health Officials (CLHO) is a 503(c)(6) non-profit organization representing the 32 local public health authorities (LPHAs) throughout Oregon. Based on review by CLHO's staff, Legislative Committee, and Board of Directors, CLHO offers the following feedback and recommendations on Oregon Health Authority's 1115 Medicaid Waiver Renewal Application for 2022-2027.

CLHO is supportive of the goals, and the suggested strategies to achieve these goals, laid out in the application. Eliminating health disparities in Oregon and employing strategies to achieve health equity are core values of public health work. The focus areas laid out in this application offer a clear vision for reaching Oregon Health Authority's goal of eliminating health disparities by 2030, and LPHAs are eager to support this work.

However, CLHO is concerned that LPHAs are not explicitly named as partners despite the clear crossover into public health work. Collaborating with LPHAs on the work outlined in this application will be beneficial on many levels:

- Local public health authorities regularly work to identify and address upstream drivers of health in their communities and work with community partners to create and implement population health interventions.
- The Oregon Legislature invested in Public Health Modernization for the 2021-23 biennium. Both LPHAs and community-based organizations (CBOs) will receive funding and need to work together to align efforts and avoid duplication. There is potential for CCO health equity investments to overlap/duplicate these efforts.
- The COVID-19 pandemic has highlighted the need for coordinated public health efforts across the state. Relationships formed between LPHAs, CCO, and CBOs during this time should be continued and supported.
- LPHAs are vital members of their communities, have many established relationships with community partners, and have been doing aspects of the work laid out in these strategies for many years.
- Many LPHAs have already done extensive equity work and have implemented equity and cultural diversity within their hiring practices. Because of this, many LPHAs' staff represent members of diverse communities and are trusted messengers of public health information. Ensuring that this work is honored and more of it encouraged moving forward should be a consideration.

For more information, please contact Sarah Lochner, Executive Director  
[sarah@oregonclho.org](mailto:sarah@oregonclho.org) | 503-507-7786 | [oregonclho.org](http://oregonclho.org)



**Public Health**  
Prevent. Promote. Protect.



# The Oregon Coalition of Local Health Officials

- Some CCOs cover multiple counties, and some counties are covered by more than one CCO. LPHAs are established, centralized entities within their counties and have specific knowledge of community partnerships, understand their communities' needs and the strategies that work best, and function as conveners on health matters.

Given this, CLHO recommends that CCOs and the Oregon Health Authority work collaboratively with LPHAs to align efforts when implementing the strategies in this application. There are two specific areas CLHO has identified for this collaboration to begin:

- CCOs are required by HB 3353 to direct 3% of their budgets to health equity investments, and a portion of that investment will go to the new Community Investment Collaboratives (CICs) proposed in this application. CLHO is supportive of redistributing power among communities and wishes to support the efforts of the CICs through collaboration and alignment. We recommend that local public health authorities have a seat on these CICs in order to avoid duplication of efforts coming from Public Health Modernization. This would align “with other health policy initiatives across the state” and “increase our likelihood of success by shaping the direction of the entire health system, including beyond Medicaid” (p. 12).
- OHA has recommended restructuring the Health Plan Quality Metrics Committee into the Health Equity Quality Metrics Committee. This committee will review and approve all upstream and downstream metrics for the Quality Incentive Program and may identify additional upstream metrics. CLHO recommends that an LPHA representative be included on this restructured committee to provide feedback on upstream metrics and population health measures.

Oregon's LPHAs look forward to collaborating with OHA and Oregon's CCOs in the implementation of this Medicaid Waiver period and in eliminating health disparities in Oregon. Please reach out if you have any questions on these recommendations.

Jocelyn Warren, PhD, MPH  
Lane County Public Health  
Chair, Oregon Coalition of Local Health  
Officials

Sarah Lochner, MPS  
Executive Director, Oregon Coalition of  
Local Health Officials

**\*Approved by the CLHO Legislative Committee on 12/9/21\***

**\*Approved by the CLHO Board 12/16/21\***

For more information, please contact Sarah Lochner, Executive Director  
[sarah@oregonclho.org](mailto:sarah@oregonclho.org) | 503-507-7786 | [oregonclho.org](http://oregonclho.org)



**Public Health**  
Prevent. Promote. Protect.

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield

RE: 1115 Medicaid Demonstration Renewal Comments

Dear Oregon Health Authority:

Thank you for the opportunity to comment on the 1115 Medicaid Demonstration Renewal. My name is Bobby Cochran. I am writing as an Oregon resident, and someone with a background in health equity as a Robert Wood Johnson Foundation Culture of Health Leader, and 20 years of supporting health in rural and urban communities at the intersections of environment, community development, and health. For me, this renewal application lines up with what years of community voices and science-based research has said—that our health is as much connected to our zip codes as our genetic codes. There are several critical elements of this knowledge that are important to retain:

A requirement that CCOs invest at least 33% of the 3% of their global budgets with community investment collaboratives with flexible authority to invest in health equity

Community-led investment works—to improve health, and reduce healthcare costs. Oregon has a rich tradition of collaborative decisionmaking that works (from Regional Health Equity Coalitions to Forest Collaboratives to Regional Solutions Centers). When communities have the flexibility to address health equity, they have invested in new transit lines that increase access to primary care AND to jobs. They have invested in youth leadership programs that create new job pathways and community healthworkers. This element is ESSENTIAL to retain. Other states have experimented with investing in health equity and social determinants (e.g., North Carolina), but this innovation is something communities across the United States have asked for. Oregon has the collaborative infrastructure, experience, and data to demonstrate this community-led investment approach will lead to better health and potential savings.

Authority for expenditures on population health and climate supports

Oregon's Waiver Renewal is explicit about the health risks posed by climate change and events such as fire and extreme heat. I appreciate that attention. Climate and other forms of resilience are built through strong social interactions, a health built environment, and the opportunity to earn a good living. Some of the greatest long-term healthcare savings will come from stronger communities who are resilient. The Waiver's flexibility allows Oregon's Medicaid program to direct other investments more directly toward health and health equity in the communities that need it most (e.g., FEMA post-disaster mitigation funds, US Forest Service recreation funds, and HUD housing supports).

Broaden authority to improve climate resilience, not just respond to disaster

The focused equity investment final policy concept paper refers to “Increasing green space and other improvements to the built environment, such as climate resilient housing, can ameliorate the impact of climate change. Further, the evidence linking time outdoors with better mental health and social cohesion is substantial.” (p15). Yet the Waiver application itself frames climate supports as a ‘response to climate disasters’. There is no explicit request for expenditure authority of federal or OHP funds that would actually build climate equity and resilience. For example, emergency transportation and ability to stay housed is critical during a disaster. But if a community knows that neighborhood greenways and

cooling centers in libraries can prevent catastrophic fire or heat stroke, then investment in those actions should be explicitly authorized as part of the focused equity investments. This framing of “climate supports” runs through the application (from strategy 3 on p 23, to the climate supports on p68). Please add a bullet to the list of Climate Supports on p68 such as, “Increasing access to natural areas with shade.”

This flexible “glue” will help braid services, preventative investments, and disaster response into a more cohesive, effective, and efficient approach to building health so that everyone has the opportunity to thrive—no exceptions.

Thank you again for the opportunity to comment!

Sincerely,

Bobby Cochran  
Portland, Oregon  
bcochran@rcap.org



January 7, 2022

Oregon Health Authority  
Attn: Lori Coyner  
500 Summer Street NE, E-20  
Salem, OR 97301

**Subject: Comment on Draft §1115 Medicaid Demonstration Waiver Renewal**

Coalition for a Healthy Oregon (COHO) is comprised of seven of the state’s coordinated care organizations (CCOs), all of which are deeply committed to Oregon’s innovative Medicaid program and achieving health equity in our state. This letter is to provide formal comment on Oregon’s §1115 Medicaid Demonstration Waiver Renewal application.

In July 2021, COHO submitted comments on the proposed Waiver concepts. Thank you for including some of our suggestions, particularly by addressing high-cost drugs. While we support many aspects of the Waiver application, the questions and concerns we raised in our July letter and in subsequent public meetings have not been adequately addressed. This letter includes some of the major changes we support, with considerations, as well as elements for which we request changes.

**Elements to keep, with considerations:**

- **Health equity commitment, including coverage for undocumented adults and demographic data collection (REALD-SOGI)**—COHO is deeply committed to improving health equity and was a strong supporter of HB 3352 (2021), known as Cover All People. On data collection, we urge the state to ensure processes are streamlined, data are actionable, and patient privacy is respected.
- **Coverage expansions and transitional supports**—We support increasing access to coordinated, high-quality care. We continue to request a plan for the state to sustainably cover its financial obligation for this expansion. Further, we urge the state to ensure the workforce is sufficient to provide current and added benefits.
- **Flexibility to exclude drugs with limited or inadequate clinical efficacy, with a pathway for coverage for non-preferred drugs**—COHO supports efforts to address high-cost drugs. Thank you for adding this at our request.

- **Paying for population health**—COHO supports movement toward paying for population health on a predictable basis, though we caution against penalizing “low-value care” to the detriment of the patient-provider relationship. Targeted rate adjustments, when necessary, should not call into question CCOs’ financial solvency or result in retroactive rate reductions. Increasing financial flexibility is important, as long as it does not erode local control.
- **Restructuring the Quality Incentive Program**—COHO supports these changes and would like to note that metrics fatigue among providers has been a challenge. Since upstream metrics could include multiple components, we need to incentivize quality improvement in a way that does not lead to provider burnout.

**Elements to change:**

- **One percent of CCO budgets to Community Investment Collaboratives**—We continue to have major concerns that this creates a funding silo outside existing accountability structures, such as CCOs’ Community Advisory Councils. It is unclear how these dollars would be connected to Community Health Improvement Plans, Health Equity Plans, and Comprehensive Behavioral Health Plans, as well as CCO financial requirements and risk arrangements. The proposal seems to contradict HB 3353 (2021), which empowered CCOs to spend flexible dollars through integrated, community-based approaches.
- **Community Information Exchanges (CIE)**—CCOs are working to build infrastructure that improves the member experience while maximizing limited resources, particularly workforce. We suggest asking for flexibility to include this in the medical spend and ask the federal government to invest in expanding Health Information Exchanges to include non-medical social services.

Thank you for your work on the Waiver and for considering our comments. We will continue to be a strong partner as Oregon moves forward in this work.

Sincerely,

Advanced Health  
AllCare Health  
Cascade Health Alliance, LLC  
InterCommunity Health Network CCO  
Trillium Community Health Plan  
Umpqua Health Alliance  
Yamhill Community Care



Monday, December 20, 2021

To: Medicaid Advisory Committee  
Attention: Co-Chair Leslee S. Huggins and Co-Chair Jeremiah Rigsby  
C/O: Jackie Wetzel, Oregon Health Authority  
[Jackie.Wetzel@dhsosha.state.or.us](mailto:Jackie.Wetzel@dhsosha.state.or.us)  
[MAC.Info@dhsosha.state.or.us](mailto:MAC.Info@dhsosha.state.or.us)

From: Members from the Curry, Josephine/Douglas, and Jackson Community Advisory Councils of AllCare CCO  
1701 NE 7<sup>th</sup> St  
Grants Pass, OR 97526

Written public comment to the Medicaid Advisory Committee for the December 15<sup>th</sup> 2021 meeting --  
RE: Draft Application for the 1115 Medicaid Waiver

Co-Chair Leslee S. Huggins, Co-Chair Jeremiah Rigsby and Members of the of Medicaid Advisory Councils,

We are members of the AllCare CCO's Community Advisory Councils. Our membership is made up of Members of the Oregon Health Plan, Community Benefit Organizations and other essential partners like County Public Health Departments.

AllCare CCO's Community Advisory Councils have been focused on community investment to improve the SDOH-E for over 7 years. Along with our work on our regions' Community Health Improvement Plans, our Councils have directed investments of over \$1.25 million to improve the health of the community. During this process we have worked with over 75 local community partners to fund programs, share expertise, and expand services. Most of these investments have been to improve the health of our community regardless of their insurance carrier or status.

The Councils have made wide-ranging, non-medical health related investments in education, housing, food security, personal safety, transportation, etc. Each of these investment has helped break down silos to work collaboratively to improve health in our community regardless of setting.

Our councils work in a collective process ensuring that our OHP member representatives have just as much of a voice as community partners.

While what we have accomplished has been positive, our Councils are limited to focus on giving out one year "grants" or pilot projects in large part because the Medicaid funding structure of CCOs mandated by CMS. With our years of experience engaging the community we have been looking for an opportunity to go beyond one year grants or pilot projects.

We saw the concept of HB 3353 as way to build on the community relationships we have built over the last 6+ years and move investments into sustainable, long-term projects that could truly transform communities. Our councils offered written letters of support highlighting specific projects that would likely benefit from this kind of flexibility. These suggestions made it into HB 3353.

Unfortunately the draft 1115 waiver has taken a different approach than what is written inside HB 3353. They are proposing siloing out dollars into a new, undefined entity with no specific geographic or membership make up. In the waiver the role of the CCO's Community Advisory Council to do oversight of these funds is not fully developed; rather the waiver looks to be in conflict with what was written in 3353.

We are also disappointed that our Community Advisory Councils were not engaged at a development level along with some other community interests. This is concerning because (by law) Community Advisory Councils are made up over 50% of Medicaid Members; voices critical for making sure the waiver is not creating unintended consequences for Oregon Health Plan members or the community.

We ask that the Oregon Health Authority take the path laid out inside HB 3353 to achieve equity goals. We supported HB 3353 because of the vital tenet of increased accountability, especially for traditionally underserved populations, of CCOs and Community Advisory Councils all across Oregon. We must elevate and empower more voices to achieve health equity - something we have been working achieve and will continue to do.

But an equally important tenet of 3353 was building on good parts of the near decade of work of breaking down silos and letting local communities make decisions about addressing the health needs of the community.

Our suggestion on a way to accomplish this would be to use these CICs, not to be different silos separate from the 99% of the budget, but rather a local group to hold CCOs and Community Advisory Councils accountable to ensure we are actually accomplishing our equity requirements and goals. Who better to grade local equity investments than our local communities?

We request that the Medicaid Advisory Committee ask that the Wavier be changed to support HB 3353 as written. We also further ask that as changes are made to the waiver that the OHA engage the Community Advisory Councils in their internal processes as with other stakeholders. Finally, we ask that the waiver make a clearer ask for flexibility and sustainability of these SDOH-E and equity efforts.

While we agree with OHA's goal of increasing community voices in decision making and oversight we don't believe that centralization and siloing for funds and efforts will accomplish these goals.

Sincerely,

Sandra Maxwell (Consumer), Vice-Chair of Josephine/So. Douglas Community Advisory Council  
Chelsea Rosenberg (Consumer), Josephine/So. Douglas Community Advisory Council  
Connie Dillinger, Josephine/So. Douglas Community Advisory Council  
Victor Van Sickle (Consumer), Jackson Community Advisory Council  
Wendy Lang, Curry Community Advisory Council  
Sarah Kaplansky (Consumer), Chair of Curry Community Advisory Council  
Leslie McIntyre (Consumer), Josephine/So. Douglas Community Advisory Council  
Machell Carroll (Consumer), Curry Community Advisory Council  
Leah Swanson, Emergency Preparedness Coordinator Josephine Public Health and Josephine/So. Douglas Community Advisory Council  
Beth Barker-Hidalgo, (Consumer), Vice-Chair of Curry Community Advisory Council  
Shawn Martinez, Juvenile Justice Prevention & Treatment Services Manager for Josephine County and Josephine/So. Douglas Community Advisory Council  
Kevin Roeckl (Consumer), 5-year member of Curry Community Advisory Council  
Don Bruland, 5-year member of Jackson Community Advisory Council  
Alexandria Jones (Consumer), Jackson Community Advisory Council  
Elizabeth Roth (Consumer), Chair of Josephine/So. Douglas Community Advisory Council  
Linda Maxon, CEO Coast Community Health Center, member of Curry Community Advisory Council



January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Deputy Director Hittle,

The Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program. As the largest provider of social and emotional support services for people impacted by cancer, CSC has a unique understanding of the cancer patient experience. In addition to our direct services, our Research and Training Institute and Cancer Policy Institute are industry leaders in advancing the evidence base and promoting patient-centered public policies.

CSC is committed to ensuring that Oregon's Medicaid program provides quality and affordable healthcare coverage. We appreciate the focus that the Oregon Health Program has placed on equitable access to healthcare in the waiver. In addition, Oregon's request to provide continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver contains multiple proposals that undermine access to care for cancer patients and survivors. We are concerned with the proposed closed formulary for adult beneficiaries, which will make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries, as the proposal jeopardizes access to care for cancer patients and survivors.

We offer the following comments and suggested changes on the 1115 demonstration waiver for the Oregon Health Program.

#### *Continuous Eligibility*

We support the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage (Osorio & Alker, 2021). Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits (Sugar et al., 2021). Continuous eligibility will help reduce these negative health outcomes.

#### *Closed Formulary*

We are strongly concerned by the proposal to transition to a closed prescription drug formulary for adult beneficiaries. A closed formulary limits the ability of providers to make the best medical decisions for their patients, based on the patient's individual needs. A formulary that may only cover one or two drugs in a class could harm patients and potentially raise medical costs as patients do not react, or react poorly, to the limited medications that can be prescribed to them. This is particularly true for cancer patients who

often receive personalized or combination therapy. Rather, providers should be prescribing based on clinical guidelines and a shared decision-making process with the patient.

We are disappointed that Oregon's proposal does not even include an appeals process for patients to access non-formulary medications. However, even an appeals process or exemptions for certain classes of drugs would not eliminate the barriers to care that patients would face with a closed formulary. The closed formulary has the potential to create delays in appropriate care, cause patients to forgo care completely, increase patient distress, and ultimately even contribute to higher health care costs. In CSC's *Access to Care in Cancer 2016* study, we found that 25% of patients experience delays in accessing needed care (due to policy barriers such as prior authorization or step therapy), with Medicaid patients experiencing the greatest care delivery delays.

Additionally, Oregon's proposal to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through the U.S. Food and Drug Administration's (FDA's) accelerated approval process, may also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new treatments have been approved through an accelerated approval process which makes therapeutically-important drugs available sooner without compromising the standards of safety and effectiveness of drugs for serious conditions like cancer. All patients enrolled in Oregon's Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life.

We request that the Oregon Health Program remove these requests and provide a robust, open prescription drug formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

#### *Retroactive Coverage*

The demonstration waiver also continues to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind, and disabled. We have serious concerns with the continued limitations to retroactive coverage and encourage the state to expand retroactive coverage to include all Medicaid beneficiaries.

Medicaid's retroactive eligibility prevents gaps in health care coverage by covering individuals for up to 3 months prior to a beneficiary's application date, provided that the individual would have been eligible for Medicaid coverage during that period. Many people only become aware that they are eligible for Medicaid when they get diagnosed with a serious illness, such as cancer, or have a major health emergency and cannot complete the application process while undergoing treatment. Retroactive eligibility allows patients in these situations to begin treatment without being financially burdened prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility (CMS, 2016). Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy. Retroactive coverage is especially important during the COVID-19 pandemic, protecting patients and providers by ensuring that medical bills are paid even if a Medicaid application is not filed until the calendar month following a health crisis.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver (Dickson, 2016). Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the

COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs.

Thank you again for the opportunity to provide comments. Should you have any questions, please contact Phylicia L. Woods, Executive Director of the Cancer Policy Institute at the Cancer Support Community at [pwoods@cancersupportcommunity.org](mailto:pwoods@cancersupportcommunity.org).

Sincerely,



Phylicia L. Woods, JD, MSW  
Executive Director – Cancer Policy Institute  
Cancer Support Community Headquarters

## References

- Cancer Support Community. (2016). *Access to Care in Cancer 2016: Barriers and Challenges*. Retrieved from <https://www.cancersupportcommunity.org/sites/default/files/migrated/pdf/csc-access-to-care-barriers-challenges.pdf>.
- Centers for Medicare & Medicaid Services. (2016). *Healthy Indiana Plan 2.0 CMS Redetermination Letter*. Retrieved from <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>
- Dickson, V. (2016). Ohio Medicaid waiver could cost hospitals \$2.5 billion. *Modern Healthcare*. Retrieved from <http://www.modernhealthcare.com/article/20160422/NEWS/160429965>.
- Osorio, A., Alker, J. (2021). Gaps in Coverage: A Look at Child Health Insurance Trends. *Center for Children & Families of the Georgetown University Health Policy Institute*. Retrieved from <https://ccf.georgetown.edu/2021/11/22/gaps-in-coverage-a-look-at-child-health-insurance-trends/>.
- Sugar, S., Peters, C., De Lew, N., & Sommers, B.D. (2021). Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic. *Assistant Secretary for Planning and Evaluation Office of Health Policy*. Retrieved from <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

12-16-2021

Designing the future of OHP Workshop 3

Public Comment: Transcript

Dharia McGrew-Pharma

We understand the state of Oregon faces considerable challenges ensuring residents have access to quality affordable care and applaud the agency's goals of improving equity in closing gaps in health disparities. Aligned in that priority we believe in building more just equitable healthcare system and believe diversity, equity, and inclusion are essential to the discovery of new medicines that people of all backgrounds should have access to treatment and heartened by the state's commitment to improving that. However, Oregon's proposal to impose a closed formulary would not promote the state's laudable goals of advancing health equity.

Your concept papers and the presentation tonight highlighted known existing health disparities, and some of the issues that led to these among OHP members and communities of concern. Research shows that limiting formulary choice can lead to worsened health outcomes and ultimately can increase costs to the system rather than producing the intended savings.

The pandemic has had harmful effects on the social, economic, and healthcare related outcomes among lower income and racially and ethnically diverse groups, therefore timely access to provide a recommended medicine is central to reversing that trend, decreasing avoidable healthcare utilization and costs and reducing mortality.

The proposed amendment will impede access to medically necessary drugs for more than 700,000 Oregonians, and it raises serious concerns about the long-term impacts. Moreover, the proposed amendment doesn't meet fundamentals of 1115 waivers, and picks and chooses which parts of Medicaid rebate statute to abide by.

We will be submitting full comments in more detail but appreciate the time and to briefly speak here tonight. In summary, pharma believes closed formulary proposal is ill advised for both legal and policy reasons and should be withdrawn from this application. Thank you.



DEVELOPING THRIVING COMMUNITIES

Thursday, January 6th, 2022

To: Oregon Health Policy Board  
Attention: David Bangsberg MSc, MD, MPH  
C/O: Tara Chetock, Oregon Health Authority  
[tara.a.chetock@dhsosha.state.or.us](mailto:tara.a.chetock@dhsosha.state.or.us)

RE: Draft Application for the 1115 Medicaid Waiver

Chair Bangsberg and Oregon Health Policy Board Members:

DevNW is an affordable housing development and counseling agency serving six counties in Oregon. Our mission is serve low and moderate income Oregonians to increase their financial security, build assets and develop thriving communities. We administer the Linn Benton Health Equity Alliance, one of five Regional Health Equity Coalitions (RHEC) in Oregon.

We know that that systemic racism has led to disproportionately higher inequities for people of color within the health system. We also know that this can be undone, most notably when communities impacted are leading. When we give power and resources to communities they can direct them to the most important health-related issues their neighbors and families face. By shifting power and granting agency, we can make significant progress toward eliminating health disparities and achieving health equity in Oregon.

We are pleased to see focused equity investments in the final policy concepts that the Oregon Health Authority (OHA) has developed for Oregon's next 1115 Medicaid Waiver. The RHECs participated in co-writing HB 3353, and in an Oregon Health Authority (OHA) waiver workgroup related to the focused equity investments concept, and supported the creation of the Community Investment Collaborative (CIC) model specifically to address health inequities because *current efforts and investments are not working for our communities.*



DEVELOPING THRIVING COMMUNITIES

We stand behind the work of the RHECs and it is our hope that all waiver concepts will be aligned with these principles as reflected in HB 3353:

- Target investments and efforts to populations and communities who have been most impacted by historic and contemporary injustices and health inequities including but not limited to Tribal Nations, Tribal communities, Latino/a/x, Black/African American, Asian, Pacific Islander, and American Indian/Alaska Native populations, communities of color, people with disabilities, people with limited English proficiency, and immigrants and refugees.
- Shift power and decision-making authority so community voice related to needs ultimately leads to development of actions to mitigate ineffective approaches and unintended consequences.
- Create opportunities to build sustainable infrastructure that works to develop and maintain systems and programs that recognize, reconcile, and rectify historical and contemporary injustices.
- Support community leadership development.
- Build and rebuild trust between health systems and community.

We believe that this shift is fundamental to centering community voice and wisdom, allowing experts in their own lives to express where investments are most necessary. Thank you for all of your work on behalf of Oregonians and in considering this input as you move forward to finalize the waiver application and enter into negotiations with the Centers for Medicaid and Medicare Services.

Sincerely,

A handwritten signature in black ink, appearing to read "KSaxe".

Karen Saxe  
Chief Program Officer



January 7, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Oregon Health Plan 1115 Demonstration Waiver Application for Renewal

Dear Ms. Hatfield:

We appreciate this opportunity to provide comments as the Oregon Health Plan (OHP) applies to the Centers for Medicare & Medicaid Services (CMS) for a new five-year Medicaid waiver, known as the 1115 Demonstration. We hope that the state will incorporate the perspectives of people with disabilities that disproportionately are impacted by the state's prioritized list of services by barring the use of the discriminatory quality-adjusted life year (QALY) as a consideration; by ensuring that individuals with disabilities and significant health conditions do not face discrimination in accessing suicide prevention services; and by discontinuing the EPSDT waiver that too often fails to give children the care they need.

As you know, in 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage that was denied by the U.S. Department of Health and Human Services as "discriminatory and inconsistent with the Americans with Disabilities Act."<sup>1</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance. Despite ADA concerns, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Officially, Oregon excluded the survey-based QALY data that triggered denial of its initial waiver application in 1992. Yet, the voting members of Oregon's Health Policy Commission have authority to

---

<sup>1</sup> <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

override the results of non-QALY considerations, which they did in over 70% of the cases. The discriminatory outcome for how care is valued and prioritized is the same.<sup>2</sup>

Today, the Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, continues to use QALY-driven data and analysis in the formula for the prioritized list of services. As reconstructed in 2008, Oregon's revised prioritization framework emphasizes preventive services and chronic disease management in order to keep the "population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health." This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. Although Oregon removed a direct and explicit reference to QALYs from its cost-effectiveness framework in 2017, it continues to rely upon the QALY-driven prioritization scores for condition-treatment pairs that were already established at that time. In addition, HERC continues to consider QALY-based analysis in evaluating other factors in the formula.<sup>3</sup>

The HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by entities such as the Institute for Clinical and Economic Review (ICER) as they vote. After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list. A few excluded services for people with disabilities include treatment for hearing impairment, Bell's Palsy, Spastic Diplegia, and certain personality disorders.<sup>4</sup>

Oregon also chooses to provide coverage for some services that aren't on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of physician-assisted suicide, including counseling and lethal prescriptions. It has been reported that OHP patients who have been denied coverage of potentially life-extending health services that were "below the line" have been advised by OHP that physician assisted suicide is a covered alternative.<sup>5</sup> This outcome – preference for assisted suicide over treatment – is the direct result of the state's discriminatory policies and is clearly unethical and in violation of disability and civil rights protections.

The ethical challenges of Oregon's use of discriminatory metrics to ration services it will cover are exacerbated for children. Oregon is the only state with an EPSDT waiver. In every other state, under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called "Early and Periodic Screening, Diagnostic and Treatment" (EPSDT) to ensure that they receive "age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting." Critically, the EPSDT provision requires comprehensive coverage of health services for children – *regardless of whether or not such services are otherwise covered* under the state

---

<sup>2</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf>

<sup>3</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx>

<sup>4</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>

<sup>5</sup> <https://abcnews.go.com/Health/story?id=5517492&page=1>

Medicaid plan for adults ages 21 and older – to make certain that rationing is not imposed for this vulnerable population.<sup>6</sup> Even still, Oregon’s Section 1115 Medicaid waiver includes a provision authorizing it to withhold medically necessary care from children over the age of one if it is “below the line” on its “Prioritized List” of health services. A few examples include noncoverage of treatment for selective mutism, conduct disorder, recurrent ear infections, minor burns, and pica.

We believe it is time to end this failed experiment of relying on discrimination to ration care. Our specific recommendations are as follows:

**1. Full Compliance with EPSDT**

The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.

**2. Prohibit the Use of Discriminatory QALY Measures**

The waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, such as this:

“Prohibition on Reliance on Discriminatory Measures. The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per- quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”

**3. Non-discrimination in Suicide Prevention Services**

The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for lethal drugs under Oregon’s “Death with Dignity Act,” will be provided with the same harm and suicide prevention services<sup>7</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to die by suicide because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.

---

<sup>6</sup> <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>

<sup>7</sup> The term “harm and suicide prevention services” includes screening, diagnosis, psychiatric treatment, therapy, counseling, and other services whose purpose is the detection and treatment of suicidal ideation and tendencies and the causes thereof, including depression, mental disorders, and lack of access to rehabilitative and supportive care.

We appreciate the opportunity to comment.

Sincerely,

[Disability Policy Consortium](#)

[Disability Rights California](#)

[Disability Rights Education and Defense Fund](#)

[Not Dead Yet](#)

[Patients Rights Action Fund](#)

[Partnership to Improve Patient Care](#)

[The Coelho Center for Disability Law, Policy, and Innovation](#)

January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Oregon Health Plan 1115 Demonstration Waiver Application for Renewal

Dear Ms. Hatfield:

We appreciate this opportunity to provide comments as the Oregon Health Plan (OHP) applies to the Centers for Medicare & Medicaid Services (CMS) for a new five-year Medicaid waiver, known as the 1115 Demonstration. We hope that the state will incorporate the perspectives of people with disabilities that disproportionately are impacted by the state's prioritized list of services by barring the use of the discriminatory quality-adjusted life year (QALY) as a consideration; by ensuring that individuals with disabilities and significant health conditions do not face discrimination in accessing suicide prevention services; and by discontinuing the EPSDT waiver that too often fails to give children the care they need.

As you know, in 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage that was denied by the U.S. Department of Health and Human Services as "discriminatory and inconsistent with the Americans with Disabilities Act."<sup>1</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance. Despite ADA concerns, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Officially, Oregon excluded the survey-based QALY data that triggered denial of its initial waiver application in 1992. Yet, the voting members of Oregon's Health Policy Commission have authority to override the results of non-QALY considerations, which they did in over 70% of the cases. The discriminatory outcome for how care is valued and prioritized is the same.<sup>2</sup>

Today, the Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, continues to use QALY-driven data and analysis in the formula for the prioritized list of

<sup>1</sup> <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html> <sup>2</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf>

services. As reconstructed in 2008, Oregon’s revised prioritization framework emphasizes preventive services and chronic disease management in order to keep the “population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health.” This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. Although Oregon removed a direct and explicit reference to QALYs from its cost-effectiveness framework in 2017, it continues to rely upon the QALY-driven prioritization scores for condition treatment pairs that were already established at that time. In addition, HERC continues to consider QALY-based analysis in evaluating other factors in the formula.<sup>3</sup>

The HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by entities such as the Institute for Clinical and Economic Review (ICER) as they vote. After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list. A few excluded services for people with disabilities include treatment for hearing impairment, Bell’s Palsy, Spastic Diplegia, and certain personality disorders.<sup>4</sup>

Oregon also chooses to provide coverage for some services that aren’t on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of medical aid in dying. It has been reported that OHP patients who have been denied coverage of potentially life-extending health services that were “below the line” have been advised by OHP that medical aid in dying is a covered alternative.<sup>5</sup> This outcome – intentional or not – implies some patients lives are not worth living.

The ethical challenges of Oregon’s use of discriminatory metrics to ration services it will cover are exacerbated for children. Oregon is the only state with an EPSDT waiver. In every other state, under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called “Early and Periodic Screening, Diagnostic and Treatment” (EPSDT) to ensure that they receive “age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting.” Critically, the EPSDT provision requires comprehensive coverage of health services for children – *regardless of whether or not such services are otherwise covered* under the state Medicaid plan for adults ages 21 and older – to make certain that rationing is not imposed for this vulnerable population.<sup>6</sup> Even still, Oregon’s Section 1115 Medicaid waiver includes a provision authorizing it to withhold medically necessary care from children over the age of one if it is “below the line” on its “Prioritized List” of health services. A few examples include noncoverage of treatment for selective mutism, conduct disorder, recurrent ear infections, minor burns, and pica.

<sup>3</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx>

<sup>4</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>

<sup>5</sup> <https://abcnews.go.com/Health/story?id=5517492&page=1>

<sup>6</sup> <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>

We believe it is time to end this failed experiment of relying on discrimination to ration care. Our specific recommendations are as follows:

### **1. Full Compliance with EPSDT**

The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.

### **2. Prohibit the Use of Discriminatory QALY Measures**

The waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, such as this:

“Prohibition on Reliance on Discriminatory Measures. The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per- quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”

### **3. Non-discrimination in Suicide Prevention Services**

The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for Oregon’s “Death with Dignity Act,” will be provided with the same harm and suicide prevention services<sup>7</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to utilize medical aid in dying because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.

<sup>7</sup> The term “harm and suicide prevention services” includes screening, diagnosis, psychiatric treatment, therapy, counseling, and other services whose purpose is the detection and treatment of suicidal ideation and tendencies and the causes thereof, including depression, mental disorders, and lack of access to rehabilitative and supportive care.

Sincerely,

Disability Rights Oregon  
Allergy & Asthma Network  
Alliance for Aging Research  
American Association of Kidney Patients (AAKP)  
American Speech-Language-Hearing Association  
Association of University Centers on Disabilities  
Autism Business Association  
Autism Insurance for Oregon  
Autism Society of Oregon  
Autism Speaks  
Autistic Self Advocacy Network  
Behavioral Health Center of Excellence  
*CancerCare*  
Care About Fibroids  
Caring Ambassadors Program  
Center for Autism and Related Disorders  
Cockayne Syndrome Network - Share & Care  
Colorado Cross-Disability Coalition  
Council of Autism Service Providers  
Cystic Fibrosis Research Institute  
Disability Policy Consortium  
Epilepsy Foundation  
Epilepsy Foundation Oregon  
FACT Oregon  
Familia Unida Living with MS  
Genetic Alliance and PXE International  
GO2 Foundation for Lung Cancer  
HCMA - Hypertrophic Cardiomyopathy Association  
Health Hats  
ICAN, International Cancer Advocacy Network  
Independent Health Care Policy Consultant  
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

M-CM Network  
Men's Health Network  
Mental Health and Autism Insurance Project  
MLD Foundation  
National Coalition for Access to Autism Services (NCAAS)  
National Council on Severe Autism  
National Disability Rights Network (NDRN)  
NBIA Disorders Association  
New York State Sickle Cell Advocacy Network, Inc,  
Northwest PANDAS/PANS Network  
One Rare  
Oregon Family Support Network, Inc.  
Oregon Speech-Language Hearing Association  
Organic Acidemia Association  
Partnership to Fight Chronic Disease  
Partnership to Improve Patient Care  
Pulmonary Hypertension Association  
Rare New England  
SYNGAP1 Foundation  
The Bonnell Foundation: Living with Cystic Fibrosis  
The Migraine Diva, LLC  
TSC Alliance  
Whistleblowers of America



January 7, 2022

Interim Deputy Medicaid Director Dana Hittle  
500 Summer St. NE, E65  
Salem, OR 97301

Submitted via email to: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Interim Deputy Director Hittle:

On behalf of the Dravet Syndrome Foundation, I am writing in regards to the Oregon 1115 Demonstration Waiver for the Oregon Health Program (OHP). There are 42,900 people with epilepsy in Oregon and about one-third of people with epilepsy rely on Medicaid for health coverage – so this waiver proposal and its implications are of utmost importance. We appreciate the focus on equitable access to healthcare in this waiver. We support Oregon’s request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over.

Unfortunately, this waiver also contains multiple proposals that would undermine access to care and needed medications for people with epilepsy. We are very concerned with the new proposed closed formulary for adults, as well as Oregon’s proposals to continue the waiver of retroactive eligibility, continue to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children over the age of one, and continue to use of a Prioritized List of services that relies, in part, on a quality-adjusted life year.

The Dravet Syndrome Foundation (DSF) represents individuals living with Dravet syndrome and their families. Dravet syndrome affects approximately 1:15,700 individuals. DSF supports individuals and families navigating life with Dravet syndrome through research funding, advocacy, educational activities, and direct support services. Dravet syndrome is a catastrophic disease that onsets with prolonged, medication-resistant seizures in the first year of life and progresses with an accumulating burden of comorbid conditions including developmental delays, motor impairment, sleep disturbances, and behavioral disruptions, among others. In addition to these disease-specific efforts, DSF represents and advocates for all individuals living with epilepsy through collaborations with the Rare Epilepsy Network, the Epilepsy Leadership Council, the Epilepsy Foundation, the Seizure Action Plan Coalition and the Epilepsy Learning Healthcare System. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime, and people living with epilepsy must have meaningful and timely access to physician-directed, person-centered care, to avoid breakthrough seizures and related complications and costs. We outline our specific thoughts and concerns about this proposal below, modified from a statement originally drafted by our partners at the Epilepsy Foundation.

### ***Support Continuous Eligibility***

We support the request for continuous enrollment for children under age six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent people from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage. Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits. Continuous access to care is especially important for people with epilepsy, where even one missed dose of medication can lead to significant complications, including death.<sup>1</sup>

---

<sup>1</sup> Faught E, Duh MS, Weiner JR, Guérin A, Cunnington MC. Nonadherence to antiepileptic drugs and increased mortality: findings from the RANSOM Study. *Neurology*. 2008;71(20):1572.



### ***Oppose Closed Formulary***

We are strongly opposed to the proposal to transition to a closed formulary for adults. For the majority of individuals living with epilepsy, anti-seizure medications are the most common and cost-effective treatment for controlling and/or reducing seizures, and they must have meaningful and timely access to physician-directed and person-centered care. There is no “one size fits all” treatment option for

epilepsy, and the response to medications can be different for each person. For example, many of the most commonly utilized medications to treat seizures are contraindicated for individuals with Dravet syndrome and can actually worsen seizures and cognitive outcomes. Individuals with Dravet syndrome are generally on several (3 or more) different anti-seizure medications and will often need to add or make changes to anti-seizure medication regimens throughout their lifetime, including in adulthood. Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by physicians and their patients. To change, limit, or deny access to the prescribed, most effective medications could be extremely dangerous.

Oregon proposes an unprecedented change to Medicaid coverage of prescription drugs by waiving the requirement that the state comply with Section 1927 of the Social Security Act, which requires Medicaid to cover Food and Drug Administration (FDA) approved drugs, subject to certain conditions and exclusions, if the manufacturer of such drugs has signed an agreement to pay rebates. Under current law, Oregon can already impose preferred drug lists that require prior authorization before a prescription drug may be covered under Medicaid and use the preferred drug list to negotiate additional rebates with manufacturers. Except for certain classes of drugs that states may exclude, states are barred from imposing fully “closed” formularies under which drugs cannot be covered under any circumstance.

Oregon’s proposal would allow the state to exclude FDA-approved drugs entirely. The state could offer **just one drug per therapeutic class**, which is wholly unacceptable, detrimental, and dangerous to people living with epilepsy and seizures. Oregon’s proposal closely resembles a 2017 Massachusetts proposal to establish a closed formulary in its Medicaid program – which CMS rightly rejected in 2018<sup>2</sup> – and a Tennessee proposal currently under review by CMS that we strongly oppose.<sup>3</sup> Oregon’s proposal is even more restrictive than what Tennessee proposed: Tennessee’s closed formulary would have included protections for epilepsy medications and other classes, Oregon’s proposal has no such protections.

The proposed closed formulary would cover as little as one medication per therapeutic class. This means that only one epilepsy medication could be covered for all adults in Medicaid. As noted above, epilepsy medications are not interchangeable and there is no one treatment that works best for everyone with seizures. For example, many commonly utilized medications for seizure control are mechanistically contraindicated for Dravet syndrome and can exacerbate seizure activity and worsen long-term outcomes. Furthermore, the response to medications, including effectiveness at controlling seizures and side effects, can be different for each person, even those with a shared diagnosis. Even anti-seizure medication specifically indicated for the treatment of seizures in Dravet syndrome can have differential effectiveness from patient to patient, necessitating an individualized approach to medication selection for each patient. Impeding or delaying access to the prescribed, most effective epilepsy medications increases the likelihood of breakthrough seizures and related complications including injury, disability or even death. Further, many people with epilepsy need to take more than one anti-seizure medication to gain or approach seizure control; as mentioned above, in Dravet syndrome, it is common for patients to utilize three or more anti-seizure medications to reach acceptable levels of seizure control. The waiver does not appear to include any kind of appeals or exceptions process for people in various situations such as already being stable on a medication, or those who need to take more than one medication at a time to treat their condition. Physicians and people with epilepsy work together to determine the appropriate regimen, based on the type of seizure, seizure frequency, age, gender, other health conditions, other medications, and side effects.

---

<sup>2</sup> Centers for Medicare & Medicaid Services, MassHealth Demonstration Amendment Approval, June 27, 2018, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf>.

<sup>3</sup> Health Partners Comments on Special Terms & Conditions for TennCare III. September 9, 2021. [https://www.lung.org/getmedia/4a6256df-73e6-43ef-9fb6-4aefc979375a/health-partner-letter-re-tenncare-1115-waiver-\(final\).pdf](https://www.lung.org/getmedia/4a6256df-73e6-43ef-9fb6-4aefc979375a/health-partner-letter-re-tenncare-1115-waiver-(final).pdf)



Oregon's proposal could result in sudden loss of coverage for anti-seizure medications that beneficiaries are currently taking. Most anti-seizure medications need to be titrated to an individualized dose, and that dose needs to be determined to be effective in a specific individual. When switching medications, anti-seizure medications must be titrated down to safely wean the individual off. This process can take months. The formulary change could have significant negative impact on people with epilepsy who are currently stable on their medications. People who are seizure free have been found to have a 16.7% rate of seizure recurrence after a medication switch, compared to 2.8% among those remaining on the same drug.<sup>4</sup>

Oregon states that it seeks to implement a "commercial-style" and points to the rising restrictions in the commercial market. However, those restrictions are not without consequences. One study found formulary restrictions resulted in an average of 6.9 days of delay and 35% lower likelihood of successful dispensing, compared to claims that did not meet with formulary restrictions.<sup>5</sup> Oregon also points to restrictions allowed by Medicare Part D plans without recognizing that Part D plans are required to cover all or substantially all drugs in classes of clinical concern, often known as the "Six Protected Classes," which includes anti-convulsant medications. Oregon includes no such protections for these vulnerable populations in their proposal.

The waiver application makes clear that Oregon's intent in seeking a closed formulary is to reduce costs. However, on top of the dangerous possible consequences to health and life detailed above, restricting access to epilepsy medications will not achieve savings. People with epilepsy whose medications are switched have a high chance of seizure recurrence and in turn, higher medical costs. A review of studies has shown that the direct, epilepsy-related medical costs associated with uncontrolled epilepsy are 2 to 10 times higher than costs associated with controlled epilepsy.<sup>6</sup> There are 42,900 people with epilepsy in Oregon. Oregon's closed formulary could force many of them to switch medications, resulting in costly and avoidable ambulance services, emergency room visits, injuries, and hospital stays.

Additionally, Oregon proposes to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through FDA's accelerated approval processes. This will also harm patients by restricting access to novel and lifesaving therapies. To date, no epilepsy medications have been approved through accelerated approval, but we are concerned that this proposal could extend to any other new treatment which the state deems ineffective, despite the decisions of the FDA. States should not be in the position of determining the safety and efficacy of medications; that role is reserved for the FDA.

All patients enrolled in Oregon's Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life. We request that the Oregon Health Program remove these requests and

provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that they and their providers have determined are best for them.

### ***Oppose Continuing to Eliminate Retroactive Coverage***

We are concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding those eligible through a disability pathway. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common for people to be unaware that they are eligible for Medicaid until a medical crisis. Retroactive eligibility allows people with epilepsy who have either been newly diagnosed or need a new treatment regime to begin treatment right away, avoiding delays in lifesaving care and without the burden of medical debt while they work on eligibility paperwork. This is particularly important for some groups that experience health disparities, such as African Americans, who are more likely to be diagnosed with epilepsy in an emergency room.<sup>7</sup> Retroactive eligibility

<sup>4</sup> Seizure outcome after switching antiepileptic drugs: A matched, prospective study. *Epilepsia*, 57(8), 1294–1300.

<https://doi.org/10.1111/epi.13435>

<sup>5</sup> Mehta, D., Davis, M., Epstein, A.J. et al. (2020). Impact of formulary restrictions on antiepileptic drug dispensation outcomes. *Neurol Ther* 9, 505–519. <https://doi.org/10.1007/s40120-020-00195-3>.

<sup>6</sup> Begley, Charles E. & Durgin, Tracy L. (2015). The Direct Cost of Epilepsy to the United States: A Systematic Review of the Estimates. *Epilepsia*, 56(9), 1376-1387. Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084>.

<sup>7</sup> Epilepsy Foundation, "Epilepsy and African Americans." Available at: <https://www.epilepsy.com/living-epilepsy/epilepsy-and/african-americans>



also helps low-income residents avoid medical debt they cannot afford to take on. Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>8</sup> Without retroactive eligibility, people with epilepsy who are eligible for Medicaid could face substantial costs and delays at their doctor's office or pharmacy.

People with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>9</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. We oppose the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries. Retroactive coverage is a critical part of Medicaid's safety net.

### ***Oppose Prioritized List and Use of Quality Adjusted Life Years***

We are concerned about the use of a Prioritized List to determine coverage and access to treatments in Oregon, including the use of the quality adjusted life year (QALY) in determining coverage and access.

QALYs are typically developed by surveying the general public about their preferences for health states. Significant evidence exists that the general public has strong anti-disability bias, up to and including withholding health care on the basis of disability. These societal preferences were on display during the COVID-19 pandemic, when many hospital Crisis Standards of Care included plans to discriminate on the basis of disability and de-prioritize care for people with disabilities.<sup>10</sup> Fortunately, HHS OCR issued guidance early in the pandemic stating, "Persons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative 'worth' based on the presence or absence of disabilities or age."<sup>11</sup> Disability advocacy organizations filed complaints to change initial crisis standards of care, including in Oregon.<sup>12,13</sup>

In 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage. This application was denied by the U.S. Department of Health and Human Services as violating the Americans with Disabilities Act (ADA).<sup>14</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance.

According to Disability Rights Oregon, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Oregon's Prioritized list is created by the Health Evidence Review Commission (HERC). HERC relies on QALYs for some of its reviews of clinical and cost effectiveness to determine placement on the prioritized list. For example, QALYs are cited in the recent reports: Multisector Intervention Report: Community Health Workers for Patients with Chronic Disease;<sup>15</sup> Multisector Intervention Report: Multicomponent

<sup>8</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>9</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>10</sup> Center for Public Representation, "COVID-19 Medical Rationing & Facility Visitation Policies." Available at: <https://www.centerforpublicrep.org/covid-19-medical-rationing/>

<sup>11</sup> U.S. Department of Health and Human Services Office for Civil Rights. Bulletin: Civil Rights, HIPAA, and Coronavirus Disease 2019. March 28, 2020. Available at: <https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>

<sup>12</sup> Disability Rights Oregon. Press Release. May 8, 2020. Available at: <https://www.centerforpublicrep.org/wp-content/uploads/2020-05-08-Release-on-OCR-Letter.pdf>

<sup>13</sup> Oregon Health Authority. Principles in Promoting Health Equity During Resource Constrained Events. December 7, 2020. Available at: <https://sharedsystems.dhsosha.state.or.us/DHSForms/Served/le3513.pdf>

<sup>14</sup> Sullivan, Louis W., Oregon Health Plan Is Unfair to the Disabled, The New York Times. August 13, 1992. Available at: <https://www.nytimes.com/1992/09/01/opinion/1-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

<sup>15</sup> Oregon HERC. Multisector Intervention Report: Community Health Workers for Patients with Chronic Disease. November 14, 2019. <https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CHW-Multisector-Report-Final.pdf>



Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer;<sup>16</sup> and Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring.<sup>17</sup>

We are concerned with the existence of the Prioritized List at all, and further concerned about the use of QALYs to determine who gets care. QALYs discriminate against people with disabilities by devaluing lives lived with disability.

In 2019, National Council on Disability (NCD), an independent federal agency, released series of reports on bioethics and disability.<sup>18</sup> One of these reports *Quality-Adjusted Life Years and the Devaluation of Life with a Disability* found “sufficient evidence of QALYs being discriminatory (or potentially discriminatory to warrant concern.”<sup>19</sup> NCD recommended an explicit ban on the use of QALYs in Medicare and Medicaid.<sup>20</sup> They also recommended that Medicaid “should not rely on cost-effectiveness research or reports that gather input from the public on health preferences that do not include the input of people with disabilities and chronic illness.”<sup>21</sup> NCD also recommended the use of alternative value assessment mechanisms and provided examples for the federal government and states to use.

The use of QALYs may also violate federal law. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be “excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination,” under any program offered by the federal government.<sup>22</sup> Title II of the Americans with Disabilities Act (ADA) extends this protection to programs and services offered by state and local governments.<sup>23</sup>

During the COVID-19 pandemic, OHP responded to the concerns of disability rights advocates about the allocation of scarce resources by developing a negotiated document on how to allocate scarce inpatient critical care resources in the pandemic. The Prioritized List should be given the same treatment. We urge OHP to abandon the use of the QALY and work with Disability Rights Oregon, Epilepsy Foundation Oregon, and other disability rights organizations to develop a better way to allocate scarce Medicaid dollars and care for people with disabilities in an equitable way.

### ***Oppose Restricting EPSDT Benefit***

We are opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). There are 5,400 children in Oregon with epilepsy and the purpose of the EPSDT benefit is to ensure that children receive appropriate health care. Limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services. We appreciate that Oregon is not proposing to limit access to medications for children. However, children with epilepsy do not need just their anti-seizure medications alone. They frequently, nearly always in Dravet syndrome, have related developmental disabilities or mental health needs, yet the current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including selective mutism, conduct and impulse disorders, deformities of the upper body and limbs, sleep disorders, and pica. Lack of sleep is a known seizure trigger,<sup>24</sup> and children with epilepsy are known to already have more sleep problems,<sup>25</sup> so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications,

<sup>16</sup> Oregon HERC. Multisector Intervention Report: Multicomponent Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer. October 1, 2020. [https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/MSI%20Cancer%20Screening\\_finalized\\_10-1-2020PDF.pdf](https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/MSI%20Cancer%20Screening_finalized_10-1-2020PDF.pdf)

<sup>17</sup> Oregon HERC. Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring. October 4, 2018. <https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG-CardioMEMS-final.pdf>

<sup>18</sup> National Council Disability. Bioethics and Disability Report Series. Available at: <https://ncd.gov/publications/2019/bioethics-report-series>

<sup>19</sup> National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. November 6, 2019. [https://ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf), pg. 13.

<sup>20</sup> Ibid., pg. 14.

<sup>21</sup> Ibid., pg. 15.

<sup>22</sup> 29 USC Sec 794, 2017.

<sup>23</sup> 42 USC Sec 12131, 2017.

<sup>24</sup> Lanigar, S., & Bandyopadhyay, S. (2017). Sleep and Epilepsy: A Complex Interplay. Missouri medicine, 114(6), 453–457. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6139974/>

See also: <https://www.epilepsy.com/learn/triggers-seizures> and <https://www.epilepsy.com/learn/triggers-seizures/lack-sleep-and-epilepsy>

<sup>25</sup> <https://www.epilepsy.com/learn/challenges-epilepsy/sleep-and-epilepsy>



emergency room visits, hospital stays, and lost school days. The prioritized list also currently excludes treatment for conditions that can be a risk or side effect of epilepsy treatment, including paralysis of vocal cords or larynx, which can result from implantation of a Vagus Nerve Stimulation (VNS) device which is commonly utilized in patients with Dravet syndrome. Limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. Children of color are enrolled in Medicaid at disproportionately higher rates<sup>26</sup> and are also more likely to be affected by gaps in coverage.<sup>27</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit.

We strongly support the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

We appreciate the opportunity to comment on this proposal and sincerely hope that our concerns are heeded so that people with Dravet syndrome and other forms of epilepsy can continue to access the care and medications that they need. If you have any questions, please contact us at [veronica@dravetfoundation.org](mailto:veronica@dravetfoundation.org).

Sincerely,

Veronica Hood, PhD  
Scientific Director  
Dravet Syndrome Foundation

---

<sup>26</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. <https://ccf.georgetown.edu/wp-content/uploads/2017/06/EPSDT-At-Risk-Final.pdf>

<sup>27</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)



**Oregon Early Learning Council**

700 Summer Street NE, Suite 350

Salem, OR 97301

January 4, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team

Attn: Michelle Hatfield

500 Summer St. NE, E65

Salem, OR 97301

SUE MILLER  
*Chair, Early Learning  
Council*

PATRICK ALLEN  
*Director, Oregon Health  
Authority*

ANGELA BLACKWELL

KATY BROOKS

PETER BUCKLEY

COLT GILL  
*Deputy Superintendent,  
Oregon Department of  
Education*

ANNE KUBISCH

GEORGE MENDOZA

DR. MARGARET MILLER

MARGARET SALAZAR  
*Executive Director,  
Oregon Housing and  
Community Services*

KALI THORNE LADD

LIESL WENDT  
*Deputy Director,  
Oregon Department of  
Human Services*

ALYSSA CHATTERJEE  
*Early Learning  
System Director*

Dear Members of the Health Policy and Analytics Medicaid Waiver Renewal Team,

I write on behalf of the Early Learning Council in support of strategies aimed to bolster young children (0-5) and their families in Oregon's Medicaid 1115 Waiver. Thank you for prioritizing the youngest Oregonians by aligning several strategies of the Waiver with those of *Raise Up Oregon: A Statewide Early Learning System Plan*, specifically the goals to ensure that children and their families are healthy and supported to enter school. As noted in the Waiver, families with young children are at the poorest stage in their lifetimes, and families of color disproportionately make up young families in poverty.

We commend you for the proposal of continuous enrollment for young children in Medicaid, which will facilitate access to routine care and needed specialized services, during the most critical growth and development period in their lives. We also support the proposed changes in the metrics and note the delineation of upstream and downstream metrics with the focus on equity and prevention. We note as well the focus on meeting the health care needs of children in the child welfare system, and appreciate this as so many of the children impacted by this system are in the birth to five age range. Finally, the proposed Community Investment Collaborative provide an important opportunity to give voice to community members.

As you seek to implement these, we encourage connection with the Early Learning Hubs and with families and providers who are part of the early care and education system and who are also participants in the Oregon Health Authority's Waiver programming.

Thank you again for your dedication to supporting the youngest Oregonians and their families through strengthening safety nets that keep young families thriving. You have our endorsement for the proposed Waiver.

Sincerely,

Sue Miller, Chair  
Early Learning Council

## **EOCCO Comments on OHA 1115 Demonstration Waiver, Draft Application**

The Eastern Oregon Coordinated Care Organization (EOCCO) appreciates the overall direction of the proposed waiver concepts and draft application and we appreciate the opportunity to provide comment prior to the final submission. EOCCO has already adopted many elements of the key foundations of the 1115 waiver renewal and looks forward to the advancements of the coordinated care model in Oregon.

While EOCCO supports the overall intent of the proposed waiver concepts and draft application, further discussion is needed to ensure successful implementation of these concepts statewide. One area is maximizing OHP coverage. EOCCO applauds OHA for the innovative thought around continuous enrollment for kids however, a more robust process for CCOs and OHA to regularly validate members eligibility based on residency or other circumstances are needed. In addition, see comments below that outline additional areas that need further discussion prior to implementation.

### **Maximizing Continuous and Stabilizing Transitions Comments:**

1. One of our observations and an unintended consequence of keeping people enrolled without redetermination throughout the Public Health Emergency is that there are a growing number of individuals who appear to have moved out of State but that remain enrolled in the Oregon Health Plan. This information is determined via claims and prior authorization requests received from Out of State providers where members are seeking non-emergency services. This has resulted in expenses to the State and CCO's that may ultimately be the responsibility of another State agency. As mentioned above, EOCCO fully supports the concept of longer continuous enrollment periods, but processes to routinely validate that members remain a resident of Oregon, and as a result remain eligible for OHP coverage, are needed to avoid unnecessary costs to Oregon's Medicaid program. CCOs are willing to assist the State in validating member residency in situations like this, but today CCOs are not currently allowed to assist.
2. Currently, when people are in custody, they are treated by jail staff and providers under a restrictive and outdated medication formulary. Many of these members will be new to the behavioral health system and to Medicaid, and the bulk of the provision of care would fall to the Community Mental Health Programs. Behavioral health in general is severely understaffed at the moment and having to provide care for people in custody will overtax an already stressed system. If this provision goes through, it would be helpful if jail providers become enrolled in the Medicaid system and have the ability to bill for the services provided.
3. OHA is highly encouraged to have a robust and flexible process to assign members to a CCO to avoid delays in care and proper transition of care and care coordination. For

example, Baker City has a minimum-security prison that holds very few eastern Oregon residents. Upon release, these individuals leave the eastern Oregon region.

4. Consideration for exclusion in the Incentive Metrics should also be considered for the timeframe in which the member is still in the facility, as many services may be difficult to perform prior to release.
5. To ensure success in the housing strategy, the housing shortage, outside of the CCO work, needs to be addressed. In many of the counties across Oregon there is a severe housing shortage. Rental subsidies, while an incredible benefit, do not help when housing units are not available and are not in development. EOCCO intends to support efforts related to housing through the SHARE initiative, but additional support from the State is needed.
6. Peer support trainings, especially for youth and families, need to be expanded outside of the metro area to be successful in the future. Currently, there are only trainings located in the Salem and Portland area and only by a few organizations. OHA has disallowed many of the rural peer support trainings that were available. Centralizing these trainings to only the metro areas makes them inaccessible to rural areas due to cost, distance and time. The costs of training and supporting peers starts to become unmanageable when they are only allowed to bill to the lowest paying services codes, for example, peer support and skills training.
7. Statewide, there is a lack of adequate PRTS beds within the Child Welfare system and we look to OHA to have specific discharge plans prior to being able to "hold" a bed. While the need for children involved in child welfare is clearly articulated, these children are hard to place, and child welfare lacks foster parents and/or discharge plans. There are children that have been in PRTS beds for over 2 years that child welfare has no ability to transition. We look to further advance this conversation before overtaxing an already severely strained system.

EOCCO fully supports the continued concept of making financial investment to address health inequities and social determinants of health and equity (SHOH-E). EOCCO has a long history in investing in the communities we serve. While EOCCO supports investments in SDOH-E spending, available funding that reaches in the millions of dollars needs to have clear regulations around calculation and fund allocation.

**Flexible, value-based global budget and Focused Equity investment Comments:**

1. Further clarity from OHA is needed around the requirements and calculation of the spending required under HB 3353. This encompasses the methodology that will be used to calculate the total of 3% of the CCOs budget.
2. Collaboration with key stakeholders, including CCO representatives, is needed to ensure transparent requirements on how funds will be passed to the Community Investment Collaboratives (CICs). Additionally, careful consideration is needed as it relates to

reporting requirements, as many of the partners within the CICs even with funding of staff through the HEI grants, will still struggle to find qualified staff to maintain the agencies supporting the CICs.

3. Clarification is needed if the 3% of the annual CCO budget will include or exclude the SHARE Initiative and Health-Related Services. Having funds shift from Health-Related Services to the CICs can have financial impact through the Performance Based Rewards program.
4. Additionally, the SHARE Initiative, under the new rule, may allocate up to 20% of CCOs profits to the Initiative. If this amount is excluded from the 3% of the annual CCO budgets, it may lead to excess funds needing to be spent in communities where there is not enough infrastructure to support the funding. While providing additional funding at the local level is important, investments at this level need careful planning and need to be a sound investment with sustainability and staff to implement the projects.
5. This is important to understand how these funds will be reported on the exhibit L, prior to the implementation of these programs to ensure accurate reporting.
6. We propose an update to the wording of the first strategy for managing pharmacy costs. Currently, the strategy is titled “adopt a commercial-style closed formulary approach”. We recommend updating the wording to “adopt a commercial-style narrow formulary approach”. Many of the CCOs already have closed formularies. Additionally, other options such as “limited formulary” can imply we are restricting benefits from members.

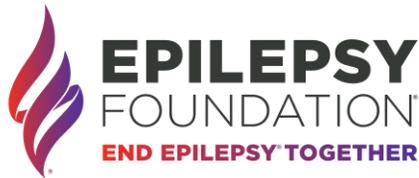
The CCO quality incentive program has been a successful vehicle to show improvements in a number of incentivized metrics statewide. EOCCO is supportive of the program and the direction to further address health inequities by strengthening community voice and decision making in the CCO model.

**Incentivizing Equitable Care Comments:**

1. EOCCO strives to close inequitable performance gaps within the metrics space. However, if 50 members within a subpopulation would be implemented as a requirement to meet individual metrics, that is approximately .08% of EOCCO's December 2021 membership. The end result of having these members sought out to meet metrics is a potential unintended consequence. This could be viewed as targeting members and is exactly the opposite of health equity. The 50 members should be moved to a certain percentage of the total CCO membership, such as the language translation requirements of the CCO's membership, to ensure a proper denominator for each metric subpopulation. The concept papers note this as an "option" however, it should be reassessed prior to translation into formal policy.
2. Consideration for metric evaluation should occur with assessing rural and frontier counties separately than urban areas, as challenges faced in rural and frontier areas are

not consistent with urban populations. In addressing social determinates of health, geographic location is a key component in making strides to equitable outcomes.

To ensure CCOs are properly assessing issues of inequity, adequate and complete race/ethnicity data is needed. We encourage OHA to ensure accurate and complete REALD and SOGI data collection efforts prior to requiring CCOs to be evaluated by these factors of health.



January 6, 2022

Interim Deputy Medicaid Director Dana Hittle  
500 Summer St. NE, E65  
Salem, OR 97301

Submitted via email to: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Interim Deputy Director Hittle:

On behalf of the Epilepsy Foundation and our local chapter Epilepsy Foundation Oregon, we write regarding the Oregon 1115 Demonstration Waiver for the Oregon Health Program (OHP). There are 42,900 people with epilepsy in Oregon and about one-third of people with epilepsy rely on Medicaid for health coverage – so this waiver proposal and its implications are of utmost importance. We appreciate the focus on equitable access to healthcare in this waiver. We support Oregon’s request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over. Unfortunately, this waiver also contains multiple proposals that would undermine access to care and needed medications for people with epilepsy. We are very concerned with the new proposed closed formulary for adults, as well as Oregon’s proposals to continue the waiver of retroactive eligibility, continue to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children over the age of one, and continue to use of a Prioritized List of services that relies, in part, on a quality-adjusted life year.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of at least 3.4 million Americans with epilepsy and seizures. We foster the well-being of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime, and people living with epilepsy must have meaningful and timely access to physician-directed, person-centered care, to avoid breakthrough seizures and related complications and costs. We outline our specific thoughts and concerns about this proposal below.

#### *Support Continuous Eligibility*

We support the request for continuous enrollment for children under age six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent people from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage. Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits. Continuous access to care is especially important for people with epilepsy, where even one missed dose of medication can lead to significant complications.<sup>1</sup>

---

<sup>1</sup> Faught E, Duh MS, Weiner JR, Guérin A, Cunnington MC. Nonadherence to antiepileptic drugs and increased mortality: findings from the RANSOM Study. *Neurology*. 2008;71(20):1572.



### *Oppose Closed Formulary*

We are strongly opposed to the proposal to transition to a closed formulary for adults. For the majority of individuals living with epilepsy, anti-seizure medications are the most common and cost-effective treatment for controlling and/or reducing seizures, and they must have meaningful and timely access to physician-directed and person-centered care. There is no “one size fits all” treatment option for epilepsy, and the response to medications can be different for each person. Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by physicians and their patients. To change, limit, or deny access to the prescribed, most effective medications could be extremely dangerous.

Oregon proposes an unprecedented change to Medicaid coverage of prescription drugs by waiving the requirement that the state comply with Section 1927 of the Social Security Act, which requires Medicaid to cover Food and Drug Administration (FDA) approved drugs, subject to certain conditions and exclusions, if the manufacturer of such drugs has signed an agreement to pay rebates. Under current law, Oregon can already impose preferred drug lists that require prior authorization before a prescription drug may be covered under Medicaid and use the preferred drug list to negotiate additional rebates with manufacturers. Except for certain classes of drugs that states may exclude, states are barred from imposing fully “closed” formularies under which drugs cannot be covered under any circumstance.

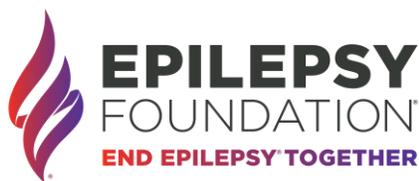
Oregon’s proposal would allow the state to exclude FDA-approved drugs entirely. The state could offer **just one drug per therapeutic class**, which is wholly unacceptable, detrimental, and dangerous to people living with epilepsy and seizures. Oregon’s proposal closely resembles a 2017 Massachusetts proposal to establish a closed formulary in its Medicaid program – which CMS rightly rejected in 2018<sup>2</sup> – and a Tennessee proposal currently under review by CMS that we strongly oppose.<sup>3</sup> Oregon’s proposal is even more restrictive than what Tennessee proposed: Tennessee’s closed formulary would have included protections for epilepsy medications and other classes, Oregon’s proposal has no such protections.

The proposed closed formulary would cover as little as one medication per therapeutic class. This means that only one epilepsy medication could be covered for all adults in Medicaid. As noted above, epilepsy medications are not interchangeable and there is no one treatment that works best for everyone with seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Impeding or delaying access to the prescribed, most effective epilepsy medications increases the likelihood of breakthrough seizures and related complications including injury, disability or even death. Further, many people with epilepsy need to take more than one anti-seizure medication to gain or approach seizure control. The waiver does not appear to include any kind of appeals or exceptions process for people in various situations such as already being stable on a medication, or those who need to take more than one medication at a time to treat their condition. Physicians and people with epilepsy work together to determine the appropriate regimen, based

---

<sup>2</sup> Centers for Medicare & Medicaid Services, MassHealth Demonstration Amendment Approval, June 27, 2018, <https://www.medicare.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/masshealth-demo-amndmnt-appvl-jun-2018.pdf>.

<sup>3</sup> Health Partners Comments on Special Terms & Conditions for TennCare III. September 9, 2021. [https://www.lung.org/getmedia/4a6256df-73e6-43ef-9fb6-4aefc979375a/health-partner-letter-re-tenncare-1115-waiver-\(final\).pdf](https://www.lung.org/getmedia/4a6256df-73e6-43ef-9fb6-4aefc979375a/health-partner-letter-re-tenncare-1115-waiver-(final).pdf)



on the type of seizure, seizure frequency, age, gender, other health conditions, other medications, and side effects.

Oregon's proposal could result in sudden loss of coverage for anti-seizure medications that beneficiaries are currently taking. Most anti-seizure medications need to be titrated to an individualized dose, and that dose needs to be determined to be effective in a specific individual. When switching medications, anti-seizure medications must be titrated down to safely wean the individual off. This process can take months. The formulary change could have significant negative impact on people with epilepsy who are currently stable on their medications. People who are seizure free have been found to have a 16.7% rate of seizure recurrence after a medication switch, compared to 2.8% among those remaining on the same drug.<sup>4</sup>

Oregon states that it seeks to implement a "commercial-style" and points to the rising restrictions in the commercial market. However, those restrictions are not without consequences. One study found formulary restrictions resulted in an average of 6.9 days of delay and 35% lower likelihood of successful dispensing, compared to claims that did not meet with formulary restrictions.<sup>5</sup> Oregon also points to restrictions allowed by Medicare Part D plans without recognizing that Part D plans are required to cover all or substantially all drugs in classes of clinical concern, often known as the "Six Protected Classes," which includes anti-convulsants. Oregon includes no such protections for these vulnerable populations in their proposal.

The waiver application makes clear that Oregon's intent in seeking a closed formulary is to reduce costs. However, on top of the dangerous possible consequences to health and life detailed above, restricting access to epilepsy medications will not achieve savings. People with epilepsy whose medications are switched have a high chance of seizure recurrence and in turn, higher medical costs. A review of studies has shown that the direct, epilepsy-related medical costs associated with uncontrolled epilepsy are 2 to 10 times higher than costs associated with controlled epilepsy.<sup>6</sup> There are 42,900 people with epilepsy in Oregon. Oregon's closed formulary could force many of them to switch medications, resulting in costly and avoidable ambulance services, emergency room visits, injuries, and hospital stays. Seizure recurrence can also result in decreased independence with financial consequences such as loss of a driver's license which can make it difficult for people to retain employment. In Oregon, a person with epilepsy must be seizure free for at least three months in order to re-gain their driver's license. This compounds discrimination that people with disabilities and people of color already face on the job market. People with epilepsy and low incomes already face barriers controlling their seizures; 53% of adults with uncontrolled seizures live in households earning less than \$25,000 a year.<sup>7</sup>

By limiting access to epilepsy medications, Oregon's closed formulary could result in a cascade of events in Medicaid enrollees' lives that exacerbate the negative social determinants of health and health disparities that

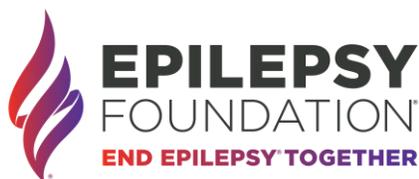
---

<sup>4</sup> Seizure outcome after switching antiepileptic drugs: A matched, prospective study. *Epilepsia*, 57(8), 1294–1300. <https://doi.org/10.1111/epi.13435>

<sup>5</sup> Mehta, D., Davis, M., Epstein, A.J. et al. (2020). Impact of formulary restrictions on antiepileptic drug dispensation outcomes. *Neurol Ther* 9, 505–519. <https://doi.org/10.1007/s40120-020-00195-3>.

<sup>6</sup> Begley, Charles E. & Durgin, Tracy L. (2015). The Direct Cost of Epilepsy to the United States: A Systematic Review of the Estimates. *Epilepsia*, 56(9), 1376-1387. Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084>.

<sup>7</sup> Kobau R, Cui W, Kadima N, et al. Tracking psychosocial health in adults with epilepsy--estimates from the 2010 National Health Interview Survey. *Epilepsy Behav.* 2014;41:66–73. doi:10.1016/j.yebeh.2014.08.002  
Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health. [www.cdc.gov/epilepsy/communications/infographics/cdc-epilepsytext.htm](http://www.cdc.gov/epilepsy/communications/infographics/cdc-epilepsytext.htm)



other parts of this waiver seek to ameliorate. The effects of a closed formulary will not fall evenly across the community. Black people in the U.S. are more likely to develop epilepsy over a lifetime than white people.<sup>8</sup> Black people are also more likely to experience discrimination in the workplace if they lose access to transportation, either by being fired or facing discrimination in finding a new job. There is also evidence, based on worldwide prevalence, that transgender people may be more likely to have epilepsy. Many anti-seizure medications have potential interactions with hormone treatments.<sup>9</sup> Transgender people on Medicaid in Oregon may lose access to the anti-seizure medications that work best with their hormone treatments.

Additionally, Oregon proposes to exclude prescription drugs that the state deems to have “limited or inadequate evidence of clinical efficacy,” including those approved through FDA’s accelerated approval processes. This will also harm patients by restricting access to novel and lifesaving therapies. To date, no epilepsy medications have been approved through accelerated approval, but we are concerned that this proposal could extend to any other new treatment which the state deems ineffective, despite the decisions of the FDA. States should not be in the position of determining the safety and efficacy of medications; that role is reserved for the FDA.

All patients enrolled in Oregon’s Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life. We request that the Oregon Health Program remove these requests and provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that they and their providers have determined are best for them.

#### *Oppose Continuing to Eliminate Retroactive Coverage*

We are concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding those eligible through a disability pathway. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common for people to be unaware that they are eligible for Medicaid until a medical crisis. Retroactive eligibility allows people with epilepsy who have either been newly diagnosed or need a new treatment regime to begin treatment right away, avoiding delays in lifesaving care and without the burden of medical debt while they work on eligibility paperwork. This is particularly important for some groups that experience health disparities, such as African Americans, who are more likely to be diagnosed with epilepsy in an emergency room.<sup>10</sup> Retroactive eligibility also helps low-income residents avoid medical debt they can’t afford to take on. Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>11</sup> Without retroactive eligibility, people with epilepsy who are eligible for Medicaid could face substantial costs and delays at their doctor’s office or pharmacy.

People with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm

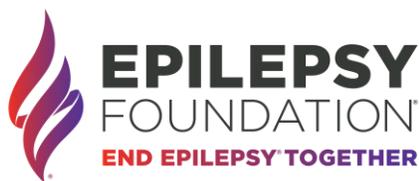
---

<sup>8</sup> Epilepsy Foundation, “Epilepsy and African Americans.” Available at: <https://www.epilepsy.com/living-epilepsy/epilepsy-and/african-americans>

<sup>9</sup> Johnson, E. L. and Kaplan, P. W. (2017), Caring for transgender patients with epilepsy. *Epilepsia*. doi:10.1111/epi.13864

<sup>10</sup> Epilepsy Foundation, “Epilepsy and African Americans.” Available at: <https://www.epilepsy.com/living-epilepsy/epilepsy-and/african-americans>

<sup>11</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>



advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>12</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. We oppose the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries. Retroactive coverage is a critical part of Medicaid's safety net.

#### *Oppose Prioritized List and Use of Quality Adjusted Life Years*

We are concerned about the use of a Prioritized List to determine coverage and access to treatments in Oregon, including the use of the quality adjusted life year (QALY) in determining coverage and access.

QALYs are typically developed by surveying the general public about their preferences for health states. Significant evidence exists that the general public has strong anti-disability bias, up to and including withholding health care on the basis of disability. These societal preferences were on display during the COVID-19 pandemic, when many hospital Crisis Standards of Care included plans to discriminate on the basis of disability and de-prioritize care for people with disabilities.<sup>13</sup> Fortunately, HHS OCR issued guidance early in the pandemic stating, "Persons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative 'worth' based on the presence or absence of disabilities or age."<sup>14</sup> Disability advocacy organizations filed complaints to change initial crisis standards of care, including in Oregon.<sup>15,16</sup>

In 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage. This application was denied by the U.S. Department of Health and Human Services as violating the Americans with Disabilities Act (ADA).<sup>17</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance.

According to Disability Rights Oregon, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Oregon's Prioritized list is created by the Health Evidence Review Commission (HERC). HERC relies on QALYs for some of its reviews of clinical and cost effectiveness to determine placement on the prioritized list. For example, QALYs are cited in the recent reports: Multisector Intervention Report: Community Health Workers for Patients with Chronic Disease;<sup>18</sup> Multisector

---

<sup>12</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>13</sup> Center for Public Representation, "COVID-19 Medical Rationing & Facility Visitation Policies." Available at: <https://www.centerforpublicrep.org/covid-19-medical-rationing/>

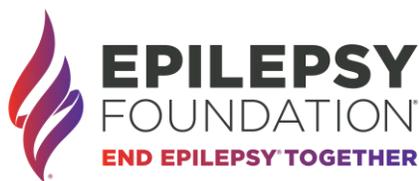
<sup>14</sup> U.S. Department of Health and Human Services Office for Civil Rights. Bulletin: Civil Rights, HIPAA, and Coronavirus Disease 2019. March 28, 2020. Available at: <https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>

<sup>15</sup> Disability Rights Oregon. Press Release. May 8, 2020. Available at: <https://www.centerforpublicrep.org/wp-content/uploads/2020-05-08-Release-on-OCR-Letter.pdf>

<sup>16</sup> Oregon Health Authority. Principles in Promoting Health Equity During Resource Constrained Events. December 7, 2020. Available at: <https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le3513.pdf>

<sup>17</sup> Sullivan, Louis W., Oregon Health Plan Is Unfair to the Disabled, The New York Times. August 13, 1992. Available at: <https://www.nytimes.com/1992/09/01/opinion/1-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

<sup>18</sup> Oregon HERC. Multisector Intervention Report: Community Health Workers for Patients with Chronic Disease. November 14, 2019. <https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CHW-Multisector-Report-Final.pdf>



Intervention Report: Multicomponent Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer;<sup>19</sup> and Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring.<sup>20</sup>

We are concerned with the existence of the Prioritized List at all, and further concerned about the use of QALYs to determine who gets care. QALYs discriminate against people with disabilities by devaluing lives lived with disability.

In 2019, National Council on Disability (NCD), an independent federal agency, released series of reports on bioethics and disability.<sup>21</sup> One of these reports *Quality-Adjusted Life Years and the Devaluation of Life with a Disability* found “sufficient evidence of QALYs being discriminatory (or potentially discriminatory to warrant concern.”<sup>22</sup> NCD recommended an explicit ban on the use of QALYs in Medicare and Medicaid.<sup>23</sup> They also recommended that Medicaid “should not rely on cost-effectiveness research or reports that gather input from the public on health preferences that do not include the input of people with disabilities and chronic illness.”<sup>24</sup> NCD also recommended the use of alternative value assessment mechanisms and provided examples for the federal government and states to use.

The use of QALYs may also violate federal law. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be “excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination,” under any program offered by the federal government.<sup>25</sup> Title II of the Americans with Disabilities Act (ADA) extends this protection to programs and services offered by state and local governments.<sup>26</sup>

During the COVID-19 pandemic, OHP responded to the concerns of disability rights advocates about the allocation of scarce resources by developing a negotiated document on how to allocate scarce inpatient critical care resources in the pandemic. The Prioritized List should be given the same treatment. We urge OHP to abandon the use of the QALY and work with Disability Rights Oregon, Epilepsy Foundation Oregon, and other disability rights organizations to develop a better way to allocate scarce Medicaid dollars and care for people with disabilities in an equitable way.

### *Oppose Restricting EPSDT Benefit*

We are opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). There are 5,400 children in Oregon with epilepsy and the purpose of the EPSDT benefit is to ensure that children receive appropriate health care. Limiting of that care to a prioritized list of services leaves

---

<sup>19</sup> Oregon HERC. Multisector Intervention Report: Multicomponent Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer. October 1, 2020. [https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/MSI%20Cancer%20Screening\\_finalized\\_10-1-2020PDF.pdf](https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/MSI%20Cancer%20Screening_finalized_10-1-2020PDF.pdf)

<sup>20</sup> Oregon HERC. Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring. October 4, 2018. <https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG-CardioMEMS-final.pdf>

<sup>21</sup> National Council Disability. Bioethics and Disability Report Series. Available at: <https://ncd.gov/publications/2019/bioethics-report-series>

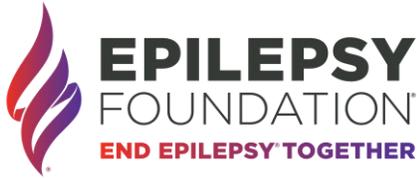
<sup>22</sup> National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. November 6, 2019. [https://ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf), pg. 13.

<sup>23</sup> Ibid., pg. 14.

<sup>24</sup> Ibid., pg. 15.

<sup>25</sup> 29 USC Sec 794, 2017.

<sup>26</sup> 42 USC Sec 12131, 2017.



families vulnerable to the cost of care for non-prioritized services. We appreciate that Oregon is not proposing to limit access to medications for children. However, children with epilepsy do not need just their anti-seizure medications alone. They frequently have related developmental disabilities or mental health needs, yet the current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including selective mutism, conduct and impulse disorders, deformities of the upper body and limbs, sleep disorders, and pica. Lack of sleep is a known seizure trigger,<sup>27</sup> and children with epilepsy are known to already have more sleep problems,<sup>28</sup> so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days. The prioritized list also currently excludes treatment for conditions that can be a risk or side effect of epilepsy treatment, including paralysis of vocal cords or larynx, which can result from implantation of a Vagus Nerve Stimulation (VNS) device, or aseptic meningitis, which can be a rare side effect of common anti-seizure medication lamotrigine. Limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. Children of color are enrolled in Medicaid at disproportionately higher rates<sup>29</sup> and are also more likely to be affected by gaps in coverage.<sup>30</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit.

We strongly support the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

We appreciate the opportunity to comment on this proposal and sincerely hope that our concerns are heeded so that people with epilepsy can continue to access the care and medications that they need. If you have any questions, please contact Senior Director of Federal Relations & Policy Rachel Patterson at [rpatterson@efa.org](mailto:rpatterson@efa.org).

Sincerely,

Kevin Koppes  
Executive Director  
Epilepsy Foundation Oregon

Laura Thrall  
President & CEO  
Epilepsy Foundation

<sup>27</sup> Lanigar, S., & Bandyopadhyay, S. (2017). Sleep and Epilepsy: A Complex Interplay. *Missouri medicine*, 114(6), 453–457. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6139974/>

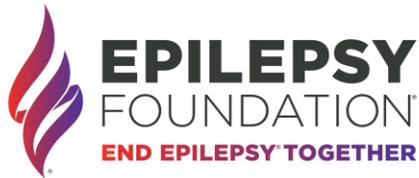
See also: <https://www.epilepsy.com/learn/triggers-seizures> and <https://www.epilepsy.com/learn/triggers-seizures/lack-sleep-and-epilepsy>

<sup>28</sup> <https://www.epilepsy.com/learn/challenges-epilepsy/sleep-and-epilepsy>

<sup>29</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017.

<https://ccf.georgetown.edu/wp-content/uploads/2017/06/EPSDT-At-Risk-Final.pdf>

<sup>30</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/ccf/child-health-insurance-trends)



Oral Comments submitted to the Oregon Health Policy Board by Kevin Koppes, Executive Director, Epilepsy Foundation Oregon regarding the Oregon Health Plan 2022-2027 1115 waiver

January 4, 2022

Members of the Oregon Health Policy Board:

Thank you for hearing my comments today. I am here on behalf of Epilepsy Foundation Oregon and the 42,900 people with epilepsy in Oregon, including 5,400 children. There are aspects of this waiver proposal that we support, but there are also others with which we must raise grave concerns.

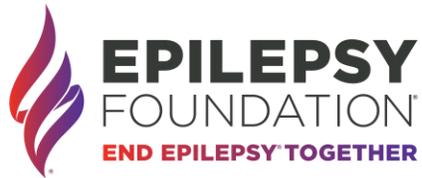
We support the proposal to maximize Oregon Health Plan coverage through continuous enrollment. People who are eligible for Medicaid often have fluctuating incomes and can “churn” on and off the program. Continuous enrollment reduces gaps in coverage that prevent people from accessing the care that they need during these fluctuations. Continuous access to care is especially important for people with epilepsy, where even one missed dose of medication can lead to significant complications.

However, we have significant concerns with a number of other proposals, including the requests to implement a new commercial-style closed formulary and the requests to continue waivers of retroactive coverage and the waiver of Early and Periodic Screening, Diagnostic, and Treatment services benefit for children.

The proposed closed formulary would cover as little as one medication per therapeutic class. This means that only one epilepsy medication could be covered for all adults in Medicaid. Epilepsy medications are not interchangeable and there is no one treatment that works best, or even works at all, for everyone with seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Further, many people with epilepsy need to take more than one anti-seizure medication to gain seizure control. Physicians and patients work together to determine the appropriate regimen, based on the type of seizure, seizure frequency, age, gender, other health conditions, other medications, and side effects. Limiting coverage to one anti-seizure medication

Retroactive coverage is a critical part of Medicaid’s safety net. It is common for people to be unaware that they are eligible for Medicaid until a medical crisis. Retroactive eligibility allows people with epilepsy, who have either been newly diagnosed or need a new treatment regime, to begin treatment right away without the burden of medical debt while they work on eligibility paperwork and are approved. This is particularly important for some groups that experience health disparities, such as African Americans, who are more likely to be diagnosed with epilepsy in an emergency room.

Finally, the continuation of the waiver of EPSDT would continue to deprive children with epilepsy in Oregon of needed services. Children with epilepsy do not only need their anti-seizure medications. They frequently have related developmental disabilities or mental health needs, yet the current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including selective



mutism, conduct and impulse disorders, deformities of the upper body and limbs, sleep disorders, and pica.

Thank you for hearing me today. We will be submitting more detailed written comments by the January 7 deadline.

Kevin Koppes  
Executive Director  
Epilepsy Foundation Oregon



January 7, 2022

**BOARD OF DIRECTORS**

**Mark Dant, Chair**

Executive Director  
Ryan Foundation

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Frank Sasinowski, MPH, JD, Vice Chair**

Director, Hyman, Phelps &  
McNamara, P.C.

**RE: Application for Renewal and Amendment Oregon Health Plan, Section 1115 Demonstration Waiver**

**Vicki Seyfert-Margolis, PhD,**

**Treasurer**  
Founder and CEO, MyOwnMed

On behalf of the EveryLife Foundation for Rare Diseases, which is dedicated to empowering the rare disease patient community to advance laws and policies to improve lives of all people and families impacted by rare diseases and disorders, we are pleased to provide comments to inform the Oregon Health Authority's (OHA) Section 1115 Waiver Application for the period of 2022-2027.

**Julia Jenkins, Secretary**

Executive Director  
EveryLife Foundation

EveryLife's policy priorities are informed by the needs of our community and our shared mission of advancing the equitable development of, and access to, lifesaving diagnoses, treatments, and cures. To inform our policy work, we convene the Community Congress, a forum for collaboration across stakeholders, representing over 200 individual rare disease patient advocacy organizations in addition to over 90 other healthcare and biotechnology organizations.

**Emil D. Kakkis, MD, PhD**

Founder  
President/CEO, Ultragenyx

The EveryLife Foundation appreciates the many worthy goals laid out by OHA in the Waiver planning process, however we are concerned that the policies proposed under Strategy 3: *Increase predictability of costs and ensure value for spending through closer management of pharmacy costs by adopting commercial-style closed formularies and by excluding drugs with limited or inadequate evidence of clinical efficacy* will have serious adverse consequences for rare disease patients and families. These proposed policies stand in direct conflict with the overall goals that the Waiver request is premised on.

**Ritu Baral**

Managing Director  
Senior Biotechnology Analyst  
Cowen and Company

**Jennifer Bernstein**

Executive Vice President, Horizon  
Government Affairs

**Richard S. Finkel, MD**

Director, Center of Experimental  
Neurotherapeutics  
St. Jude Children's Research  
Hospital

Over 30 million Americans live with one or more rare diseases, 95% of which have no approved treatment<sup>1</sup>. Rare disease patients and families navigate how to manage expenses from multiple inpatient and outpatient encounters, costs for prescription therapies and medical devices, and the support services that are critical for managing their health and wellbeing. For millions of these patients and families, Medicaid is their lifeline. It is imperative that policies support timely access to all care and treatments recommended by clinical providers, including innovative therapies that address the significant unmet need, without restrictive formularies that do not reflect the individualized nature of rare disease care.

**Stephen C. Groft, PharmD**

Special Volunteer, NCATS, NIH

**Amrit Ray MD, MBA**

Senior Advisor, Bain Capital Life  
Sciences

Patients and families need relief from the high costs associated with managing a rare disease. But such relief must take into account the total cost of patient care, not just the cost of pharmaceutical therapies. [EveryLife Foundation's National Economic Burden of Rare Disease Study in the U.S.<sup>2</sup>](#) included 379 rare diseases affecting 15.5 million people and found the overall economic impact in 2019 exceeded \$966 billion. Non –medical and In-direct costs, costs absorbed directly by affected families, accounted for nearly 60 percent of overall costs. Relief is needed. But such relief must not come at the expense of access to life changing therapies or the next generation of innovation that 95% of rare diseases are still awaiting.

To reflect the realities of the need to lower costs across stakeholders, the EveryLife Foundation engaged with Community Congress members to create the Rare Disease Community Statement on Drug Pricing Policy Priorities. Principles from this statement are reflected throughout our comments and the full statement can be found at <https://everylifefoundation.org/drug-pricing/>.

*Policy solutions should recognize FDA's statutory authority in determining a medical product's safety and effectiveness and promote timely access to approved therapies.*

OHA's proposal to "allow exclusion of drugs with limited or inadequate evidence of clinical efficacy" and to establish their own review procedure to make this determination undermines the FDA's statutory authority, their expertise and understanding of the complexities involved in bringing therapies to the market for complex rare diseases, and the high level of rigor in the FDA regulatory review process.

In 1992, in response to the HIV/AIDS crisis, the U.S. Food and Drug Administration (FDA) instituted the Accelerated Approval pathway to improve the time to approve drugs that treat serious conditions that fill an unmet medical need based on substantial evidence of safety and efficacy and a surrogate endpoint that is reasonably likely to predict outcomes like irreversible mortality or morbidity. In the years since establishing the accelerated approval pathway, it has also facilitated the transformation of oncology care and enabled rare disease treatments to reach patients who otherwise had limited or no options.

*OHA's proposal is predicated on several misperceptions about the use of the accelerated approval pathway in rare diseases and will serve to undermine the purpose and future use of the pathway.*

During the EveryLife Foundation's Annual [Scientific Workshop in December 2021](#), rare disease scientific, clinical, patient and regulatory experts examined the use of the Accelerated Approval Pathway in rare disease to identify common challenges and opportunities for optimizing the pathway to transform rare disease care in the way that is has been transformational for HIV/AIDS and oncology.

A summary of the Workshop's proceedings is pending release, however several key themes emerged that address the concerning misperceptions of accelerated approval that underly OHA's decision to pursue exclusionary policies based on the use of this pathway.

- ❖ Therapies approved via the accelerated approval pathway are not the main driver of costs to state Medicaid programs. A 2021 study showed that spending on drugs approved through AAP accounted for less than one percent of annual Medicaid spending between 2007 and 2018<sup>3</sup>.
- ❖ Surrogate biomarkers are often superior to traditional clinical endpoints. In many cases, because surrogate biomarkers are intermediate markers of disease progression or improvement, they offer a way to more accurately capture patient data in real-time and be more accurate due to the complex and variable nature of rare diseases as compared to traditional clinical endpoints.
- ❖ The FDA has rigorous requirements for biomarker qualification that result in only a small fraction of biomarker based rare disease therapy approvals. In fact, less than 20 rare disease therapies have been approved using accelerated approval.<sup>4</sup>
- ❖ The safety of rare disease treatments approved via the accelerated approval pathway is evaluated in the same rigorous manner as in traditional drug approvals.

We urge OHA to reconsider their problematic proposals related to the accelerated approval pathway and to instead consider engaging in efforts prioritized by the Scientific Workshop participants as essential to ensuring the optimization of accelerated approval to transform rare disease outcomes and to consider the actions suggested within the Rare Disease Community Statement on Drug Pricing Policy Priorities. These actions include;

- ❖ The need for payer entities such as Medicaid programs to engage early and often with patient, scientific, clinical and regulatory stakeholders to develop the knowledge and evidence available for rare disease biomarkers. As payers engage early in the process, the understanding of the biomarkers being used and the rationale for their use will produce outcomes that payers can meaningfully incorporate into their decision-making process.
- ❖ Reject policies that treat all AAP medications as experimental, thus exacerbating health inequality among communities eligible for life-saving medications.
- ❖ Support the robust collection of real-world outcomes to enhance the evidence for AAP therapies in the post-market setting.
- ❖ Seek new and alternative payment models, including outcomes-based contracting, that allow rare disease patients to have access to novel therapies and ensure reimbursement policies encourage development of future curative therapies
- ❖ Exclude rare disease therapies from policy experiments or demonstrations (such as those proposed under Strategy 3) until or unless it is proven that the changes do not threaten patient access and medical innovation.

Oregon's proposal to implement a closed formulary, including the exclusion of therapies approved via the accelerated approval pathway, will have serious adverse consequences for rare disease patients and families. These proposed policies stand in direct conflict with the overall goals the Waiver request is premised on. Further, the proposed policies will create further disparities in care between adults and children and will result in increasing burdensome utilization management barriers which lead to delays

accessing life sustaining and life-saving therapies, while also not addressing the biggest cost drivers in rare disease care for state Medicaid programs.

Meaningful policy solutions must focus on the total cost of patient care. Policy reforms that focus on only one aspect of healthcare costs and that threaten access to the few treatment options available to those with rare diseases will result in negative repercussions for patient health and have detrimental economic outcomes for families and society overall. We urge OHA to consider the extensive unmet needs and scientific challenges inherent in the rare disease community and ensure policy solutions reflect these complexities by removing Strategy 3 from the 1115 Waiver Extension and investing in long-term actions that will support future policy innovation to ensure the sustainable delivery of life-saving treatments to those most vulnerable Oregonians.

Thank you for the opportunity to provide comments on Oregon's 1115 Waiver Extension application. Please contact Jamie Sullivan, Director of Policy at [jsullivan@everylifefoundation.org](mailto:jsullivan@everylifefoundation.org) if we can provide any additional information to inform your process.

Sincerely,



Julia Jenkins  
Executive Director  
EveryLife Foundation for Rare Diseases



Annie Kennedy  
Chief of Policy, Advocacy, & Patient Engagement  
EveryLife Foundation for Rare Diseases

<sup>1</sup> <https://www.fda.gov/patients/rare-diseases-fda>

<sup>2</sup> [https://everylifefoundation.org/wp-content/uploads/2021/02/The\\_National\\_Economic\\_Burden\\_of\\_Rare\\_Disease\\_Study\\_Summary\\_Report\\_February\\_2021.pdf](https://everylifefoundation.org/wp-content/uploads/2021/02/The_National_Economic_Burden_of_Rare_Disease_Study_Summary_Report_February_2021.pdf)

<sup>3</sup> <https://www.fightchronicdisease.org/sites/default/files/FINAL%20Quantifying%20Impact%20-%20White%20Paper%20v6.pdf>

<sup>4</sup> <https://www.fda.gov/media/151146/download>



January 06, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer Street NE, E65  
Salem, OR 97301

Dear Ms. Hatfield,

Findhelp (formerly Aunt Bertha), would like to thank you for the opportunity to comment on Oregon's 1115 Draft Waiver Renewal Application for the Oregon Health Plan (OHP) and commend you on the person-centered, integrated, and holistic approach to meeting the medical, behavioral, emotional, functional, and social needs of all OHP members.

Founded in 2010, findhelp is a Public Benefit Corporation that runs the largest social care network in the United States and has served more than eight million Americans. Our interoperable social care network is used by over 250 health systems, health plans, community health centers, and health departments in the United States to manage social care referrals, as well as by tens of thousands of community organizations. Our mission is to connect people in need with the programs that serve them, with dignity and ease.

We commend OHA on your efforts to advance health equity through the OHP, including the emphasis in the Renewal Application on addressing the social determinants of health (SDOH), focus on streamlining transitions for individuals in state custody and youth in the juvenile justice and child welfare systems through defined SDOH benefits packages, and refined methodology to pay for population health. We also commend the state for seeking expenditure authority to invest in implementation capacity at the community level, including payments for provider and community-based organizations (CBO) infrastructure and capacity building. To address health-related social needs and advance health equity, it is critical that CBOs are adequately and sustainably funded. We applaud OHA for prioritizing funding and capacity building for CBOs.

Through the proposed Waiver Renewal, you have the opportunity to thoughtfully drive the way that Oregon strengthens connections between social care providers and health care providers to better address people's social care needs and advance health equity. A truly interoperable approach to social care navigation can support your vision by making it easier for individuals to navigate to available community resources, on their own, or with assistance from a health care provider or professional care coordinator. We believe that to advance health equity, we must adopt approaches that serve all people, including individuals who receive care through the OHP, as well as those who access services through other channels.

We also want to commend OHA on the recent charter of the Health Information Technology Oversight Council (HITOC) Community Information Exchange (CIE) Workgroup, and the diversity of voices OHA brought to the



table to shape the CIE approach. As you embark on the next phase of the Oregon Health Plan, the direction set by the CIE Workgroup's recommendations will be critical for shaping the way that the state builds capacity to support SDOH benefits for transition populations and progress toward meeting upstream metrics related to SDOH screening and referral. The CIE work will provide critical infrastructure for advancing the OHP's health equity goals.

As you further refine the Waiver Renewal, we would like to highlight three critical areas related to social care navigation and community information exchange that will require thought leadership from OHA and the HITOC CIE Workgroup: 1) supporting a truly interoperable approach, 2) fostering an open and focused network; and 3) protecting individual data privacy.

**Interoperability:** A truly interoperable approach is founded on agreed upon data standards and incentivizes vendors to support consistent data reporting. Approaches like the Accountable Health Communities Grant Model, which requires documentation, reporting, and standards consistency, provides a good model in which any vendor can be certified to support a state's reporting needs. As part of efforts to build CBO capacity, it is critical that we continue to develop integrations that allow systems to communicate with each other, and prioritize the ability of CBOs to continue to use their existing Systems of Record to manage screenings, needs assessments, appointment scheduling, and tracking of service delivery. OHP can play a role in this process by requiring integration and advancing interoperability standards. Healthcare systems, providers, and CBOs must be able to receive social care data from various sources within their own environment and Systems of Record.

**Open and Focused Network:** An open network ensures that members have access to a broad array of services, including services that are trusted in their community and culturally competent. An open network can also be focused and include preferred providers, meaning that health plans and providers have targeted, and sometimes contractual, relationships with specific CBOs to target specific member needs. To advance health equity requires an active open AND focused network of service providers, to meet the needs of all communities. In addition, members should be empowered and afforded the opportunity to seek services through self-navigation, without being required to have someone else do it for them.

**Protecting Individual Privacy:** Incorporating referrals to social care into our healthcare infrastructure relies on the collection, storing, and sharing of some of the most private and personal information. As you expand upon the current infrastructure for facilitating referrals from healthcare providers to CBOs, OHA must address critical questions of who will own the data, who will be able to view and analyze the data, and how the data will be protected from unauthorized access and cyber attacks. With the inclusion of more CBOs that are not HIPAA-covered entities, it will be imperative that the protection of privacy is at the center of this conversation, with individuals maintaining control over their personal information. We should not compromise privacy to build an interconnected social care network that allows referrals to services for those in need, produces high-quality data, measures outcomes, and builds upon best practices.



Other states are developing best practices that should be implemented to ensure that individual data and privacy is protected, which include:

- Requiring a per-referral consent model, in which individuals are asked to *opt-in* to share their information for each referral and network members' access to referral history is permission-based.
- Maintaining the individual's right to obtain help without conditioning referrals on consent to share personal information.
- Requiring that individuals seeking help maintain the right to opt-out of sharing their information at any time, and that revoking network access to personal information is simple for the individual.
- Establishing provisions governing the length of time non-health identifiable information will be maintained in a database, and;
- Prohibiting the sale of personal information without explicit individual consent.

Again, we commend you on the innovative and holistic approach you have outlined in the Waiver Renewal Application to meet the medical, behavioral, emotional, functional and social needs of all OHP members. We appreciate your leadership in this important area as we are at a pivotal moment that will set the course for how states construct coordinated systems of care, and welcome the opportunity for further discussion of these issues and how we might partner in this area.

*Submitted on behalf of findehelp, a Public Benefit Corporation*



January 6, 2022

**VIA ELECTRONIC SUBMISSION**

Michelle Hatfield  
Health Policy and Analytics Medicaid Waiver Renewal Team  
500 Summer St. NE, E65  
Salem, OR 97301

RE: Oregon Health Plan 1115 Demonstration Waiver Renewal and Amendment

To Whom It May Concern:

Thank you for the opportunity to comment on the draft renewal application for the “Oregon Health Plan” 1115 demonstration waiver. The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005. As part of the McCourt School of Public Policy, Georgetown CCF conducts research, develops strategies, and offer solutions to improve the health of America’s children and families, especially those with low and moderate incomes.

As explained below, we strongly support the proposal to provide multiple years of continuous eligibility for children and adults. We commend Oregon for leading the country with this request. We also applaud the state’s focus on and investments in health equity, which would work to address racial and health disparities in the state.

However, we strongly oppose the request to waive the Early and Periodic Screening, Diagnostic Treatment (EPSDT) benefit for children over age one, which is critical to ensure children receive all services necessary for their growth and development. Waiving this benefit serves no demonstration purpose and is potentially harmful to children’s health and development. We also strongly oppose the request to waive the three-month retroactive coverage period for almost all Medicaid beneficiaries as well as the proposed closed formulary and exclusions of certain prescription drugs. These provisions reduce coverage and services for children and their families and do not promote the objectives of Medicaid. The flexibilities requested related to managed care raise serious concerns, especially for the potential effects on beneficiaries, and some are not allowable under a section 1115 demonstration. Finally, Oregon does not enumerate the specific waiver and expenditure authorities needed for its renewal request and therefore fails to comply with federal regulations for an extension application.

## **Multi-year continuous eligibility would reduce gaps in coverage and improve continuity of care.**

Oregon already provides 12-month continuous eligibility to children in its Medicaid program and Children’s Health Insurance Program (CHIP) at state option. In its proposal, the state would test extending the length of the continuous eligibility period by providing continuous coverage for children until the age of six and two years of continuous eligibility for all beneficiaries age six and up with the goal of maximizing access to coverage. *We strongly support Oregon’s proposals on continuous eligibility.* Oregon is the first state to make such a request – and we commend you for the state’s bold vision. Such a proposal is exactly the kind of request that section 1115 demonstrations are well-suited for, and we will strongly encourage CMS to approve it.

Continuous eligibility is a significant tool to reduce gaps in coverage and enhance continuity of care. Covering children from birth to six can help form the backbone of a new nationwide commitment to children’s health.<sup>1</sup> The policy improves health status and well-being, promotes health equity, allows for better measurement of quality of care, and reduces administrative burdens.<sup>2</sup> Extending continuous eligibility for longer periods for children would promote consistent access to health care to address any concerns that may affect school readiness, especially for young children who are at the most critical development period.<sup>3</sup> The benefits of continuous eligibility are also afforded to adults. As CMS noted in its 2013 guidance, providing continuous eligibility to parents and other adults results in greater stability of coverage for the whole family.<sup>4</sup>

The proposal would also help reduce “churn” for both child and adult beneficiaries. Individuals with Medicaid are at risk of moving on and off coverage due to temporary changes in income that affect eligibility; continuous eligibility can help mitigate the effects of this income volatility that result in churn. Individuals that experience churn or other coverage disruptions are more likely to delay care and have periods of uninsurance.<sup>5</sup> According to recent data from MACPAC, even in states with 12-month continuous eligibility, almost three percent of children in Medicaid and over seven percent of children

---

<sup>1</sup> Kelly Whitener and Joan Alker, “Covering All Children,” Georgetown University Center for Children and Families, February 2020, <https://ccf.georgetown.edu/wp-content/uploads/2020/02/CoverAllKidsFinal.pdf>.

<sup>2</sup> Tricia Brooks and Allegra Gardner, “Continuous Coverage in Medicaid and CHIP,” Georgetown University Center for Children and Families, July 2021, <https://ccf.georgetown.edu/wp-content/uploads/2021/07/Continuous-Coverage-Medicaid-CHIP-final.pdf>.

<sup>3</sup> Elisabeth Wright Burak, “Promoting Young Children’s Healthy Development in Medicaid and the Children’s Health Insurance Program,” Georgetown University Center for Children and Families, October 2018, <https://ccf.georgetown.edu/wp-content/uploads/2018/10/Promoting-Healthy-Development-v5-1.pdf>.

<sup>4</sup> Center for Medicaid and CHIP Services, “SHO #13-003: Facilitating and CHIP Enrollment and Renewal in 2014,” May 2013 <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SHO-13-003.pdf>.

<sup>5</sup> Sarah Sugar, *et. al.*, “Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic,” HHS Assistant Secretary for Planning and Evaluation, April 12, 2021, [https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files//199881/medicaid-churning-ib.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//199881/medicaid-churning-ib.pdf).

in CHIP had less than a full year of coverage.<sup>6</sup> Research has shown that children have the highest rates of Medicaid enrollment churn compared to other eligibility groups.<sup>7</sup>

We encourage you to examine how providing multiple years of continuous eligibility affects administrative cost for the state and CCO's. In Montana, state officials reported administrative spending savings and fewer staff hours needed to process individuals moving on and off the program as a result of adopting continuous eligibility for adults.<sup>8</sup>

### **Significant investments in health equity would address racial disparities the state.**

We applaud the state's intent to center on health equity in its request. The proposal would include several significant changes to invest in community investment collaboratives and utilizing Traditional Health Workers to promote culturally responsive care. We are strongly supportive of the state's goals and efforts to reduce racial disparities.

The state seeks to engage communities as a key part of its health equity investments, specifically in the proposed community investment collaboratives (CICs). CICs would serve as a "community-led accountability structure" that would help oversee all spending on health equity and are intended to focus on populations that have been most harmed by health inequities including communities of color, people with disabilities, and immigrant communities, among others. Though progress has been made in reducing racial disparities, people of color still experience worse health outcomes and lower coverage rates than white individuals.<sup>9</sup> By engaging in a community-based approach to health equity, the state will ensure spending truly addresses the needs and barriers faced by populations that have been historically marginalized and can help improve persistent disparities.

Under the proposal, Traditional Health Workers would be utilized to improve access to services particularly among beneficiaries experiencing life transitions. Traditional Health Workers would include community health workers, peer wellness and support specialists, and doulas. These providers may be more trusted by beneficiaries and can assist them in receiving culturally competent care. For example, doulas have been found to be beneficial to women of color or with low incomes; expanding access to these providers can help reduce health disparities.<sup>10</sup>

---

<sup>6</sup> MACPAC, "An Updated Look at Rates of Churn and Continuous Coverage in Medicaid and CHIP," October 2021, <https://www.macpac.gov/wp-content/uploads/2021/10/An-Updated-Look-at-Rates-of-Churn-and-Continuous-Coverage-in-Medicaid-and-CHIP.pdf>.

<sup>7</sup> Bradley Corallo, *et al.*, "Medicaid Enrollment Churn and Implications for Continuous Coverage Policies," Kaiser Family Foundation, December 14, 2021, <https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-churn-and-implications-for-continuous-coverage-policies/>.

<sup>8</sup> Niranjana Kowlessar *et al.*, "Federal Evaluation of Montana Health and Economic Livelihood Partnership (HELP): Summative Evaluation Report," Social & Scientific Systems, November 30, 2020, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-montana-2020.pdf>.

<sup>9</sup> Nambi Ndugga and Samantha Artiga, "Disparities in Health and Health Care: 5 Key Questions and Answers," Kaiser Family Foundation, May 11, 2021, <https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/>.

<sup>10</sup> Tomas Guarnizo and Maggie Clark, "Lessons Learned from Early State Experiences Using Medicaid to Expand Accesses to Doula Care," Georgetown University Center for Children and Families, December 15, 2021,

## Waiving the EPSDT benefit risks children’s access to necessary services.

Oregon is requesting to continue waiving the Early and Periodic Screening, Diagnostic Treatment benefit, Medicaid’s comprehensive, child-focused benefit. As you know, children represent a substantial portion of Medicaid beneficiaries in the state, with 469,000 children under 19 currently covered.<sup>11</sup> In 2019, 36.8 percent of children in Oregon were covered by Medicaid.<sup>12</sup> EPSDT guarantees that children and young adults under age 21 receive the full scope of services necessary for their growth and healthy development. Oregon is the only state in the country to have a limit in place on these benefits for children under 19.

EPSDT ensures children with Medicaid coverage are screened regularly for health problems and developmental delays, *and* treatment must be provided as needed. Without this critical benefit, children are at risk of not receiving necessary services. This risk is especially true since the Oregon Health Plan’s covered services are determined by the state’s “prioritized list of health services,” which excludes services that fall below the designated funding line. On the state’s current prioritized list of 662 services, only the first 471 are covered.<sup>13</sup>

Medicaid’s EPSDT benefit is especially important for children with special health care needs or disabilities. These children may have more extensive health care needs or chronic conditions that require types or amounts of services that most children do not generally need.<sup>14</sup> EPSDT is also important for children of color who are more likely to have Medicaid coverage. In Oregon, approximately 60 percent of the child population who are American Indian/Alaskan Native, Black, or Latino are covered by Medicaid (57 percent of AIAN children; 60 percent of Black children; 65 percent of Latino children).<sup>15</sup> Limiting their benefits undermines the very core of what Oregon purports to do with its demonstration—advance health equity and maximize equitable access to coverage.

Oregon has been restricting EPSDT benefits since the inception of the OHP demonstration in 1994. The purpose of a section 1115 demonstration is to test new approaches that promote the objectives of Medicaid. While there was never a justification for stripping children of their entitlement to EPSDT, any potential experiment has long

---

<https://ccf.georgetown.edu/2021/12/15/lessons-learned-from-early-state-experiences-using-medicaid-to-expand-access-to-doula-care/>.

<sup>11</sup> Oregon Health Authority, “Monthly Medicaid Population Report, August 2021 (Preliminary),”

<https://www.oregon.gov/oha/HSD/OHP/DataReportsDocs/August%202021%20Physical%20Health%20Service%20Delivery%20by%20Age%20Group.pdf>.

<sup>12</sup> Kaiser Family Foundation, “Health Insurance Coverage of Children 0-18,” <https://www.kff.org/other/state-indicator/children-0->

[18/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22oregon%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D](https://www.kff.org/other/state-indicator/children-0-18/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22oregon%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

<sup>13</sup> Oregon Health Authority, “Prioritized List of Health Services,” <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>.

<sup>14</sup> Tricia Brooks and Kelly Whitener, “At Risk: Medicaid’s Child-Focused Benefit Structure Known as EPSDT,” Georgetown University Center for Children and Families, June 2017, <https://ccf.georgetown.edu/wp-content/uploads/2017/06/EPSDT-At-Risk-Final.pdf>.

<sup>15</sup> Tricia Brooks and Alexa Gardner, “Snapshot of Children with Medicaid by Race and Ethnicity, 2018,” Georgetown University Center for Children and Families, July 2020, <https://ccf.georgetown.edu/wp-content/uploads/2020/07/Snapshot-Medicaid-kids-race-ethnicity-v4.pdf>.

expired. Denying needed health care to children does not serve any valid experimental purpose and should not be continued.

Furthermore, in the application, there is no explanation of the services that would not be covered nor what protections the state has in place to ensure that restrictions on EPSDT services do not have a disparate impact on children of color. With the omission of these details, Oregon has not explained the potential impact the waiver has, and will continue to have, which does not allow for full public engagement on the proposal.

We urge you to remove this waiver as part of Oregon's extension request.

### **The proposed closed formulary and exclusion of certain prescription drugs from coverage undermines Medicaid.**

The state is seeking to adopt a closed prescription drug formulary for adult beneficiaries, with only a minimum of one drug per class. Cost, not just clinical efficacy, would be a key criteria. Separately, the proposal would also exclude drugs, including but not limited to those coming to the market through the Food and Drug Administration's accelerated approval pathway, that the state determines to have "limited or inadequate clinical efficacy" as well as drugs that are determined to have "no incremental clinical benefit" compared to others in its therapeutic class. Unlike the broader closed formulary authority the state is seeking, this proposal would apply to pediatric drugs as well.

These proposals are a drastic change to the current requirement under the Medicaid Drug Rebate Program that Medicaid programs must cover nearly all FDA-approved outpatient drugs. As a result, they will likely restrict beneficiary access to needed prescription drugs; this does not promote the objectives of Medicaid but rather undermines them.

The proposal fails to outline any appeals process to allow beneficiaries to obtain off-formulary drugs under either provision, let alone describe in detail how such a process would work and the criteria for determining whether off-formulary coverage would be approved. The proposed changes to the Medicaid prescription drug benefit would likely be most detrimental to beneficiaries with multiple or complicated health conditions including individuals with chronic conditions or with disabilities who require very high-cost specialty drugs.

The state also holds up Medicare Part D as an example of a program that is permitted to operate a closed formulary. Yet, the proposal is actually more restrictive than Medicare Part D as it does not include some key protections that are a requirement in Medicare Part D. First, Oregon's closed formulary would only cover at least one drug per therapeutic class compared to two in Medicare Part D. Also, the state does not include any exemptions for six "protected" classes of drugs—anti-depressants, anticonvulsants, antipsychotics, immunosuppressants, antineoplastics, and antiretroviral drugs—that Medicare Part D is required to cover.

While the first proposal would maintain an open formulary for children, the state does not define the age ranges that comprise the child population. Specifically, it is unclear whether 19-and-20-year-olds are considered children or if they are included in the adult eligibility category. This is particularly important because, with the waiver of EPSDT benefits (which normally apply to individuals under 21), 19-and-20-year-olds may have their access to prescription drugs restricted. And, as noted above, the second proposal would apply not just to adults but also to children.

The state claims it is pursuing the proposed prescription drug changes in order to obtain larger supplemental rebates from drug manufacturers. It is important to recognize that Medicaid already obtains the lowest prices, net of rebates and discounts, compared to other federal programs and agencies, including not just Medicare Part D but also the Department of Veterans Affairs.<sup>16</sup> This is driven by the mandatory rebates required under the highly successful Medicaid Drug Rebate Program, with supplemental rebates only a small share of total rebates.<sup>17</sup> It is not clear the proposal would actually result in significant new savings, as states already have levers such as preferred drug lists and prior authorization when negotiating with manufacturers today. The proposal would therefore likely only generate significant savings if the state used its two proposed new authorities to substantially restrict access to needed prescription drugs and thus reduce utilization and spending.

There is no research or experimental justification to reduce prescription drug coverage for beneficiaries and it is inconsistent with the purpose of Medicaid. In fact, federal courts have ruled that “[a] simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy” the section 1115 requirement for an experiment.<sup>18</sup>

### **Eliminating retroactive coverage does not promote the objectives of Medicaid.**

Under the proposal, almost all Medicaid beneficiaries including pregnant women, infants, and children, would not have protection from the financial burden of medical debt resulting from the costs of care they need during the three months prior to applying for Medicaid. With the continued waiver of three-month retroactive coverage, low-income children and their families are exposed to medical bills that may be financially devastating. The policy reduces coverage and therefore fails to promote the principal objective of Medicaid.

Furthermore, while we do not believe there was ever a legitimate purpose for eliminating retroactive coverage, the state’s continued waiving of coverage is well past the

---

<sup>16</sup> Edwin Park, “New CBO Study Compares Net Prices for Brand-Name Drugs Among Federal Programs, Finds Medicaid Gets Largest Discounts,” Georgetown University Center for Children and Families, February 22, 2021, <https://ccf.georgetown.edu/2021/02/22/new-cbo-study-compares-net-prices-for-brand-name-drugs-among-federal-programs-finds-medicaid-gets-largest-discounts/>.

<sup>17</sup> Edwin Park, “How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs,” Georgetown University Center for Children and Families, January 9, 2019, <https://ccf.georgetown.edu/2019/01/09/how-to-strengthen-the-medicaid-drug-rebate-program-to-address-rising-medicaid-prescription-drug-costs/>.

<sup>18</sup> *Beno v. Shalala*, 30 F. 3d 1057 (9<sup>th</sup> Cir. 1994)

point of being an experiment; the waiver has been in place for *over two decades*. The state does not provide a hypothesis for this policy nor does it include the policy in its proposed evaluation. The waiver of retroactive coverage does not meet the statutory requirement to be an experiment that is likely to assist in furnishing coverage. In fact, it does the opposite. There is no justification to continue waiving retroactive coverage, especially when the state identifies reducing gaps in coverage as one of its goals of the renewal request, and that the policy would disproportionately affect people of color, which is counter to the efforts to reduce health inequities.

**The requested managed care flexibilities are fundamentally flawed and several lack adequate details.**

The proposal contains multiple requests related to new or additional flexibilities in managed care. While we are supportive of the intent of Oregon's initiatives aiming to expand access to services addressing health-related social needs (HRSN), we have serious concerns regarding some of the waiver requests related to managed care.

Medicaid regulations at 42 C.F.R. § 438.5(d) require that managed care rate-setting trend factors "be reasonable and developed in accordance with generally accepted actuarial principles and practices" and "be developed primarily from actual experience of the Medicaid population or from a similar population." We do not believe the state's proposed trend rates (ranging from 3.0 to 3.4%) meet any of these standards. It is particularly important, legally and practically, that managed care rates be actuarially sound, as defined in the law at section 1903(m)(2)(A)(iii) of the Social Security Act, and based upon the actual costs of providing services to enrollees. While CMS has historically waived freedom of choice many times, there is no authority for CMS to waive managed care standards or section 1903 through section 1115. Approving rates that are not actuarially sound also does not promote the objectives of Medicaid.

More broadly, while we do not object in principle to the state considering HRSN-related services in the rate-setting and MLR processes, we do not support such proposals when the HRSN services replace needed state plan services. We are concerned that Oregon's proposal, which includes prioritized lists of services, would do that. We recommend the state make two adjustments to its proposal. First, we recommend the state drop the list of prioritized services. This provision is clearly no longer needed as the state projects its accrued historical savings will grow to more than \$11 billion over the life of the demonstration. Second, we recommend that the state develop rates based on all state plan services *and* supplement those rates by adding HRSN-services. There is no statutory barrier to such an approach, and effective investments will lead to state plan services reductions over time based on beneficiaries' reduced need, as opposed to artificial timelines and budgets.

We recommend the state retract several waiver provisions related to mandatory enrollment and prohibiting disenrollment that violate the statutory standards set out in sections 1903 and 1932 of the Social Security Act. These provisions are not waivable and

exist to protect at-risk populations, such as older adults, persons with disabilities, and individuals who are newly enrolled into managed care plans.

Finally, we are unable to comment on several of the proposed waiver authorities which are undefined but raise questions. The state suggests that it is considering options for “risk-sharing arrangements” and “brokering re-insurance or stop-loss insurance,” and lists several critical Medicaid requirements, including contract requirements, access standards, and solvency standards, which may need to be waived to pursue the policy. The state should not pursue such policies without offering the public a chance to comment on concrete and detailed policies and waiver requests, and even then, we again note that there are limits to what the state can waive through section 1115 (as described above). It is similarly unclear what the state’s request to “[i]mplement Value-based payment methodologies” by waiving 42 C.F.R. § 438.6 is intended to accomplish, as no waiver is generally needed to implement § 438.6 strategies. Thus, we are unable to comment on this proposal.

**The application does not meet federal requirements for the state public notice process.**

As part of a section 1115 extension application, under federal regulations Oregon is required to provide the “the specific waiver and expenditure authorities that [it] believes to be necessary to authorize the demonstration.”<sup>19</sup> The state’s application does include a section on waiver and expenditure authorities; however, *the section does not describe the specific authorities that would be needed to implement its new and existing proposals*. For example, the state says that for new provisions it is requesting, it will determine with CMS whether additional waiver authority is needed to authorize those provisions. The failure to explain the authorities necessary to implement its requests undercuts the ability of the public to understand the proposal and meaningfully comment on it. Oregon should revise its application to specify the authorities needed for its demonstration and reopen the state comment period.

Thank you for consideration of our comments. If you need any additional information, please contact me at [jca25@georgetown.edu](mailto:jca25@georgetown.edu).

Joan Alker  
Research Professor, McCourt School of Public Policy, Georgetown University  
Executive Director, Center for Children and Families

---

<sup>19</sup> 42 CFR § 431.408



January 7, 2022

Mr. Patrick Allen  
Director, Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Re: Comments on Oregon’s Draft 2022-2027 Medicaid 1115 Demonstration Application**

Dear Director Allen:

Gilead Sciences, Inc. (Gilead) welcomes this opportunity to comment on Oregon’s Draft 2022-2027 Medicaid 1115 Demonstration Application (the “Draft Application”). Gilead is a US-based, global biopharmaceutical company that is committed to discovering, developing, and delivering innovative therapeutics for people with life-threatening diseases in areas of unmet medical need. Our marketed products include medicines for the prevention and treatment of HIV/AIDS and treatment of liver diseases including hepatitis B and C, cancer, and COVID-19, as well as certain cardiovascular and respiratory diseases.

Gilead has significant concerns with the Draft Application, specifically its provisions relating to the adoption of a closed-formulary in the Oregon Medicaid program outpatient prescription drug benefit. As a member of both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO), we join their critique of the Draft Application. We write separately to emphasize the following points for your consideration:

- The State cannot waive protections for access to the full range of FDA approved medications granted under SSA Section 1927.
- The requested waiver would fail to meet the essential criteria under SSA Section 1115, because it does not specify an experiment that supports the objectives of the Medicaid program.
- The state has existing authorities that it can leverage in order to manage formularies.
- The proposed waiver would undermine a crucial component of health equity.
- The proposed waiver would inhibit the coverage of drugs approved under accelerated approval pathways by substituting the state’s judgment for the FDA approval process.
- The proposed waiver would result in substandard coverage for Medicaid compared to Medicare or Exchanges.

Our comments on each of these points are below.

**1. The State cannot waive protections for access to the full range of FDA approved medications granted under SSA Section 1927.**

In the Draft Application, Oregon seeks to “increase predictability of costs and ensure value for spending” in its Medicaid program through implementation of a “commercial-style closed formulary” and “exclusion of drugs with limited or inadequate evidence of clinical efficacy.” Oregon seeks to accomplish this through a SSA Section 1115 waiver of SSA Section “1902(a)(54) insofar as it incorporates” SSA Section 1927(d)(1)(B) – the provision of the Medicaid Rebate Statute that limits the state’s ability to exclude certain drugs from coverage. Notably, Oregon’s request would leave the remainder of SSA Section 1927, including the rebate obligation for participating manufacturers under SSA Section 1927(b), intact. There are several reasons why Oregon’s request is legally impermissible.

As a threshold matter, by its express terms, SSA Section 1115 does not permit waiver of any requirements of SSA Section 1927. Pursuant to SSA Section 1115(a)(1), the Secretary may waive compliance “with any of the requirements of section 402, 454, 1402, 1602, or 1902....” Notably, SSA Section 1927 is not among the enumerated statutes subject to waiver. This interpretation is supported by the D.C. Circuit’s holding in *PhRMA v. Thompson*, which addressed whether Section 1115 permits waivers of the rebate statute requirements:

The Social Security Act, of which the Medicaid statute is a part, authorizes HHS to approve experimental “pilot” or “demonstration” projects that the Secretary determines are “likely to assist in promoting the objectives of [Medicaid].” [42 U.S.C.] § 1315(a). Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r-8’s [SSA Section 1927’s] rebate provision.<sup>1</sup>

Furthermore, an almost identical closed formulary proposal was rejected by CMS in 2018 in response to the Commonwealth of Massachusetts’ SSA Section 1115 Demonstration Amendment request. Massachusetts argued that waiving the open formulary requirements would “improve [its] ability to negotiate additional supplemental rebates.”<sup>2</sup> CMS determined, however, that it would be impermissible for the Commonwealth to exclude certain Medicaid covered outpatient drugs from coverage and continue to: (a) provide drug coverage pursuant to its state plan under SSA Section 1902 and (b) claim mandatory rebates from manufacturers under SSA Section 1927(b).<sup>3</sup> Oregon’s proposal is similarly flawed for the same reasons, among others.

Moreover, the state’s proposal to categorically deny coverage of covered outpatient drugs would undermine the congressionally-declared objective of SSA Section 1927 and its carefully designed bargain between manufacturers, the States, and the Federal government. Congress enacted SSA

---

<sup>1</sup> *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001).

<sup>2</sup> Office of Medicaid, Mass. Executive Office of Health & Human Services, MassHealth Section 1115 Demonstration Amendment Request at 8 (Sept. 8, 2017).

<sup>3</sup> Letter from Tim Hill, Acting Director, CMS, to Daniel Tsai, Assistant Secretary, MassHealth at 2 (June 27, 2018).

Section 1927 to guarantee that “[s]tates that elect to offer prescription drugs . . . cover all the products of any manufacturer that agrees to provide price rebates.”<sup>4</sup> As Congress made abundantly clear, “[s]tates that elect to offer prescription drug coverage under their Medicaid programs will be required to cover all of the drugs of any manufacturer entering into and complying with such an agreement, with the exception of drugs (e.g., cosmetic drugs) on a statutory list (which may be revised by the Secretary).”<sup>5</sup> As the Supreme Court has emphasized, “strict adherence to the language and structure of an act is particularly appropriate where . . . a statute is the result of a series of carefully crafted compromises.”<sup>6</sup>

But Oregon’s proposal, which would enable the state to escape its coverage obligations under SSA Section 1927, would unravel this carefully designed bargain. That is, Oregon would continue to provide prescription drug coverage under its Medicaid state plan, and thus continue to subject manufacturers to rebate obligations, all without complying with its corresponding obligation under the Medicaid Drug Rebate Program (MDRP) – coverage of all of a participating manufacturer’s covered outpatient drugs. This would contravene the terms of the compromise Congress carefully designed between manufacturers and the government; it would be fundamentally unfair to require manufacturers to uphold their side of the arrangement and could dissuade some manufacturers from participating in the MDRP, if states were permitted to avoid their set of reciprocal requirements.

## **2. The requested waiver would fail to meet the essential criteria under SSA Section 1115, because it does not specify an experiment that supports the objectives of the Medicaid program.**

Oregon’s draft proposal would fail to satisfy the plain language requirement of SSA Section 1115(a)(1), which only allows “Secretary [to] waive compliance with any of the requirements” of SSA Section 1902 “[i]n the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of” Medicaid. This is because the state failed to specify what would be tested by waiving the Medicaid coverage requirements, the waiver would conflict with the objectives of the Medicaid program, and the waiver proposal does not include essential beneficiary protections.

First, Oregon has failed to specify a research or experimental proposition that it seeks to test under its demonstration project as a result of the requested waiver. A waiver of compliance with SSA Section 1927 to enable a truly closed formulary would be tantamount to nothing more than a “simple benefits cut”, which, as the Ninth Circuit Court of Appeals has ruled, does not serve an experimental purpose.<sup>7</sup> In particular, the Ninth Circuit has held that the Secretary, in reviewing a proposed demonstration project, “must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement . . . . The statute was not enacted to enable

---

<sup>4</sup> H. R. NO. 101-881, at 98 (1990).

<sup>5</sup> STAFF OF H. COMM. ON WAYS AND MEANS, H. COMM. ON ENERGY AND COMMERCE, & S. COMM. ON FINANCE, 101ST CONG., SUMMARY OF MEDICARE AND MEDICAID PROVISIONS IN THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990 19 (Comm. Print. 1990).

<sup>6</sup> *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 748 n.14 (1989).

<sup>7</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

states to save money or to evade federal requirements but to ‘test out new ideas and ways of dealing with the problems of public welfare recipients.’”<sup>8</sup> Oregon has failed to set forth any meaningful research proposition or purpose that would be tested as a result of the requested waiver.

Second, under SSA Section 1115(a), a demonstration project must, in the judgment of the Secretary, be “likely to assist in promoting the objectives of ... [the Medicaid statute].”<sup>9</sup> Medicaid was enacted by Congress in order to provide medical care to the needy and medically needy.<sup>10</sup> Indeed, recently the D.C. Circuit determined in striking down CMS’ approval of an Arkansas waiver that “[T]he intent of Congress is clear’ that Medicaid’s objective is to provide health care coverage and, as a result, [CMS] ‘must give effect to [that] unambiguously expressed intent of Congress.’”<sup>11</sup> Put another way, Medicaid beneficiaries cannot be “significantly burdened—that is, for example, their eligibility significantly restricted or benefits significantly cut—in the name of saving money.”<sup>12</sup> If a state were allowed to deny access to otherwise-covered and potentially life-saving therapies, as Oregon contemplates here, a demonstration project would do precisely that – it would substantially limit Medicaid beneficiaries’ access to medically-necessary therapies, many of which have life-saving potential. This would undermine, as opposed to promote, the attainment of Congress’ fundamental objective in enacting the Medicaid program.

Finally, through SSA Section 1927, Congress also intended to provide Medicaid beneficiaries with key safeguards to protect their access to medically necessary therapies. In enacting SSA Section 1927, “Congress made it clear that Medicaid recipients should be assured access to all medically necessary covered outpatient drugs.”<sup>13</sup> This guarantee has endured over the ensuing decades as SSA Section 1927 has been amended by Congress over time.<sup>14</sup> A waiver of a state’s obligation to comply with SSA Section 1927’s coverage obligations would undercut, rather than further, Congress’ key goal of ensuring access to covered outpatient drugs.

---

<sup>8</sup> *Id.*; cf. *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011) (finding, in examining the research value of a state’s proposal to impose cost-sharing requirements on Medicaid beneficiaries, that “[p]laintiffs’ public health expert stated that ‘[o]ver the last 35 years, a number of studies have looked at the effects of cost sharing on the poor. Of all forms of cost sharing, copayments are the most heavily studied.’ The administrative record contains no finding from the Secretary that Arizona’s demonstration project will actually demonstrate something different than the last 35-years’ worth of health policy research.”).

<sup>9</sup> SSA § 1115(a).

<sup>10</sup> See STAFF OF H. COMM. ON WAYS AND MEANS, 89TH CONG., SUMMARY OF MAJOR PROVISIONS OF H.R. No. 6675, THE “SOCIAL SECURITY AMENDMENTS OF 1965” 1 (Comm. Print 1965); see also S.R. No. 89-404, pt. 1, at 73-74 (1965) (“[the Medicaid statute] is designed to liberalize the Federal law under which States operate their medical assistance programs so as to make medical services for the needy more generally available”).

<sup>11</sup> *Gresham v. Azar*, 950 F.3d 93, (D.C. Cir. 2019).

<sup>12</sup> *Stewart v. Azar*, 366 F. Supp. 3d 125, 152 (D.D.C. 2019).

<sup>13</sup> See 60 Fed. Reg. 48,442, at 48,454 (citing H.R. Rep. No. 881, 101st Cong., 2d Sess. 96-98 (1990)).

<sup>14</sup> Even when Congress added SSA Section 1927(d)(4), thereby enabling states to establish formularies that meet specific requirements, it remained the case that “section 1927(d)(4)(D) provides that the State plan must permit coverage of a drug excluded from the formulary (other than any drug excluded or restricted under section 1927(d)(2)) pursuant to a prior authorization program.” 60 Fed. Reg. at 48,454.

### **3. The state has existing authorities that it can leverage in order to manage formularies.**

In its draft application, Oregon notes that “taking a closed formulary approach” would enable its Medicaid program “to negotiate more favorable agreements with manufacturers.” However, Oregon does not need a waiver of compliance with SSA Section 1927 in order to achieve its apparent objective. Under SSA Section 1927(d)(5), states have the authority to impose prior authorization requirements for drugs based upon valid criteria through a preferred drug list (PDL) program. Under such a program, the state can negotiate supplemental rebates in a manner that encourages the use of preferred drugs over non-preferred drugs. Preferred drugs, for which the state receives supplemental rebates from the manufacturer, can be covered without prior authorization. Non-preferred drugs, for which the state does not receive supplemental rebates, are in turn subject to prior authorization.

These existing authorities have provided states ample opportunities to negotiate significant additional rebates from manufacturers. Specifically, Gilead reviewed publicly available CMS-64 reports for states with similar Medicaid enrollments as Oregon and found that Oregon received supplemental rebates that were significantly lower than the other states.<sup>15</sup> This further suggests that the state may be able utilize existing authority to seek additional supplemental rebates as part of its preferred drug list.

### **4. The proposed waiver would undermine a crucial component of health equity.**

We are concerned the closed formulary component of the Draft Application would further exacerbate health inequities, conflicting with one of the objectives laid out by the state.<sup>16</sup> The adults served by Oregon’s Medicaid program are not only low-income, but also disproportionately people of color and people with disabilities.<sup>17</sup> In June 2020, Governor Kate Brown released a new diversity, equity, and inclusion framework of the state of Oregon, which states “[O]ur state government must take proactive and anti-racist measures to build a more equitable Oregon.<sup>18</sup> To redress longstanding health inequities, Oregon must ensure that Medicaid beneficiaries are able to access the medications they need, as determined by their healthcare provider.

If Oregon were permitted to limit therapies (potentially to as few as a single drug per therapeutic class), the results would be highly detrimental to Medicaid beneficiaries. Medicaid patients often have one or more chronic health conditions and require multiple, specific prescription drugs in

---

<sup>15</sup> Gilead analysis of CMS-65 reports from FY2016-2020.

<sup>16</sup> See Draft Application page 3. “Focusing our waiver application on meaningful progress toward health equity... will allow us to improve health outcomes in communities most harmed by social injustices.”

<sup>17</sup> Black and Hispanic Oregonians are substantially more likely than White Oregonians to be enrolled in the Medicaid program. *Compare QuickFacts: Oregon*, U.S. Census Bureau (last updated July 1, 2019), <https://www.census.gov/quickfacts/OR> with *Medicaid Coverage Rates for the Nonelderly by Race/Ethnicity: Oregon*, Kaiser Family Foundation (2019), <https://www.kff.org/medicaid/state-indicator/nonelderly-medicaid-rate-by-raceethnicity/?currentTimeframe>. Nationwide, “nearly a quarter of nonelderly adults with Medicaid report having a disability.” M. Musumeci & K. Orgera, *People with Disabilities Are At Risk of Losing Medicaid Coverage Without the ACA Expansion*, Kaiser Family Foundation (Nov. 2, 2020), <https://www.kff.org/medicaid/issue-brief/people-with-disabilities-are-at-risk-of-losing-medicaid-coverage-without-the-aca-expansion/>.

<sup>18</sup> <https://www.myoregon.gov/2020/06/11/oregons-equity-guidelines/> (last visited Dec. 29, 2021).

order to adequately manage those conditions.<sup>19</sup> Such a narrow coverage policy would deprive Medicaid beneficiaries of medically necessary therapies on which they have long relied to address their conditions and co-morbidities.

Sadly, these health disparities are particularly stark with respect to HIV. The incidence rates of new HIV infection in Oregon between 2009-2018 are nearly five times higher among Black and African Americans than among Whites, and Black and African Americans are less likely to be virally suppressed than Whites.<sup>20</sup> Limiting access to HIV drugs for Medicaid beneficiaries could delay treatment initiation or interrupt therapy and exacerbate these distressing health disparities, undermining President Biden's commitment to end the HIV/AIDS epidemic by 2030.<sup>21</sup> Given that Black people are both more likely to be diagnosed with a new HIV infection, more likely to not be virally suppressed, and more likely to be enrolled in Oregon's Medicaid program than other racial groups, policies and programs are needed to support vulnerable communities in achieving fair outcomes in care.<sup>22</sup> Strong coverage and access protections are necessary to protect against potential discrimination—intentional or inadvertent—in the design and implementation of healthcare benefits, as demonstrated by the long history of complaints against health plans for discrimination against those living with HIV.<sup>23</sup> As discussed further below, this is why antivirals are one of Medicare's protected classes.

Similarly, despite the development of policies to support breast cancer patients, recognition of the specific effects of health disparities and inequities on Triple Negative Breast Cancer (TNBC) patients and actions to mitigate them are limited. TNBC is an aggressive form of breast cancer, is often diagnosed at later stages, and presents a higher chance at becoming metastatic than other types of cancers.<sup>24</sup> Black women are two times more likely to be diagnosed with TNBC than white women in the US.<sup>25</sup> Studies have shown that TNBC disease-specific mortality rates are often

---

<sup>19</sup> See, e.g., *The Role of Medicaid for Adults with Chronic Illnesses*, Kaiser Family Foundation (Nov. 2012), available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8383.pdf>.

<sup>20</sup> Oregon Health Authority, HIV Infection in Oregon as of Dec. 31, 2018, <https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le9985.pdf>.

<sup>21</sup> The White House. Fact Sheet: The Biden-Harris Administration Marks World AIDS Day 2021 With Renewed Commitments to Ending the HIV/AIDS Epidemic by 2030. December 1, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/01/fact-sheet-the-biden-%E2%81%A0harris-administration-marks-world-aids-day-2021-with-renewed-commitments-to-ending-the-hiv-aids-epidemic-by-2030/>

<sup>22</sup> See *Id.* at 15.

<sup>23</sup> See, e.g., Nat'l Health Law Program, *Florida Insurance Commissioner fines Humana \$500,000* (Feb. 18, 2016) (describing litigation that resulted in a consent order in which “Humana agreed to ‘maintain procedures to ensure that it does not by effect or design treat people living with HIV/AIDS less favorably than any other condition.’”), <https://healthlaw.org/news/florida-insurance-commissioner-fines-humana-500000/>; Ctr. for Health Law & Policy Innovation (CHLPI), *CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States*, Harvard Law School (Sept. 6, 2016), <https://www.chlpi.org/chlpi-launches-groundbreaking-campaign-enforce-health-care-rights-people-living-hiv-seven-states/>.

<sup>24</sup> American Cancer Society, Triple-Negative Breast Cancer, 2019. <https://www.cancer.org/cancer/breast-cancer/understanding-abreast-cancer-diagnosis/types-of-breast-cancer/triple-negative.html>

<sup>25</sup> American Cancer Society. *Breast Cancer Facts and Figures 2019-2020*. Atlanta, GA: American Cancer Society Inc; 2021

higher if patients have Medicaid or Medicare or are lower socio-economic status;<sup>26</sup> and compared with non-Hispanic white women, Black women are 48% less likely to receive guideline adherent care and have an approximate 2-fold higher mortality incidence, resulting in a disproportionately higher risk of death from TNBC.<sup>27,28</sup> Recent innovation in targeted therapies has led to advances in treatment for TNBC, yet barriers in care and treatment remain significant for minority women disproportionately impacted. Targeted policy strategies are needed to comprehensively address these barriers to ensure early TNBC diagnosis and effective treatment initiation. We are concerned however, that a closed formulary approach could create difficulty in obtaining needed therapies for some of the most vulnerable women impacted by TNBC in the state.

The two examples above illustrate the potential of the Medicaid program to remedy health inequities, but only if Medicaid beneficiaries are allowed broad and timely access to medically necessary medications and other care.

##### **5. The waiver would inhibit the coverage of drugs approved under accelerated approval pathways by substituting the state’s judgement for the FDA approval process.**

Oregon’s Draft Application seeks to “allow exclusion of drugs with limited or inadequate evidence of clinical efficacy.” Specifically, Oregon seeks authority to deny access to “drugs coming to market through the FDA’s accelerated approval pathway” on the grounds that they “have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints.” Gilead strongly objects to this characterization of the accelerated approval pathway and to the exclusion of such drugs, given that the FDA instituted the accelerated approval pathway “to allow for earlier approval of drugs...that fill an unmet medical need based on a surrogate endpoint.”<sup>29</sup> Exclusion of such drugs would represent a significant departure from current law, which protects access to cutting edge therapies for Medicaid beneficiaries. Oregon’s Medicaid beneficiaries should not be restricted from accessing therapies approved under FDA’s accelerated approval pathway as soon as they are available.

First, by attempting to limit Medicaid beneficiaries’ access to these therapies, Oregon would deprive patients suffering from serious or life-threatening diseases of medicines that FDA has determined are safe and effective for their condition after a full review of available data. This barrier may negatively impact health outcomes for Medicaid beneficiaries, who are already some

---

<sup>26</sup> Ubbaonu C, Chang J, Ziogas A, et al. Disparities in the receipt of National Comprehensive Cancer Network (NCCN) guideline adherent care in triple-negative breast cancer (TNBC) by race/ethnicity, socioeconomic status, and insurance type. Presented at: ASCO20 Virtual; May 29-31, 2020. Accessed June 15, 2020.

<https://meetinglibrary.asco.org/record/185233/abstract>; Cho B, Han Y, Lian M, et al. Evaluation of Racial/Ethnic Differences in Treatment and Mortality Among Women With Triple-Negative Breast Cancer. *JAMA Oncol.* 2021;7(7):1016–1023. doi:10.1001/jamaoncol.2021.1254

<sup>27</sup> Lu Chen and Christopher I. Li, Racial Disparities in Breast Cancer Diagnosis and Treatment by Hormone Receptor and HER2 Status, *Cancer Epidemiol Biomarkers Prev* November 1 2015 (24) (11) 1666-1672; DOI: 10.1158/1055-9965.EPI-15-0293

<sup>28</sup> Cho B, Han Y, Lian M, et al. Evaluation of Racial/Ethnic Differences in Treatment and Mortality Among Women With Triple-Negative Breast Cancer. *JAMA Oncol.* 2021;7(7):1016–1023. doi:10.1001/jamaoncol.2021.1254

<sup>29</sup> FDA, Accelerated Approval Program. Available at: <https://www.fda.gov/drugs/information-health-care-professionals-drugs/accelerated-approval-program>

of the sickest and most vulnerable residents of the state. Moreover, accelerated approval drugs, are often the latest cures and advances in medical science. Medicaid beneficiaries would, thus, have inferior healthcare as compared to other Oregonians and Medicaid beneficiaries in other states jeopardizing health outcomes. This contravenes CMS' long-standing "commit[ment] to Medicaid beneficiaries continuing to have access to needed prescribed medications."<sup>30</sup>

Second, we are also deeply concerned that Oregon's proposal to "use its own rigorous review process" to define coverage of new drugs and determine which drugs are "clinically proven, effective drugs" improperly supplants the FDA's clearly established role in the determination of safety and effectiveness of a particular drug. Drug manufacturers rely on this defined process in bringing new therapies to market. Given that Congress has granted the FDA authority to determine a particular product's efficacy, we believe they are best suited to conduct this rigorous analysis rather than the State. As one state court recently noted, "it is the FDA's job, not that of the [state] Medicaid agency, to evaluate the clinical data to determine whether a drug meets efficacy and safety standards. So long as FDA has approved the drug and the manufacturer has signed a Medicaid Drug Rebate Agreement ... the Social Security Act mandates that a state Medicaid agency cannot rely on new or different clinical data to determine whether it deems a drug worthy of coverage."<sup>31</sup>

Third, we also object to Oregon's unfounded assertion that accelerated approval drugs may have "limited or inadequate clinical efficacy." Both Congress and the FDA have made clear that nothing about accelerated approval dilutes the FDA's approval standards. In 2016, the 21<sup>st</sup> Century Cures Act incorporated FDA's existing regulatory program for accelerated approval<sup>32</sup> into statute, expressly providing, "Nothing in this section shall be construed to alter the standards of evidence" for approval.<sup>33</sup> Like all other drugs approved under New Drug Applications, drugs approved through the accelerated approval pathway are subject to a demanding standard of review — demonstration of "substantial evidence" of effectiveness.<sup>34</sup> Instead of altering the approval standard, the program is intended to encourage FDA "to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs."<sup>35</sup> It should also be noted that surrogate endpoints commonly used as the basis for granting accelerated approval are thoroughly evaluated and must be reasonably likely to predict clinical benefit in patients who are very ill and without good options.<sup>36</sup> By denying Medicaid patients access to therapies that rely on surrogate endpoints, the state could effectively discriminate against individuals with rare diseases or few treatment options and compromise the health of Oregon Medicaid members.

In response to a question about whether the accelerated approval pathway provides for a less rigorous standard, the FDA confirmed that it does not:

---

<sup>30</sup> See CMS, Medicaid Drug Rebate Program Notice, Release No. 172, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015).

<sup>31</sup> *Ark. Dep't of Human Servs. v. Sarepta Therapeutics, Inc.*, 2021 Ark. App. 330, 2021 Ark. App. LEXIS 356.

<sup>32</sup> See 57 Fed. Reg. 58697 (Dec. 11, 1992) (FDA's final regulations establishing the accelerated approval program).

<sup>33</sup> 21 U.S.C. § 356(e)(2).

<sup>34</sup> 21 U.S.C. § 355(d)(5).

<sup>35</sup> 21 U.S.C. § 356(e)(1).

<sup>36</sup> FDA. Accelerated Approval. Available at: <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>

Approval under this rule requires ... that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. ***This judgment does not represent either a "lower standard" or one inconsistent with section 505(d) of the act,*** but rather an assessment about whether different types of data show that the same statutory standard has been met.<sup>37</sup>

Senior Biden Administration FDA officials also recently reiterated that all drugs, regardless of the pathway, are held to the same approval standards.<sup>38</sup>

Congress has clearly outlined the circumstances under which the FDA can consider a drug for accelerated review. Specifically, the FDA must determine “that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit ... taking into account the severity, rarity, or prevalence of the condition and availability or lack of alternative treatments.”<sup>39</sup>

Fourth, Gilead is further concerned about the Draft Application because the accelerated approval pathway has been vital for patients suffering from a wide range of serious diseases where alternative therapies do not exist, including cancer and HIV. According to Dr. Richard Pazdur, director of the FDA’s Oncology Center of Excellence (OCE), “[t]he FDA has successfully applied accelerated approval in oncology over the past three decades, making innovative therapies available to patients years earlier than they would otherwise have been available.”<sup>40</sup> Further, studies have found that drugs approved through the accelerated approval process have provided larger health gains compared to drugs approved through the traditional approval process.<sup>41</sup>

Beyond cancer, the accelerated approval pathways can help patients with rare disease with no approved treatment to date, such as a Hepatitis D virus (HDV) and Hepatitis B virus (HBV) co-infection. The HDV-HBV co-infection is the most severe form of chronic viral hepatitis due to its more rapid progression towards hepatocellular carcinoma and liver related death.<sup>42</sup> Patients with HDV have a mortality rate of 20 percent, the highest mortality rate of any viral hepatitis.<sup>43</sup> Further, the risk of developing cirrhosis is three times higher in HDV infected patients compared to those

---

<sup>37</sup> 57 Fed. Reg. at 58944 (emphasis added).

<sup>38</sup> B. Wang, *Woodcock, Marks: Expedited Approval Paths Do Not Lower FDA Standards*, Inside Health Policy (Aug. 28, 2019), <https://insidehealthpolicy.com/daily-news/woodcock-marks-expedited-approval-paths-do-not-lower-fda-standards>.

<sup>39</sup> 21 U.S.C. § 356(e)(2), (c)(1)(A).

<sup>40</sup> J. A. Beaver & R. Pazdur, “Dangling” Accelerated Approvals in Oncology, *N Engl J Med* 384:18 (May 6, 2021), <https://www.nejm.org/doi/pdf/10.1056/NEJMp2104846?articleTools=true>.

<sup>41</sup> J. D. Chambers et al., *Drugs Cleared Through The FDA’s Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process*, *HEALTH AFFAIRS* 36, NO. 8 (2017): 1408–1415, <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2016.1541>.

<sup>42</sup> World Health Organization. (2021, January 28). *Hepatitis D*. Retrieved from <https://www.who.int/news-room/fact-sheets/detail/hepatitis-d>

<sup>43</sup> Romeo R, Petruzzello A, Pecheur EI, et al. Hepatitis delta virus and hepatocellular carcinoma: an update. *Epidemiol Infect.* 2018;146(13):1612-1618. doi:10.1017/S0950268818001942.

with HBV alone.<sup>44,45</sup> Given that there are no approved therapies for this unmet, rare disease, Oregon should not restrict access to future medicines based on a product's regulatory pathway for approval.

Additionally, Gilead believes that by excluding accelerated approval drugs from coverage, the Oregon Health Authority effectively removes clinical decision-making from practitioners and from patients. Given the complex nature of cancer treatment, no single drug is medically appropriate to treat all cancers, as tumors respond differently depending on the cancer type, stage of diagnosis, and other factors. By attempting to interfere with Medicaid beneficiaries' current access to these therapies based on a long-standing and well-established regulatory pathway for accelerating approval of therapies to treat the most serious and unmet illness, Oregon would deny patients access to treatments their medical practitioner determines are the most appropriate, safe, and effective.

Lastly, if Oregon or other states restrict access to drugs approved through the accelerated approval pathway, this could discourage the development of innovative therapies, and ultimately deprive Medicaid beneficiaries (and others) of access to potentially life-savings drugs.

## **6. The proposed waiver would result in substandard coverage for Medicaid compared to Medicare or Exchanges.**

In the Draft Application, Oregon states "Given that Medicare and other commercial plans are permitted to adopt closed formularies, we believe Oregon should have the same flexibility for Medicaid."<sup>46</sup> However, this ignores important differences between Medicaid and Medicare and commercial plans. For example, Medicare Part D beneficiaries currently have a broad choice, among multiple coverage options, with transparency into the drugs included on any individual formulary and protections against mid-year formulary changes. As a result, Medicare Part D beneficiaries can choose, on an annual basis, the formulary that best suits their medical needs. Medicaid patients have no comparable choices and will often face limited provider networks. Given that Medicaid is traditionally the "payer of last resort" any restrictions on coverage must be carefully weighed against the risk they could lead to a loss of access to medically necessary care.

Furthermore, as the Draft Application notes, Medicare Part D formularies are generally required to cover two drugs per class, while the State seeks flexibility to limit coverage to just one drug per class. In Medicare Part D, plans are only permitted to include one drug in a class when there is actually only one drug available (or only two drugs are available but one drug is clinically superior to the other for a particular category or class).<sup>47</sup> The significance of this difference in coverage levels cannot be overstated.

---

<sup>44</sup> Farci P, Niro GA. Clinical features of hepatitis D. *Semin Liver Dis.* 2012;32(3):228-236. doi:10.1055/s-0032-1323628.

<sup>45</sup> Fattovich G, Giustina G, Christensen E, et al. Influence of hepatitis delta virus infection on morbidity and mortality in compensated cirrhosis type B. The European Concerted Action on Viral Hepatitis (Eurohep). *Gut.* 2000;46(3):420-426. doi:10.1136/gut.46.3.420.

<sup>46</sup> Draft Application. Page 31.

<sup>47</sup> Medicare Prescription Drug Benefit Manual, ch. 6 § 30.2.1.

In addition, the Part D program has an exceptions and reconsideration process that provides access to off-formulary therapies as well as the six protected classes of drugs, for which Part D plans must include all, or substantially all, drugs in the class on-formulary. These classes include anti-convulsants, anti-depressants, anti-psychotics, anti-neoplastics (oncology), immunosuppressants, and anti-retrovirals (which are used to treat HIV and AIDS). The Oregon Health Authority has not suggested that it would provide such protections in its Draft Application.

The requirement to cover all protected class drugs in Medicare Part D was established by Congress and the importance of open access to antiretrovirals has been reaffirmed by CMS. When Congress enacted Part D, it recognized that ensuring comprehensive access to drug treatments for patients, and ensuring prescriber choice of the full range of treatment options (including antiretrovirals) is critical. Moreover, the legislative history of the Medicare Part D program further illustrates this point. For example, a colloquy in the United States Senate among Senators Dianne Feinstein (D-CA), Max Baucus (D-MT), and Chuck Grassley (R-IA) during discussions of the Medicare Modernization Act of 2003 emphasized that one purpose of Medicare Part D is to ensure broad medication coverage for patients, especially those “who need exactly the right medicine for them.”<sup>48</sup> The protected classes were later codified in statute as part of the 2008 Medicare Improvements for Patients and Providers Act (MIPPA) and strengthened by the Affordable Care Act. CMS has repeatedly reaffirmed the importance of sustained access to protected class drugs, including in its final rule on modernizing Medicare Part D.<sup>49</sup>

CMS has provided further protection for antiretroviral medications in Part D by prohibiting prior authorization and step therapy for that class.<sup>50</sup> This safeguard is critical because a provider’s careful selection of an effective treatment regimen for the patient, and a patient’s ability to access and start on that regimen as soon as possible after diagnosis, helps people living with HIV stay healthy and have a better chance of living nearly as long as someone without HIV.<sup>51</sup> In contrast, delays in initiating therapy – which could occur under a closed formulary – may lead people to stop or delay engaging in care and lengthen the time for them to reach viral suppression. Immediate treatment upon diagnosis has been associated with improved virologic suppression even five years later.<sup>52</sup> In fact, the Department of Health and Human Services guidelines (DHHS guidelines) recommend “initiating [antiretroviral therapy or ART] immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to

---

<sup>48</sup> 149 Cong. Rec. S15887 (Nov. 25, 2003).

<sup>49</sup> 42 C.F.R. § 423.120(b)(2)(vi)(C).

<sup>50</sup> Id.

<sup>51</sup> Marcus JL, Leyden WA, Alexeeff SE, et al., “Comparison of Overall and Comorbidity-Free Life Expectancy Between Insured Adults With and Without HIV Infection, 2000-2016,” JAMA Netw Open, June 2020, 2020;3(6):e207954, <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2767138>.

<sup>52</sup> See S. Lodi et al., *Comparative effectiveness of immediate antiretroviral therapy versus CD4- based initiation in HIV-positive individuals in high-income countries: observational cohort study*, 2 LANCET HIV E335 (2015) (demonstrating that “rapid start”, or immediate initiation of HIV therapy upon diagnosis, has been shown to suppress the virus faster, and to improve retention in care); Liz Highleyman, *RAPID Program Leads to Faster HIV Suppression*, AIDSmag, <https://www.aidsmap.com/news/jul-2015/same-day-start-antiretroviral-treatment-leads-faster-hiv-suppression-san-francisco> (2015) (stating that participants in San Francisco General Hospital’s “Rapid- start” ART program achieved an undetectable viral load within 56 days of diagnosis, compared with 119 days for those on a standard treatment schedule).

viral suppression for patients, and improve the rate of virologic suppression among persons with HIV.”<sup>53</sup>

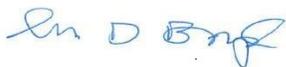
Like Medicare Part D beneficiaries, patients who obtain coverage through the health insurance exchanges can choose plans with a formulary that is best suited to their individual needs and can also change their plan during the annual open enrollment period. In addition, these patients would have access to an exceptions process to obtain their medically necessary medications.<sup>54</sup> Thus, for prescription drugs, the Draft Application would result in a system in which Medicaid beneficiaries receive a demonstrably lower level of access than similarly situated Oregonians who receive coverage through Medicare Part D or the health insurance exchanges under the Affordable Care Act.

\*\*\*

Gilead has been serving and supporting people enrolled in Medicaid for years, including those in Oregon. We are dedicated to ensuring that the state’s policy decisions support health and wellbeing for these individuals, and for all vulnerable populations in Oregon. We, therefore, encourage the Oregon Health Authority to carefully reconsider its demonstration proposal, specifically by continuing to cover all medicines subject to a National Drug Rebate Agreement through the Medicaid program. This is especially critical for infectious diseases and for cancer in which many innovative life-saving therapies have been approved by the FDA via an accelerated pathway. A closed formulary clearly exceeds CMS’s authority and fails to promote the recognized objectives of the Medicaid program. Accordingly, we ask that Oregon ensure that Medicaid beneficiaries have continued access to quality, medically necessary care.

Thank you for the opportunity to provide comments on Oregon’s Draft 2022-2027 Medicaid 1115 Demonstration Application. If you have any questions about our comments, please contact Ryan Faden at [ryan.faden@gilead.com](mailto:ryan.faden@gilead.com).

Yours sincerely,



Michael D. Boyd  
Senior Vice President,  
Government Affairs and Policy

---

<sup>53</sup> Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed [September 8, 2021] [Page E-1]

<sup>54</sup> Know Your Rights in the Health Insurance Marketplace. Available at: <https://marketplace.cms.gov/outreach-and-education/know-your-rights.pdf>.



January 7, 2022

Health Policy and Analytics Waiver Renewal Team  
Atten: Michelle Hatfield  
500 Summer St., NE, 5<sup>th</sup> Floor, E65  
Salem, OR 97301  
**Email:** [1115Waiver.Renewal@dhsoha.state.or.us](mailto:1115Waiver.Renewal@dhsoha.state.or.us)

*Re: Health Share Public Comment on 1115 Waiver*

To Whom It May Concern:

Thank you for the opportunity to offer public comment on Oregon's 1115 Waiver application. As Oregon's largest CCO, Health Share serves 400,000 Oregon Health Plan (OHP) members throughout Clackamas, Multnomah and Washington Counties. We have a demonstrated track record of responsibly and sustainably integrating Social Determinants of Health (SDOH) into health care. Health Share has set an example for our industry by cultivating a guaranteed supportive housing benefit that includes wrap-around services for members confronting major life transitions. Our CCO is committed to connecting the OHP members we serve to the care and resources they need. We believe the vision outlined in the draft 1115 Waiver Application represents a positive step towards building upon the integrated framework first started with CCOs in a manner that recognizes the reality of our members' lives. Nevertheless, Health Share is seeking additional information on the financing, timelines and operational planning mechanisms needed to ensure that these proposals achieve their goals.

**More information is needed on the financing of newly proposed benefits to understand whether they are sustainable.** The Waiver application outlines newly proposed benefits consisting of housing, food, transportation and employment assistance to 374,800 individuals who are at risk of becoming homeless. Similarly, the proposal also shapes broad benefits for 129,549 individuals vulnerable to extreme climate events as well as 48,000 youth who are involved or at risk of involvement with the child welfare system. Health Share seeks further clarification on the funding mechanisms that would be used to pay for these new benefits in a sustainable manner. We seek a clearer understanding of the resources that would be used to fund new benefits in years 1-3 as well as information on the extent of risk that a CCO should expect to absorb in their global budget during years 4-5 and beyond. Throughout Health Share's work developing a guaranteed supportive housing benefit for our members, we have tried to strike the right balance between introducing new benefits while also sustaining existing physical, behavioral health and oral care services. Since predictability is key to the successful administration of the OHP benefit, it is critical that we be able to ensure the financial viability of all current services alongside any new services that become available.

**CCOs and other stakeholders require more detailed information and meaningful engagement on the recommended timeline and process to operationalize new benefits.** The administration of the new SDOH transition benefits will require a monumental operational lift for CCOs, delivery systems and organizations providing social services to OHP members. This is especially true given the scale and breadth of these new programs. A timeline that allows for proper planning is critical to ensure that we build new benefits correctly and avoid any unintended harm or waste. Similarly, it will be important to have a process in place that allows CCOs, providers, Community-Based organizations, and other community stakeholders to work together in understanding each other's work. New benefits can only be administered successfully through a network of providers that are willing to take referrals and carry out the work. Health Share is currently in the process of developing a network of housing providers through relationships and contracts with housing service providers, community-based organizations, and traditional health workers for the purpose of operationalizing our supportive housing benefit. Simply put, the work takes time and patience and there are new lessons learned every day about how we can change or improve things. Therefore, any clarification on how Oregon plans to work with all stakeholders within a reasonable time frame to stand up the newly proposed benefits would be welcomed.

**The relationship between Community Investment Collaboratives (CICs) and CCOs must be structured in a manner that ensures deep and ongoing connection between institutions as our work unfolds.** Health Share recommends that there be both alignment and an explicit connection between the work of CCOs and the creation of CICs. Health Share supports investments in the community to address the needs of OHP members from a grassroots lens. We also, however, believe that it is critical for CCOs and CICs to work together towards a defined common goal and share information as to how we can collectively address health equity disparities in a complementary manner. To improve the population health of marginalized communities, it is essential that all stakeholders work on defining problems and posing solutions in a collaborative and connected manner. The work of CCOs and CICs will be interconnected because we serve many of the same individuals and cannot afford to ignore each other's efforts. As such, we recommend a more formal association be developed between CCOs and CICs to ensure we can carry out our work together.

**Oregon must take advantage of any opportunities in the 1115 Waiver, and other policy-making spheres, to bolster the Behavioral Workforce and broaden the ability of OHP to capture federal match funds to pay for expanded Traditional Health Worker (THW) services.** We acknowledge that much of the work needed to improve the Behavioral Health system is not limited to the renewal of the 1115 Waiver. Nevertheless, we encourage Oregon to make sure that we are doing everything possible through the 1115 waiver to bolster the state of our fragile Behavioral Health system. This includes, but is not limited to, expanding the role and scope of services that can be offered by traditional health workers and reimbursed through Medicaid. In addition, we believe it is critical to call attention to all arenas of public policy throughout the state and do everything possible to support Behavioral Health providers. The sad reality is that many existing residential service providers have significantly reduced capacity and others have closed entirely. Access to culturally and linguistically appropriate behavioral health services is critical to achieving CCO and OHA equity goals. Health Share recommends that we do everything possible to appropriately fund and staff existing bed capacity in our residential system to pre-covid levels. The failure to address the

behavioral health crisis in a strategic manner by enhancing access to care will only lead to greater costs down the line and will continue to shift the burden to other parts of the system.

**Health Share is concerned about the use of a single closed pharmacy formulary, and respectfully requests that the state allow the CCOs and their partners be able to continue to use their existing formularies to best manage care for patients.** We support reforms that address the root causes of the high cost of prescription drugs and endorse efforts allowing insurers to use their power as part of the health care system to drive investment toward therapies that provide the greatest benefit for patients. Mandating CCOs and their partners to use a single formulary will dramatically increase costs by disrupting efficiencies inherent to integrated systems. We anticipate that OHP rates would need to be adjusted upward to recognize the increase in service and administrative costs. Health Share is also concerned that once the redetermination process resumes, individuals transitioning off OHP to other forms of coverage will be forced to move from one formulary to another within the same integrated care model.

Thank you for the opportunity to provide comment. If you have any further questions, please contact Yoni Kahn-Jochowitz, Director of Public Policy, at [kahn-jochowitz@healthshareoregon.org](mailto:kahn-jochowitz@healthshareoregon.org).

Sincerely,

James Schroeder  
CEO, Health Share of Oregon

December 9<sup>th</sup>, 2021

Co-Chairs: Eric Du Vivier, and Kate Wells

Oregon Health Policy Board Health Equity Committee

Oregon Health Authority

Re: Medicaid 1115 Waiver Public Comment

Many in the medical field have difficulty understanding why community groups continue to push for system changes to reduce health inequities. The most common quote I hear is “Well, that is already a law, and we have a policy.” When we look at Systemic Oppression and inequities within our society, the law of generality, or one size fits all approaches, protects positions of power.

Oppression, evidenced through discrimination, is systemic in our society. It is more than individual acts of violence, segregation, or discrimination motivated behavior and actions. Oppression is endemic in our institutions and has the effect of exclusion. It is a part of our society and inextricably linked to the equality rights of marginalized populations.

The systems we have designed to be equal to all, and best for the majority, are clearly disenfranchising a large segment of our communities. By not structurally building supports for differences in economic circumstance, racially disparate impacts, barriers in literacy, physical abilities, and negative attitudes towards LGBTQ+ folks, the oppression of these groups continues.

“Well, that is already a law, and we have a policy.” Stop and reflect. Ask yourself the following questions:

- Are we actually following the law?
- How does this policy affect different people?
- How do our practices affect different people?

After we have answered these questions and critically analyzed those answers. Are we recognizing the power of an organization or field societally and how that power results in societal privilege and benefit to the exclusion of marginalized people?

HB 3353 explicitly says CCOs are to “spend” their global budgets on specific investments. (Reference: Section 2(1)(a) of HB 3353). Instead, the OHA’s draft application tells CCOs to give money to a newly formed third party that would “grant out” funds. The OHA’s draft waiver request ignores the legislative directive to cause CCOs, at the local level, to engage the entire community in making health investments. (Reference Section 2(3)(a) & (b) of HB 3353).

The 1115 Draft waiver does not call out the many of the accountability measures in HB 3353 that ensures community voices are included in the spending strategies and effort to hold both CCOs and the OHA accountable. The bill says that in order for these dollars to be counted as this 3% they have to be part of "... a plan developed in collaboration with or directed by members of organizations or organizations that serve local priority populations that are underserved in communities served by the coordinated care organization." ) That these investments must include voices from priority and underserved populations in the development of that plan. To include current entities and power structures that exist in the Community Health Assessment and Community Health Improvement plan will uphold the law of generality in each CCO's region.

There are is also clear direction that these investments either show "practice-based or community-based evidence" giving CCO the flexibility need to innovate with new community organizations that likely server smaller populations of underserved communities.

AllCare asks ask the OHA to change Oregon's 1115 Waiver Request, in the following areas:

- 1.) Removal of the third party equity silos.
  - a. Should a third party entity be involved, it shall directed by a majority of underserved community members, and members of organizations or organizations that serve local priority populations that are underserved in communities served by the Coordinated Care Organization. Underserved community members shall also be the ultimate decision makers of local funding.
- 2.) Make clearer the request that the identified 3% of investments in Social Determinants of Health and Equity be recognized as Medical expenditures. This is key to making these investments sustainable, and not relying on a "grant" model.
- 3.) Make clearer a request for full federal funding of these important upstream investments.

CCO's have demonstrated that they can drive regional, collaborative change within the regions that they serve. Historical and contemporary injustices have persisted underneath the CCO's programs within the regions they serve. These injustices that persist have been for multiple reasons.

The Oregon Health Authority for example did not fund the Office of Equity and Inclusion sufficiently over the last waiver time period to audit how CCO's were focusing Quality Improvement plans to eliminate racial, ethnic and linguistic disparities in access, quality of care, experience of care, and outcomes.

Coordinated Care Organizations did not leverage existing contract language to focus Quality Improvement plans to eliminate racial, ethnic and linguistic disparities in access, quality of care, experience of care, and outcomes.

Oppression endemic in regional institutions of power that excluded voices affected by economic circumstance, racially disparate impacts, barriers in literacy, physical abilities, and negative attitudes



Changing healthcare to work for you.

towards LGBTQ+ folks, to further perpetuate inequities in the State. Some of these regional institutions have directly targeted, and dismantled coalitions of the aforementioned community groups, to protect the law of generality and positions of power.

The Office of Equity and Inclusion has, in partnership with this committee, created a very robust equity analysis tool as part of waiver implementation. AllCare asks that this framework be used when determining future policy for implementing this waiver and the Oregon Medicaid Program. This tool could be used as a roadmap in all policies to understand if Oregon Medicaid is:

- Actually follow the law?
- How does this policy affect different people?
- How do our practices affect different people?

HB 3353 has created a regulatory framework and funds to radically address our system and the financial components to make it successful. It is now up to the OHA, CCO's, Hospital Systems, Medical Groups, and Individual provider offices to treat this the same as regulatory requirements around HIPAA, CLIAA, OSHA, and the Joint Commission, to overhaul the system to achieve the goal of eliminating healthcare inequities in ten years.

Stick Crosby

Sr Director Provider Network and Health Equity

541-944-5962

[Stick.Crosby@allcarehealth.com](mailto:Stick.Crosby@allcarehealth.com)



An Oregon Benefit Company

1701 NE 7th St.  
Grants Pass, OR 97526  
Phone (541) 471-4106  
Fax (541) 471-3784  
Toll free (888) 460-0185  
TTY 711  
AllCareHealth.com



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority (OHA)  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Prescription Drug Limitations in Proposed Oregon Medicaid Waiver

Dear Ms. Hatfield:

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. **We write to express our strong opposition to the proposed limits to the prescription drug formulary that have been included as part of Oregon's 1115 Medicaid Demonstration Waiver. The stated goal of the waiver is to promote greater equity; however, not only do we believe what Oregon is proposing is not legal, but it will have the opposite effect of promoting equity. We urge you to not include these proposals in your waiver submission.**

People with HIV, hepatitis, and others with serious and chronic conditions rely on an array of medications to remain healthy and alive. People with HIV and hepatitis B rely on drug regimens that they must take for the rest of their lives, while people with hepatitis C can be cured of their disease in as little as 8 to 12 weeks. For those who are at risk of HIV, there are daily oral medications and just recently, a long-acting injectable that can lead to better adherence. Having a full range of medications available will lead to better health outcomes and greater equity.

Not all medications are the same, and each person may react differently to a particular medication. Together, doctors and patients make careful treatment decisions about which therapies are most appropriate on a case-by-case basis. Some individuals may develop side effects to a particular drug, while another person may need a certain therapy to avoid a harmful interaction with a drug being taken for another health condition. Drug resistance can occur, and they must have the ability to switch to another drug without interruption.

While the focus of these comments is on HIV, since that is our area of expertise, the same reasoning can be made for many other classes of drugs to treat other health conditions as well.

**HIV + HEPATITIS** POLICY INSTITUTE

1602B Belmont Street NW | Washington DC 20009 | 202-462-3042  
HIVHep.org | Twitter: @HIVHep | Facebook: HIVHep

## **HIV and Disparities**

According to the Kaiser Family Foundation, Medicaid is the largest source of insurance coverage for people with HIV, estimated to cover 42 percent of the adult population, compared to just 13 percent of the adult population overall.<sup>1</sup> HIV disproportionately impacts Blacks/African-Americans and Hispanics/Latinos. According to the CDC, while Blacks/African-Americans represent just 13.4 percent of the overall population, they represent 40.3 percent of all people living with HIV. For Hispanics/Latinos, they represent 18.5 percent of the population but 24.7 percent of people living with HIV. Gay and bisexual men are the most disproportionately affected group. They account for about 66 percent of new HIV infections each year, even though they account for only 2 percent of the population, with the highest burden among Black and Latino gay and bisexual men and young men. In 2019, 26 percent of new HIV infections were among Black gay and bisexual men and 23 percent were among Latino gay and bisexual men.<sup>2</sup>

Black women are also disproportionately affected compared to women of other races/ethnicities. The rate of new HIV infections among Black women was 11 times that of White women and 4 times that of Latina women. Transgender people, particularly those who are Black/African-American, are also disproportionately impacted by HIV.<sup>3</sup>

These same disparities exist in Oregon. According to the Oregon Public Health Division, the rate of Blacks/African-Americans with HIV is 20.2 per 100,000, while it is at least 8 per 100,000 for American Indians/Alaska Natives, Native Hawaiians/Pacific Islanders, and Latinos; however, for Whites it is just 4.2 per 100,000.<sup>4</sup>

## **Ending HIV**

Due to the remarkable advancements in antiretroviral therapy, we believe we can end HIV, which is still an infectious disease of significant public health concern. If people with HIV have access and are adherent to the medications they are prescribed, they can live relatively healthy lives. In addition, the medications suppress the virus so well that they cannot sexually transmit the virus to other people. Therefore, HIV treatment is also HIV prevention. There are also drugs called pre-exposure prophylaxis, or PrEP, that people who are at risk of HIV can take that prevent infection of HIV. Due to these advancements, we can end HIV by reducing the level of virus in the population, if people have access to these medications. In fact, there is a concerted effort to end HIV by 2030 and the Biden administration recently released an updated *National HIV/AIDS Strategic Plan* to end HIV. The strategic plan recognizes the importance of Medicaid

---

<sup>1</sup> "Medicaid and HIV," Kaiser Family Foundation, updated October 1, 2019, accessed January 6, 2022, <https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/>.

<sup>2</sup> *National HIV/AIDS Strategy for the United States: 2022–2025*, White House, 2021, p. 15, <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>.

<sup>3</sup> *National HIV/AIDS Strategy for the United States: 2022–2025*, White House, 2021, p. 16.

<sup>4</sup> *End HIV Oregon*, Oregon Public Health Division—HIV, STD, & TB Section, updated January 6, 2022, accessed January 5, 2022,

<https://public.tableau.com/app/profile/oregon.health.authority.public.health.divison/viz/EndHIVOregon/EndHIVORHome>.

and the role of prescription drugs by stating, “Medicaid is the largest source of insurance coverage for people with HIV, covering a broad range of services from inpatient and outpatient care, **to prescription medications**, to preventive services” (emphasis added).<sup>5</sup>

Oregon has its own program to end HIV, the End HIV Oregon initiative run by the Oregon Health Authority (OHA) and its community partners (EndHIVOregon.org). It incorporates the same elements of increasing treatment for people living with HIV to lead to greater viral suppression and increasing access to PrEP for those who are at risk of HIV.

### **Oregon Proposals to Limit Prescription Drugs**

Oregon is proposing to drastically curtail the number of drugs that its Medicaid program must cover by creating a drug formulary that only includes one drug per class from its current open formulary that is required under federal law. Additionally, Oregon is proposing to exclude altogether certain FDA approved drugs.

**Proposal Violates Federal Medicaid Law.** Section 1927 of the Social Security Act requires states to cover all drugs of a pharmaceutical manufacturer that participates in the federal Medicaid rebate program, while allowing them to use “permissible restrictions.” In exchange for this requirement, states receive a minimum 23.1 percent rebate plus additional rebates when manufactures increase the price of their drug above inflation. States may receive supplemental rebates by using a preferred drug list. The closed formulary Oregon is proposing that would only include one drug per therapeutic class violates current federal law, cannot be waived, and should not be proposed by the state.

Oregon is also proposing to exclude certain FDA-approved drugs that gain their approval through its accelerated approval pathway. This also would circumvent current Medicaid law. Section 1927 does not allow states to pick and choose what types of medications that must be covered but requires coverage of all FDA-approved drugs of manufactures that participate in the rebate program. These drugs are FDA-approved. Secondly, these accelerated approval drugs still must meet FDA standards for approval and are on the accelerated approval process in order to meet the needs of patients who have rare or complicated diseases with few or no treatment options.

**Flawed Basis for Proposal.** In making this proposal, Oregon states incorrectly that by doing so it will match what is done by commercial payers and by Medicare. In both those instances, this is not correct.

Under the rules implementing the Affordable Care Act (ACA), plans must cover *at least the greater of*: (i) One drug in every United States Pharmacopeia (USP) category and class; or (ii) The same number of prescription drugs in each category and class as the Essential Health Benefit-benchmark plan. (See 45 CFR § 156.122) These essential health benefits benchmark plans are widely used commercial plans and include a wide array of drugs in each class. These same regulations also state that plans must have a pharmacy and therapeutic committee to

---

<sup>5</sup> *National HIV/AIDS Strategy for the United States: 2022–2025*, White House, 2021, p. 13.

help formulate drug formularies that are based on “scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.”

Recently, in the proposed *Notice of Benefits and Payment Parameters Rule for 2023*, CMS reminded plans “issuers should expect to cover and provide sufficient access to treatment recommendations that have the highest degree of clinical consensus based on available data, such as professional clinical practice guidelines.”<sup>6</sup>

The mention of at least one drug per class is to ensure that every plan has at least one drug to treat a certain condition. However, commercial plans are required to cover more than this and follow clinical guidelines.

For HIV, there are NIH treatment guidelines, which include a wide range of medications, and for PrEP, the CDC recently released the Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update—A Clinical Practice Guideline, which includes all current FDA-approved drugs for PrEP. Allowing Oregon to cover only one drug per class would not keep its Medicaid formulary current with scientific based clinical guidelines for the treatment and prevention of HIV.

Oregon states that Medicare Part D also employs a closed formulary and can limit a plan to just one drug per class. Again, Oregon has not fully or accurately described current Medicare Part D law and regulations. Medicare regulations, which have been codified by the Congress, including as part of the ACA, require Medicare plans to cover all or substantially all medications to treat some of the most serious health conditions. Part D requires plans to cover basically all drugs in the six classes: antidepressants, immunosuppressants, antipsychotics, anticonvulsants, and antiretrovirals. Drugs in these six “protected classes” (as defined in Section 1860D-4(b)(3)(G)(iv)) are used to treat the most vulnerable of patients for whom medicines are not interchangeable due to sensitivity or resistance to a drug, the unique biochemistry of the individual, or severe side effects.

Like many Medicare beneficiaries, Medicaid beneficiaries, including those with HIV or at risk of HIV, are among the most vulnerable in society and should have access to the full range of medications, not just one drug per class, to treat their health conditions. In order to promote greater equity and to end HIV, Oregon must maintain its statutorily required open formulary. While we do not like it, Oregon can utilize a preferred drug list in order to gain additional rebates from drug manufacturers.

Thank you for this opportunity to comment on this proposal. Should you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at [cschmid@hivhep.org](mailto:cschmid@hivhep.org).

---

<sup>6</sup> *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023*, Department of Health and Human Services, Federal Register, updated January 5, 2022, p. 235, <https://public-inspection.federalregister.gov/2021-28317.pdf>.

Sincerely,

A handwritten signature in blue ink, appearing to read "Carl E. Schmid II". The signature is fluid and cursive, with a prominent loop at the end.

Carl E. Schmid II  
Executive Director

Lori Coyner, Senior Medicaid Policy Advisor  
Jeremy Vandehey, Director, Health Policy & Analytics  
Oregon Health Authority 500 Summer Street, NE, E-20  
Salem, OR 97301-1097

Delivered electronically: 1115Waiver.Renewal@dhsoha.state.or.us

**RE: InterCommunity Health Network Coordinated Care Organization (IHN CCO) Comments on 2022-2027 § 1115 Medicaid Demonstration Waiver Concept Papers**

Dear Ms. Coyner and Mr. Vandehey:

InterCommunity Health Network (IHN) Coordinated Care Organization (CCO) IHN-CCO was formed in 2012 by local public, private, and non-profit partners to unify health services and systems for Oregon Health Plan (Medicaid) Members in Benton, Lincoln, and Linn counties. Through the strength of Oregon's coordinated care model, IHN-CCO has a demonstrated history of improving the health of its communities while lowering or containing the cost of care. IHN CCO accomplishes this by coordinating health initiatives, seeking efficiencies through blending of services and infrastructure, and leveraging its strong relationships with community partners and providers to increase the quality, reliability, and availability of care. IHN CCO supports the overall direction of the Oregon Health Authority's (OHA's) draft application for the next § 1115 demonstration waiver with the Centers for Medicare and Medicaid Services ("CMS") and the proposed waiver concepts to further the coordinated care model but has some concerns regarding how the concepts will be operationalized. IHN CCO appreciates the opportunity to provide comments on the waiver as organized by the concept papers:

- Maximizing Coverage through the Oregon Health Plan
- Improving Health Outcomes by Streamlining Life and Coverage Transitions
- Value-Based Global Budget
- Incentivizing Equitable Care
- Focused Equity Investments

**Maximizing Coverage through the Oregon Health Plan**

IHN CCO supports the goal to ensure children remain eligible for uninterrupted Medicaid coverage for five years and believes that earlier interventions and care coordination for our youth could serve as a central strategy for meeting the OHA's goal of eliminating health inequities. IHN CCO also supports two-year continuous enrollment for people ages six and up and an expedited Medicaid enrollment path for people who apply for Supplemental Nutrition Assistance Program benefits. While the proposed goals could provide much needed assistance to Oregon's population, IHN CCO is concerned that self-attestation of income for eligibility may create a repayment scenario if a person attested that they were eligible, but a later determination found that attestation inaccurate. It may be difficult to carry out the proposal to cover an entire family as different family members receive various income streams. Maintaining accurate addresses and demographic information on members will be further compromised as OHA collects this information on a less frequent basis.

IHN CCO supports the goal of expanding upon current culturally appropriate outreach and education efforts to connect people to state-based or Medicaid coverage depending on their circumstances, and to ensure they can access health care services when needed. It is unclear if the expansion will align with the breadth of efforts currently employed by CCOs, including IHN CCO. IHN CCO works closely with providers its communities to provide culturally appropriate outreach and education and would ask that OHA consider engaging CCOs and other stakeholders in designing the proposed expansion to leverage existing experience and efforts.

Expansions in coverage and care will be most successful with improved infrastructure elements, such as Health and Community Information Exchanges. Connect Oregon and similar platforms are critical in urban and rural communities as we continue to transform the delivery of care to ensure referrals, warm handoffs, a quality member experience, and making the best use of the already stretched health and social service workforce. IHN CCO believes this work is critical to guarantee that the proposed coverage expansions lead to the delivery of successful and sustainable whole person quality care and will engage with the Health Information Technology Oversight Committee's work over the next year(s) to scale this work across Oregon.

The implementation of policy solutions to enroll uninsured people in OHP or in subsidized coverage through the Oregon Health Insurance Marketplace could take many forms. IHN CCO urges OHA to consider complications in overlapping commercial insurance coverage that may result in more fragmented coverage for individuals and less sustainable commercial coverage for others that may not be in the same eligibility categories. The policy solutions, although undefined, may also result in dual coverage scenarios that may complicated third-party liability and challenges considering the ONE system's capabilities which will require robust stakeholder input and ample time to implement successfully.

### **Improving Health Outcomes by Streamlining Life and Coverage Transitions**

IHN CCO supports ensuring Medicaid coverage across life transitions and changes in coverage and addressing the full set of factors that impact health, both medical and non-medical, during life transitions. While the details are unclear, the proposed temporary, enhanced care coordination and case management for persons interfacing with institutional systems is appreciated by IHN CCO and its community partners. An IHN CCO community partner was recently faced with an immediate need to support a pregnant woman with housing and medical care that was recently released from incarceration. The ability to pursue a more proactive, case managed approach to health care and support services would relieve the system and individuals of anxiety and risk in such transitions. IHN CCO asks the Authority for more detail on its understanding of coordinated transition support and the administration of limited benefits, including the program parameters, and roles and responsibilities for parties engaged in the work.

OHA's goal to develop and fund a defined set of Social Determinants of Health transition services to support members in need during transition in coverage periods and life transitions is appreciated but operationalizing this requires key stakeholder engagement to inform the effort so that it does not result in duplication or complexity in administering the pre-defined set of benefits. IHN CCO urges OHA to ensure CCOs, Oregon Housing and Community Services Department, the Department of Environmental Quality, the Department of Corrections, and county and city governments have visibility and a voice in this concept. We have concern about the financial impact and sustaining a required shrinking rate of growth, given the infusion of federal funding for years 1-3 and then years 4-5 and beyond the CCOs becoming at risk for these services.

The proposal to link Medicaid with social service providers as well as limited non-clinical services supports the improvement of equity but is unclear as to the specific of how that could happen considering the barriers that exist around training and certification, as well as reimbursement, for providers of these services. Traditional health workers, including peer support specialists, need stable funding, but there are considerable barriers to traditional health workers

operating in the community and receiving Medicaid funding for their services (outside of grants or employment or affiliation relationships with county mental health programs, primary care providers, and other partners in the care team). CCOs and community-based traditional health workers may have different expectations about the requirements necessary to accept heavily regulated Medicaid funds in a sustainable payment model—including background checks, insurance, treatment plans, documentation, etc. While IHN CCO and its community partners appreciate that OHA is considering steps it can take to streamline and improve the application and certification process for traditional health workers, community partners have expressed concern regarding structured and more complicated billing requirements outside of value-based payment contracts and streamlined grant requirements.

### **Value-Based Global Budget**

IHN CCO supports OHA’s proposal for adjusting rate setting to be more predictable and able to support longer-term investment outcomes in health equity, prevention, and community improvement. OHA’s proposal to include required HRS spending in global budgets is unclear in how that will be managed and where ultimate accountability is placed given that a percentage is intended to be managed through proposed community investment collaboratives (CICs) overseen by a statewide oversight committee.

Many CCOs, including IHN CCO, fund community-based organization (CBO) infrastructure and capacity building through Health Related Services (HRS) funding managed by community partners, including Community Advisory Councils. Introducing another layer of community engagement through the proposed CICs to manage community investments that includes a statewide oversight committee may introduce many complexities and disjointed or duplicative efforts. IHN CCO specifically works with CBOs to fund these initiatives through a community led process that allows CBOs and other key partners to define parameters for evaluating and funding community partner pilot projects that support innovative approaches to provide support services to members and elevate population health. This community driven process strives to align with regional priorities (e.g., housing, equity, mental health crisis) and minimize the complexities related to governmental funding requirements. It is unclear how the current community advisory councils and regional health equity coalition leaders will align with the CICs. Furthermore, IHN CCO feels it is important for other state agencies, such as those administering housing, education, and criminal justice, to partner with the OHA in this work to maximize all opportunities for funding and eliminate barriers to care, services, and supports.

IHN CCO appreciates the inclusion of strategies to address the impact of pharmacy costs on Medicaid spending in Oregon. However, we are concerned about the use of a single closed pharmacy formulary, the removes the ability of CCOs and their partners to use community-based and evidence-based decision making on formularies to best manage care for the greatest benefit of our members. Mandating CCOs to use a single formulary has proven in other states to dramatically increase cost and will challenge the a goal of reducing the overall cost of health care.

### **Incentivizing Equitable Care**

IHN CCO appreciates the focus on equity in developing upstream metrics and the ability to provide input on the develop of these metrics through public comment as they are developed. Due to challenges in collecting specific data components for such metrics, as experienced with the language access metric developed in 2021, IHN CCO would caution OHA that the ability to collect data on components of metrics can place burdens on providers and community partners. IHN CCO supports the overall need for such metrics, with consideration for the various unintended consequences resulting from the complexity in metrics related to how health care services are delivered to Medicaid members in Oregon.

### **Focused Equity Investments**

IHN CCO appreciates the ability to capture HRS spending as medical and quality improvement expenditures for the purposes of rate-setting. As mentioned under Value-Based Global Budget, IHN CCO urges OHA to consider the complexities of adding another layer of governance through CICs that could result in a less regionally focused approach

to supporting community programs and services, and conflict with current community-driven efforts supported by CCOs across Oregon. Again, it is unclear how the current community advisory councils and regional health equity coalition leaders will align with the CICs and whether CCOs will have accountability for the investments made by the CICs. The original intent of the coordinated care model was to partly to ensure CCOs could drive change locally in a way that resonated with the challenges faced by the unique communities in which they serve.

Public comment in community partner forums led by IHN CCO captured positive reactions to enhanced investments into community supports but concerns were simultaneously raised about CBOs' ability to manage investments/grants through a government entity, which tend to have more robust process and reporting requirements. IHN CCO's community partners asked that OHA consider the challenges smaller, but critical, CBOs may face in the proposed structure. These partners also had concerns about whether they would be involved in funding decisions similar to how IHN CCO has collaborated with them in community-driven funding decisions. IHN CCO requests OHA to consider current efforts and community-led forums, including the CACs, when developing statewide infrastructure to manage the CICs; ensuring alignment and local community focus to the extent possible. It may be appropriate to build this community oversight, with appropriate reporting requirements, into CCO contracts to avoid duplication and ensure aligned coordination of OHA's goals and minimized complexity in administering investments.

Furthermore, IHN CCO feels it is important for other state agencies, such as those administering housing, education, and criminal justice, to partner with the OHA in this work to maximize all opportunities for funding and the elimination of barriers to care, services, and supports. Numerous state and local government entities offer grant opportunities in various ways with various levels of requirements, which can be difficult for CBOs to administer. In addition, IHN CCO requests that OHA consider allowing for longer-term investment opportunities to support measurable changes and sustainable community infrastructure.

IHN CCO has significant concerns about funding the CICs using one percent of the CCO budget. This proposal creates a siloed entity that has accountability to the state and is a state managed entity and the entities will lack community accountability. This is a missed opportunity to influence the CCO model and community health services delivery system to truly move the needle on health equity and reducing disparities. We continue to encourage OHA to revise this concept so that it is integrated into the CCO model.

In closing, the sustained success of many of the proposed concepts in the draft waiver application will be realized in implementation and detailed operational requirements. We know many of these elements are yet to be determined and understand that the submission of the application is the start of the process. We look forward to partnering with the OHA, regional and systems partners, providers, and advocates on next steps and those details that will ensure success. We appreciate the consideration of our comments and look forward to next steps. Thank you for your work.

Thank you for the opportunity to provide comment. If you have further questions, please contact Bill Bouska, Director Government Relations, at [wbouska@samhealth.org](mailto:wbouska@samhealth.org)



## Immigration Legal Services as a Defined Benefit Under Oregon's 2022-2027 Medicaid Waiver

To help solve our state's health inequities, Oregon must empower communities by recognizing both historic and contemporary injustices, and by acknowledging that segments of the Oregon Health Plan membership must overcome additional social determinants of health in order to be physically and mentally well.

The draft 1115 Waiver rightfully signals OHA's commitment to focus on communities most harmed by health inequities, including immigrants and refugee communities. For immigrant and refugee OHP-enrolled community members, the pressing social determinants of health of housing, childcare and transportation are compounded by the additional SDoH of immigration status.

**We call for the 2022-2027 1115 Demonstration to explicitly cover the immigration legal services costs borne by OHP members, including green card holders, refugees, asylees and humanitarian visa holders.** OHP members with humanitarian visas include those who have secured specialized immigration protection because they are, for example, survivors of domestic violence, human trafficking or female genital mutilation or cutting (FGM/C).

**One out of every ten Oregon residents is foreign-born, while one in nine residents is a native-born American who has at least one immigrant parent.**

- *American Immigration Council*<sup>1</sup>

OHP members who are newly-arrived refugees and immigrants – and whose immigration cases could determine whether they remain in Oregon, become reunited with loved ones or enjoy a stability so many others take for granted – have complex legal needs that must be addressed by a qualified legal professional to ensure case compliance and accuracy in following immigration law processes.

Unfortunately, the cost of immigration legal services can be prohibitive for many new Oregonians living at or below the poverty level. This creates enormous strain for the OHP member, with family stability and community connections at risk when many are forced to choose between paying for the legal services or basic necessities like housing, nutritious food or other pillars to social determinants of health.

Such impossible and inequitable choices cause not only psychological distress but can contribute to chronic mental health issues including anxiety, depression, PTSD, suicidal ideation, isolation and grief. The extreme challenges of an insecure or insufficient immigration status can also contribute to acute

---

<sup>1</sup> American Immigration Council. *Fact Sheet: Immigrants in Oregon*. August 6, 2020.  
<https://www.americanimmigrationcouncil.org/research/immigrants-oregon>

and chronic physical health issues, including but not limited high blood pressure, angina, tachycardia, heart disease, stomach ulcers, gastritis and arthritis.

Oregon's health care providers and health care leaders are rightfully determined to address health inequities. Providing no-cost access to crucial immigration status remedies – many of which are relatively low-cost, one-time legal processes – would ensure OHP members who are immigrants and refugees are able to permanently minimize the likelihood of the negative health outcomes above, and have the mental and financial space to focus on existing and future chronic health challenges.

In the days and weeks ahead, we ask for your partnership and consideration of this proposal. We welcome the opportunity to meet to discuss this issue in more detail.

Thank you.

Sincerely,

Daisy Hollick, Catholic Charities of Oregon  
Kat Kelly, Catholic Charities USA  
Britt Conroy, Ecumenical Ministries of Oregon



January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

RE: Comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

Dear Deputy Director Hittle:

At The Leukemia & Lymphoma Society (LLS), our mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and to improve the quality of life of patients and their families. We support that mission by advocating that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. On behalf of the thousands of Oregonians whose lives have been changed forever by blood cancer, we appreciate this opportunity to comment on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

LLS supports the focus that the Oregon Health Program has placed on equitable access to healthcare in the 1115 Demonstration Waiver and thanks the department for its innovative thinking and leadership to eliminate inequities in access to care. In addition, Oregon's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver contains multiple proposals that undermine access to care for patients with blood cancer. LLS is concerned the proposed closed formulary for adult beneficiaries will make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries and to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one, as both proposals will significantly jeopardize access to care for patients we represent.

LLS offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Program.

***Continuous Eligibility***

LLS supports the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>i</sup> Research has also shown that individuals with disruptions in coverage during a year are

more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>ii</sup> People in the midst of cancer treatment, for example, rely on regular visits with healthcare providers, and many of those patients must adhere to frequent, if not daily, medication regimens. The loss of coverage or a gap in coverage is a grave prospect for anyone living with blood cancer. Continuous eligibility will help reduce these negative health outcomes.

### ***Closed Formulary***

LLS is concerned that the proposal to adopt a commercial-style closed formulary and to exclude from that formulary drugs with “limited or inadequate evidence of clinical efficacy” will reduce access for certain cancer patients to the only appropriate treatment available. This proposal may negatively impact access to care for patients living with a range of serious diseases and conditions. But for patients living with cancer, this proposal is especially grave, as there is very little interchangeability among the drug therapies used to treat most cancers, including most blood cancers. Typically, treating cancer is a profoundly complex undertaking. Indeed, even among patients with the same diagnosis, the same treatment may be insufficient or altogether inappropriate.

In particular, LLS is alarmed by the language on page 31 of the Application for Renewal and Amendment stating that “[m]any drugs coming to market through the FDA’s accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints” and by Oregon seeking “the ability to use its own rigorous review process to determine coverage of new drugs and to prioritize patient access to clinically proven, effective drugs.”

In our own analysis of drugs with an FDA-approved blood cancer indication approved prior to July 2021, more than 40 were approved through accelerated pathways, including 31 just in the past decade. Furthermore, the State’s claim that this will induce programmatic savings is diminished by the intent to “use its own rigorous review process” to determine a drug’s efficacy. LLS is alarmed by the prospect of a secondary state-level review process that claims rigor without any transparency around the methods or standards the state intends to put in place to achieve it. Indeed, the application provides no detail on how Oregon will establish such a review process. Given the rigorous standards the FDA and manufacturers follow before a drug reaches the market through even an accelerated pathway, such a program is likely to be expensive: to Oregon’s Medicaid budget, to those beneficiaries who may be denied access to a treatment or therapy while the State decides whether they think it merits coverage, and potentially even to the broader healthcare system if such a secondary review process results in health spending that would have been obviated by timely adherence to the FDA-approved medication. If adopted in multiple states, this could result in dramatic variation in access to new cancer therapies across the country.

In its application, the State suggests that they seek the same “discretion” regarding formulary design as that available to commercial payers. Enrollees in commercial plans, however, have access to appeals and exception processes that can provide access when necessary to excluded drugs, whereas the Oregon application includes no indication of intent to provide that same due process to Medicaid beneficiaries impacted by a formulary limitation. To make adequate comparisons between Medicaid

and commercial payer formularies, it is also important to note that commercial payers do not receive the same mandatory rebates that Medicaid programs, including Oregon's, receive for all drugs covered under the program. Moreover, patients covered by commercial plans can choose alternative coverage, while Oregonians on Medicaid have no similar alternative.

Given the small population of cancer patients relying on these new medications and the importance of timely adherence to treatment regimens, LLS believes the creation of a closed formulary, without a clear and robust exception process, would be harmful to blood cancer patients.

While LLS certainly appreciates the need for state resources to be spent on benefits and services of high value, adopting this as a blanket approach will no doubt prevent or delay some cancer patients from accessing medically appropriate and potentially life-saving therapies simply because they are Medicaid beneficiaries. LLS requests that the Oregon Health Program remove these requests and provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

### ***Retroactive Coverage***

LLS is concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. Eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as blood cancer, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>iii</sup> Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>iv</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. LLS opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

### ***EPSDT Benefit***

LLS is opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). The purpose of the EPSDT benefit is to ensure that children receive appropriate healthcare, however, the limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services or simply unable to access those needed services. Many of the services that have not been prioritized are for serious and concerning conditions, such as the special health care needs of children with cancer. In fact, blood cancers are among the most common pediatric cancers, with leukemia and lymphoma accounting for more than 1 in 3 cancer diagnoses among patients under the age of 20.<sup>v</sup> These limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. For example, children of color are enrolled in Medicaid at disproportionately higher rates<sup>vi</sup> and as mentioned before, are also more likely to be affected by gaps in coverage.<sup>vii</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit. LLS supports the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

### ***Conclusion***

LLS believes that healthcare coverage should be affordable, accessible and adequate for children and adults with cancer. Questions or requests for further information on LLS and our position can be addressed to [sara.kofman@lls.org](mailto:sara.kofman@lls.org).

Thank you for the opportunity to provide comments.

Sincerely,

Sara Kofman  
Regional Director, Government Affairs  
Leukemia & Lymphoma Society

---

<sup>i</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)

<sup>ii</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>

<sup>iii</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

---

<sup>iv</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016.

(<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>v</sup> "Childhood and Adolescent Blood Cancer Facts and Statistics," The Leukemia & Lymphoma Society. Available at:

<https://www.lls.org/facts-and-statistics/childhood-and-adolescent-blood-cancer-facts-and-statistics>

<sup>vi</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. EPSDT-At-Risk-Final.pdf (georgetown.edu)

<sup>vii</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)



January 7, 2022

VIA ELECTRONIC FILING

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Lilly USA, LLC**

Lilly Corporate Center  
Indianapolis, Indiana 46285  
U.S.A.  
+1.317.276.2000  
[www.lilly.com](http://www.lilly.com)

**RE: Application for Renewal and Amendment Oregon Health Plan, Section 1115  
Demonstration Waiver**

Dear Director Allen:

Lilly USA, LLC (Lilly) appreciates the opportunity to submit comments on the proposed application by Oregon Health Authority for renewal and amendment of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver. Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies, as well as through the analysis and distribution of health information. Ultimately, our goal is to develop products that save and improve patients' lives.

Lilly supports Medicaid beneficiaries' access to high quality health care and medicines and is concerned that the Oregon Health Authority's Section 1115 waiver, which proposes to impose a closed formulary and exclude important innovative drugs approved through the FDA instituted Accelerated Approval Program which would seriously limit patient access to medicines and is not permissible by law. Our primary arguments are as follows:

- The closed formulary may harm patients, reduce medication adherence, and will not result in a reduction in health care costs;
- Denied access of the FDA's accelerated approved drugs will significantly restrict patient access to innovative and complex medicines;
- CMS has rejected a nearly identical proposal by Massachusetts due to the violation of the existing Social Security Act law. Provisions of the Medicaid Drug Rebate Statute cannot be waived under Section 1115 of the Social Security Act;
- The closed formulary and medication coverage restrictions are not permitted under Section 1115 of the Social Security Act as they sever the compact in the Medicaid Drug Rebate Statute; and,
- Cost containment options and tools are available to help control drug expenditures and mitigate risk.

Lilly also supports the comments provided to the Centers for Medicare & Medicaid Services (CMS) by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO).

## **I. Oregon Health Plan Closed Formulary Could Harm Patients, Reduce Medication Adherence, and Will Not Result in a Reduction in Health Care Costs**

The Oregon Health Plan, Section 1115 waiver, proposes to restrict access to one drug per class with intent to exclude drugs approved through the FDA's accelerated approval process. Implementation of both policies would hinder patients' access to a diverse range of innovative treatment options that could best serve their needs, including the individual plaintiffs in the case of *McCutchen v. Becerra* (pending, D.D.C). This is particularly troubling given the vulnerability of the Medicaid population. Non-elderly Medicaid beneficiaries are more likely to be in poor health than those with private insurance.<sup>1</sup> Children covered by Medicaid are also more likely to be in fair or poor health as well as have a higher prevalence of certain behavioral health conditions than those with private coverage.<sup>2</sup> Unlike patients with commercial or Medicare insurance, Medicaid patients do not have the ability to choose amongst various plans for coverage that better fits their individual health challenges, so the application of a commercial-like benefit design is wholly inappropriate in this context.

Moreover, research has shown that formulary restrictions can harm medication adherence<sup>3</sup>. In addition, they may have unintended consequences and result in increased costs. For example, a study found that formulary restrictions for Arizona Medicaid beneficiaries living with arthritis had unintended consequences including increasing hospitalizations and costing an additional \$900 annually per beneficiary. For these reasons, CMS should be highly skeptical of any proposal to limit Medicaid beneficiary access to necessary medications.

## **II. Restricting Access to Drugs Approved under FDA's Accelerated Approval Pathway Will Harm Patients Facing Greatest Unmet Need**

For nearly 30 years, the Accelerated Approval pathway has facilitated approval of medicines that treat serious and life-threatening diseases and conditions for patients who have no adequate treatment options. Nearly 270 medicines have received accelerated approval,<sup>4</sup> extending – even saving – patients' lives by providing earlier access to novel therapies than would have been possible using the traditional approval pathway.

Oregon's proposal to exclude drugs approved through the accelerated approval (AA) process is wholly inappropriate and reflects a substantial misunderstanding of FDA's drug approval process and evidentiary standards.<sup>5</sup> Oregon suggests this proposal is part of an effort to "prioritize patient

---

<sup>1</sup> MACPAC, "MACStats: Medicaid and CHIP Data Book," December 2016, Available at: [https://www.macpac.gov/wp-content/uploads/2016/12/MACStats\\_DataBook\\_Dec2016.pdf](https://www.macpac.gov/wp-content/uploads/2016/12/MACStats_DataBook_Dec2016.pdf), cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 58.

<sup>2</sup> MACPAC, "Chapter 4: Behavioral Health in the Medicaid Program—People, Use, and Expenditures," June 2015, Available at: <https://www.macpac.gov/wp-content/uploads/2015/06/Behavioral-Health-in-the-Medicaid-Program%E2%80%94People-Use-and-Expenditures.pdf>, cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 59.

<sup>3</sup> Happe LE, Clark D, Holliday E, Young T, "A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and HealthCare Resource Utilization," *J Manage. Care Spec. Pharm.* 2014; 20(7):677-84, cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 72.

<sup>4</sup> U.S. Food & Drug Admin., CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint as of June 30, 2021, <https://www.fda.gov/media/151146/download>.

<sup>5</sup> Separately, Oregon also mischaracterizes the 21<sup>st</sup> Century Cures Act, suggesting it was "intended to expedite the drug approval process by reducing the level of evidence required for drugs to reach the market and allowing

access to clinically proven, effective drugs.” Yet, drugs that have received accelerated approval must meet the same standards of safety and efficacy as a therapy that is approved under the traditional pathway. The difference between the two pathways is the type of endpoints that may be utilized in the clinical trials supporting approval. CMS itself recognized this in 2018 guidance when it stated, unambiguously, that accelerated approval drugs must be covered by Medicaid, like all other drugs:

Therefore, as with any other drug, if the drug is labeled by a manufacturer that has signed a Medicaid National Drug Rebate Agreement, and the drug meets the definition of covered outpatient drug, then the drug is covered by the Medicaid Drug Rebate Program (MDRP) and is to be covered by state Medicaid programs.<sup>6</sup>

Imposing policies that make it harder for patients suffering from serious or life-threatening conditions to access approved medicines would undermine the important policy goal behind accelerated approval – facilitating earlier patient access to approved therapies. Furthermore, there is no data to suggest that drugs that go through the AA pathway are driving spending for Medicaid. In fact, a recent analysis of Medicaid spending found that accelerated approval drugs consistently accounted for less than 1% of spending. Since passage of the Food and Drug Safety and Innovation Act which encouraged accelerated approval use for serious and life-threatening conditions in addition to oncology and HIV/AIDS, Medicaid spending on accelerated approval drugs remained steady at 0.6% to 0.8% a year.<sup>7</sup>

Denying Medicaid patients access to medicines approved under the Accelerated Approval pathway deprive some of the sickest patients, who are most in need of treatment, access to innovative, life-saving drugs.

### **III. CMS has rejected a nearly identical proposal by Massachusetts due to the violation of the existing Social Security Act law. Provisions of the Medicaid Drug Rebate Statute cannot be waived under Section 1115 of the Social Security Act.**

In 2017, Massachusetts, MassHealth Section 1115 Demonstration Amendment suggested a similar proposal that failed to meet the intended goal of ensuring robust access to medically necessary drugs and ultimately excluded a vast number of FDA-approved drugs for vulnerable populations. The proposed demonstration amendment mischaracterized the FDA Approval Process, failed to consider the importance of individualized patient-centered care, and disregarded research that revealed the negative effects of closed formularies. Furthermore, CMS responded to the Massachusetts waiver amendment by issuing “Release No. 185” stating that a drug approved by the FDA under the accelerated approval pathway must be covered by state Medicaid programs, if the drug meets the definition of “covered outpatient drug” as found in Section 1927 of the Social Security Act and has signed a Medicaid National Drug Rebate Agreement.<sup>8</sup>

---

doctors, patients, and payers to decide whether to purchase them.” This is simply false. Nothing in the Cures Act altered FDA’s strict approval standards. The legislative history also reflects an ongoing commitment to maintain these high standards. *See e.g.*, House E&C Subcommittee on Health Ranking Member Frank Pallone (Nov. 30, 2017) (“At FDA, the Cures Act aims to bolster the medical product review process in order to get treatments to patients faster while also maintaining FDA’s gold standard for safety and effectiveness.”).

<sup>6</sup> CMS, MDRP Notice for State Technical Contacts, Release No.185, at 1 (June 27, 2018), [state-rel-185.pdf](#).

<sup>7</sup> Thorpe, K. E., PhD, & Holtz-Eakin, D., PhD. (2021). Limiting Medicaid Access to Accelerated Approval Drugs: Costs and Consequences. *American Journal of Managed Care*.

<sup>8</sup> CMS State Release No. 185, June 27, 2018.

Social Security Act § 1115(a)(1) provides that, “[i]n the case of any experimental, pilot, or demonstration program which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid or certain other programs], in a state or states— (a) the Secretary may waive compliance with any of the requirements of section 402, 454, 1402, 1602, or 1902 . . . to the extent and for the period he finds necessary to enable such state or states to carry out such project.” SSA § 1927 (the Medicaid rebate statute, codified at 42 U.S.C. § 1396r-8 [SSA 1927’s] is not on the list of waivable provisions. Accordingly, the D.C. Circuit held in *PhRMA v. Thompson*, CMS had no authority to waive requirements of the rebate statute under § 1115. *PhRMA v. Thompson* is the only case that has addressed whether SSA § 1115 permits waivers of rebate statute requirements. The D.C. Circuit’s ruling has never been overturned or questioned by later cases<sup>9</sup>.

No later cases have overturned this decision. Other courts have agreed that benefit cuts are not valid “demonstrations” under federal law. For example, in the context of a work requirement to qualify for food stamps, the federal court of appeals for the Ninth Circuit emphasized that “[a] simple benefits cut, which might save money but has no research or experimental goal, would not satisfy th[e] criteria [of] ha[ving] a research or demonstration value.” That logic is applicable here, as all the Oregon Health Plan “demonstration” seeks to test is whether cutting benefits by limiting the drugs that are covered by the state, results in “savings.” This is not a good-faith demonstration exercise but is simply an effort for the state of Oregon to shirk its obligations under the Medicaid Drug Rebate program.

Any 1115 demonstration project must be “likely to assist in promoting the objectives of [Medicaid].” Based on the language of the Medicaid statute, courts generally describe Medicaid’s objectives as providing medical assistance to those whose income and resources are inadequate to meet the costs of such care. Allowing a waiver of the drug coverage requirements in the rebate statute would not promote those purposes. Instead of enabling states to assist people who cannot afford necessary medical care, such a waiver would reduce beneficiaries’ access to medicines and adversely affect their health in two ways: directly, by permitting the State to cut back on drug coverage; and indirectly, by eliminating or curtailing manufacturers’ incentive to participate in the Medicaid rebate program—a program that has successfully provided Medicaid beneficiaries “access to the same range of drugs that the private patients of their physicians enjoy” since its start in 1991. The rebate program could unravel quickly if one selective waiver of the rebate statute’s coverage requirements were granted, as other states would likely seek the same waiver once the precedent was established; this would be a serious setback for Medicaid objectives and for beneficiaries’ health and well-being.

#### **IV. The Medicaid Drug Rebate Statute (Section 1927) Represents a Two-Part Agreement That Cannot be Severed by Waiving the Coverage Requirements Alone**

Even if CMS could waive the Medicaid Drug Rebate Statute, it could not waive only the statute’s coverage requirements while leaving in place the obligation that manufacturers pay rebates on Medicaid utilization. The existing statute requires states to cover all products of manufacturers with Medicaid rebate agreements. This coupling of the rebate and coverage requirements was described by a key sponsor of the Medicaid Drug Rebate Statute, Congressman Henry Waxman, as a “government-industry compact.” CMS has also explained the connection between the coverage and rebate requirements as follows:

---

<sup>9</sup> *PhRMA v. Meadows*, 304 F. 3d 1197 (11th Cir. 2002); *PhRMA v. Thompson*, 362 F. 3d 817, 823-24 (D.C. Cir. 2004).

[The Medicaid Drug Rebate Statute] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.

As elucidated by CMS 2013 regulatory preamble regarding Medicaid coverage: “[D]rug manufacturers must pay statutorily-defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.” CMS’s respect for this statutory compact was evident when, in 2018, CMS rejected Massachusetts’ request to establish a closed formulary under the state plan. This policy “would have allowed the State to continue to collect manufacturer rebates under Section 1927, while enabling the State to exclude certain drugs from coverage,” thereby rupturing the statute’s careful balance. CMS expressed its willingness to “consider a demonstration” that would provide “coverage of outpatient drugs under the expenditure authority in section 1115(a)(2),” thereby giving the state the “ability to exclude certain Medicaid covered outpatient drugs from coverage.”

Hence, CMS has recognized and validated the link between the coverage and rebate requirements. It therefore follows that, were Oregon to fail to comply with the coverage requirements of the Medicaid Drug Rebate Statute through implementation of the closed formulary and other proposed coverage restrictions, it would not be in compliance with the statute. This would thereby remove manufacturers’ obligation to pay rebates under the Medicaid Drug Rebate Statute. Instead, manufacturers could negotiate price concessions directly with the state.

#### **V. Oregon Has Access To Cost Containment Options And Tools Are Available To Help Control Drug Expenditures And Mitigate Risk**

The benefits of the statutory Medicaid rebate program are significant. Of the many services Oregon provided for its Medicaid beneficiaries in FFY2019, only 2.9% of the total budget was spent on retail brand and generic drugs. Brand drugs alone were only 1.4% of the total Medicaid budget. Furthermore, manufacturers rebated \$403 million back to Oregon and the federal government, 57% of the total Medicaid spending on drugs.

The states’ tools to save money on prescription drugs provide it with meaningful chances to reduce prescription drug spending. For example, states may: 1) impose prior authorization requirements on any drug, subject to certain timing and supply requirements; 2) impose restrictions authorized by an agreement with a drug manufacturer; 3) create Medicaid formularies and exclude drugs from such formularies under certain specified conditions; 4) create Preferred Drug Lists (PDLs) and may demand supplemental rebates as the price for including a drug on the PDL, among other options; and 5) implement reinsurance mitigation risk programs to decrease the pharmacy expenditures for high-cost enrollees and stabilize premiums.

Furthermore, as noted above, the closed formulary proposal would disrupt the compact of the Medicaid Drug Rebate Statute. This could result in the State losing access to statutorily defined

rebates, which could lead to increased costs to the State for prescription drugs and ultimately result in access challenges for Medicaid beneficiaries.

\*\*\*

Thank you for the opportunity to submit comments in opposition to Oregon's 1115 Demonstration Waiver proposal. We respectfully request that CMS deny these portions of the request as they will pose a serious threat to patient access to health care and could result in higher health care costs. If you have any questions, please do not hesitate to contact me at [oneail\\_shawn@lilly.com](mailto:oneail_shawn@lilly.com).

Sincerely,

A handwritten signature in black ink, appearing to be 'Shawn O'Neil', written in a cursive style.

Shawn O'Neil  
Vice President, Government Affairs



Changing healthcare to work for you.

January 7<sup>th</sup>, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Medicaid 1115 Waiver- CONCEPT PAPER – FOCUSED EQUITY INVESTMENTS

AllCare Health, Inc. is a physician-led organization, leading the way to better healthcare for Oregon and its people, with a range of plans designed to meet the state's diverse communities and their health needs.

AllCare Health will continue to work tirelessly towards identifying and adjusting to the needs of our communities and proving our dedication to insuring equitable access to healthcare for everyone. This equitable access includes listening to and accounting for cultural, economic, and language differences experienced by all those who live in Southern Oregon. We understand that change often takes hard work and that we, along with our communities, have more to do.

AllCare is committed to providing an environment free of all forms of oppression, discrimination and bias, where all people are treated with respect and dignity. AllCare recognizes that the responsibility extends to all individuals involved with, or funded by, the organization. From this perspective, AllCare asks that the following changes be made to the 1115 Waiver, within the Concept Paper - Focused Equity Investments.

**We respectfully request consideration of the following:**

1. **Concern:** HB 3353 explicitly says CCOs are to "spend up to 3%" of their global budgets on specific investments. (Reference: Section 2(1)(a) of HB 3353). The OHA's draft application, does not outline how these funds will be accounted for within the CCO budget. AllCare requests a commitment from OHA be included within the draft application, to have a line item in CCOs budget for the 3% regardless of 'additional' future federal funding being asked. That funding needs to be accounted for within the CCOs annual rates and contract rate sheets. We seek a clear request that the identified 3% of investments in Health Equity and SDoH (HE-SDoH) be recognized as medical expenditures, we see this as a key to making these investments intentional and sustainable.

Section 2(1)(a) of HB 3353 explicitly says, "(a) Require a coordinated care organization to spend up to three percent of its global budget on investments: (A)(i) In programs or services that improve health equity by addressing the preventable differences in the burden of disease, injury



An Oregon Benefit Company

1701 NE 7th St.  
Grants Pass, OR 97526  
Phone (541) 471-4106  
Fax (541) 471-3784  
Toll free (888) 460-0185  
TTY 711  
AllCareHealth.com

or violence or in opportunities to achieve optimal health that are experienced by socially disadvantaged populations; (ii) In community-based programs addressing the social determinants of health; (iii) In efforts to diversify care locations; or (iv) In programs or services that improve the overall health of the community; or (v) The OHA's draft application", does not outline how these funds will be accounted for within the CCO budget.

- **Request:** Please include, within the waiver concept, that the allocation of these funds will be accounted for in the annual CCO rate development process, published here <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/OHP-Rates.aspx>, and Contract Rate Sheets and that the available funding should be outlined in each CCO's rate sheets. AllCare's most current rates are published here <https://www.oregon.gov/oha/HPA/ANALYTICS/OHPRates/CRS-2022-01-CCO-Medicaid-ALLC.pdf>
2. **Concern:** The waiver concept papers should also include that a state-level oversight committee, as established by HB 3353, will be charged with overseeing the 3% global budget spend. This state-level oversight committee should be housed in the Oregon Health Authority Office of Equity and Inclusion.

"The authority shall convene an oversight committee in consultation with the office within the authority that is charged with ensuring equity and inclusion. The oversight committee shall be composed of members who represent the regional and demographic diversity of this state based on statistical evidence compiled by the authority about medical assistance recipients. The oversight committee shall:(a) Evaluate the impact of expenditures described in subsection (2) of this section on promoting health equity and improving the social determinants of health in the communities served by each coordinated care organization; (b) Recommend best practices and criteria for investments described in subsection (2) of this section; and (c) Resolve any disputes between the authority and a coordinated care organization over what qualifies as an expenditure under subsection a (2) of this section." (Reference: Section 3 (6) of HB 3353).

- **Request:** Please include a state-level oversight committee that meets the requirements established by HB 3353, to be charged with overseeing the 3% global budget spend. This state-level oversight committee should be housed in the Oregon Health Authority Office of Equity and Inclusion.

3. **Concern:** Based on how the regional Community Investment Collaborative (CIC) model is being designed, funding is to be directed by members of organizations, or by the organizations, that serve local priority populations that are underserved within the communities served by the coordinated care organization, and should also be funded by any additional federal funds that are leveraged for these services.
  - **Request(s):**
    - Please clarify that Community Investment Collaboratives will be independently funded, along with the potential of additional funds to be leveraged from the federal government for services provided.
    - As independent entities, the CICs will communicate with the oversight committee and have a clear dispute process in the event of a dispute between CCOs, the CICs, and OHA.
  
4. **Request:** Should the Federal Government allow duplicate investment from the CIC and CCOs, please clarify that the Statewide Oversight Committee will resolve disputes between these entities.

Thank you for your consideration of these requests. We ask for support in this effort, to appropriately shift decision-making ability and resources to the communities who understand the region's needs best, through clearly outlined and responsible allocation of funds and with accountability.

Respectfully,

Stick Crosby  
Sr. Director, Provider Network and Health Equity  
Pronouns: He/Him/His

**From:** [Michelle DeVoe](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** Oregon Health Plan  
**Date:** Tuesday, December 14, 2021 7:58:43 AM

You don't often get email from mdevoe@snakeriverpediatrics.com. [Learn why this is important](#)

**Think twice** before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

I thank you for the opportunity to comment on the Oregon Health Plan. I commend the fact that it intends to help as many people as it can, get the medical care that they need, but unfortunately many rural members are left without needed care due to the current processes that must be followed.

I am the medical director at Snake River Pediatrics, which is a rural health clinic in Ontario, Oregon. Because of our location, on the border between Oregon and Idaho, we have a unique perspective to positives and negatives associated with Oregon Medicaid in comparison to Idaho Medicaid. OHP helps to cover many more patients, but this is often to the detriment of the kids who need special services.

Oregon Medicaid for Malheur County is a part of the EOCCO (Eastern Oregon Coordinated Care Organization) who has made a lot of decisions that really affect our patients. Many of them have chronic conditions, like allergies and eczema, which can be exacerbated by food allergies. Removing the offending food, will improve the condition. If our patient has Idaho Medicaid, then we can get allergy testing to see what foods are the cause, and we can remove those foods from their diet. For example, many of the families don't have a clue that eggs are causing this condition, but when we remove them from their diet, they improve dramatically. With our Oregon Medicaid kids, coverage for the testing is denied, so we don't know what food should be removed and the kids continue to suffer. OHP says they can get the testing, it just won't be covered by OHP, but due to the poverty these families experience, paying out of pocket isn't an option.

Unfortunately, mental healthcare is where we see the greatest divergence. Idaho Medicaid patients can see most counselors in Ontario, the surrounding cities or in Idaho. The only limitation is when counselors themselves have decided not to take that insurance, but most do. We also have counselors in our office to see patients. If a child is diagnosed with autism, we can get them into ABA therapy through many different providers. ABA therapy is currently one of the most recommended treatments for autism. For our Oregon Medicaid kids, the treatment is very limited. For the most part, they are only able to get counseling through a company call Lifeways because they have the exclusive contract. Families aren't happy with having to go there, because it's where the court mandated mental health treatments occur, so

they have met some scary people in the waiting room. They also don't keep counselors working there for very long, and once a kid has finally felt close enough to open up to them, they leave Lifeways, they have to get a new counselor and the process starts all over again. Our office has tried to get a contract, but due to the limited payments (\$4/member/month. No payment for visits), can only afford to take 20 OHP patients a month, which we do. Currently our wait list is 90-110 patients, and most patients are in treatment for months to years, so the waitlist is just getting longer. I also have a patient with severe autism, and I can't get him on the waiting list for ABA therapy (which is 2 ½ years) until he has an ADOS completed and there isn't anyone who takes his insurance who can do this. The provider who diagnosed him used to do them but can't due to Covid restrictions. It took us over a year to get him diagnosed and now we can't get him the services that he needs to help him succeed. Words cannot adequately express the frustration I feel for these kids with the knowledge that if they just moved across the border, I could get them the treatment they need. This could easily be solved by allowing all mental health providers to see them. It also allows the parent, patients and other caregivers the option to select the mental health providers. Undoubtedly this would make the continuity of care more efficient with better long term outcomes.

Oregon Medicaid has also recently changed the way they handle Synagis. This is the monoclonal antibody that is given to high-risk infants to protect them from severe RSV bronchiolitis. Most of the kids who qualify for it, have a complex medical history and are at high risk for severe complications from RSV. Most have been born extremely premature, have a heart defect or chronic lung disease like cystic fibrosis. The treatment is very expensive and must be given monthly for 5 months. Prior to this year, when a child qualified for it, it had to be ordered from a specialty pharmacy and sent to the clinic to be administered. This year it has changed. They want the clinic to buy it, administer it, and then get reimbursed for it. The problem is they won't reimburse us as much as it will cost us. The vials cost \$1600 for a 50 mg vial or \$3100 for a 100 mg vial. The dose is based on their weight and the vials are single use. Oregon Medicaid will only reimburse us \$1100. We can't afford to lose this much on any patients, let alone 5 times for each patient. So now, our Idaho Medicaid patients are getting it, but our Oregon Medicaid kids are not. I've already had 2 patients end up in the Pediatric Intensive Care Unit because of this. One hospitalization in the PICU costs more than the entire treatment with Synagis during the season, so this change hasn't been cost effective, and it is risking the lives of the most vulnerable children.

Once again, thank you for your time and consideration.

Michelle DeVoe DO



January 7, 2022

Oregon Health Authority  
Attn: Oregon Health Policy Board  
500 Summer Street NE  
Salem, Oregon 97301

Re: Oregon Health Plan 1115 Demonstration Waiver Application

Thank you for the opportunity to comment on the Oregon Health Authority's Oregon Health Plan 1115 Demonstration Waiver Application. Multnomah County is especially encouraged by the application's efforts to uplift the values and necessary approaches to recognize and address systemic discrimination for people seeking health care coverage and services in our state. This work is particularly important to the diverse community members we provide services to in our region. People of color, LGBTQ+ community members, people living with disabilities, older adults and other populations with marginalized identities experience increased bias and discrimination, particularly in health care settings, which creates barriers to care. We know we can do better.

In hopes that we may help strengthen Oregon's health care services, housing and human services for all populations, Multnomah County's Department of County Human Services, Joint Office of Homeless Services and Health Department offer the following comments and recommendations to the demonstration application:

What we support:

- Acknowledging the negative impact of systemic racism and social determinants of health for ensuring better health care access for all populations in our state;
- Ensuring continued Medicaid coverage and access to care and medicine for marginalized and vulnerable populations during life transitions, including children, older adults (who are dual-eligible for Medicaid and Medicare), children in foster care and children aging out, people who are incarcerated and youth in the juvenile justice system;
- Increasing investments in climate event response/extreme weather support;
- Using person and community-centered approaches such as Personal Health Navigators, Traditional Health Workers, Peer Support Specialists and Peer Wellness Specialists;
- Using the proposed non-clinical screening model to provide social determinants of health housing services, ideally one with definitions aligned with housing provider best practice (right

now homelessness is defined as a transitional event that qualifies OHP recipients for housing supports); and

- Allowing exclusion of drugs with limited or inadequate evidence of clinical efficacy. There is currently an unsustainable spending increase for specialty drugs which are largely physician-administered and some of which have questionable value for both individual and population health outcomes.

What we would like to see included/changed:

- We support providing coverage for rental assistance and supportive housing services but given their 12 month timeline ask that they be tied to coordination of services to ensure homelessness does not occur at the end of this care term;
- Further emphasize and address the role of transportation in health care access, particularly gaps and breakdowns in Non-Emergent Medical Transportation for older adults, elders and people with disabilities. Further, it is critical that the waiver acknowledges the growing need for speciality transportation for people transitioning care settings or who are experiencing cognitive impairment or decline. Multnomah County's 2021-2025 Area Plan on Aging needs assessment survey showed health care coverage, access and transportation among the top needs identified and prioritized by older adults and people with disabilities across all racialized identities and communities.
- Older adults, elders, and people 18-59 with disabilities were minimally referenced. We recommend explicitly calling out age and ability, particularly when intersected with race, gender identity, and sexual orientation in the waiver language in relationship to the social determinants of health. We also request that this population be called out as a prioritized population when appropriate and that their significant and documented barriers to accessing care be included in the narrative and identified initiatives.
- Add older adults and elders to the list of populations eligible for the defined set of social determinants of health transitional services. This will promote the wellbeing of these community members by increasing access to health care, bolstering healthcare utilization for low-income and marginalized older adults, elders, and people with disabilities when accessing necessary transportation services, transitioning care settings, and/or during extreme weather emergencies, such as extreme heat and air quality events.
- Provide access to funds for non-healthcare entities and local community based organizations and ensuring that practices for obtaining funding doesn't provide a barrier to community organizations, especially those better poised to do culturally specific services;
- Define benefits that exist without variance across the OHP population (i.e. CCOs cannot decide which benefits to provide and to whom) and that there is an appeals process available when benefits are not provided (this should be possible, but it needs to be clear) in order to ensure equity and higher utilization of such benefits; and
- We have concerns about the request that "those without current valid OHP coverage would be supported by the OHA Community Partner Outreach Program and local corrections staff in initiating, completing and submitting a new OHP application within 72 hours of arrest and

booking,” because many newly incarcerated individuals are in the process of detoxification, and discussing Medicaid enrollment is often not possible.

- There is a lack of analysis of how the increase in individuals that become eligible through the SNAP pathway could increase caseload and workload for the Type B Transfer Area Agency on Aging (AAA).
- We urge caution in creating one statewide formulary for FFS and CCOs. While it could be helpful to prescribers if there is sufficient coverage in most drug classes, it is unclear what the impact will be to OHP recipients unless there is a robust grandfathering plan for drugs that are no longer covered under the new formulary.

Sincerely,



Mohammad Bader  
Director, Department of County Human Services  
Multnomah County



Jeston Black  
Director, Office of Government Relations  
Multnomah County



Ebony Sloan Clarke, LCSW, MSW  
Health Department Director  
Multnomah County



Erika L. Preuit  
Director, Department of Community Justice  
Multnomah County



January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Deputy Director Hittle:

NAMI Oregon appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

NAMI Oregon is the state chapter of the National Alliance on Mental Illness, a membership-governed grassroots organization that provides free education, support, and advocacy services to individuals and families affected by mental illness. We offer programs through our 15 chapters across the state and annually serve about 12,000 people. In Oregon, our membership is almost entirely composed of individuals living with mental illness, families with loved ones living with mental illness, and friends and allies of individuals and families affected by mental illness.

NAMI Oregon is committed to ensuring that Oregon's Medicaid program provides quality and affordable health care coverage. NAMI Oregon appreciates the focus that the Oregon Health Plan has placed on equitable access to health care in the 1115 Demonstration Waiver. In addition, Oregon's request to provide justice-involved populations with access to Medicaid benefits 90 days pre-release, multi-year continuous enrollment for children under six, and continuous eligibility for all beneficiaries ages six and older will help to eliminate critical gaps in coverage and improve health outcomes.

Unfortunately, this waiver contains several proposals that undermine access to care for patients with mental health conditions. NAMI Oregon is concerned with the proposed closed formulary for adult beneficiaries, which will make it harder for patients with mental health conditions to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries and to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one, as both proposals will significantly jeopardize access to care for patients we represent.

NAMI Oregon offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Plan.

#### *Reentry*

NAMI Oregon supports the request to provide coverage for justice-involved individuals 90 days pre-release and a ready network of health care services and supports upon release. Since prisons, jails, and other penal institutions are required to ensure the provision of appropriate and necessary health care to individuals while incarcerated, these facilities have become America's de-facto mental health providers. However, they are often unable to provide adequate care as part of a system that is not built to provide health services.

Research show that there is a significant lack of access to adequate mental health care in incarcerated settings. About 63 percent of individuals with a history of mental illness do not receive mental health treatment while incarcerated in state and federal prisons.<sup>i</sup> It is also challenging for people to remain on treatment regimens once incarcerated. In fact, more than 50 percent of those who were medicated for mental health conditions at admission did not receive pharmacotherapy once in prison.<sup>ii</sup>

Reentry is a particularly crucial period for those with mental illness because it is associated with significant stress and high risk of recidivism, relapse, or crisis. Nationally, about 80 percent of individuals released from prison in the United States each year have a SUD or chronic medical or psychiatric condition.<sup>iii</sup> On release, people with serious mental illness (SMI), particularly those with co-occurring substance use disorders, recidivate at higher rates than other offenders. This is frequently attributable to lack of timely access to needed services and supports for their condition.<sup>iv</sup> If approved, this request would help the Oregon provide uninterrupted health coverage to ensure this high-risk, high-need population receives needed care as they transition back to their communities.

#### *Continuous Eligibility*

NAMI Oregon supports the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>v</sup> Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>vi</sup> When eligible people with mental health conditions go on and off of coverage – called “churn” – they are less likely to receive outpatient mental health services.<sup>vii</sup> Continuous eligibility will help reduce these negative health outcomes.

#### *Closed Formulary*

NAMI Oregon is concerned by the proposal to transition to a closed formulary for adult beneficiaries, as the intent is in conflict with protections for mental health medications that the Oregon Legislature enacted in the 2021 legislative session via House Bill 3045. We presume Oregon law supersedes the waiver as it pertains to access to what Oregon defines as “7/11” medications — generally defined as antidepressant and antipsychotic medications.

However, the proposal would vastly curtail access to other mental health medications that fall outside of that definition, which would harm people living with mental health and/or substance use disorders. Mental health medications affect people in different ways. Prescription drugs have different indications, different mechanisms of action and different side effects, depending on the person’s diagnosis and comorbidities. People need access to the medications that works best for them because when it comes to mental health conditions, one size does not fit all.

A closed formulary limits the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to the state. Moreover, restricting access to certain types of mental health medications can also interrupt people’s lives and threaten their recovery and safety. Our organization is disappointed that Oregon’s proposal does not even include an appeals process for patients to access non-formulary medications.

Additionally, Oregon’s proposal to exclude prescription drugs that the state deems to have “limited or inadequate evidence of clinical efficacy,” including those approved through FDA’s accelerated approval processes, will also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new treatments have been approved through an accelerated approval process that benefit patients. All patients enrolled in Oregon’s Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life.

NAMI Oregon requests that the Oregon Health Plan remove these requests and provide a robust formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

### *Retroactive Coverage*

NAMI Oregon is concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is also important because many individuals are simply unaware that they are eligible for Medicaid until after they experience a traumatic event. For example, when a mental health crisis arises such as first episode psychosis, the initial focus often is on stabilizing the person’s condition. If such a crisis event occurs toward the end of a calendar month, it may take several days or weeks for the individual and their family and providers to navigate complex medical issues before they turn to considering payment, including Medicaid eligibility. During this time, sizeable medical bills can accrue. Retroactive coverage protects patients like these by ensuring that medical bills are paid even if a Medicaid application is not filed until the calendar month following a traumatic event. Patients should not be left to choose between massive medical bills and treating their illness, and NAMI Oregon urges the state to reconsider this waiver provision.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as mental health conditions, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>viii</sup> Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor’s office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>ix</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. NAMI Oregon opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

### *EPSDT Benefit*

NAMI Oregon is opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). The purpose of the EPSDT benefit is to ensure that children receive appropriate healthcare; however, the limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services. Many of the services that have not been prioritized are for serious and concerning conditions, such as mental illness. These limitations to services

can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to health care, the continued restriction of the EPSDT benefit is a step in the opposite direction. For example, children of color are enrolled in Medicaid at disproportionately higher rates<sup>x</sup> and as mentioned before, are also more likely to be affected by gaps in coverage.<sup>xi</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit. NAMI Oregon supports the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

Thank you for the opportunity to provide comments.

Sincerely,



Chris Bouneff  
Executive Director  
NAMI Oregon

---

<sup>i</sup> U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. Indicators of Mental Health Problems Reported by Prisoners and Jail Inmates, 2011-12. June 2017. <https://www.bjs.gov/content/pub/pdf/imhprpji1112.pdf>.

<sup>ii</sup> Jennifer M. Reingle Gonzalez and Nadine M. Connell. Mental Health of Prisoners: Identifying Barriers to Mental Health Treatment and Medication Continuity. *Am J Public Health* 104, no. 12 (December 2014): 2328-2333. DOI: 10.2105/AJPH.2014.302043.

<sup>iii</sup> Shira Shavit et al. Transitions Clinic Network: Challenges and Lessons in Primary Care for People Released from Prison. *Health Affairs* 36, no. 6 (June 2017): 1006–15. <https://doi.org/10.1377/hlthaff.2017.0089>.

<sup>iv</sup> Glenda Wrenn, Brian McGregor, and Mark Munetz. The Fierce Urgency of Now: Improving Outcomes for Justice Involved People with Serious Mental Illness and Substance Misuse. *Psychiatric Services*, published online (April 16, 2016), <https://ps.psychiatryonline.org/doi/10.1176/appi.ps.201700420>.

<sup>v</sup> Osorio, Aubrianna. Alker, Joan, “Gaps in Coverage: A Look at Child Health Insurance Trends”, Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/health-policy/institute/insights/gaps-in-coverage-a-look-at-child-health-insurance-trends-center-for-children-and-families-georgetown.edu)

<sup>vi</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>vii</sup> Xu Ji et al. Effect of Medicaid Disenrollment on Health Care Utilization Among Adults With Mental Health Disorders. *Medical Care* 57, no. 8 (August 2019), [https://journals.lww.com/lww-medicalcare/Abstract/2019/08000/Effect\\_of\\_Medicaid\\_Disenrollment\\_on\\_Health\\_Care.2.aspx](https://journals.lww.com/lww-medicalcare/Abstract/2019/08000/Effect_of_Medicaid_Disenrollment_on_Health_Care.2.aspx).

<sup>viii</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>ix</sup> Virgil Dickson, “Ohio Medicaid waiver could cost hospitals \$2.5 billion”, *Modern Healthcare*, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>x</sup> Brooks, Tricia. Whitener, Kelly. “At Risk: Medicaid’s Child-Focused Benefit Structure Known as EPSDT,” Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. EPSDT-At-Risk-Final.pdf (georgetown.edu)

<sup>xi</sup> Osorio, Aubrianna. Alker, Joan, “Gaps in Coverage: A Look at Child Health Insurance Trends”, Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/health-policy/institute/insights/gaps-in-coverage-a-look-at-child-health-insurance-trends-center-for-children-and-families-georgetown.edu)



December 29, 2021

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

RE: Oregon 1115 Demonstration Waiver for the Oregon Health Program

Dear Deputy Director Hittle:

The National Multiple Sclerosis Society (the Society) appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

Nearly one million people are living with multiple sclerosis (MS) in the United States, more than twice the original estimate. MS is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms vary from person to person and range from numbness and tingling, to walking difficulties, fatigue, dizziness, pain, depression, blindness, and paralysis. The progress, severity, and specific symptoms of MS in any one person cannot yet be predicted but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS.

The purpose of the Medicaid program is to provide healthcare coverage for low-income individuals and families, and the Society is committed to ensuring that Medicaid provides adequate, affordable, and accessible healthcare coverage. The Society appreciates the focus that the Oregon Health Program has placed on equitable access to healthcare in the 1115 Demonstration Waiver. In addition, Oregon's request to provide multi-year continuous enrollment for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver contains multiple proposals that undermine access to care for people living with MS. The Society is most concerned with the proposed closed formulary for adult beneficiaries, which will make it harder for people living with MS to access the medications they need to stay healthy. Additionally, we also see issues in Oregon's proposals to continue to limit retroactive coverage for nearly all Medicaid beneficiaries as this will continue to significantly jeopardize access to care for people living with MS.

The Society therefore offers the following comments and suggested changes to the 1115 Demonstration Waiver renewal for the Oregon Health Program.



### *Continuous Eligibility*

The Society supports the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>i</sup> Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>ii</sup> For patients living with MS, delaying access to treatment will almost always result in increased disease activity, loss of function, and possible irreversible disability progression. Continuous eligibility will help reduce these negative health outcomes.

### *Closed Formulary*

The Society is most concerned by the proposal to transition to a closed formulary for adult beneficiaries. A growing body of evidence indicates that early and ongoing treatment with a Food and Drug Administration (FDA) approved disease-modifying therapy (DMT) is the best way to manage the MS disease course, prevent accumulation of disability, and protect the brain from damage due to MS.

Fortunately, there are now over 20 FDA-approved DMTs for different forms of MS. The full range of MS DMTs represent various mechanisms of action and routes of administration with varying efficacy, side effects and safety profiles. No single agent is 'best' for all people living with MS<sup>iii</sup>. As MS presents differently in each individual, every person's response to a DMT will be unique. In fact, it is critically important that payers, payment models, delivery systems, and the health care stakeholders at large recognize that despite similarities in their indications and usage, these medications are not therapeutically interchangeable. It is not uncommon for people to work their way through several of the medications as they find the one that stabilizes their disease, or as different medications stop working for them. Thus, a closed formulary limits the ability of MS providers and specialists to make key medical decisions for the care of their patients.

Closed formulary proposals also represent a significant departure from traditional Medicaid policy. A closed formulary requires Oregon waive the requirement of compliance with Section 1927 of the Social Security Act. It is through Section 1927 of the Social Security Act that Congress established the drug rebate program in which all pharmaceutical manufacturers must provide rebates or discounts on the price of drugs in the Medicaid program. Through this rebate program, state Medicaid programs receive the best price for covered drugs. In exchange for participation in the rebate program, Congress requires state Medicaid programs to cover almost all drugs produced by participating manufacturers. This means that the drug rebate program has the effect of not only guaranteeing low prices to states, but also ensuring broad access to crucial medications for low-income people. Under current law, states can use preferred drug lists and require prior authorization before coverage is granted, but they are not allowed to utilize closed formularies.



**National  
Multiple Sclerosis  
Society**

Refusing to cover medications also interferes with the healthcare provider's ability to exercise discretion and identify a personalized approach for the person they are treating. This personalized approach is key in successful management of chronic conditions like MS. In addition, impeding healthcare providers' ability to prescribe the right treatment for a person with MS could potentially drive-up costs for the state, because when a person with MS receives the wrong treatment, they may end up needing more intensive and costly services down the road. In fact, there is evidence to this effect that closed formularies are unhelpful as cost-cutting measures. Reviews of more than 90 recent studies demonstrate that formulary restrictions are a lose-lose proposition: they are harmful to people's health, *and* they do not save money.<sup>iv</sup> The Society appreciates the states intention of cost control in Medicaid system overall, but the real, demonstrable harms to people living with MS and other chronic conditions that could result from a close formulary is clear, while the savings are not.

The Society also highlights that Oregon's proposal does not include an appeals process for patients to access non-formulary medications. However, even an appeals process or exemptions for certain classes drugs would not eliminate the barriers to care which patients would face with a closed formulary.

The Society asks the Oregon Health Program to amend the 1115 demonstration waiver to incorporate the changes recommended above to ensure Oregonians can continue to access the medications they and their health care providers agree is the most beneficial for the person living with MS. We ask that the waiver renewal application be amended to so Oregonians continue to benefit from a robust, open formulary which allows people living with MS and other chronic diseases to access the full range of medications available.

#### *Retroactive Coverage*

The Society is lastly concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind, and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. Eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as MS, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>v</sup> Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting



**National  
Multiple Sclerosis  
Society**

firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>vi</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. The Society opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive and presumptive coverage to include all Medicaid beneficiaries.

Thank you for the opportunity to provide comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Seth M. Greiner". The signature is fluid and somewhat abstract, with overlapping loops and a long horizontal stroke at the bottom.

Seth M. Greiner  
Senior Manager, Advocacy  
Washington State & Oregon  
National Multiple Sclerosis Society  
[Seth.Greiner@nmss.org](mailto:Seth.Greiner@nmss.org)

---

<sup>i</sup> Osorio, Aubrianna. Alker, Joan, “Gaps in Coverage: A Look at Child Health Insurance Trends”, Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/health-policy-institute/gaps-in-coverage-a-look-at-child-health-insurance-trends)

<sup>ii</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>iii</sup> MS Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. [http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT\\_Consensus\\_MS\\_Coalition\\_color](http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color). Accessed December 26, 2018.

<sup>iv</sup> Yujin Park et al., The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review 23 J. Managed Care & Specialty Pharm. 893, 898 (2017) and Laura E. Happe et al., A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical outcomes, Economic outcomes, and Health Care Resource Utilization 20 J. Managed Care & Specialty Pharm. 677, 681 (2014)

<sup>v</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>vi</sup> Virgil Dickson, “Ohio Medicaid waiver could cost hospitals \$2.5 billion”, Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield

RE: 1115 Medicaid Demonstration Renewal Comments

Dear Oregon Health Authority:

Thank you for the opportunity to comment on the 1115 Medicaid Demonstration Renewal. My name is Aaron Clark and I am a biologist and green infrastructure professional. We are excited to see Oregon's waiver application embrace the science, community voices, and experiences that show how community-led investment leads to health equity. In particular:

We support the requirement that CCOs invest at least 33% of the 3% of their global budgets with community investment collaboratives with flexible authority to invest in health equity

My work focuses on improving quality of life in communities through environmental improvement through empowerment, and education in the Pacific Northwest. I have been astounded by the abundant research and personal observations that demonstrate the value of nature as medicine. The health and mental health of our communities is profoundly impacted by nearby nature and environmental quality.

Retain the authority for expenditures on population health and climate supports

Oregon's Waiver Renewal is explicit about the health risks posed by climate change and events such as fire and extreme heat. The science and community wisdom support those linkages. The Waiver's flexibility allows Oregon's Medicaid program to direct other investments more directly toward health and health equity in the communities that need it most (e.g., FEMA post-disaster mitigation funds, US Forest Service recreation funds, and HUD housing supports).

Broaden authority to improve climate resilience, not just respond to disaster

The focused equity investment final policy concept paper refers to "Increasing green space and other improvements to the built environment, such as climate resilient housing, can ameliorate the impact of climate change. Further, the evidence linking time outdoors with better mental health and social cohesion is substantial." (p15). Yet the Waiver application itself frames climate supports as a 'response to climate disasters.' There is no explicit request for expenditure authority of federal or OHP funds that would actually build climate equity and resilience. For example, emergency transportation and ability to stay housed is critical during a disaster. But if a community knows that neighborhood greenways and cooling centers in libraries can prevent catastrophic fire or heat stroke, then investment in those actions should be explicitly authorized as part of the focused equity investments. This framing of "climate supports" runs through the application (from strategy 3 on p 23, to the climate supports on p68). Please add a bullet to the list of Climate Supports on p68 such as, "Increasing access to natural areas with shade."

This flexible "glue" will help braid services, preventative investments, and disaster response into a more cohesive, effective, and efficient approach to building health so that everyone has the opportunity to thrive—no exceptions.

Thank you again for the opportunity to comment!

Sincerely,

Aaron D. Clark Ph.D.  
Director of Strategic Partnerships  
Stewardship Partners



January 6, 2022

Oregon Health Authority  
Health Systems Division  
Health Policy & Analytics Medicaid Waiver Team  
500 Summer Street NE, E65  
Salem, OR 97301

Re: Response to 2022-2027 Medicaid 1115 Demonstration Application

To the Health Policy & Analytics Medicaid Waiver Team:

This letter is in response to OHA's 2022-2027 Medicaid 1115 Demonstration Application proposal.

First, a brief description of who we are: New Narrative is a non-profit agency established in 1977 which provides mental health treatment services, housing programs, and peer support and mentoring services to adults with persistent and severe mental illness. We serve over 1,500 program participants each year and provide housing for 261 beds. Over 52% of our funding comes from Medicaid.

In recent years we've been expanding our programming to address social determinants of health (SDOH) in areas including housing, life skills training, transition into adulthood, equity and inclusion, improved access to services, and peer support. We have been expanding our funding sources beyond Medicaid in order to provide these services that positively impact SDOH because they are not covered by Medicaid in the traditional "medical necessity" model. We believe that wellness is supported by services that impact a wide array of SDOH beyond clinical health care and behavioral health care treatments within the medical model. Our vision is that program participants seeking services can thrive and live the life they choose, not just survive.

We are pleased to see that improving SDOH is the focus of the OHA 2022-2027 Medicaid Demonstration Application and would like to address each section of the proposal:

**I. Maximizing coverage through the Oregon Health Plan**

We support initiatives that will move Oregon closer to a **universal health plan** available to all, particularly traditionally disenfranchised populations. This focus aligns with our values of equity and inclusion.

In addition to the proposed strategies regarding extended OHP coverage for children under 6, continuous OHP enrollment for people ages 6 and up, and an expedited OHP enrollment path for SNAP benefit applicants, we particularly support the following additional proposals based on our values, mission, and experiences with our program participants:

1. Developing commercial insurance market reforms to improve coverage continuity and access to health care through the Oregon Health Insurance Marketplace and making it *easier to navigate the transition* from Medicaid to commercial coverage.
2. Continuing the implementation of Cover All People to support coverage for all individuals regardless of immigration status. We believe it is a violation of our basic values of equity and

8915 SW Center St. Tigard, OR 97223 Tel 503.726.3690 Fax 503.726.3691  
NewNarrativePDX.org



inclusion and simply the value of human life to exclude individuals from coverage who do not have legal status in the U.S. but are here anyway to find a better life for themselves and their families. Our agency not only supports providing them with services, but also assisting them to find a path to legal residency so as to remove other barriers that impact their SDOH, such as jobs and housing.

3. Streamlining the OHP application process and making it easier and faster with initiatives such as allowing applicants to self-attest to their income and aligning the timing of eligibility renewal for OHP with other benefits such as SNAP and TNAF.

## II. Improving Health Outcomes by Streamlining Life and Coverage Transitions

We at New Narrative strongly believe that SDOH have a profound impact on the quality of the health and well-being of our program participants. This is why over the last decade we have expanded our services beyond traditional mental health services to provide a wide variety of housing programs, life skills training, education and job support, and peer support and mentoring to provide socialization and a sense of community. We have found that life transitions such as incarceration, aging out of foster care, loss of employment, and discharge from prolonged hospital stays, to name a few, often disrupt the fragile support systems of our disenfranchised and vulnerable program participants. We strongly support the following proposals:

1. Provide continuous Medicaid coverage for people in custody, including the State Hospital and juvenile corrections. Currently, funding for our services is often interrupted when our program participants are transitioning from jail or from OSH which handicaps our ability to provide optimal care and sometimes a delay in admission into our programs.
2. Retain child eligibility levels for youth up to age 26, even if they don't have special needs. We have found that many young adults from age 18-25 who have come from at-risk and vulnerable families are simply not prepared for independence and require additional services and support to transition to adulthood.
3. Allocating funding to SDOH transition services to support members during life transitions. For example, we are currently piloting a Transition Team to support program participants transitioning in and out of residential treatment to help them find work and housing. This is funded by a one-time grant, so we will need additional funding beyond the first year. We advocate allocation of Medicaid funding to support such teams.
4. The expansion and funding of infrastructure at the community level for programming and capacity building needed to support services that improve SDOH ***outside of the medical model***. One example is our NorthStar Clubhouse which is part of the network of Clubhouse International, a model that supports mental health recovery, community engagement, and re-entry into employment. This is a highly successful program in terms of impact and outcomes for program participants and for the community but severely underfunded in Oregon and not billable under Medicaid. ***We very strongly believe that funding only services defined as "medically necessary" severely limits the potential for positive outcomes and thriving communities.***

## III. Value-Based Global Budget

We support shifting resources to fund a value-based system that supports program participants as their health improves, not just when they are at the highest acuity of illness. We strongly advocate that a

higher percentage of funding being funneled to the community providers who actually perform the front-line services, and less funding being allowed for heavily layered bureaucracy in the CCO and county mental health organizations and system. We urge consideration of the following:

1. Ensuring that CCOs provide payment rates to community providers that are based on realistic, current economic realities such as the supply and demand of the labor force – the largest operating cost of any community provider – along with annual COLA increases in provider service contracts. Labor rates are skyrocketing for community providers who are hamstrung by static contracts that don't adjust for labor rate inflation and consumer price indices and don't allow for a reasonable operating overhead percentage. It is also a mistake to base rates on past spending given the current economic realities and the shift to covering services in support of SDOH.
2. A closed formulary could likely cause some problems for psychiatry, especially with the SPMI population. It is common that participants receive little to no benefit from the first- or second-line medications, and it requires trial and error of medications with less evidence. Sometimes when the right medication is found, it could be lifesaving. If a closed formulary is implemented, special consideration must be given to psychiatry, especially for the SPMI population, to ensure that we have access to a wide selection of medications and a simple, quick process to get authorization outside of the formulary. Burdening providers with the paperwork and bureaucracy of prior authorizations takes precious time away from expensive psychiatrists and psychiatric nurse practitioners, but more importantly, delays patient care and access. This could lead to negatives outcomes and increased system costs (e.g. hospitalizations).

#### **IV. Incentivizing Equitable Care**

We support strategies that enable equitable care including improving cultural responsiveness, mitigate social stigmas and the harm of racism, and create equitable access. These strategies are in complete alignment with our mission and values. However, the issue with incentive measures is that they are often not what actually enables the desired outcome. Some comments and questions on the proposed strategies:

1. **Restructure the Quality Incentive Program into two complementary components to reserve space for upstream work focused on equity:**
  - a. One proposal in this section is to measure and incentivize “Meaningful Language Access to Culturally Responsive Health Care Services.” Assuming that the CCO scorecards will become the service provider scorecards, this puts the burden on the community providers to find or possibly develop said services. Where is the funding for this coming from? Even if funding is available, culturally responsive services are somewhat limited in the state. Where is the effort and investment in the development of culturally responsive services? How are we attracting culturally specific talent to this state? It appears it's all on the backs of community providers who have inadequate resources to make it happen.
  - b. Most of the “Upstream Health Equity Metrics” apply to children. What about upstream metrics for the adult population being served? Why just children?
2. **Redistribute decision-making power to communities:** We encourage OHA to push for membership on the Health Equity Quality Metrics Committee to include a significant number of representatives from community non-profit agencies that are boots-on-the-ground service



providers who have a front-line view of the served populations, challenges, and socioeconomic realities.

- 3. Rethink the incentive structure to better advance equity:** It appears that OHA is trying to incent outcomes by paying the CCOs incentives across a variety of priorities; our concerns center around whether these incentives are actually passed on to frontline community providers, and if this new policy stance guarantees that there will be material pass through of funds to organizations where they are needed most. We also question the logic that the cost savings realized by the CCO model and the manner in which they were generated in the past 5 years are a net positive to our system; Oregon continues to experience some of the lowest ratings in the country in terms of access to care and quality of care, with the current staffing crisis in the sector demonstrating the latest iteration of the flow on effects of cost saving incentives. We advocate that whatever model is utilized takes into consideration that the CCO model must regulate cost responsibly and ensures providers are funded in a meaningful way to actually deliver services and produce materials results within our most vulnerable populations.

#### **V. Focused Equity Investments**

We consider this section of the Medicaid Waiver Application to be the most exciting and promising in that it indicates strong support for funding services that improve SDOH. Our comments on the subsections of this area are as follows:

- 1. Invest federal funds toward infrastructure to support health equity interventions:** We believe that it is imperative that community organizations doing the actual front-line work receive funding to build capacity to serve our program participants with equitable and culturally appropriate programs that support improved SDOH and improved access to services. This could include such things as premium funding for bi-lingual staff including clinical and peer support, training for more culturally appropriate services, housing support, employment programs, and programs that support healthy community engagement, to name a few. Our sole concern about this part of the application is that the community investment collaboratives (CICs) may become another layer of bureaucracy that prevents adequate funding from flowing to front-line services providers. Creating statewide systems to support this proposal may help with communications, allocation, and establishing standards, but it may also add administrative burden that wastes funds and capacity and results in inadequate funding to front-line providers.
- 2. Invest Federal Funds in community-led health equity interventions and statewide initiatives:** We support the concept of local management of CCO community funds. Our main concern here is the mechanism by which the CICs receive, manage, and distribute CCO community funds. We need a system that minimizes bureaucracy and administrative burden and provides more funding directly to front-line community providers.
- 3. Grant community-led collaboratives resources to invest in health equity:** We strongly support additional federal investment to support health equity investment (HEI) grants. We are particularly in favor of a non-competitive process with requests for proposal that address



identified community needs. The examples of proposed HEIs that we are prepared to implement and/or to expand are increasing housing inventory, providing more housing supports and services, improving homeless/houseless outreach, increasing access to social and mental health supports, expanding culturally and linguistically responsive work force, and dismantling structural racism as well as destigmatizing mental health conditions. We have spent the last decade, and particularly the last five years, developing programs and defining our mission and values in all of these areas. Our concern in this area is that after the initial grant period the grants are renewable or that there is other funding made available for on-going support of these programs.

***In summary, we at New Narrative support and are encouraged by the emphasis on funding services that improve SDOH and health equity outlined in this waiver application. The focus on SDOH is in alignment with our mission and vision and the needs of our communities here in Oregon and in our nation. We ask that minimization of administrative burden and bureaucratic layers become a priority in the implementation of these initiatives. We also ask that prioritization be given to making sure that as much funding as possible goes to the actual front-line community providers who are directly serving these populations and making an impact in communities throughout the state.***

Sincerely,

A handwritten signature in black ink that reads 'Julie Ibrahim'.

Julie Ibrahim, LPC  
Interim CEO



January 6, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

**Re: Oregon Health Plan 1115 Demonstration Waiver Application for Renewal**

Dear Deputy Director Hittle:

The National Organization for Rare Disorders (NORD) appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Plan. NORD is a unique federation of voluntary health organizations dedicated to helping the 25-30 million Americans living with a rare disease. We believe that all patients should have access to quality, accessible, and affordable health coverage that is best suited to their medical needs.

The Medicaid program serves as lifeline for many people living with one of the 7,000 known rare diseases. Patients with rare disorders often find their financial lives upended by the debilitating nature of their diseases, and on their behalf, NORD is committed to ensuring that the Oregon Health Plan provides quality and affordable health care coverage to all low-income individuals and families. The state is well aware of the financial and clinical benefits of access to health insurance. Oregon's seminal 2008 health insurance experiment remains the only randomized study that has ever been used to evaluate the Medicaid program, and produced significant, robust data demonstrating the importance of public health insurance coverage.<sup>1</sup> We applaud Oregon's focus on health equity in this waiver application and are supportive of the state's request to provide multi-year continuous enrollment for children under six and two-year continuous eligibility for all beneficiaries ages six and over. We believe that these policies will improve continuity of care and reduce gaps in coverage for individuals with serious, chronic, and rare health conditions in the state of Oregon.

Unfortunately, this waiver also contains multiple proposals that would impede access to care for people with rare disorders. NORD opposes Oregon's plan to limit retroactive coverage for nearly all Medicaid beneficiaries and to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one. In addition, we are strongly opposed to the state's proposal to create a closed formulary with as few as one drug per class and to exclude certain prescription drugs entirely, such as those approved through the Food and Drug Administration's (FDA) accelerated approval pathway. These provisions will make it harder for our patients to access the medications they need to stay healthy.

NORD offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Plan:

---

<sup>1</sup> Finkelstein A, Taubman S, Wright B, Bernstein M, Gruber J, Newhouse JP, Allen H, Baicker K; Oregon Health Study Group. The Oregon Health Insurance Experiment: Evidence from the First Year. *Q J Econ.* 2012 Aug;127(3):1057-1106. doi: 10.1093/qje/qjs020. Epub 2012 May 3. PMID: 23293397; PMCID: PMC3535298.



### ***Expansion of Continuous Eligibility***

NORD supports Oregon’s request for continuous enrollment for children under the age of six and two-year continuous eligibility for all beneficiaries aged six and over. Continuous eligibility reduces gaps in insurance coverage. Research has shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>2</sup> For rare disease patients who require daily, weekly, or monthly medications and/or health care provider engagement, reducing interruptions in coverage can have a significant and positive effect on health outcomes. Multi-year continuous enrollment for children has the potential to be especially impactful for the rare disease community, as rare diseases disproportionately affect children, adolescents, and young adults.<sup>3</sup> Finally, continuous eligibility will improve equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>4</sup>

This continuous eligibility proposal is an example of how the state *should* be using the power and authority of the Medicaid program to positively impact access to health care services and, ultimately, health outcomes for low-income Oregonians. Unfortunately, other provisions of this waiver renewal application would undermine the benefits gained by expanded continuous eligibility by restricting access to necessary services and treatments. NORD encourages the state to proceed with expanding continuous enrollment for Oregon Health Plan beneficiaries and to revise other portions of the waiver renewal application to align with the same spirit and intent displayed in this section.

### ***Adoption of a Closed Formulary***

NORD is deeply concerned by the state’s proposal to transition to a closed formulary for adult beneficiaries, with guaranteed coverage for only one drug per therapeutic class. Prescription drugs have different indications, different mechanisms of action and different side effects, depending on the person’s diagnosis and comorbidities. Coverage of one drug per class is not sufficient to provide comprehensive options to patients with common conditions, let alone the vast variety of rare disorders.

Diseases present differently in different patients, and rare diseases often are particularly difficult to diagnose and treat. From the onset of symptoms, it takes on average six years for a patient with a rare disorder to receive an accurate diagnosis, with many patients experiencing misdiagnoses and receiving incorrect treatment at some point.<sup>5</sup> A rare disease patient, who has already been through a lengthy diagnostic odyssey and is finally on a stable treatment regimen should not be forced to change medications to something less effective so that the state can reduce prescription drug costs. Furthermore, this detrimental proposal is made worse by the fact it does not include an appeals process for patients to access non-formulary medications, even though such a process would not alleviate the burden for patients facing a closed formulary.

---

<sup>2</sup>Sugar S, Peters C, De Lew N, Sommers, D. Medicaid Churning and Continuity of Care. ASPE. April 12, 2021. <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>3</sup> Tisdale, A., Cutillo, C.M., Nathan, R. et al. The IDEaS initiative: pilot study to assess the impact of rare diseases on patients and healthcare systems. *Orphanet J Rare Dis* 16, 429 (2021). <https://doi.org/10.1186/s13023-021-02061-3>

<sup>4</sup> Osorio, Aubrianna. Alker, Joan, “Gaps in Coverage: A Look at Child Health Insurance Trends”, Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](https://www.georgetown.edu/ccf/gaps-in-coverage-a-look-at-child-health-insurance-trends)

<sup>5</sup> Blöß S, Klemann C, Rother AK, Mehmecke S, Schumacher U, Mücke U, et al. Diagnostic needs for rare diseases and shared prediagnostic phenomena: Results of a German-wide expert Delphi survey. *PLoS ONE*. 2017; 12(2):e0172532. Available from: <http://dx.plos.org/10.1371/journal.pone.0172532>.



Without proper prescription drug coverage, a patient who may have been asymptomatic on their current medication could relapse and begin to experience symptoms again. For example, patients diagnosed with Neurotrophic Keratitis, a rare disorder that affects the retina, depend on prescription medications to prevent the further degeneration of the cornea that could lead to blindness. If a Neurotrophic Keratitis patient's prescription coverage were to change and the medication was no longer covered, the patient could go blind, requiring additional assistance to survive. A closed formulary limits the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to the state.

NORD requests that the Oregon Health Authority amend this portion of their proposal and instead maintain a robust, open formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

### ***Limiting Access to FDA-Approved Treatments***

NORD is also opposed to Oregon's proposal to limit Medicaid recipients' (both children and adults) access to prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through FDA's accelerated approval pathway. The state claims that drugs which come onto market through the accelerated approval pathway "have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints." Further, the state implies that the FDA is allowing drugs to come onto the market that have not been "fully clinically proven." This proposal is clearly premised on an inaccurate understanding of the FDA's approval process for therapies on the market via the accelerated approval pathway, and if implemented, would cause significant harm to rare disease patients by restricting access to many novel and lifesaving therapies.<sup>6</sup>

NORD recently issued a report that details the history and development of the accelerated approval pathway and its historical importance for rare disease patients and the treatments they need.<sup>7</sup> As Oregon notes in its application, the accelerated approval pathway was codified by Congress in 2012. What the state fails to describe in its application, however, is that FDA had actually enshrined the pathway in law when it implemented regulations in 1992. At that time, the HIV/AIDS epidemic had drastically altered the landscape for drug development.<sup>8</sup> The epidemic—with its staggeringly high death toll and commensurate urgency around developing treatments—catalyzed a reconsideration, by patients and regulators alike, of more traditional clinical trial requirements. New thinking was necessary for what was essential to the demonstration of efficacy, and in response, scientists sought ways to streamline and expedite clinical trials for HIV/ AIDS drugs to focus on the utility of surrogate endpoints which were known to demonstrably correlate with improved outcomes.<sup>9</sup> For example, improved T-cell count was determined to reliably predict fewer infections in AIDS patients and was accepted as a surrogate endpoint that could be

---

<sup>6</sup> U.S. Food & Drug Admin., CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint (June 30, 2021). <https://www.fda.gov/media/151146/download>

<sup>7</sup> Temkin E, Trinh, J. FDA's Accelerated Approval Pathway: A Rare Disease Perspective. October 2021. [https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report\\_Accelerated-Approval\\_FNL.pdf](https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf)

<sup>8</sup> The Centers for Disease Control and Prevention ("CDC") published its first report on HIV/AIDS in 1981. See James W. Curran & Harold W. Jaffe, AIDS: The Early Years and CDC's Response, 60 *Morbidity & Mortality Weekly Rep.* 64 (Oct. 7, 2011), available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a11.htm>.

<sup>9</sup> See U.S. Food & Drug Admin., Guidance for Industry: Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment 3 (Nov. 2015), [www.fda.gov/files/drugs/published/Human-Immunodeficiency-Virus-1-Infection--Developing-Antiretroviral-Drugs-for-Treatment.pdf](http://www.fda.gov/files/drugs/published/Human-Immunodeficiency-Virus-1-Infection--Developing-Antiretroviral-Drugs-for-Treatment.pdf)



used to demonstrate the efficacy of HIV/AIDS drugs.<sup>10</sup> This scientific advancement seemingly resolved the debate about modifying requirements regarding clinical efficacy: if approval of HIV/AIDS treatments (among others) could be predicated successfully on the use of surrogate endpoints, FDA’s “substantial evidence of efficacy” standard did not need to be compromised to get treatments to patients sooner. As consensus grew about the utility of surrogate endpoints in clinical trial design,<sup>11</sup> FDA embraced drug approval reform and promulgated regulations formalizing the accelerated approval pathway.<sup>12</sup> Under accelerated approval, FDA could expedite the approval of and patient access to drugs that were intended to treat serious and life-threatening diseases and conditions for which there were unmet medical needs.

As noted in NORD’s report, it is critical to understand that accelerated approval—both as it is set forth in law and in regulations—does not alter FDA’s gold standard of substantial evidence of safety and effectiveness. To the contrary, accelerated approval is granted based on FDA’s finding that a drug is safe and effective for its intended use—the same approval standard used for traditional approval. Traditional approval relies on a direct demonstration of clinical benefit, while accelerated approval relies on surrogate endpoints and intermediate clinical endpoints that can be measured earlier than irreversible morbidity or mortality.

Oregon’s proposal states that such drugs are studied in clinical trials using “*only surrogate endpoints.*” This language demonstrates a fundamental misunderstanding of the nature of surrogate endpoints and the rigor FDA applies in accepting such endpoints in the context of an accelerated approval drug. Such endpoints are chosen because FDA, in its scientific discretion, has decided that they are expected to predict clinical benefit. FDA can make the risk benefit calculation that an accelerated approval drug’s benefits outweigh its risks—just as the agency does for traditional approval—and then confirm the clinical benefit in post marketing confirmatory studies conducted after (and as a condition of) the accelerated approval. Both the FDA and Congress have considered – and rejected – the notion that accelerated approval is a different or lesser standard than traditional approval.<sup>13</sup> In fact, while codifying the accelerated approval pathway in 2012, Congress acknowledged the vital role the accelerated approval pathway serves for patients with rare diseases and expressed their hope that it would bring life-saving drugs to the market expeditiously.<sup>14</sup> Congress also affirmed FDA’s conclusion that accelerated approval did not create a different standard for drug approval, stating in a “Sense of Congress” Congressional understanding that accelerated approval “may result in fewer, smaller, or shorter clinical trials... without compromising or altering the high standards of the FDA for the approval of drugs.”<sup>15</sup>

Today, accelerated approval is crucial to facilitate the development of drugs indicated to treat rare diseases. As stated above, 25-30 million Americans (or 1 in 10 people) suffer from rare disorders, which are

---

<sup>10</sup> *Id*

<sup>11</sup> Approval of the first statin drug, for example, was predicated on the validated surrogate endpoint of lower cholesterol, which was accepted as a proxy for reduced risk of heart disease. Editorial, Biomarkers: The Next Generation, 9 Nature Reviews: Drug Discovery 415 (June 2010), <https://www.nature.com/articles/nrd3196.pdf>

<sup>12</sup> FDA also created the fast track, breakthrough therapy, and priority review designations to advance the development and review of new drugs and address unmet needs in the treatment of a serious medical condition. See U.S. Food & Drug Admin., Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics 1 (May 2014) (“Expedited Programs Guidance”), <https://www.fda.gov/media/86377/download>.

<sup>13</sup> 57 Fed. Reg. at 58944

<sup>14</sup> See H.R. Rep. 112-495, \*35–36 (2012).

<sup>15</sup> See 158 Cong. Rec. H3825-01, H3848 (2012).



particularly likely to be serious and life-threatening diseases with unmet medical needs.<sup>16</sup> Of the 7,000 rare diseases that have been identified, more than 90% have no FDA-approved treatment.<sup>17</sup> Many facets of rare diseases make them particularly difficult to study in clinical trials targeting direct clinical benefit. For example, the number of patients with any one condition can be small and heterogeneous, with highly diverse clinical manifestations and a long timeframe for disease progression. Furthermore, there is often a lack of prior clinical studies and a limited number of clinical investigators and treatment centers knowledgeable about a given rare disorder.<sup>18</sup> This makes accelerated approval a particularly important tool for the development of treatments for rare diseases.<sup>19</sup> Limiting coverage of drugs that come onto market through this pathway means that patients with a rare disease who *do* have an FDA-approved therapy will be unable to access vital and lifesaving treatment. NORD believes that this provision will disproportionately and unfairly limit access to care for patients with rare disorders.

Oregon's proposal ultimately puts the state in the position of second-guessing FDA's expert scientific judgment and role in the drug review process. The Oregon Health Authority lacks the capacity and expertise to overrule FDA decisions regarding the safety and efficacy of new medicines. NORD acknowledges that the high cost of many drugs, including accelerated approval products, present significant affordability challenges to the state. Indeed, we have long advocated at the federal level for state Medicaid programs to be given the resources that they need to maintain broad and accessible coverage for patients. However, it is inappropriate to attempt to resolve drug pricing challenges through the differential treatment of accelerated approval drugs or other drugs that have been FDA approved through one of the FDA's expedited programs. The core premise of FDA's expedited programs, as established by Congress, is that these drugs are exceptionally important to patients and should be provided to them in a manner that is as expedient as possible. Restrictions in patients access to these products runs counter to the clear intent of the laws that establish these programs. We urge the state to remove this request from the draft waiver renewal application.

### ***Retroactive Eligibility***

NORD opposes the state's proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. In many cases, individuals are not aware that they are eligible for Medicaid until they have an unexpected medical event or receive a new diagnosis. Eligible applicants may also delay necessary health care until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

---

<sup>16</sup> Jennifer Huron, *New Study Investigates the Number of Available Orphan Products, Generics and Biosimilars*, Nat'l Org. for Rare Disorders (Mar. 25, 2021), <https://rarediseases.org/new-study-investigates-the-number-of-available-orphan-products-generics-and-biosimilars/>.

<sup>17</sup> *Id.*

<sup>18</sup> Food and Drug Administration. Report: Complex Issues in Developing Drugs and Biological Products for Rare Diseases and Accelerating the Development of Therapies for Pediatric Rare Diseases Including Strategic Plan: Accelerating the Development of Therapies for Pediatric Rare Diseases. July 2014. <https://www.fda.gov/media/89051/download>

<sup>19</sup> U.S. Food & Drug Admin., CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint (Jan. 14, 2021), <https://www.fda.gov/media/88907/download>



Retroactive eligibility allows patients who are newly diagnosed with a serious illness, such as a rare disease, to access treatment immediately without being burdened by medical debt prior to their official eligibility determination. In Indiana, for example, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>20</sup> Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy. The financial concerns are particularly acute for patients with rare conditions, as data supplied by the National Institute of Health has shown that people with rare diseases typically incur much higher health care costs over the course of year or during a hospitalization than people without a rare disease.<sup>21</sup>

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>22</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs.

NORD opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

### ***EPSDT Benefit***

NORD is opposed to restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). The EPSDT statute is of enormous importance to the rare disease community. EPSDT provides a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children, and adolescents, and is the mechanism through which many children are diagnosed with a rare disease. By identifying rare disorders early, the EPSDT benefit allows almost immediate intervention for conditions that, if left undiagnosed and untreated during the early stages of their progression, could cause severe physical and developmental impairment or death.

The purpose of the EPSDT benefit is to ensure that children receive appropriate health care and limiting that care to a prioritized list of services leaves families vulnerable should their child need services beyond those offered on the list. As stated before, there are more than 7,000 different rare disorders, many of which are not well studied or understood. There is no way to ensure that the states list of prioritized services will be sufficient for rare disease patients.

The state has demonstrated through other efforts a desire to increase equitable access to health care. However, the continued restriction of the EPSDT benefit is a step in the opposite direction. For example,

---

<sup>20</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>21</sup> See Tisdale, *supra* note 3

<sup>22</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)



children of color are enrolled in Medicaid at disproportionately higher rates<sup>23</sup> and as mentioned before, are more likely to be affected by gaps in coverage.<sup>24</sup> These children are likely to be disproportionately affected by limitations to the EPSDT benefit. NORD urges the state to remove restrictions to EPSDT to allow children full and equitable access to health care, in keeping with the purpose of the benefit.

### ***Conclusion***

Thank you for the opportunity to provide comments. For questions about NORD or our comments please contact Corinne Alberts at [calberts@rarediseases.org](mailto:calberts@rarediseases.org).

Sincerely,

Alyss Patel  
Policy Manager, Western Region  
National Organization for Rare Disorders

---

<sup>23</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. [EPSDT-At-Risk-Final.pdf \(georgetown.edu\)](#)

<sup>24</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)

January 7, 2022

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

***BY ELECTRONIC DELIVERY***

**Re: Comments on the Oregon Health Plan (OHP) 1115(a) Draft Demonstration Waiver Renewal Application**

Dear Director Allen and Team:

Novartis Services, Inc. is submitting this letter on behalf of Novartis Pharmaceuticals Corporation, Advanced Accelerator Applications USA, Inc. (AAA), and Sandoz Inc., collectively referred herein as “Novartis.”

Novartis appreciates the opportunity to comment on the Oregon Health Authority’s (OHA) Oregon Health Plan (OHP) 1115(a) Demonstration Waiver Renewal Application (proposed waiver),<sup>1</sup> which is intended for submission to the Centers for Medicare & Medicaid Services (CMS). Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our broad portfolio of medicines includes treatments in the areas of: ophthalmics; neuroscience; immunology, hepatology and dermatology; respiratory and allergy; cardiovascular, renal and metabolism; oncology, including targeted therapies, immuno-oncology, chimeric antigen receptor T cells (CAR-T) and radioligand therapy; and gene therapies. We are also a global leader in generic and biosimilar medicines, committed to playing a leading role in driving access to medicine worldwide.

At Novartis, we are united by a single purpose to reimagine medicine to improve and extend people’s lives. Through innovative science and technology, we address some of society’s most challenging healthcare issues. Every day we work to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Our vision is to be a trusted leader in changing the practice of medicine.

Novartis applauds Oregon for addressing the significant unmet need of patients through health equity initiatives. Novartis believes an important way we can achieve greater health equity is to address persistent disparities in the way healthcare is approached, accessed, and delivered. However, the proposed waiver presents several fundamental legal and policy-based concerns that may harm Medicaid beneficiaries. Specifically, the proposed waiver:

- Undermines the bargain that Congress struck in enacting the Medicaid Drug Rebate Program (MDRP) and contradicts the basic terms of the Medicaid rebate agreement (MDRA), which have contributed to the MDRP’s success over the past

---

<sup>1</sup> OHA, Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver 30–32 (as revised Dec. 7, 2021).

- three decades;
- Excludes safeguards that Congress has affirmed as essential in the provision of services within state Medicaid programs;
- Seeks to limit drug coverage in a manner inconsistent with federal law and that would fundamentally harm Medicaid beneficiaries;
- Fails to satisfy the statutory requirements for a Section 1115 demonstration program; and
- Restricts access to life-saving medications which leads to worse outcomes and runs counter to the OHA's mission of health equity.

We firmly believe that OHA should revise its approach, and not proceed with the proposed waiver as written on several grounds. The proposed waiver should instead pursue implementation of alternative payment methodologies and stay focused on health equity for all OHP beneficiaries.

### **I. The Proposed Waiver Violates the Bargain Underlying the Medicaid Drug Rebate Program Enshrined in the Medicaid Drug Rebate Agreement**

First, the proposed waiver violates the bargain struck by Congress in enacting the MDRP, Social Security Act (SSA) § 1927. SSA § 1927 codifies a carefully constructed compromise between manufacturers and states, which is memorialized in the MDRA that manufacturers enter into with the Secretary of Health and Human Services (HHS). Under the MDRA, manufacturers agree that, in exchange for federal approval of the payment by state Medicaid programs for all of their Food and Drug Administration (FDA) approved covered outpatient drugs, the manufacturers will make generous rebate payments to the states on such drugs “for as long as an agreement with the Secretary is in force and state utilization data reports that payment was made for that drug.”<sup>2</sup>

As a result of this agreement between states and manufacturers, over the past several decades SSA § 1927 has helped provide Medicaid beneficiaries with access to critical, innovative, life-saving therapies and has helped ensure that states receive substantial rebates on the cost of those therapies. The proposed waiver would introduce an unprecedented and inappropriate departure from this long-standing arrangement. In simple terms, OHA is proposing to waive only its obligations under SSA § 1927 — to provide coverage of all covered outpatient drugs of a manufacturer that has entered into a MDRA. The state, however, appears to anticipate that manufacturers continue paying rebates on the state Medicaid program's utilization of its drugs.

This proposal is fundamentally inconsistent with the Congressional intent underlying SSA § 1927 and with the rebate agreement memorializing the terms of the § 1927 bargain.

### **II. The Proposed Waiver Fails to Include Congressionally Designed and Mandated Safeguards**

Second, the proposed waiver fails to include essential safeguards that Congress incorporated into SSA § 1927 and has since affirmed. In the plain text of SSA § 1927, Congress narrowly (and exhaustively) outlines the ways in which states may limit access to covered outpatient drugs. For example, states may limit coverage of covered outpatient drugs by creating a formulary. However, Congress requires that the formulary have various safeguards for Medicaid beneficiaries, including: (i) a drug may only be excluded from a formulary on the basis of a clinical determination based on the drug's label, (ii) the state must provide a written explanation of its decision to exclude a drug in such a manner, and (iii) the state must still make such a drug available through a federally compliant prior

---

<sup>2</sup> OHA, Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver 30–32 (as revised Dec. 7, 2021). 12785 (Mar. 23, 2018).

authorization process.<sup>3</sup>

The proposed waiver would disregard the safeguards that Congress instituted under § 1927. OHA has proposed to introduce a “closed formulary” that is not, a formulary as that term is recognized under SSA § 1927(d)(4). The “closed formulary” would restrict coverage in a manner not permissible under federal law. For example, OHA’s proposal neither limits clinical determinations regarding a drug’s therapeutic advantage based on a review of the drug’s label, nor make available to the public a written explanation of the state’s decision to exclude a particular drug from the formulary. Instead, OHA’s proposal is to include as few as one drug per therapeutic class, irrespective of whether additional drugs qualify as “covered outpatient drugs” under § 1927 or would be medically appropriate - and superior, from a patient health standpoint - to the single available drug.

Novartis is also concerned with OHA’s proposal to exclude from coverage various therapies that have been approved by the FDA through the accelerated approval pathway. OHA would thereby substitute its judgment regarding whether products meet certain clinical efficacy criteria over the judgments of the key federal regulatory agency tasked with making such determinations – the FDA. Indeed, a decision by the FDA to approve a drug based on surrogate endpoints, or contingent on confirmatory trials, does not reflect a judgment by the agency that the drug has no “demonstrated actual clinical benefit”; it is improper for OHA to make such a judgment when the federal agency with the legal and regulatory authority and clinical expertise to make such determinations has not done so. The FDA has allowed for approval of a particular therapy based on a reported surrogate endpoint, rather than a clinical outcome, where it would be too challenging or inappropriate to measure a defined clinical outcome for that therapy. As an example, the surrogate endpoint of bone mineral density might be utilized, rather than the clinical outcome of hip fractures, because requiring the clinical outcome would require an unreasonably large and lengthy clinical trial given the relatively low incidence of hip fractures. In instances where the FDA has approved a drug based on trials utilizing surrogate endpoints, OHA should not exclude coverage of these therapies merely because only surrogate endpoints have been reported.

Also concerning is the attempt by OHA to subvert the FDA’s policy priority of accelerating patient access to innovative therapies. In this age of pharmaceutical innovation, FDA has created an accelerated approval pathway in order to expedite the process for the agency’s approval of safe and effective drugs for patients with serious and/or unmet medical needs. We submit that OHA’s proposed waiver will likely harm patients with serious and unmet medical needs by undermining this important policy objective.

Notably, CMS has affirmed that such therapies qualify as covered outpatient drugs that are subject to coverage under the MDRP. Indeed, on June 27, 2018, CMS sent a notice to the states regarding Medicaid coverage for FDA approved drugs under the accelerated approval pathway stating:

... this release clarifies that drugs that are granted “accelerated approval” are drugs approved by FDA under section 505(c) of the [Federal Food, Drug, and Cosmetic Act], and are able to satisfy the definition of covered outpatient drug, and if used for a medically-accepted indication, then the drug must be covered by state Medicaid programs if the manufacturer has an applicable signed Medicaid national drug rebate agreement for participation in the MDRP. States can use utilization management mechanisms such as prior authorization to assure appropriate use of these medications.<sup>4</sup>

---

<sup>3</sup> See SSA § 1927(d)(4).

<sup>4</sup> See CMS, Medicaid Drug Rebate Program Notice, Release No. 185, State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway (June 27, 2018).

Thus, consistent with § 1927, states must cover drugs approved under this pathway. While states may utilize prior authorization to assure appropriate use of such therapies, the wholesale denial of access to such potentially life-saving therapies would be detrimental to the health and well-being of Medicaid beneficiaries and a violation of the law.

### **III. The Proposed Waiver Would Potentially Harm Medicaid Beneficiaries**

The proposed waiver would deprive Medicaid beneficiaries in Oregon of medically appropriate therapies and therapeutic advances, including personalized medicines based on patients' unique medical needs and biological make-up, that would be available to non-Medicaid beneficiaries in Oregon and Medicaid beneficiaries in other states. Indeed, the proposed "closed formulary" threatens to prevent the state's most vulnerable residents from accessing such innovative therapies without regard to the appropriateness of the therapy and the possibility of better health outcomes and fewer side effects. Medicaid beneficiaries, unlike persons with greater financial means, are not afforded an opportunity to select an alternative coverage policy when a drug is not available through the Medicaid program. As such, the proposed waiver threatens to create a profoundly inequitable brand of second-class healthcare in Oregon.

We note that, should OHA wish to limit coverage of covered outpatient drugs, it can do so by establishing a "formulary" that comports with § 1927(d)(4) requirements. Under the proposed waiver, it does not appear that OHA will attempt to design appropriate coverage policies consistent with this federally permitted option. OHA should avail itself of the opportunities that already exist under federal law rather than deprive Medicaid beneficiaries of access to innovative therapies in contravention of § 1927.

We urge OHA to consider beneficiary access as a guiding principle for designing any waiver or model, especially with regard to the Medicaid population. Limitations on access to drugs could adversely affect beneficiary health and lead to increased overall costs for the Medicaid program, and thus, for taxpayers. Every waiver or other model that is approved for Medicaid should be designed in a way that protects beneficiary access to prescription drugs, incentivizes better health outcomes, and aligns payment with value. Additionally, we encourage the state to follow a collaborative approach in working with relevant stakeholders and focus on initiatives that drive value-based care while not restricting access to medicines.

### **IV. The Proposed Waiver Fails to Satisfy the Federal Criteria for a Section 1115 Waiver**

The proposed demonstration program fails to satisfy foundational requirements of demonstration projects under SSA § 1115. Under federal law, a demonstration program must be "likely to assist in promoting the objectives of [the Medicaid program]" – i.e., it must assist in providing support to low-income individuals who, in the absence of the Medicaid program, may lack coverage for health services. The State's proposed "closed formulary" manifestly fails to satisfy this requirement. It would not assist Medicaid beneficiaries in accessing health services. Rather, it would unquestionably lead to narrower drug coverage and, for many patients, could deprive them of appropriate therapies to which patients would have had access in the absence of the proposed waiver. As CMS has previously acknowledged, drug coverage restrictions "could result in recipients being treated with alternate therapies that may not be in their best interest. This could result in increased program costs if other medical services, such as inpatient hospital services, are necessary because a drug therapy is made less accessible under the State Medicaid program."<sup>5</sup>

The proposed waiver also fails to set forth a true "experimental, pilot, or demonstration

---

<sup>5</sup> 60 Fed. Reg. 48442, 48454 (Sept. 19, 1995).

project” – another federal requirement for Section 1115 waivers. At least one court has affirmed that, in reviewing a proposed demonstration project, HHS “must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money but has no research or experimental goal, would not satisfy this requirement.”<sup>6</sup> The proposed demonstration would institute such a “simple benefits cut,” without serving a research or experimental goal. Accordingly, it lacks an essential requirement of SSA § 1115.

## **V. CMS Rejected the Massachusetts 1115 Waiver Demonstration that Sought to Limit Medication Access**

On June 27, 2018, CMS sent a letter to Massachusetts, denying its request to create a closed formulary for the state Medicaid (MassHealth) population. CMS said that it would consider a similar demonstration project that included a closed formulary if Massachusetts (or another state) instead directly negotiated with pharmaceutical manufacturers and agreed to forgo rebates under the MDRP. According to CMS, “(t)he state could then be provided flexibility to exclude specific drugs from coverage based on cost effectiveness or other approved criteria, or to employ a closed formulary structure similar to Medicare Part D or commercial plan formularies. Under such an approach, the state would have to ensure that federal expenditures under the demonstration would not exceed federal expenditures incurred without the demonstration.”<sup>7</sup> As previously discussed, the proposed waiver seeks to exclude certain covered outpatient drugs from coverage while continuing to collect manufacturers rebates under § 1927. Accordingly, the OHA proposed waiver is impermissible under the standard set forth by CMS in rejecting the Massachusetts waiver.<sup>8</sup>

## **VI. The Proposed Waiver Should Consider Alternative Payment Models**

We appreciate that OHA has significant concerns regarding prescription drug spending. However, in fiscal year 2019, only 2.9 percent of the state Medicaid budget was spent on retail medications, inclusive of all rebates.<sup>9</sup> As an alternative to severe access restrictions, a number of states are experimenting with new methods of Medicaid prescription drug contracting through alternative payment models (APMs) for higher cost medications and/or for medications that meet an urgent public health need. APMs aim to promote value via savings on the total cost of care, total savings for a specific population, improved access, and/or better outcomes.

States that pursue market-based alternatives such as these can improve access to therapies, may lower overall spending, and/or improve health outcomes while incentivizing manufacturers to compete on attributes that include access, cost, quality, and value. Alabama, Arizona, Colorado, Louisiana, Massachusetts, Michigan, North Carolina, Oklahoma, and Texas have all been approved by CMS for Medicaid supplemental rebate agreements (SRAs) that allow for value-based agreements (VBAs) with pharmaceutical manufacturers for a variety of treatments. Louisiana and Washington have received CMS approval of SRA arrangements that allow for Hepatitis C “subscription agreements,” and at least 14 states use risk distribution models including high-risk pools, reinsurance, and risk corridors to help manage program costs. These states have developed approaches that address spending concerns while also maintaining, and

---

<sup>6</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

<sup>7</sup> See CMS, 11-W-00030/1 <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-ca.pdf>.

<sup>8</sup> Novartis recognizes that in early 2021, CMS approved a demonstration proposal from Tennessee to create a closed formulary under its Medicaid program. Since then, CMS has decided to reopen implementation of the demonstration proposal and has requested a new round of public comments. Novartis firmly believes that CMS does not have the legal authority to approve Tennessee’s proposal to implement a closed formulary. Oregon should therefore not base its decision to implement the proposed waiver on CMS’s initial approval of the Tennessee waiver, especially since CMS has reopened the approval determination by seeking a new comment period.

<sup>9</sup> PhRMA, “The Facts About Medicaid in Oregon”, [https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2020/OR-One-Page\\_20.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2020/OR-One-Page_20.pdf).

even improving, Medicaid beneficiary access to innovative medicines.

Novartis has, for instance, entered into VBAs with a number of these states for the spinal muscular atrophy (SMA) gene therapy, Zolgensma, whereby the state receives additional rebates if the desired clinical outcomes are not achieved in the first five years post-administration. Furthermore, a CMS final rule becomes effective in July of this year that will make developers' commercial VBAs more accessible to state Medicaid programs and generally reduce current burdens for states pursuing VBAs.<sup>10</sup> OHA should pursue these types of program reforms and explore new CMS VBA opportunities rather than changes that threaten Medicaid beneficiary access to potentially life-saving therapies.

## **VII. The Proposed Waiver Restricts Access to Life-Saving Medications, Leading to Poorer Outcomes, and Runs Counter to the OHA's Mission of Health Equity**

Novartis believes an important way we can achieve greater health equity is to address persistent disparities in the way healthcare is approached, accessed, and delivered. We are confronting these disparities in innovative ways, such as promoting greater diversity in biopharmaceutical clinical trials and supporting educational programs that raise awareness about diseases and treatments. Often, we work in partnership with patient and community organizations that share our commitment to health equity.

Novartis appreciates the state's focus on health equity. We commend its efforts to improve coverage for vulnerable populations, addressing social determinants of health, assessing health equity quality metrics, and focusing on improving health outcomes. The proposed waiver, however, may have the opposite effect as intended, as it is well documented that restricted access to medicines reduces adherence to prescribed medication regimens, worsens health outcomes, drives up long-run costs, and exacerbates healthcare disparities. A systematic literature review concluded that "formulary restrictions were most frequently negatively correlated" with desirable outcomes, including a consistent negative effect on medication adherence.<sup>11</sup>

A closed formulary ignores and detracts from real opportunities to improve health equity. Underserved communities, who are disproportionately burdened by chronic disease, often already face barriers to accessing medicines and are often treated later for many diseases, such as certain cancers.<sup>12, 13, 14</sup> Timely access to provider-recommended medicines is central to reversing that trend, improving health outcomes, decreasing avoidable healthcare utilization and costs, and reducing mortality.<sup>15,16,17</sup> Improving health equity must begin with addressing the obstacles to accessing care that are most significant to underserved communities.

A closed formulary involves "one size fits all" determinations about clinical efficacy, fails to accommodate the diverse needs of a heterogenous patient population like in Oregon. In fact, a

---

<sup>10</sup> 85 Fed Reg. 87000 (Dec. 31, 2020).

<sup>11</sup> Happe LE, Clark D, Holliday E, Young T. A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. *J Manag Care Spec Pharm.* 2014;20(7):677-84.

<sup>12</sup> Minority Population Profiles. Office of Minority Health. <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=26>.

<sup>13</sup> Gracia JN. COVID-19's Disproportionate Impact on Communities of Color Spotlights the Nation's Systemic Inequities. *Journal of Public Health Management and Practice* 2020; 26(6):518-521. doi: 10.1097/PHH.0000000000001212.

<sup>14</sup> Halpern MT, Holden DJ. Disparities in timeliness of care for US Medicare patients diagnosed with cancer. *Curr Oncol.* 2012;19(6):e404-e413. doi:10.3747/co.19.1073

<sup>15</sup> Lloyd JT, Maresh S, Powers CA, Shrank WH, Alley DE. How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program? *Med Care.* 2019 Mar;57(3):218-224. doi: 10.1097/MLR.0000000000001067. PMID: 30676355.

<sup>16</sup> Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care.* 2005 Jun;43(6):521-30. doi: 10.1097/01.mlr.0000163641.86870.af. PMID: 15908846.

<sup>17</sup> Khunti K, Seidu S, Kunutsor S, Davies M. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. *Diabetes Care.* 2017 Nov;40(11):1588-1596. doi: 10.2337/dc16-1925. Epub 2017 Aug 11. PMID: 28801474.

recent study found if the Medicaid program implemented rigid cost-effectiveness criteria for a set of chronic conditions treated with long-term drug regimens, a significant percentage of beneficiaries would be required to change their current prescriptions.<sup>18</sup> As a result of the OHA's proposal, patients with chronic conditions may lose access to their current treatments or experience interruptions in care. The state should take this opportunity to revise its harmful formulary policy proposal that, if implemented, would exacerbate existing healthcare inequalities for vulnerable patients in Oregon.

## Conclusion

In sum, the proposed waiver poses a significant risk to the health and well-being of Medicaid beneficiaries in Oregon. It would also mark a serious departure from the principles undergirding SSA § 1927, and from CMS' long-standing policy of "remain[ing] committed to Medicaid beneficiaries continuing to have access to needed prescribed medications."<sup>19</sup> It also fails to satisfy the essential criteria for a § 1115 demonstration program. As such, Novartis strongly objects to the prescription drug restrictions in the proposed waiver and encourages OHA to revise its OHP proposal to ensure appropriate access to prescription drugs and the inclusion of beneficiary protections.

Moving forward, Novartis would like to work with OHA to develop meaningful solutions to meet its budgetary and health equity goals while upholding the current Medicaid rebate statute. We stand ready to work with the state if there is interest in applying for a state plan amendment to implement VBAs and health equity strategies to ensure that OHP beneficiaries have access to life-saving and life-enhancing medications.

\* \* \* \* \*

We appreciate the opportunity to comment and would be happy to provide further information regarding our comments above. Please feel free to contact me at 862-778-3284 if we can provide further assistance.

Sincerely,

Leigh Anne Leas  
Vice President and Head, North America Public Policy  
Novartis Services, Inc.

---

<sup>18</sup> Xcenda, Impact Analysis of ICER Formulary Implementation in Medicaid, [https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/icer-medicaid-analysis\\_march-2019.pdf?la=en&hash=03590A12822FB95144692F0BF6FFF846E2E26F1A](https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/icer-medicaid-analysis_march-2019.pdf?la=en&hash=03590A12822FB95144692F0BF6FFF846E2E26F1A). The conditions studied were: multiple sclerosis (99% of prescriptions would need to be changed), rheumatoid arthritis (87%), non-small cell lung cancer (78%), psoriasis (77%), and multiple myeloma (42%).

<sup>19</sup> See CMS, Medicaid Drug Rebate Program Notice, Release No. 172, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015).



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Via email: 1115Waiver.Renewal@dhsosha.state.or.us

RE: 1115 Medicaid Waiver Submission

The Oregon Association of Hospitals and Health Systems (OAHHS) appreciates this chance to provide public comments on the 1115 Medicaid Waiver submission. OAHHS and its members have been supportive and integral partners in the development, implementation, and success of health system transformation since 2011. Oregon is and can continue to be a leader in how care is delivered for those eligible for the Oregon Health Plan through a local, community driven model that is foundational to how Oregon has been so successful to this point.

Following our comments in July 2021 after the release of the first draft concept papers, we believe a transparent, focused discussion on the 1115 waiver renewal helps identify successes and opportunities to prioritize what is most important in the next phase of Oregon's health system transformation to ensure our shared vision of better health, better care and lower costs – which we began with the initial formation of coordinated care organizations in 2012 – continues to meet the needs of our most vulnerable Oregonians.

In the early discussions and formation of CCOs and health system transformation, the collective work was grounded in extensive, transparent and robust public input and feedback. Through two legislative sessions, a large stakeholder workgroup, multiple technical workgroups and continued stakeholder support through the initial waiver process, we all worked together to produce the best outcome for Oregonians under a shared vision. That work of collaboration, input and constant feedback are critical now as Oregonians and the providers who serve them depend on the Oregon Health Plan more than ever.

The pandemic has highlighted the critical need for the Oregon Health Plan, especially for underserved and vulnerable populations. Doubling down on the path we set for ourselves almost 10 years ago requires we also double down on the commitment to each part we play in the health of Oregonians as hospitals, providers, CCOs, advocates, community-based organizations, policy makers and all who can and will contribute to the health of those served by the Oregon Health Plan. The following are some initial comments and questions.

**Create opportunities to ensure operational feasibility and policy discussion.**

Throughout the initial concept papers and continued through the final application, whether around the value based global budget or improving health outcomes, how OHA is viewing this policy and how the conversation continues with CMS creates challenges for hospitals and others in providing meaningful feedback about how to operationalize any new or changing policy. If the pandemic response has taught us one lesson over these last twenty-two months, operational expertise is critical – not just on the back end of a policy goal, but throughout the discussion to continue to ask the hard questions, understand the tradeoffs to policy choices and inform any other connected policy which may or may not be apparent to those who are developing the policy. This work is too important for serving Oregonians to not have the right expertise throughout the discussions - from hospitals to providers to CCOs to health equity

4000 Kruse Way Place, Bldg. 2, Suite 100  
Lake Oswego, Oregon 97035  
503-636-2204

coalitions – to best provide real time input and a constant feedback loop to OHA and its team to continue to meet health system transformation goals. In addition to informing the product with the hope of making it better, continuing to connect policy and operations across varying functions of the system is equally important. We recommend connecting and will continue to advocate for OHA to work with operational and content experts throughout the wide range of areas covered by the waiver proposal through the continued waiver submission process and continued discussions with CMS.

**Eligibility and enrollment process should reduce administrative burden and ensure those eligible remain on the Oregon Health Plan.**

OAHHS has supported a fully funded, sustainable Oregon Health Plan and supports OHA’s discussions to make strides to make the eligibility and enrollment process as streamlined as possible for OHP members, potential OHP members, and hospitals who may have a role in any expanded or new process. The focus of the state, providers, CCOs and others should be on ensuring seamless coverage for those eligible for the Oregon Health Plan. OAHHS supports policy and additional conversation to support these goals as long as we can continue to sustainably fund the Oregon Health Plan and the providers who serve those members, which needs to continue to be a priority for state leaders as more and more Oregonians depend on this critical program. As we have in the past, OAHHS will continue to advocate for sustainably funding the Oregon Health Plan without sacrificing funding hospitals, providers or CCOs, and continuing to fund organizations and providers who care for our most vulnerable.

**Importance of the value-based global budget requires hospital and health system expertise during development and implementation.**

Oregon’s health system transformation was built towards a budget concept to integrate funding streams while providing local flexibility to meet outcomes for the member being served. While there continue to be challenges with this concept OHA needs to address, especially as we collectively work towards value-based payment and other alternative payment models that reward value and outcomes, OHA should continue to investigate opportunities with their federal partners for additional flexibility, while allowing full funding for the Oregon Health Plan to deliver on the outcomes. These approaches should also not come at the cost of increasing administrative burden or reducing resources for providers serving the Oregon Health Plan. Approaches should reward providers for outcomes and should not carve up an already limited budget to deliver the quality of care expected for the population being served. In addition, the health care system is under (and will be under for some time) enormous strain from the response and recovery of the pandemic. Any budget policy that intentionally or unintentionally has the effect of moving incentives or resources from the health care system could have the opposite effect on the outcomes the waiver is attempting to achieve. Innovation in this will take work with OHA, CCOs, hospitals and other providers who have technical expertise to understand both the data aspects and real-world implications of policy choices as OHA begins the conversations with their federal partners. The policy discussed in the waiver is novel and requires further discussion as it moves forward in negotiation with CMS and in any form it takes. Providers, hospitals, and stakeholders need to be at the table to implement policy and likely continue to discuss it to ensure its intended outcomes. Each discussion will have implications for Oregon Health Plan members and the hospitals and providers who serve them, so the sooner OHA can begin to understand these risk/reward and transparent discussions, the better throughout this process.

**Focus on health equity.**

We appreciate the focus on health equity and the work OHA has put forward. We continue to encourage the state to review their strategies around health equity so they encompass the full inclusivity of the state’s own definition of health equity. As we reviewed the waiver about how OHA can address health equity through this process, we continue to have questions about how OHA is considering supporting this

work to ensure its success. How are the structures and programs designed and operationalized to not duplicate governance and maximize success, while continuing to support investments in the health care system to support health outcomes?

Thank you for the opportunity, and we will continue to provide feedback in writing and through OHA provided venues.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sean Kolmer', with a long horizontal flourish extending to the right.

Sean Kolmer  
Senior Vice President of Policy & Strategy



January 6, 2022

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Re: Comments on Oregon's Application for Renewal and Amendment of Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

The Oregon Academy of Ophthalmology (OAO) is a professional association of eye physicians and surgeons who specialize in the medical and surgical treatment of eye diseases and other conditions, and also provide vision care services. The Academy's purpose is to promote and improve the practice of medicine and surgery in relation to the eye. Our members are glad to practice in a state that is so innovative with regard to Medicaid delivery. There are many positive aspects of the 1115 Waiver application that if approved, we believe will increase access to equitable care—a goal we all support.

That said, our members have expressed concerns with portions of the application that seek to create a closed formulary. In general, OAO is always concerned about limiting a patient's access to the drugs or treatments that their physician recommends. OAO physicians report that similar systems used on the commercial side are a significant driver of administrative cost and burden, as well as patient frustration and abandonment or noncompliance of care.

OAO members are particularly concerned that if a closed formulary is adopted, Oregon Health Plan patients will have no avenue to access potentially vision-saving drugs if they are not included in the formulary.

These kinds of restrictions could negatively impact any patient, but it is of particular concern to our physicians who treat patients with injectable medications in the office for diseases like diabetic retinopathy, a leading driver of vision loss. There are limited treatment options for these patients and no single medication works well in all patients. Furthermore, the loss of visual function due to under-treatment is staggering on a personal and societal level. Moreover, with new biosimilar medications expected to hit the market soon, a closed formulary could put these vision-saving medications out of reach for patients.

417 2nd Street, Ste 101  
Lake Oswego, Oregon 97034  
503-222-EYES (3937)  
staff@oregoneyephysicians.org  
www.oregoneyephysicians.org

2020-2022 Officers

Julie Falardeau, M.D.  
*President, Portland*

Jonathan Yoken, M.D.  
*Vice President, Portland*

Nisha Nagarkatti-Gude, M.D.  
*Secretary-Treasurer*

Jennifer Lyons, M.D.  
*Past President, Portland*

Chad Bingham, M.D.  
*AAO Councilor, Salem*

Michael Lee, M.D.  
*OMA Delegate, Portland*

Ross Passo, M.D.  
Alex Walters, M.D.  
*Resident Liaisons, Portland*

2020-2022 Board Members

Francisco Castillo, M.D.  
*Portland*

Mary DeFrank, M.D.  
*Hillsboro*

Jason Dimmig, M.D.  
*Bend*

Albert Edwards, M.D., Ph.D.  
*Eugene*

Jane Gilbert, M.D.  
*North Bend*

Jonathan Kemp, M.D.  
*Portland*

Helen Koenigsman, M.D.  
*Medford*

Andreas Lauer, M.D.  
*Portland*

Steven Mansberger, M.D., MPH  
*Portland*

J. Kevin McKinney, M.D., MPH  
*Portland*

David Poulsen, M.D.  
*Hood River*

Leah Reznick, M.D.  
*Portland*

Christen Richard, M.D.  
*Portland*

Eric Suhler, M.D., MPH  
*Portland*

Jack Tian, M.D.  
*Astoria*

Elizabeth Verner-Cole, M.D.  
*Clackamas*

Jeffrey Welder, M.D.  
*Ashland*

James B. Wentzien, M.D.  
*Portland*

---

Amanda Dalton, *Executive Director*  
Sabrina Riggs, *Legislative Advocate*  
Shelley Shirley, *Membership*



A closed formulary is also a concern for physicians treating patients with glaucoma—an irreversible disease that requires individualized treatments. Vision lost from glaucoma is permanent, and commonly treated using ocular hypotensive eye drops. While many patients respond to generic medications, many patients require special eye drop medications that avoid preservatives (preservative-free eye drops) or brand-name medications that avoid side effects or increase effectiveness. If these are not allowed, patients will suffer gaps in treatment or ineffective treatment, which will lead to permanent vision loss. Physicians need flexibility to act swiftly to ensure that patients are prescribed the most effective drug(s) for their case. While step therapy may provide benefits to the large majority of patients, patients commonly require non-formulary medications and the application should avoid onerous requirements for non-formulary medications that may accompany a closed formulary, which can lead to unnecessary vision loss and/or abandonment of treatment.

A “one-size-fits-all” approach like a closed formulary is not the best option for highly individualized diseases like glaucoma, or diabetic retinopathy. Loss of vision can be incredibly debilitating for a patient, potentially impacting their quality of life, ability to care for themselves, hold a job, or otherwise function. OAO encourages OHA to keep an open formulary, at least for vision-related drugs, to ensure that all Oregonians have access to vision-saving medications recommended by their physicians.

Thank you for your consideration and for your leadership in this space,

Julie Falardeau, MD  
President  
Oregon Academy of Ophthalmology

417 2nd Street, Ste 101  
Lake Oswego, Oregon 97034  
503-222-EYES (3937)  
staff@oregoneyephysicians.org  
www.oregoneyephysicians.org

2020-2022 Officers

Julie Falardeau, M.D.  
*President, Portland*

Jonathan Yoken, M.D.  
*Vice President, Portland*

Nisha Nagarkatti-Gude, M.D.  
*Secretary-Treasurer*

Jennifer Lyons, M.D.  
*Past President, Portland*

Chad Bingham, M.D.  
*AAO Councilor, Salem*

Michael Lee, M.D.  
*OMA Delegate, Portland*

Ross Passo, M.D.  
Alex Walters, M.D.  
*Resident Liaisons, Portland*

2020-2022 Board Members

Francisco Castillo, M.D.  
*Portland*

Mary DeFrank, M.D.  
*Hillsboro*

Jason Dimmig, M.D.  
*Bend*

Albert Edwards, M.D., Ph.D.  
*Eugene*

Jane Gilbert, M.D.  
*North Bend*

Jonathan Kemp, M.D.  
*Portland*

Helen Koenigsman, M.D.  
*Medford*

Andreas Lauer, M.D.  
*Portland*

Steven Mansberger, M.D., MPH  
*Portland*

J. Kevin McKinney, M.D., MPH  
*Portland*

David Poulsen, M.D.  
*Hood River*

Leah Reznick, M.D.  
*Portland*

Christen Richard, M.D.  
*Portland*

Eric Suhler, M.D., MPH  
*Portland*

Jack Tian, M.D.  
*Astoria*

Elizabeth Verner-Cole, M.D.  
*Clackamas*

Jeffrey Welder, M.D.  
*Ashland*

James B. Wentzien, M.D.  
*Portland*

---

Amanda Dalton, *Executive Director*  
Sabrina Riggs, *Legislative Advocate*  
Shelley Shirley, *Membership*



1/7/22

To: OHA Health Policy and Analytics Medicaid Waiver Renewal Team  
From: Oregon Council for Behavioral Health (OCBH)  
Re: 2022-2027 Medicaid 1115 Demonstration Application

Oregon Council for Behavioral Health is the statewide member association comprised of behavioral health providers that serve and treat individuals with substance use disorders and mental illness. Our members provide the full continuum of behavioral healthcare from prevention to outpatient and residential treatment for both youth and adults living with the chronic diseases of addiction and mental illness.

We are grateful to the Oregon Health Authority for their work solidifying Oregon as a state at the forefront of healthcare transformation and health equity. OCBH members and partners are pleased to see many meaningful system improvements proposed in this waiver including network adequacy, documenting, and tracking services that improve health equity, improving access for those transitioning across multiple systems, formalized reporting, and auditing procedures to track and incentivize access for the larger healthcare system.

Robust and innovative healthcare policy proposals like these are part of Oregon's identity, and we are proud to stand alongside OHA in this work. Creating cutting edge healthcare policy is not without controversy and it is rare that Oregon's healthcare stakeholders reach unanimous agreement on anything. However, over the last several years, **we've found one aspect of our system in which this agreement exists: behavioral health rates are dangerously insufficient.** Across CCOs, hospital systems, state agency partners, legislators, and consumers we hear the same fundamental question: how can we improve behavioral health rates?

Current rates do not allow providers to pay a livable wage, much less a professional wage, to their workforce. Without a workforce to do this work, capacity is diminished and unscalable. We've seen this continue to play out for the last several decades. Short-term temporary infusions have provided stop-gap funding, preventing total collapse of the system. However, this incremental funding has been both inefficient and insufficient. Without ongoing, adequate, and stable resources that providers can anticipate, providers are unable to offer growth opportunities to current employees or consciously recruit underrepresented BH workforce and thus increase health equity and overall access. Thus, the workforce continues to churn, and experienced providers leave. Churn of the BH workforce increases overhead costs and causes disrupted, lower quality care for patients.

As mentioned, this cycle has hampered our behavioral health system's efforts to eliminate health inequity. Providing quality behavioral healthcare requires recruiting and retaining a workforce reflective of the population being served. However, recruiting a diverse workforce in a system that is unable to offer a professional wage is not only challenging, it undermines our equity goals.



**With far reaching agreement that behavioral health rate improvement is needed, we are left to ask: why hasn't it happened?** In asking this question we've received an incongruous series of answers from those with institutional knowledge of the waiver, our CCO model, and Oregon's history funding behavioral health. These responses have included the following explanations:

- We cannot, within the current waiver, require CCOs to raise rates for a specific sector, so the only option is to raise the OHA rate for those on "open card" and hope CCOs follow suit.
- The current waiver disincentivizes/prohibits a CCO from moving investments between areas of healthcare spend (i.e. moving money from physical health to behavioral health).
- Additional investment, above and beyond what is currently allocated to CCOs, is required to improve rates. However, this would put us above the 3.4%. This may jeopardize our ability to receive match on all these additional dollars and is therefore an untenable cost for the state/CCOs to absorb.
- Any additional investment in behavioral health rates would have to be funded using general fund up front. Actuarial soundness requirements are such that this investment would then take several years to be reflected in the rates from the federal government.

While we imagine the correct answer to this question may include aspects of several of the above theories, **Oregon Council for Behavioral Health is very concerned to see no clear evidence behavioral health rate improvement is being explored in this waiver.**

Furthermore, it is disheartening to see no mention of behavioral health rates in OHA's "Behavioral Health and Oregon's 1115 Medicaid Waiver" document. If behavioral health rates can be addressed outside the waiver, we see no reference to this on page four of the document (which mentions work being done on behavioral health outside the waiver but continues to point only to inefficient and insufficient stop-gap funding.)

We have broad agreement and willingness to improve behavioral health rates among our partners in Oregon. We are no longer tasked with the work of convincing partners *why* this work needs to be done; we are instead asking for direction from the experts about *how* this work can be done. We hope we can work together to seize this unique opportunity and make longstanding sustainable improvements to behavioral health access for the most vulnerable Oregonians.

Thank you,

Heather Jefferis, MA  
Executive Director, Oregon Council for Behavioral Health



1/7/22

To: OHA Health Policy and Analytics Medicaid Waiver Renewal Team  
From: Oregon Council for Behavioral Health (OCBH)  
Re: 2022-2027 Medicaid 1115 Demonstration Application

Oregon Council for Behavioral Health is the statewide member association comprised of behavioral health providers that serve and treat individuals with substance use disorders and mental illness. Our members provide the full continuum of behavioral healthcare from prevention to outpatient and residential treatment for both youth and adults living with the chronic diseases of addiction and mental illness.

We are grateful to the Oregon Health Authority for their work solidifying Oregon as a state at the forefront of healthcare transformation and health equity. OCBH members and partners are pleased to see many meaningful system improvements proposed in this waiver including network adequacy, documenting, and tracking services that improve health equity, improving access for those transitioning across multiple systems, formalized reporting, and auditing procedures to track and incentivize access for the larger healthcare system.

Robust and innovative healthcare policy proposals like these are part of Oregon's identity, and we are proud to stand alongside OHA in this work. Creating cutting edge healthcare policy is not without controversy and it is rare that Oregon's healthcare stakeholders reach unanimous agreement on anything. However, over the last several years, **we've found one aspect of our system in which this agreement exists: behavioral health rates are dangerously insufficient.** Across CCOs, hospital systems, state agency partners, legislators, and consumers we hear the same fundamental question: how can we improve behavioral health rates?

Current rates do not allow providers to pay a livable wage, much less a professional wage, to their workforce. Without a workforce to do this work, capacity is diminished and unscalable. We've seen this continue to play out for the last several decades. Short-term temporary infusions have provided stop-gap funding, preventing total collapse of the system. However, this incremental funding has been both inefficient and insufficient. Without ongoing, adequate, and stable resources that providers can anticipate, providers are unable to offer growth opportunities to current employees or consciously recruit underrepresented BH workforce and thus increase health equity and overall access. Thus, the workforce continues to churn, and experienced providers leave. Churn of the BH workforce increases overhead costs and causes disrupted, lower quality care for patients.

As mentioned, this cycle has hampered our behavioral health system's efforts to eliminate health inequity. Providing quality behavioral healthcare requires recruiting and retaining a workforce reflective of the population being served. However, recruiting a diverse workforce in a system that is unable to offer a professional wage is not only challenging, it undermines our equity goals.



**With far reaching agreement that behavioral health rate improvement is needed, we are left to ask: why hasn't it happened?** In asking this question we've received an incongruous series of answers from those with institutional knowledge of the waiver, our CCO model, and Oregon's history funding behavioral health. These responses have included the following explanations:

- We cannot, within the current waiver, require CCOs to raise rates for a specific sector, so the only option is to raise the OHA rate for those on "open card" and hope CCOs follow suit.
- The current waiver disincentivizes/prohibits a CCO from moving investments between areas of healthcare spend (i.e. moving money from physical health to behavioral health).
- Additional investment, above and beyond what is currently allocated to CCOs, is required to improve rates. However, this would put us above the 3.4%. This may jeopardize our ability to receive match on all these additional dollars and is therefore an untenable cost for the state/CCOs to absorb.
- Any additional investment in behavioral health rates would have to be funded using general fund up front. Actuarial soundness requirements are such that this investment would then take several years to be reflected in the rates from the federal government.

While we imagine the correct answer to this question may include aspects of several of the above theories, **Oregon Council for Behavioral Health is very concerned to see no clear evidence behavioral health rate improvement is being explored in this waiver.**

Furthermore, it is disheartening to see no mention of behavioral health rates in OHA's "Behavioral Health and Oregon's 1115 Medicaid Waiver" document. If behavioral health rates can be addressed outside the waiver, we see no reference to this on page four of the document (which mentions work being done on behavioral health outside the waiver but continues to point only to inefficient and insufficient stop-gap funding.)

We have broad agreement and willingness to improve behavioral health rates among our partners in Oregon. We are no longer tasked with the work of convincing partners *why* this work needs to be done; we are instead asking for direction from the experts about *how* this work can be done. We hope we can work together to seize this unique opportunity and make longstanding sustainable improvements to behavioral health access for the most vulnerable Oregonians.

Thank you,

Heather Jefferis, MA  
Executive Director, Oregon Council for Behavioral Health

January 4, 2022



Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Doernbecher  
Children's Hospital

School of Medicine  
Division of General Pediatrics

Benjamin Hoffman MD, FAAP  
CPST-I

Professor of Pediatrics  
Vice Chair for Community Health  
and Advocacy  
Director, Oregon Center for  
Children and Youth with  
Special Health Needs  
Medical Director, Tom Sargent  
Safety Center

Mail code: CDRCP  
707 SW Gaines Street  
Portland, OR 97239-2998  
hoffmanb@ohsu.edu  
tel 503 494-6513  
fax 503 494-1542  
www.ohsu.edu

RE: Oregon 1115 Medicaid Waiver for 2022-2027

Dear Ms. Hatfield and team:

The Oregon Center for Children and Youth with Special Health Needs is the state Title V public health agency for children and youth with special health care needs. We are funded by the federal Maternal Child Health Bureau of the Health Services and Resourced Administration, and work in partnership with the Oregon Health Authority Maternal Child Health team.

Thank you for the opportunity to provide comments on the proposed Oregon Health Plan 1115 Demonstration Waiver Application for Renewal and Amendment.

First, we would like to acknowledge and thank the Oregon Health Authority (OHA) for the tireless commitment to serving all enrollees, and for the thoughtfulness and inclusiveness that has gone into crafting this waiver application. The Oregon Health Plan (OHP) remains the envy of many states, and has shown us to be a national leader in improving the health of our citizens, families and communities.

The Oregon Health Plan is a critical program for the children and youth of our state, providing coverage for 37% of the state's children and 49% of Oregon's children with special health care needs.<sup>1</sup> We also know that the Medicaid provides coverage for the majority of children and youth of color in our state, ensuring access to care for 57% of AI/AN; 26% of Asian, Hawaiian and other Pacific Islander; 65% of Black and 65% of LatinX children. Issues of equity and justice are central to any proposed actions regarding how Medicaid functions in Oregon.

In reviewing specific aspects of the 1115 Waiver proposal, there are several components that we feel will have significant positive impacts on children, youth, families and communities in Oregon, and will improve access and equity. We wholeheartedly support these, and applaud you for your vision and commitment in proposing them:

- **Continuous enrollment for children until age six, and 2-year continuous enrollment for all older than six:** Lapses in coverage can have catastrophic impacts in children. As a practicing pediatrician, I have personally witnessed the potentially disastrous consequences of





Doernbecher  
Children's Hospital

School of Medicine  
Division of General Pediatrics

Benjamin Hoffman MD, FAAP  
CPST-I

Professor of Pediatrics  
Vice Chair for Community Health  
and Advocacy  
Director, Oregon Center for  
Children and Youth with  
Special Health Needs  
Medical Director, Tom Sargent  
Safety Center

Mail code: CDRCP  
707 SW Gaines Street  
Portland, OR 97239-2998  
hoffmanb@ohsu.edu  
tel 503 494-6513  
fax 503 494-1542  
www.ohsu.edu

kids losing their health insurance, a fact borne out in the literature.<sup>3</sup> Children of color are more likely to experience "churning" on and off Medicaid coverage.<sup>3</sup> Moving to uninterrupted coverage up to age 6 years will have an enormous, positive effect on the ability of children to maintain coverage, courses of treatment, and relationships with both their primary care medical homes and necessary specialty and subspecialty care. Moreover, it will help address health inequities caused by churn among families of color.

- **Extending OHP coverage at existing income levels to youth with special health care needs (YSCHN) to age 26:** One of the 2 federal Title V priorities that OCCYSHN has as a focus is the transition from the pediatric to the adult health care system. Issues of transition are complex, and there are significant systems-level approaches to addressing the needs, from the planning to implementation.<sup>5</sup> Further, many youth of transition age come from populations at risk, including BIPOC (including AI/AN), LGBTQAI+, those experiencing intellectual and developmental disability (IDD), and those experiencing houselessness and poverty. This coverage extension at 305% FPL to age 26 will help with transition preparation and ensure continuity of care during this critical time.
- **Expedited enrollment for those with SNAP benefits:** Simplification and streamlining of enrollment and eligibility processes not only can decrease the burden on families applying for different programs, but also reduce administrative costs to the State.<sup>6</sup>
- **Covering all individuals regardless of immigration status:** The health and well-being of children is deeply influenced by the health of their parents and caregivers. Oregon's "Cover All Kids" program has allowed children access to crucial services. "Cover All People" will help ensure that parents, other caregivers, and extended family are covered by OHP and can receive needed care. This is particularly important right now as many adult immigrants are uninsured and work in jobs where the current pandemic has exposed them to considerable health risk.<sup>7</sup>
- **Providing SDOH services to vulnerable populations:** Optimal health and well-being requires much more than just access to health care. Families suffering housing instability/houselessness, food insecurity, and other adverse social impactors have worse health outcomes. Utilizing OHP funds to support critical family needs will have a significant impact on outcomes for children and their families.





Doernbecher  
Children's Hospital

School of Medicine  
Division of General Pediatrics

Benjamin Hoffman MD, FAAP  
CPST-I

Professor of Pediatrics  
Vice Chair for Community Health  
and Advocacy  
Director, Oregon Center for  
Children and Youth with  
Special Health Needs  
Medical Director, Tom Sargent  
Safety Center

Mail code: CDRCP  
707 SW Gaines Street  
Portland, OR 97239-2998  
hoffmanb@ohsu.edu  
tel 503 494-6513  
fax 503 494-1542  
www.ohsu.edu

- **Investments in community-based organization (CBO) infrastructure and capacity building as well as statewide health equity initiatives.** Such initiatives will help the state build its capacity to address service needs in places where families live, and better address root causes of health inequities.
- **A "comprehensive accountability structure" to address health inequities, ensure member/provider satisfaction, and protect member access to and quality of care.** Through better monitoring and data collection, this will help OHP identify coverage gaps, address health equity needs, and improve outcomes and satisfaction with the program. Moreover, it is important to note that when examining network adequacy for children, their access to *pediatric* primary, and medical, surgical and allied therapies subspecialty is paramount. Children are not little adults, and have significantly different patterns of illness, injury, and death, and children. They have distinct needs in regard to their anatomic, physiologic, developmental, and psychological characteristics, and the care they require is unique. Access to an adult physician or specialist must not substitute for care by pediatricians or pediatric specialists when measuring network adequacy.

One of the long-standing signatures of OHP has been a CMS approved waiver of EPSDT, and it is this area that we would respectfully ask be reconsidered, and rescinded.

- **Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit is a critical protection and must be part of the OHP.** EPSDT guarantees that all Medicaid-eligible children receive screening to assess and identify problems early, and ensures the provision of health and health related services necessary to optimally address those needs.<sup>8</sup> It has been demonstrated that children in low-income families have higher rates of asthma, heart conditions, hearing problems, digestive disorders, and elevated blood levels, among other issues.<sup>9</sup> EPSDT is designed to address a broad range of child health needs, including preventive care; physical and mental health; oral, hearing and vision care; habilitative care; and social and emotional development. EPSDT serves as the safety net for children's health, and the backbone of the Medicaid program for children. Waiving that provision fundamentally discriminates against children. Further, as children of color are disproportionately served by OHP, the EPSDT waiver is a fundamentally racist policy. As equity is a core tenet of OHA's operational principles, this is unacceptable. Children are not little adults, and their health needs must be considered separately from the adult health system. The HERC system, with its Prioritized List of





Doernbecher  
Children's Hospital

School of Medicine  
Division of General Pediatrics

Benjamin Hoffman MD, FAAP  
CPST-I

Professor of Pediatrics  
Vice Chair for Community Health  
and Advocacy  
Director, Oregon Center for  
Children and Youth with  
Special Health Needs  
Medical Director, Tom Sargent  
Safety Center

Mail code: CDRCP  
707 SW Gaines Street  
Portland, OR 97239-2998  
hoffmanb@ohsu.edu  
tel 503 494-6513  
fax 503 494-1542  
www.ohsu.edu

Health Services, is foundational to the EPSDT waiver, and does not acknowledge the unique health needs of children, lumping them in with the adult population who are the greatest cost drivers in the system.

EPSDT should be the guarantee that ensures that the health and developmental needs of children and youth are identified and addressed early and appropriately. This is particularly important for those with special health care needs. We urge OHA to reexamine any waiver of EPSDT.

- **Three months of retroactive Medicaid coverage is essential and must also not be waived.** This longstanding protection—one not offered in the private market but explicitly included in Medicaid—ensures that health care expenses for three months prior to the Medicaid application date are also covered, provided the enrollee would have been eligible for Medicaid. This is particularly important for families who may lose coverage from an employer or face a sudden illness or injury. Eliminating retroactive eligibility could deter beneficiaries from seeking needed care for fear they would be responsible for medical bills they cannot afford. This can result in higher medical costs in the long-term as Medicaid beneficiaries delay seeking care. It could also result in increased rates of uncompensated care as physicians and other health care providers, hospitals, and pharmacies—many of whom may have agreed to provide acutely-needed services even before ensuring Medicaid coverage was secure—are not reimbursed for (some of the) services they have already provided.

We are grateful for the opportunity to submit input on the 1115 waiver process, and deeply appreciate the thoughtfulness, innovation, and commitment to equity that has driven the process. I look forward to next steps, and further collaboration as we strive to improve the health and well-being of Oregon's children, families and communities.

Sincerely,

Benjamin Hoffman MD CPST-I FAAP  
Professor, Department of Pediatrics  
Doernbecher Children's Hospital  
Oregon Health & Science University

Dana A. Braner, MD, FAAP, FCCM  
Credit Unions for Kids Chair  
Professor and Chair, Department of Pediatrics  
Physician in Chief, Doernbecher Children's Hospital





Doernbecher  
Children's Hospital

School of Medicine  
Division of General Pediatrics

Benjamin Hoffman MD, FAAP  
CPST-I

Professor of Pediatrics  
Vice Chair for Community Health  
and Advocacy  
Director, Oregon Center for  
Children and Youth with  
Special Health Needs  
Medical Director, Tom Sargent  
Safety Center

Mail code: CDRCP  
707 SW Gaines Street  
Portland, OR 97239-2998  
hoffmanb@ohsu.edu  
tel 503 494-6513  
fax 503 494-1542  
www.ohsu.edu

As the Institute on Development and Disability Director, which includes OCCYSHN and the Child Development and Rehabilitation Center, I support and concur with Dr. Hoffman's comments. In particular, I strongly advocate for the importance of EPSDT and retroactive Medicaid coverage. Early identification of potential developmental, behavioral, and emotional differences is critical to accessing effective interventions.

Kurt A. Freeman, PhD, ABPP  
Director, Institute on Development and Disability  
Fred Fax Professor of Pediatric Excellence

### References:

1. Kaiser Family Foundation Medicaid In Oregon Fact Sheet. <http://files.kff.org/attachment/fact-sheet-medicaid-state-OR>
2. An Evidence Map for Interventions Addressing Transition from Pediatric to Adult Care: A Systematic Review of Systematic Reviews. <https://www.sciencedirect.com/science/article/abs/pii/S0882596319301678>
3. **Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic.** <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>
4. MACPAC Research Shows Closing the Continuous Coverage Gap for Kids is Within Reach. <https://ccf.georgetown.edu/2021/10/08/macpac-research-shows-closing-the-continuous-coverage-gap-for-kids-is-within-reach/>
5. An Evidence Map for Interventions Addressing Transition from Pediatric to Adult Care: A Systematic Review of Systematic Reviews. <https://www.sciencedirect.com/science/article/abs/pii/S0882596319301678>
6. Using SNAP Data for Medicaid Renewals Can Keep Eligible Beneficiaries Enrolled. <https://www.cbpp.org/sites/default/files/atoms/files/9-9-20health2.pdf>
7. Snapshot of Children with Medicaid by Race and Ethnicity, 2018. <https://www.shvs.org/wp-content/uploads/2021/10/State-Funded-Affordable-Coverage-Programs-for-Immigrants.pdf>
8. <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>
9. Woolf, S, Laudan A, et al. *How are Income and Wealth Linked to Health and Longevity?* Urban Institute, April 2015. Available at: <https://www.urban.org/sites/default/files/publication/49116/2000178-How-are-Income-and-Wealth-Linked-to-Health-and-Longevity.pdf>





Doernbecher  
Children's Hospital

School of Medicine  
Division of General Pediatrics

**Benjamin Hoffman MD, FAAP  
CPST-I**

Professor of Pediatrics  
Vice Chair for Community Health  
and Advocacy  
Director, Oregon Center for  
Children and Youth with  
Special Health Needs  
Medical Director, Tom Sargent  
Safety Center

Mail code: CDRCP  
707 SW Gaines Street  
Portland, OR 97239-2998  
hoffmanb@ohsu.edu  
tel 503 494-6513  
fax 503 494-1542  
www.ohsu.edu



**From:** [Patricia Durkin](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Wednesday, January 5, 2022 12:15:40 PM

---

[You don't often get email from [pldurkin@theoregonshore.com](mailto:pldurkin@theoregonshore.com). Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

My daughter was born with charge syndrome over 41 years ago. At 25 she started having seizures. The medication that she is on now is absolutely essential for her to keep using.

She is highly sensitive to many things. She is on a special diet needing to avoid many foods she is sensitive to in allergy response and ill health response.

A few years ago our pharmacy gave us a prescription for her that was same generic medication but made by a different manufacturer. After two doses she wasn't in a pre-seizure state verified by doctor and pharmacist both. Since there have been times when getting only the one medication by the one manufacturer has been challenging. Our pharmacist has been very helpful. She cannot switch medications nor manufacturer. She cannot be put on a "one size fits all" medication!!!

She has been disabled and on Medicaid and SSI since birth.

Please do not change system!

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Patricia Durkin  
441 Silver Point Ct  
Cannon Beach, OR 97110  
pldurkin@theoregonshore.com

**From:** [Adam Haynes](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 5:23:53 AM

---

[You don't often get email from adam@stickfort.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

I have a few close friends that would be hurt deeply by this proposal. Epilepsy is a serious condition and should be treated as such. Please reconsider this proposal.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Adam Haynes  
1135 NW Albany Ave  
Bend, OR 97703  
adam@stickfort.com

**From:** [Annie Fast](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 5:23:27 AM

---

[You don't often get email from anniefast@gmail.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

I'm writing on behalf of my good friend's daughter who has undergone several years of Epilepsy treatment. We have been along on their journey and continue to support the family in their healthcare journey.

I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Annie Fast  
2041 NW Glassow Dr  
Bend, OR 97703  
[anniefast@gmail.com](mailto:anniefast@gmail.com)

**From:** [Elyse Haynes](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 5:23:18 AM

---

[You don't often get email from user@votervoice.net. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

I am requesting that the message below is taken with careful consideration. Without proper coverage, it's my understanding that epilepsy can not be easily as managed.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Elyse Haynes  
1135 NW Albany Ave  
Bend, OR 97703  
[elysehaynes@yahoo.com](mailto:elysehaynes@yahoo.com)

**From:** [joshua.dirksen](mailto:joshua.dirksen)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 5:23:33 AM

---

[You don't often get email from [josh.ranchorelaxo@gmail.com](mailto:josh.ranchorelaxo@gmail.com). Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a friend of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

joshua.dirksen  
2030 NW Cascade View Dr  
Bend, OR 97703  
[josh.ranchorelaxo@gmail.com](mailto:josh.ranchorelaxo@gmail.com)

**From:** [Kristin Spurkland](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Wednesday, January 5, 2022 12:20:22 PM

---

[You don't often get email from kristinsprkln@gmail.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As someone diagnosed with epilepsy in adulthood, I know how important it is to have options when it comes to seizure drugs. Had I been limited to the first drug I tried, I would have faced an impossible choice: seizure control or the ability to work. On my first drug, the dosage that controlled my seizures left me so nauseous and dizzy that I literally could not stand. Because I was able to change medications, I now have a medication that controls my seizures while allowing me to work and be an active participant in my community. There is no "one size fits all" medication when it comes to epilepsy.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Kristin Spurkland  
2507 NE 62nd Ave  
Portland, OR 97213  
kristinsprkln@gmail.com

**From:** [Marissa Mireles](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 5:20:59 AM

---

[You don't often get email from mireles1238@gmail.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

There is no one medication is the end all, be all. When I was first diagnosed with epilepsy, I started on a medication that was commonly used and it worked. Eventually though, I started breaking out in small hives and I was always itchy. I ended up being allergic to that medication. At the age of 18, I was finally able to get a medication that I could take. That worked with my body - I wasn't allergic to, or didn't have any problems with. I'm grateful that Medicaid is able to purchase my medication because otherwise, I wouldn't be able to get this medication. A necessary medication for my health, and to continue a healthy life and lifestyle is \$500. I cannot afford that. It took me three medications to find the one that I can actually take. My brother also has epilepsy, and his is severe. Medicaid won't pay for his medication, and we cannot afford \$700 to get him it every month. With cost of living and a bad economy, \$700 barely covers the rent. How're we supposed to be able to cover that? Unfortunately, because we cannot, and Medicaid won't, he has to live a lifestyle paranoid. Paranoid he's going to be at work and have a fourteen, yes I said fourteen, minute seizure. Paranoid that anytime he yawns, he's not getting enough sleep so he has to cut his work time in half and life in half, so he does not put himself at risk of having a seizure. That is not a way to live. Limiting people with epilepsy to ONE covered medication, is limiting our future. We do not want these medications, we NEED them.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Marissa Mireles  
125 SW 9th St  
Ontario, OR 97914  
mireles1238@gmail.com

**From:** [Sarah Westhusing](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 5:23:53 AM

---

[You don't often get email from sarah@houseofmilo.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Sarah Westhusing  
2445 NW Marken St  
Bend, OR 97703  
[sarah@houseofmilo.com](mailto:sarah@houseofmilo.com)

**From:** [Nick Guerrero](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 8:51:08 AM

---

[You don't often get email from user@votervoice.net. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

Please continue to cover all epilepsy medications. My dear best friend has had epilepsy for almost a decade now, and I've been there with her through all the tests, all the hospital stays, and the different medications. She finally has a few medications she relies on that help manage and control her epilepsy. Without these medications, she would be in danger of constant seizures. Her quality of life has already changed over these past years; please do not threaten this more. Please continue to cover all epilepsy medications.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Nick Guerrero  
822 NE 23rd Ave  
Portland, OR 97232  
[nickvguerrero@yahoo.com](mailto:nickvguerrero@yahoo.com)

**From:** [Anthony Cook](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Tuesday, December 28, 2021 8:30:06 PM

---

[You don't often get email from brigancook@gmail.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

My Name is Anthony Cook, and I have been living with epilepsy since 1980. In my travels abroad four other continents I have always been surprised by the ease with which I have been able to obtain my prescription. This can be taken out of context, as it sometimes is in the US, as being a problem with other countries' ability to keep dangerous drugs from the public. On the contrary, I have seen only professionalism and compassion from foreign doctors and pharmaceutical staff, just as I have here in the United States. Where professionalism is lacking is in the healthcare industry, and it is here that Oregon can again make an example of what good, safe and humanitarian healthcare should be. "Commercial Healthcare" is an industry which makes a profit off the needs of people. Whether you are healthy or well, rich or poor, you should feel free to see a doctor. Every friend I know in a country outside of my own, is appalled by the way our "healthcare" treats its patients. They are also confused because of the great doctors and healthcare professionals that are here. but so many can't or won't go to see because of fear of being unable to pay the bills.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Anthony Cook  
7108 NE Ronler Way Apt 2835  
Hillsboro, OR 97124  
brigancook@gmail.com

**From:** [Danielle A Espindola](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Tuesday, December 28, 2021 8:10:07 PM

---

[You don't often get email from user@votervoice.net. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Danielle A Espindola  
4829 N 65th Ave  
Phoenix, AZ 85033  
espindola915@yahoo.com

**From:** [Hillary Neun](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 5:23:03 AM

---

[You don't often get email from [hillarybenhardt@gmail.com](mailto:hillarybenhardt@gmail.com). Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Hillary Neun  
155 SW McKinley Ave  
Bend, OR 97702  
[hillarybenhardt@gmail.com](mailto:hillarybenhardt@gmail.com)

**From:** [Jordan Harris](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Wednesday, January 5, 2022 12:19:22 PM

---

[You don't often get email from user@votervoice.net. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

I'm a 28 year old epileptic who after 20 years of seizures, finally received a proper diagnosis and have almost figured out the right combination of seizure medications to control my seizures. This has required a lot of dose and medication adjustments because some medications have actually caused my seizures to become worse, increasing the level of medical care I required. For people like me, one medication alone does not provide effective seizure control and the type of medication used isn't interchangeable. For me, being limited to one type of medication could lead to an increase in seizures and result in further delay in my education, increased limitations in my ability to support myself financially by working and paying for medical costs, and a dramatic decrease in quality of life due to the limitations placed on me and the mental health effects of having uncontrolled seizures. Thank you for continuing to provide full coverage for all epilepsy medications and keeping people like me well and alive.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Jordan Harris

174 S 21st St  
Saint Helens, OR 97051  
jordanroseharris@hotmail.com

**From:** [Kelly Cobb](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Wednesday, December 29, 2021 8:10:06 AM

---

[You don't often get email from [kelly.cobb@gmail.com](mailto:kelly.cobb@gmail.com). Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As the parent of an adult child with epilepsy, learning of the OHP plan to severely restrict the formulary is alarming to say the least. My daughter has what is called medically refractory epilepsy. That means that her condition does not respond optimally to treatment. As a result, more than 10 medications, and two implant devices, have failed to fully control her seizures. She currently takes 3 different seizure medications, and still has at least 8 seizures a month. The thought of having her care options reduced to one arbitrarily chosen medication is mind-boggling.

We were fortunate to be able to have employee-sponsored health coverage when she was a child, but my heart goes out to those who do not have that option, and depend on OHP for their child's care. Mental health treatment is such an integral part of epilepsy treatment. I know for a fact that without psychiatric support, my daughter's condition would be markedly worse than it is today.

Epilepsy is a complicated, multi-faceted, very individualized condition. There is simply no one medication or treatment for every person who lives with it. Please do not so severely limit the options for treatment. The consequences for those who need a combination of medications could be life-threatening. That is not hyperbole. It is fact. Seizures can be fatal, and making sudden changes to medication, because you have no other option, could have dire consequences.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and

stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Kelly Cobb  
3707 Anita Dr NE  
Salem, OR 97301  
kelly.cobb@gmail.com

**From:** [Kevin L Matlock](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Tuesday, December 28, 2021 6:20:05 PM

---

[You don't often get email from kmatlock@earthlink.net. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Kevin L Matlock  
11795 NW Cedar Falls Dr Apt 412  
Portland, OR 97229  
kmatlock@earthlink.net

**From:** [Lorena Beloso](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Wednesday, January 5, 2022 9:30:08 PM

---

[You don't often get email from [lorebeloso@gmail.com](mailto:lorebeloso@gmail.com). Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

We struggle for more than three years to be have a proper diagnosis and now after a long painful , scary and uncertainty we have finally found a medication that helps our son to be able to live a normal life. This can change at any time of his meds stop working and even though we are willing to loose sleep to watch him over night to make sure he gets assistance while having a seizure , we need to be able to get his medication and also services that have been denied so he can get services to help

Him with so many other struggles he encounters due to epilepsy. Please don't leave my son and many kids without the opportunity to have treatment and medications that we couldn't afford and will make us choose if pay rent or get medication. Pandemic time have put enough struggles for all. Don't fail this kids. Please

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Lorena Beloso  
5900 SW Ellerson Ter

Beaverton, OR 97007  
lorebellos@gmail.com

**From:** [Lauren Slovic](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Tuesday, December 28, 2021 7:00:05 PM

---

[You don't often get email from slovicl@gmail.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

I have a family member with severe epilepsy. To cut medicaid access to meds would be catastrophic to him. Please do not do this!

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Lauren Slovic  
713 E 37th Ave  
Eugene, OR 97405  
slovicl@gmail.com

**From:** [Mary Cadez](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Thursday, January 6, 2022 12:00:07 PM

---

[You don't often get email from [mjcadez@gmail.com](mailto:mjcadez@gmail.com). Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Mary Cadez  
21923 Dee Dr  
Bend, OR 97701  
[mjcadez@gmail.com](mailto:mjcadez@gmail.com)

**From:** [Susan Gravelle](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Friday, January 7, 2022 7:50:09 PM

---

[You don't often get email from susangravelle68@gmail.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Susan Gravelle  
1835 Periwinkle Cir SE  
Albany, OR 97322  
[susangravelle68@gmail.com](mailto:susangravelle68@gmail.com)

**From:** [Susan Herzog, Esq.](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Tuesday, December 28, 2021 7:10:07 PM

---

[You don't often get email from susanherzog1@gmail.com. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Susan Herzog  
2223 WARREN ST  
EUGENE, OR 97405  
susanherzog1@gmail.com

**From:** [Venus Heckman](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** OHP 1115 Medicaid Waiver Comment  
**Date:** Wednesday, January 5, 2022 12:19:29 PM

---

[You don't often get email from user@votervoice.net. Learn why this is important at <http://aka.ms/LearnAboutSenderIdentification>.]

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Dear Interim Medicaid Director Hittle,

My daughter has struggled with epilepsy her entire life. She relies on her medicine to be a productive member of society. We/she cannot afford it on our/her own. Without her medicines she deteriorate so much that she needs 24 hour home care. This is not a viable scenario for us. Please reconsider this harmful legislation.

As a member of the epilepsy community in Oregon, I am writing to express concerns with the proposed "commercial style" closed formulary. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions. There are almost 43,000 Oregonians living with epilepsy.

I am very concerned with the state's proposal to limit coverage for prescription medications. Epilepsy medications are not interchangeable and there is no one treatment that works for everyone with epilepsy or seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Selection of the appropriate medication to prevent seizures is determined by a number of variables, including type of seizure, seizure frequency, age, gender, and other health conditions.

People with epilepsy who have their medications switched are at a high risk for developing breakthrough seizures. Uncontrolled seizures lead to significantly increased medical costs, such as hospitalizations and treatment for complications like injuries. Uncontrolled seizures also result in lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities. Access to the full range of available treatments is critical. The state should not move forward with this proposal.

I am also writing to express concern with the state's request to renew a waiver of services for children, known as EPSDT. Children with epilepsy frequently have related developmental disabilities. The current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including and sleep disorders. Lack of sleep is a known seizure trigger and children with epilepsy are more prone to sleep problems, so lack of treatment for sleep disorders in children could result in more frequent seizures, which could result in more and stronger medications, emergency room visits, hospital stays, and lost school days.

I urge you to not move forward with the closed formulary proposal or renewal of the EPSDT waiver.

Sincerely,

Venus Heckman  
859 S Hill Island Rd  
Cedarville, MI 49719  
dianne811971@yahoo.com



January 7, 2022

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer Street NE, 5th Floor, E65  
Salem, OR 97301

**Re: Comments on Oregon’s Application for Renewal and Amendment of Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

The Oregon Medical Association is the state’s largest professional membership organization engaging in advocacy, policy, community-building, and networking opportunities for Oregon’s physicians, physician assistants, medical students, and physician assistant students. A critical part of OMA’s mission is to advocate for a sustainable, equitable and accessible healthcare environment, and we envision an Oregon that is the healthiest state and the best place to practice medicine. The OMA wishes to submit the following comments regarding the 1115 Demonstration Waiver.

**Maximizing continuous and equitable access to coverage**

The OMA highly supports the waiver’s overall lens of equity. As a state, we must strive to ensure all Oregonians have access to care. Patients with health coverage have improved access to healthcare goods and services, and correspondingly, experience better health outcomes. OMA believes that health coverage should be readily identifiable, consistent across communities and populations, and affordable and portable, allowing patients to access care regardless of personal circumstance or employment. We are supportive of the focus on upstream health, taking into consideration those services that can have a greater health impact.

**Improving health outcomes by streamlining life and coverage transitions**

OMA shares the goal of maintaining care through transitional periods, incarceration, detention, or a period of unhoused, without a gap in coverage, or with the option of limited benefits. Specifically, the OMA advocates for changes to incarceration and detention practices to address human rights issues which impact the health of inmates, those who work with them, and the families and communities they return to, including but not limited to: expanding access to substance use disorder and mental health treatment during incarceration; continuity of that care upon release; consistent needs assessment on entry into correctional institutions; and provision of age appropriate physical and mental health care for incarcerated or detained juveniles.

As mentioned above, patients with health coverage have better outcomes. The focus on non-medical evidence-based interventions, including housing assistance, transportation, food assistance, employment support, and a consideration of climate exposure will impact and improve the long-term health of individuals, provided there is the opportunity to have OHP benefits while in custody or in other transition.

Director Patrick Allen  
January 7, 2022  
Page Two

**Moving to a value-based global budget, and incentivizing equitable care**

Value-based systems are intended to reduce cost and eliminate waste while prioritizing patient outcomes. OMA believes the patient and their personal physician or other health care provider should make decisions on the most appropriate medical treatment or intervention for a given health condition. Under a value-based system, incentivizing care that helps patients improve their health, reduce chronic disease, and live a healthier life, will improve the health of the overall population.

The OMA does want to share a specific concern in the waiver regarding the approach of a closed formulary. Although the OMA and its members are well aware of skyrocketing pharmaceutical costs, closing the formulary could have negative consequences for Oregon’s Medicaid population. Patients without access to clinically appropriate medication could in turn have life altering illness or forgo care all together.

We are concerned that a closed formulary could end up leading to increased paperwork, medication errors, and suboptimal medication choices and, in the long run, costlier care for the state and reduce—not improve—health outcomes for patients. That is, patients may need further care if a rigidly limited formulary of medications are not clinically sufficient. Clinicians may not have the ability to act quickly and with flexibility needed in the frontline clinical relationship. We value clinical standards where there is an evidence-based approach and not a one size fits all approach that could lean solely on cost, rather than the quality of the patient’s care.

**Improving health through focused equity investments led by communities**

To advance health and health equity, the OMA believes it is crucial to invest in communities, improving the social and physical environments to create a platform for the development of a healthier community.

The OMA recognizes the need to address the social determinants of health to improve the health of Oregonians, including shifting resources to those places locally where they will have the greatest impact and where they are most needed, especially investments that support and build infrastructures and provide support for community-led interventions and initiatives. Federal investments are needed for the statewide initiatives that have been identified to address health equity.

Thank you for the opportunity to comment. We stand with you in your commitment to the health of Oregonians and look forward to working with you.

Sincerely,



Mark Fischl, MD  
President



Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team

**Re: Comment on 1115 Medicaid Demonstration Waiver Renewal Application**

January 7, 2022

The Oregon Primary Care Association, on behalf of its 34 members, whom collectively serve **one in six OHP patients** and make up a critical portion of the provider networks within CCOs, would like to express its gratitude for your work on the 1115 Medicaid Demonstration Waiver renewal and amendment application. We understand the opportunity this provides to further innovation as well as improve and strengthen the care members on the Oregon Health Plan (OHP) receive across the delivery system and coordinated care model.

The Oregon Primary Care Association is the non-profit membership association of Oregon's 34 community health centers, also known as Federally Qualified Health Centers (FQHCs), and FQHC Look-Alikes. Community health centers deliver exceptional primary care, including behavioral health and oral health care, to over **450,000 Oregonians living in urban, rural and frontier communities** who may otherwise not have access to care.

As one of the state's larger Medicaid provider networks, FQHCs are largely supportive of the strategies proposed in the policy concepts and application as a whole and we appreciate the inclusion of our association in early waiver discussions. We would like to offer our recommendations on a few select strategies, articulated below, for your consideration.

**Advancing Health Equity**

OPCA's member health centers have over 270 sites statewide and are in all but 2 counties in Oregon, and for those who are designated as rural or frontier sites, concern was expressed about the lack of rural or "locality" in OHA's definition of health equity as well as the lack of reference throughout the application. To be clear, we understand the health equity definition was done separately from this application, as part of the Oregon Health Policy Board, and we would be remiss in representing our member voices if we didn't articulate that lack of inclusion or application felt by our rural and frontier providers. For those who are on the frontlines serving rural or frontier patient populations, their locality and rurality is intrinsically understood as an inequity in their care, and the lack of this inclusion in the definition makes it difficult for providers and their patients to understand their role in helping the state reduce health inequities.

**Recommendation** (in **blue**):

Oregon will have established a health system that creates health equity when all people can reach their full potential and well-being and are not disadvantaged by their race, ethnicity, language, disability, age, gender identity, sexual orientation, **locality**, social class, intersections among these communities or identities, or other socially determined circumstances.

*And/or,*

Achieving health equity requires the ongoing collaboration of all regions and **localities** of the state, including tribal governments to address: ...

### 3.2 Improving Health Outcomes by Streamlining Life and Coverage Transitions

#### *Strategy 4: Covering more providers outside the medical model*

In the context of today's racial/ethnic disparities in both COVID-19 cases and vaccination rates, the role of the CHW has become increasingly important, but often does not fit within the classical medical model for lack of mentorship, appropriate supervision, and financial incentive to enter the field. Many CHWs are left isolated, underutilized, or cannot stay employed due to lack of a living wage, at the same time that we watch disparities widen.

**Recommendation:** Ensure the roles articulated in the concept paper – Traditional Health Workers, Community Health Workers, navigators – are covered at a livable wage rate to promote the quality and quantity of these positions in our state. Expanding infrastructure so CHWs can provide services directly to OHP members and support for capacity building cannot be overstated. Engaging folks from rural communities and people of color should be a top priority moving forward as community members feel safe when they see health care workers that look like them.

**Recommendation:** If payors are required to focus on equity (and supporting THWs specifically), indicating where these funds come from is imperative. Building infrastructure, sustainable payments to these types of roles, and credentialing is a necessary step in implementation that is currently missing. It should be clear that this work is resourced as part of a CCOs global budget and/or separate funding needs to be earmarked for these services.

#### *Strategy 5: Invest in CBOs/health equity spending*

We understand the 1115 Waiver renewal is an integral part of a statewide strategy designed to center equity. However, we are concerned that multiple layers of additional administration are potentially being built “to support infrastructure for health equity investments.” There is a vast network of CBOs, Regional Health Equity Alliances, and CCO Community Advisory Councils in existence currently. CBOs have been a leading voice in the fight for health equity and equal access to health care. CBOs also have substantial trust in the community and are best positioned to provide culturally- and linguistically- appropriate outreach to communities, particularly those who are not currently engaged in the healthcare system.

**Recommendation:** We encourage the use of existing forums/channels, such as CCO Community Advisory Councils (CACs) and/or Regional Health Equity Coalitions, to drive community-level investment to avoid creating additional administrative overhead, and to ensure the largest investment can reach those who need it: the clients served by the CBOs and their community health centers.

**Recommendation:** Consider creating learning space for CBOs that have established themselves in the healthcare space to leverage connection and partnership with health systems in support of younger/newer CBOs.

### 3.4 Incentivizing Equitable Care

#### *a) Upstream metrics*

Community health centers are rooted in their communities – our model of care combines the resources of local communities with federal funds to establish “neighborhood” primary care homes in rural and urban areas. Integral to the communities they serve, FQHCs have also rooted their work in upstream health interventions, from job application assistance to transportation to the clinic. As social determinants of health have taken root and become shared language across the health systems and payors, FQHCs have often been at the forefront of piloting how to collect and utilize data that demonstrates a patients’ non-medical needs. OPCA and our members were instrumental in developing one of the first screening tools (Protocol for Responding to and Assessing Patients Assets, referred to as PRAPARE) and participated in the development of the Social Determinants of Health: Social Needs Screening and Referral metric referenced in the application. We recently completed a yearlong collaborative that partnered health centers with their CCO to assess not only screening methods but coding and referral processes. Incentivizing social needs is critical to reducing health inequities, and it must be done in tandem with both HIE and CIE initiatives across the state that link patients to community-based services and pay providers (Z-codes) for the inclusion of non-medical needs.

**Recommendation:** Screening tools (like PRAPARE) are generally administered by a clinician during a medical visit and the resulting information is contained in the medical record (as EMR allows). To better facilitate resources and ensure that social needs are addressed, screening tools could be administered at different entry points for Medicaid beneficiaries and the resulting data used to best meet their needs, rather than just held by the entity that screens.

### Changes to Prescription Drug Benefits

#### *Ability to define a preferred drug list for pharmacy benefits*

We appreciate the inclusion of strategies to address the impact of pharmacy costs on Medicaid spending in Oregon and, would like to express our deep concern about the impact the strategies, as included, could have in terms of significant impacts on already deep Medicaid rebates as well as limiting choice for OHP patients.

#### *A) Adopt a commercial style closed formulary approach*

In response to a similar recent effort by Massachusetts to implement its own drug formulary for its Medicaid program, Georgetown’s Center for Children and Families stated that pursuing the demo CMS is currently supportive of, “would harm access to drugs as its unlikely that state will get discounts as deep as the ones offered under the Medicaid drug rebate program”<sup>1</sup>. We understand that Oregon is electing to use CMS’ recommended pathway by including it in the demonstration, and want to ensure that the implementation of the proposed strategy does

---

<sup>1</sup> CMS Denies Massachusetts’ request to choose which drugs Medicaid covers. Modern Healthcare <<https://www.modernhealthcare.com/article/20180627/NEWS/180629925/cms-denies-massachusetts-request-to-choose-which-drugs-medicaid-covers>> accessed December 15, 2021.

account for disruptions to patients caused by changes (at any time) to formularies. Pharmacists at our FQHCs shared that “rebate managed formularies can cause a lot of disruption if rebate terms change and another drug becomes more favorable” and that one strategy to mitigate this impact, especially for patients who cannot change insurance plans to better fit their medical conditions, would be to build in strong grandfathering plans for drugs that are no longer covered under the new formulary. This must be done thoughtfully, and with intention, so that the goal of a closed formulary can be met without disruption or reducing access to drugs for a patient population that is already underserved and faces a number of inequities within our health care system. One of our member health centers shared the impact to their pharmacy program, which using the revenues it generates through programs like 340B and rebates, supports the following for their patients and the entire health center, including:

- *operating costs of 7 in-house, integrated pharmacies,*
- *access to medications for the uninsured and underinsured*
- *laboratory services*
- *7 FTE clinical pharmacists (who do diabetes and hypertension management, adherence support, transitions of care etc.)*
- *FTE support for an MA at our HIV clinic*
- *FTE support for drug assistance program enrollment*

While this is only one example, it is an example of how FQHCs do reinvest revenues and pharmacy savings (from the 340B program) back into patient care; that same health center fully understands the intention of tackling the drug spend in our state and believes that both strategies in this section would accomplish this. To ensure that this exercise in reducing prescription drug spend is done without the loss of “deep Medicaid rebates” or harming vulnerable patients by limiting/changing drugs, we recommend the following:

**Recommendation:** Any committee, workgroup or state commission charged with overseeing the development of a Medicaid formulary includes representation from entities who have clinical pharmacies that dispense to a large population of Medicaid beneficiaries, such as Federally Qualified Health Centers.

Thank you for your attention and consideration of our recommendations related to the 1115 Medicaid Demonstration Waiver. We look forward to continued partnership with the OHA in advancing the states equity goals and innovation within its Medicaid program. We are glad to provide clarification or additional information should it be needed.

Sincerely,



Danielle Sobel, MPH  
Sr. Director of Policy and Government Affairs



**To: Oregon Health Authority**

**From: Colleen Reuland, Director of the Oregon Pediatric Improvement Partnership.**

**Re: Oregon 1115 Demonstration for 2022-2027**

Our organization works across sectors on **population-based improvement efforts**, with the common purpose of improving the **health of the children and youth of Oregon**. A key component of our mission to ensure that all efforts are informed by parents, youth and young adults.

As an organization and person deeply committed to and experienced with systemic change, we have found developing reliable and meaningful measures has always been a critical tool to drive and inform valid improvement efforts that impact the health of children. **What is measured, and HOW it is measured, is WHAT will be focused on.**

Given that nearly 40% of Oregon's Medicaid-insured are children (the majority age demographic of enrollees) and because Medicaid provides insurance for the majority of children of color in our state ([60% of Black children, 65% of Latino children, and 57% of AI/AN children](#)), we are extremely supportive of the elements of the waiver that **focus on children and focus on addressing structural racism**. Both areas of focus are root sources of where the drivers of inequity begin and are sustained.

Within OHA's and OHPB health equity definition and aims, a key component we see for children in Medicaid/CHIP is the **intentional inclusion of "disability"**.

- For **children with special health care needs** in Oregon, OHP **IS the safety net** for addressing and covering their **medical, behavioral, oral and care coordination** needs.
- To highlight? underscore? the magnitude of children (and their families) that count on Medicaid/CHIP to provide access, quality and coordinated care - according to the [2021 Child Health Complexity data](#), there are **145,000 children** enrolled in Medicaid/CHIP, which is **more than 1 in four children**, have some level of medical complexity, with 50,000 having a complex, chronic condition.

We have **significant concerns with the Waiver proposal related to *Incentivizing Equitable Care***. We appreciate and **overall support the intent and purpose of the upstream and downstream metrics**. However, the current proposal will result in no metric that will ensure equitable access to, or receipt of, high-quality care for children with special health care needs - in the very program meant to ensure these children's needs are met.

The upstream measures proposed, although critical in addressing some of the historical inequities and social challenges faced, do not contain metrics focused on children and youth with disabilities. The etiology of children with disabilities is different than adults, in that a

majority are not caused by lifestyle or life circumstances that could be addressed by upstream efforts.

The current proposal calls for “downstream metrics” that would ensure quality, access and outcomes of the health care system to ONLY be chosen from the CMS Medicaid Adult and Child Core Sets and potential MCO Quality Rating System.

- I personally know the [metric set](#) and identification of which metrics go into that set well as I am one of the only measure stewards that is not NCQA. I do not believe that narrowing our measures to this CMS Core Set - which need to be applicable to all 50 states, will allow Oregon to reach their goal of eliminating health inequities by 2030.
- There are **NO metrics for the population of children and youth with special health care needs**. While there is one metric focused on children who experience asthma, this is just one condition of the hundred chronic conditions that children experience. The result – we will have no quality metrics and levers to ensure **quality** for a population that this program is meant to serve.
- There are **NO metrics focused on the essential and critical function of care coordination and care integration that are essential for CYSHCN and central to the CCO model**. When this function is not measured and assured in a high-quality way, the responsibility inevitably falls on the family and the child, which can result in poor health outcomes, school absenteeism, and child risk for out of home placement.
- The metrics included in the Core Set focused on behavioral health that could be considered for inclusion in the downstream set, do not measure or focus on the innovative models of behavioral health that Oregon has been known to support including IBH and dyadic behavioral health. In Oregon, nearly [two in five \(38%\)](#) children have three or more social complexity factors, majority of which are aligned with adverse childhood events, for which behavioral health is an essential service for which equitable access and quality care is needed. In the current proposal, there would be no metrics to ensure this quality and innovation would continue.

We have seen the transformative and integral power that the metrics and, in particular, metrics tied to incentives to galvanizing improvements in quality.

As an organization that works with and hears from parents, youth and young adults every day, we hear **consistently** and **persistently** how their access and care coordination needs continue to be unmet.

It is imperative that the metrics program is designed in a way such that metrics of quality can be considered is an essential component to ensuring equitable access and high-quality care for this population, and therefore we strongly recommend reconsideration of the waiver language related to the downstream metrics.

We are ready and willing to partner on solutions that could address these concerns should there be an opportunity.



January 7, 2022

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

Re: **Oregon's Application for Renewal and Amendment of Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

On behalf of the 300 members of the Oregon Dermatology Society, we are writing to express our strong opposition to a proposal that would restructure the Oregon Health Plan ("OHP") pharmacy benefit to create a commercial-style closed formulary for adult patients, as outlined in Oregon's 1115 Medicaid Waiver Demonstration renewal. The proposal would authorize the state to exclude drugs that have limited evidence, but still have demonstrated clinical efficacy that can be very beneficial to subgroups of patients. The broad guidelines for such determinations will negatively impact the sickest and most vulnerable patients and will conflict with the overarching goal of the waiver renewal to advance health equity. The creation of a closed formulary will only exacerbate existing health inequities by limiting patient access to medically necessary prescription medications.

Our members are keenly aware of the nation's increased health care costs and their own responsibility to prescribe a treatment plan that wisely manages limited

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

health care resources; however, a closed formulary is an ineffective, draconian approach to reducing health care costs by creating a one-size-fits-all solution. If approved, more than 700,000 Oregonians will unnecessarily be at risk, as explained below. Therefore, we urge Oregon policymakers to explore alternative strategies to reduce health care costs. Patients should not be expected to bear this burden.

Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases and many genetic disorders. When developing a treatment plan for our patients, dermatologists base their recommendations and decisions on a thorough understanding of their patients' medical history and medical needs. This knowledge enables them to identify potential contraindications and life-threatening adverse reactions, which is particularly critical for patients covered by OHP, many of whom have multiple chronic conditions. Comorbidity often results in adverse health outcomes and complex clinical management. Requiring a patient to take a medication that the physician knows is not in the patient's best interest and in some instances, will jeopardize the patient's health, not only defies logic but violates the Hippocratic oath.

The American Academy of Dermatology's guiding position on access to effective and affordable drugs is set forth in its *Position Statement on Patient Access to Affordable Treatments*<sup>1</sup>:

*"Physicians should have the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient's unique circumstances.*

*"Each formulary must be developed based on scientifically valid evidence that the selected pharmaceuticals sufficiently provide the most effective therapies for any given condition and that options are available should patients not be able to utilize a given agent due to lack of response, side effects, allergy, etc."*

---

<sup>1</sup> <https://server.aad.org/Forms/Policies/Uploads/PS/PS-Patient%20Access%20to%20Affordable%20Treatments.pdf>

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

A closed formulary will significantly limit the physicians' ability to treat patients with complicated skin diseases, such as cutaneous autoimmune disorders. Forcing these patients to make consequential, potentially lengthy and disease-altering changes is a great challenge and hardship. Withdrawal of a medication for a patient, particularly abrupt withdrawal, can aggravate a quiescent disease and result in disease that is resistant to prior effective therapy or the development of aggressive disease. The consequences, which cannot be predicted for individual patients, include worsening life-threatening disease, severe flares including those requiring hospitalization, therapeutic failure, antibody development and risk for greater adverse effects than those associated with current therapy. For many patients, the disease burden extends beyond physical findings; there is lost work and wages and a significant psychological impact.

A specific example is pemphigus vulgaris, which is a rare, auto-immune disease that causes blistering of the skin and mucous membranes. Treatment typically involves the prolonged use of steroids and immunosuppressive/immunomodulating agents, many of which do not have specific "approved indications" to treat pemphigus. This condition requires a patient-centric customized approach because if it is left untreated, the complications can be fatal. Each patient who presents with this disease is a unique challenge due to the diversity in the disease. Comorbidities, which include diabetes, hypertension, malignancies, chronic infections, among others, affect the choice of the most appropriate treatment.

Additionally, the waiver request will profoundly impact patients with chronic conditions and who are stable on a drug that is no longer included in the closed formulary. Forcibly switching a patient to another drug poses significant risk to patients, possibly resulting in harmful outcomes like flaring of the disease, immunogenicity, adverse effects, and secondary nonresponse. It may also lead to the loss of effectiveness of the original medication, should the patient switch back in the future.

As physicians, our number one priority is the health and welfare of our patients. We appreciate the opportunity to provide written comments on this important issue. Retaining physicians' medical judgement in patients' treatment plans is a cost-effective way to prevent health care dollars from being used on medications that are not effective. We respectfully urge you to carefully consider the ramifications of moving to a closed formulary and reject such provisions of the waiver renewal. Please contact Patrick Sieng, Executive Director for the Oregon

Page 4 of 4

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

Dermatology Society at [patrick@oregondermatology.org](mailto:patrick@oregondermatology.org) or (503) 799-8280 if you require clarification on any of the points above or would like further information.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Bar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anna Bar, MD, FAAD, FACMS  
President  
Oregon Dermatology Society



Oregon  
Law Center

WORKING TOGETHER TO ACHIEVE JUSTICE FOR LOW INCOME OREGONIANS

Beth Englander, Attorney at Law  
522 SW Fifth Ave.  
Suite 812  
Portland, OR 97204  
P: 503.473.8321  
F: 503.295.0676  
[benglander@oregonlawcenter.org](mailto:benglander@oregonlawcenter.org)

January 7, 2022

Via Electronic Submission

Michelle Hatfield  
Health Policy and Analytics Medicaid Waiver Renewal Team  
500 Summer St., NE E65  
Salem, OR 97301  
[MICHELLE.M.HATFIELD@dhsosha.state.or.us](mailto:MICHELLE.M.HATFIELD@dhsosha.state.or.us)>

David Bangsberg, Chair  
Oregon Health Policy Board  
500 Summer Street NE  
Salem, OR 97301  
[HealthPolicyBoard.Info@state.or.us](mailto:HealthPolicyBoard.Info@state.or.us)

Re: Oregon Health Authority Application for 1115 Demonstration Waiver Renewal and Amendment

Dear Ms. Hatfield and Mr. Bangsberg:

We appreciate the opportunity to comment on the draft renewal application for the Oregon Health Plan 1115 waiver. Oregon Law Center is a non-profit legal services provider that represents low income Oregonians on civil legal matters, including legal matters regarding Medicaid and other publicly funded health benefits. We staff a statewide public benefits hotline, and regularly talk to and represent individuals who need or receive Medicaid or state funded health care programs.

On behalf of our low income clients, Oregon Law Center appreciates many of the new goals and commitments expressed in the current application for 1115 waiver, especially those focused on health equity. These health equity measures represent an important shift in focus to make sure that the benefits of the Affordable Care Act

and Medicaid in Oregon reach all low income communities. We are also grateful for the many important changes that the leadership at the Oregon Health Authority have made over the past 5 years to improve health care and access to health care in Oregon.

However, we have deep concerns that this current 1115 waiver application continues to request permission for Oregon to deny medically necessary and medically appropriate health care to low income Oregonians using the Prioritized List of Services. The current 1115 waiver application aims toward addressing health equity and social determinants of health, but does so on top of a foundation of outdated, inappropriate, and unprecedented health care rationing that undermines those important aims. Oregon cannot build an equitable system of health care while it denies low income Oregonians, including children, medically necessary and medically appropriate health care through the continued use of the Prioritized List of Services. We firmly believe that Oregon should modify the current 1115 waiver application to stop the inflexible use of the Prioritized List of Services, at the very least for children who should have the right to EPSDT. If the state of Oregon intends to go forward with the use of the Prioritized List of Services, it should exclude Early and Periodic Screening, Detection, and Treatment (EPSDT) from adherence to the Prioritized List, and must change the 1115 application to very explicitly require flexibility and individualized decision making in the application of the Prioritized List.

- I. Rationing health care through the use of the Prioritized List of Services is no longer an “experiment” and does not promote the objectives of the Medicaid Act, therefore should not be included in an 1115 waiver application.**

Oregon’s 1115 waiver application asks the federal Health and Human Services agency for permission to provide less health care to Oregonians than they would otherwise be required to provide under traditional Medicaid. In order to justify this (or any) 1115 waiver, the waiver must be an “experimental, pilot, or demonstration project”, and must be found to be “likely to assist in promoting the objectives of the

Medicaid Act.” 42 U.S.C. § 1315(a). The objectives of the Medicaid Act are to enable states to furnish medical assistance to individuals whose incomes and resources are insufficient to meet the costs of necessary medical care and to furnish such assistance and services to help these individuals attain or retain the capacity for independence and self-care. 42 U.S.C. § 1396

Oregon was given approval to waive the minimum requirements of the Medicaid program in 1993 in order to experiment with the use of the Prioritized List of Services in 1993. Originally, the idea behind Oregon’s waiver to limit health care to the Prioritized List was to provide limited health care treatment to low income Oregonians, so that more low income Oregonians to get at least some health care. Providing less health care allowed Oregon to save money and enroll more people (people at a slightly higher income level than was supported by the federal government in 1993) onto the Oregon Health Plan. That original purpose for experimenting with the Prioritized List is gone. Now, Oregon provides the Oregon Health Plan to people up to 138% of the federal poverty level due to the Affordable Care Act, and the federal match money that comes with it.

The state has had ample time to demonstrate how the rationing of health care through the strict application of this Prioritized List has furthered the goals of the Medicaid program. However, the state has not provided analysis or data to demonstrate that this “experiment” is actually promoting the objectives of the Medicaid Act. Oregon has failed to justify the continued use of this controversial aspect of their 1115 waiver which denies medically necessary and medically appropriate health care to low income Medicaid recipients. Without adequate demonstration that this experiment is actually furthering the goals of the Medicaid program, this 1115 waiver application is inappropriate and should not be submitted without modification. The lack of justification for denying medically necessary and medically appropriate health care to low income Medicaid recipients threatens the success and legitimacy of the more recent, important, and admirable other aspects of Oregon’s 1115 wavier application.

**II. Continued inflexible adherence to the Prioritized List of Services and Line of Funding do not support the goals of the Medicaid program or the Oregon Health Authority and should not be included in this renewal application.**

As mentioned above, Oregon's current 1115 waiver application does not sufficiently address how the goals of the 1115 demonstration waiver program are met by the continued use of the Oregon Health Plan Prioritized List of Services that functions to ration health care services to Medicaid recipients in Oregon.

Currently, the Prioritized list of Services is applied with such inflexibility that medically necessary and medically appropriate services are routinely denied to low income individuals who cannot afford to pay for treatment on their own, if their condition requires any variance from the strictly applied list of condition and treatment pairings. This inflexibility and lack of variance procedures results in health care denials that thwart, not promote, the goals of the Medicaid program, and therefore violate the conditions for approval of an 1115 waiver. This inflexibility leaves low income Oregonians to suffer from debilitatingly painful "below the line of coverage" conditions like hernias without surgery that could treat their condition. This inflexibility even leaves low income Oregonians who have a condition above the line of coverage on the Prioritized List (considered a high priority even under the waived program) without adequate treatment because, due to their particular combination of health conditions, the treatments "paired" with their condition on the Prioritized list do not work, and they are denied any other treatment because it isn't paired with their condition on the Prioritized list.

Over the years, it appears that the 1115 waiver applications have de-emphasized the need for individualized decisions when the strict application of the Prioritized List does not allow for medically necessary and medically appropriate health care. This current 1115 waiver application does not address this important deficiency and must be amended. The current 1115 waiver application needs to be changed to include specific instructions requiring approval of medically necessary, medically appropriate

care for OHP enrollees if their particular combination of conditions requires treatment that does not perfectly match the Prioritized List condition/treatment pairings. Without such flexibility, the Oregon Health Plan discriminates against individuals with disabilities and certain conditions, undermines the agency's goals to promote health and health equity, and leaves low income Oregonians to suffer from common and serious health conditions without any treatment.

**III. Oregon should remove from the 1115 waiver application the request to continue to waive EPSDT.**

Oregon is one of the few (if not the only) state in the nation to eschew the foundational Medicaid principle that children should receive medically necessary and medically appropriate health care. Oregon's current practice of denying medically necessary and medically appropriate treatment to children is shocking and violates the federal Medicaid Act by failing to provide health care treatment to those who can't afford it, and promote the attainment of independence and ability for self care. Oregon's waiver of EPSDT hurts low income children throughout our state. Right now, children living in poverty are forced to live with painful and dangerous conditions like chronic ear infections, and conditions with potential lifelong negative impacts like selective mutism, among many others, because Oregon has waived our children's right to EPSDT.

This waiver of EPSDT undermines the other stated goals of the proposed waiver which are to provide equitable access to coverage and improve health through equity measures. We request that the state remove the request to waive EPSDT from the current 1115 waiver application. If the state is unwilling to remove EPSDT from the waiver request, we request that the state include very specific requirements for flexibility and individualized decision making to approve medically necessary and medically appropriate treatment for children even when that treatment does not match perfectly with the Prioritized List of Services condition/treatment pairs.

**IV. The current 1115 application should extend Flexible Services to Fee For Service enrollees, and apply due process protections to requests for Flexible/Health Related Services.**

Oregon Law Center supports the Oregon Health Authority's waiver request to provide Flexible Services/health related services to support low income Oregonians' health. However, it appears from past waivers and the current 1115 waiver application that Flexible services are only available to people enrolled in CCOs. We request that the application specify that the state will make Flexible services available to those enrolled in Fee For Service (FFS) Medicaid as well as those enrolled in CCOs.

Additionally, we believe that the current request for Flexible Services should not be approved unless state specifies that any denials of requests for Flexible Services be afforded the basic due process rights that any Medicaid service would receive – a written denial with an explanation for the denial and an opportunity to challenge it. We know that it is still rare for an OHP enrollee (or even many OHP providers) to know about the existence of flexible services. However, if an enrollee is lucky enough to have a provider ask for such services, but they are denied, the enrollee does not even have a right to know the basis for the denial or have an opportunity to challenge the denial. We request that the state make it very clear in the application for extension/amendment that “health related services” and all “flexible services” are Medicaid services and include basic Medicaid and constitutional due process protections.

If Flexible Services/ Health Related Services are not provided to FFS enrollees, and if enrollees have no legal right to question or challenge a denial of Flexible Services, then this innovative program is furthering health inequity instead of promoting health equity. Many people with disabilities or severe health conditions require enrollment in FFS Oregon Health Plan in order to meet their special health care needs. Those individuals should not be deprived of an important health care benefit solely because they need the flexibility of FFS enrollment. Additionally, the

fact that there is no way to challenge a denial of a request for flexible services deprives individual OHP enrollees of even the most basic ability to question the appropriateness of such a denial. This contradicts the basic principles of due process and means that there is essentially no transparency or accountability in the provision of these services by CCOs. As currently proposed in the 1115 waiver application, the Flexible Services would promote health inequity, and undermine the stated goals of the agency. The application should be changed to include FFS flexible services, basic due process after denial of Flexible Services, and a clear mechanism for oversight and evaluation of the equity impact of approvals and denials of Flexible Services.

#### **V. Comments on Other aspects of the 1115 Waiver.**

Oregon Law Center wholeheartedly approves and applauds other aspects of this waiver application. The incredibly important success of Oregon's Cover all Kids program and the imminent Cover all People program are critical components of OHA's health equity goals. These programs demonstrate strong and ethical leadership by legislators and the agency in Oregon and are an incredibly admirable commitment to equity in healthcare in the state. The proposals in this application to maximize OHP coverage with continuous eligibility for children and adults to minimize health care disruption from "churn" are very important and commendable. Expedited enrollment and more attention during coverage transitions are also critical goals and would be welcome changes to the current system. While we support the provision of health related services and support for social determinants of health, we think it is important to note (as mentioned above) that given the current rationing of health care through use of the Prioritized List of Services, Oregon is proposing to spend Medicaid money on social determinants of health, while denying coverage for the actual determinants of health – actual health care treatment. We firmly believe that Oregon's 1115 waiver application would better achieve its stated goals by providing both adequate medically necessary and appropriate health care and also social determinants of health. We have general concerns about CCO accountability and

measuring whether underutilization is occurring, as well as concerns about whether and how adequate language access is achieved by each CCO, and we wish .

Again, we thank you for the opportunity to provide comment on the current 1115 waiver application and we would be happy to provide more information on any topic mentioned herein, or any other topic concerning the current application.

Submitted on **January 7, 2022** by:

**/s/ Beth Englander**

Beth Englander, Attorney at Law  
Oregon Law Center  
522 SW 5<sup>th</sup> Ave, Suite 812  
Portland, OR 97204  
[benglander@oregonlawcenter.org](mailto:benglander@oregonlawcenter.org)  
503-473-8321

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

**RE: Oregon's Draft Medicaid Demonstration 1115 Waiver Application**

Dear Ms. Hatfield,

The ALS Association of Oregon and Southwest Washington is concerned with the proposal by Oregon Health Authority to potentially restrict access for Medicaid patients to new ALS treatments. We request that you remove "Strategy 3" from the 1115 Medicaid Demonstration Waiver.

Our organization is the central source for services and education for people with Amyotrophic Lateral Sclerosis (ALS), their families, caregivers, and health care professionals in all of Oregon and the six counties of SW Washington. We provide a range of services: direct services to people with ALS including clinics, support groups, access to medical and speech equipment, funding cutting-edge research and generally connecting those whose lives have been impacted by ALS.

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. ALS robs people of their ability to walk, talk, eat and speak; it is always fatal disease with an average life expectancy for of 2-5 years from diagnosis. There is no current cure for ALS, and only a few drugs approved for treating various symptoms of ALS. The pipeline for ALS treatments depends on the FDA accelerated approval pathway, as ALS has a serious condition with unmet needs. Moreover, the short life expectancy of a person diagnosed with ALS makes every second count, whether in research, approval, access and treatment.

Stated plainly, there are very few reasons for people living with ALS and their families to be hopeful following diagnosis. The pipeline for new treatments is one thing they cling to, and the FDA accelerate approval process makes that hope real. Unfortunately, Oregon Health Authority's (OHA) draft 1115 Waiver application would create one more potential barrier for access if OHA determined that it would not cover a new, approved ALS drug. This would be crushing to a patient and family on Medicaid, already inundated with the challenges of coverage while facing a complex labyrinth of health care costs and administration in light of an impossible diagnosis.

While the ALS Association sympathizes with OHA's challenges in containing costs, focusing on the accelerate approval process as a mechanism for restricting access or reducing utilization is dangerously misplaced. The proposed language directly undermines the FDA's scientific approach for determining that a drug is safe and effective (and purports to replace it with a "rigorous state review process" which doesn't exist). Worse, the application specifically refers to accelerate approval drugs as drugs with "limited or inadequate evidence of clinical efficacy" which is plainly false and continues to undermine patients and the public's faith in scientific rigor. The purpose of the accelerated approval



**OUR VISION** Create a world without ALS.

**OUR MISSION** To discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

Main Office: 825 NE Multnomah St, Suite 940, Portland, Oregon 97232  
Phone 503.238.5559 • FAX 503.296.5590 • [www.alsa-or.org](http://www.alsa-or.org)

pathway is to benefit patients with conditions like ALS, where there are unmet medical needs and for those facing with rare diseases. It is NOT a shortcut for rigorous scientific review.

By law (21 U.S.C. § 356(e)(2)), FDA must find "substantial evidence of effectiveness" to approve any drug, including AA drugs. FDA and Congress have both made clear that neither FDASIA's accelerated approval provisions nor the 21<sup>st</sup> Century Cures Act diluted FDA's approval standards. There is no reason (nor evidence) that OHA current infrastructure, including Oregon's "Health Evidence Review Commission" or Pharmacy and Therapeutics Committee has the staff, expertise, resources to duplicate the FDA process. Any such review would be redundant, costing patients valuable time and options where treatments may be available.

Secondly, with rare disease, such as ALS, reducing access to drugs approved through the accelerated approval process won't provide meaningful savings for our state Medicaid program anyway (or at least OHA should demonstrate that it will). According to the American Journal of Managed Care, accelerated approval drugs have accounted for less than 1% of Medicaid spending consistently every year ([https://cdn.sanity.io/files/Ovv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC\\_06\\_2021\\_Thorpe\\_final.pdf](https://cdn.sanity.io/files/Ovv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC_06_2021_Thorpe_final.pdf)). Coupling the scientific rigor of the FDA process and the limited savings, there is no rational reason to seek authority to limit access to drugs for those with rare conditions or no other treatment options.

Further, the waiver application will create even more disparities in care and sends a message to Oregonians that those with high unmet need, rare conditions and needing access to new therapies are a lower priority for full Medicaid coverage. The disparity of care would only be magnified where people with ALS could access a new drug through a private insurance carrier, but low-income Oregonians seeking access through Medicaid may not (or worse, spend valuable time fighting a challenging prior authorization process while their condition continues to progress). While the value of accelerated approval drugs to our community is clear, has OHA provided evidence that excluding these drugs would result in savings to the state system? If not, this is a significant risk to patient access and their hopes and realization of better quality of life with no clearly established benefits flowing to the state.

On a broader scale, these types of proposals only further discourage innovation for diseases like ALS where the only viable pathway to bring a treatment to market is the accelerated approval pathway. With so many conditions where investment and research can provide a quicker (and already more certain) return on investment, OHA's application would only increase our community's challenges in finding researchers and companies who will focus on treatments for ALS.

On a final note, we are also concerned with the request for the state to create a closed formulary. Again, this change is counter to Oregon's purported goal of the 1115 waiver: "to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon." In addition to the few ALS treatment currently available, ALS patients rely on an array of drugs to deal with the myriad symptoms of a degenerative neurological condition. Medicaid patients should have access to the drugs their providers prescribe without OHA preliminarily determining which have more value.

OHA's Section 1115 demonstration amendment request to exclude new drugs approved under the FDA's accelerated approval pathway is misplaced and potentially significantly damaging for patients

with rare conditions and unmet needs. It could very likely lead to perverse disparities in care and limit options for ALS patients on state Medicaid.

We urge you to remove Strategy 3 from the waiver application.

Thank you,

A handwritten signature in black ink that reads "Lance Christian". The signature is written in a cursive, slightly slanted style.

Lance Christian  
Executive Director



January 7, 2022

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

Re: **Oregon's Application for Renewal and Amendment of Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

On behalf of the 300 members of the Oregon Dermatology Society, we are writing to express our strong opposition to a proposal that would restructure the Oregon Health Plan ("OHP") pharmacy benefit to create a commercial-style closed formulary for adult patients, as outlined in Oregon's 1115 Medicaid Waiver Demonstration renewal. The proposal would authorize the state to exclude drugs that have limited evidence, but still have demonstrated clinical efficacy that can be very beneficial to subgroups of patients. The broad guidelines for such determinations will negatively impact the sickest and most vulnerable patients and will conflict with the overarching goal of the waiver renewal to advance health equity. The creation of a closed formulary will only exacerbate existing health inequities by limiting patient access to medically necessary prescription medications.

Our members are keenly aware of the nation's increased health care costs and their own responsibility to prescribe a treatment plan that wisely manages limited

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

health care resources; however, a closed formulary is an ineffective, draconian approach to reducing health care costs by creating a one-size-fits-all solution. If approved, more than 700,000 Oregonians will unnecessarily be at risk, as explained below. Therefore, we urge Oregon policymakers to explore alternative strategies to reduce health care costs. Patients should not be expected to bear this burden.

Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases and many genetic disorders. When developing a treatment plan for our patients, dermatologists base their recommendations and decisions on a thorough understanding of their patients' medical history and medical needs. This knowledge enables them to identify potential contraindications and life-threatening adverse reactions, which is particularly critical for patients covered by OHP, many of whom have multiple chronic conditions. Comorbidity often results in adverse health outcomes and complex clinical management. Requiring a patient to take a medication that the physician knows is not in the patient's best interest and in some instances, will jeopardize the patient's health, not only defies logic but violates the Hippocratic oath.

The American Academy of Dermatology's guiding position on access to effective and affordable drugs is set forth in its *Position Statement on Patient Access to Affordable Treatments*<sup>1</sup>:

*"Physicians should have the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient's unique circumstances.*

*"Each formulary must be developed based on scientifically valid evidence that the selected pharmaceuticals sufficiently provide the most effective therapies for any given condition and that options are available should patients not be able to utilize a given agent due to lack of response, side effects, allergy, etc."*

---

<sup>1</sup> <https://server.aad.org/Forms/Policies/Uploads/PS/PS-Patient%20Access%20to%20Affordable%20Treatments.pdf>

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

A closed formulary will significantly limit the physicians' ability to treat patients with complicated skin diseases, such as cutaneous autoimmune disorders. Forcing these patients to make consequential, potentially lengthy and disease-altering changes is a great challenge and hardship. Withdrawal of a medication for a patient, particularly abrupt withdrawal, can aggravate a quiescent disease and result in disease that is resistant to prior effective therapy or the development of aggressive disease. The consequences, which cannot be predicted for individual patients, include worsening life-threatening disease, severe flares including those requiring hospitalization, therapeutic failure, antibody development and risk for greater adverse effects than those associated with current therapy. For many patients, the disease burden extends beyond physical findings; there is lost work and wages and a significant psychological impact.

A specific example is pemphigus vulgaris, which is a rare, auto-immune disease that causes blistering of the skin and mucous membranes. Treatment typically involves the prolonged use of steroids and immunosuppressive/immunomodulating agents, many of which do not have specific "approved indications" to treat pemphigus. This condition requires a patient-centric customized approach because if it is left untreated, the complications can be fatal. Each patient who presents with this disease is a unique challenge due to the diversity in the disease. Comorbidities, which include diabetes, hypertension, malignancies, chronic infections, among others, affect the choice of the most appropriate treatment.

Additionally, the waiver request will profoundly impact patients with chronic conditions and who are stable on a drug that is no longer included in the closed formulary. Forcibly switching a patient to another drug poses significant risk to patients, possibly resulting in harmful outcomes like flaring of the disease, immunogenicity, adverse effects, and secondary nonresponse. It may also lead to the loss of effectiveness of the original medication, should the patient switch back in the future.

As physicians, our number one priority is the health and welfare of our patients. We appreciate the opportunity to provide written comments on this important issue. Retaining physicians' medical judgement in patients' treatment plans is a cost-effective way to prevent health care dollars from being used on medications that are not effective. We respectfully urge you to carefully consider the ramifications of moving to a closed formulary and reject such provisions of the waiver renewal. Please contact Patrick Sieng, Executive Director for the Oregon

Page 4 of 4

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

Dermatology Society at [patrick@oregondermatology.org](mailto:patrick@oregondermatology.org) or (503) 799-8280 if you require clarification on any of the points above or would like further information.

Sincerely,

A handwritten signature in black ink that reads "A. Bar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anna Bar, MD, FAAD, FACMS  
President  
Oregon Dermatology Society



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

DATE: January 7, 2022

TO: Oregon Health Authority

RE: Protecting Kids under Oregon's 1115 Medicaid Waiver for 2022-2027

The Oregon Pediatric Society (OPS)—the state chapter of the American Academy of Pediatrics (AAP)—is a nonprofit organization representing approximately 700 primary care, medical subspecialty, and surgical specialty pediatricians and child health providers from across the state who are dedicated to the health, safety, and well-being of all Oregon infants, children, adolescents, and young adults. Thank you for the opportunity to provide comments on the proposed Oregon Health Plan 1115 Demonstration Waiver Application for the 2022 – 2027 Renewal and Amendment (December 1, 2021).

First, we acknowledge and thank the Oregon Health Authority (OHA) for the significant thought and commitment to serving all enrollees that have gone into the crafting of this waiver application. Beginning with the original federal waiver from traditional Medicaid rules (granted in March 1993), Oregon remains a national, transformative leader in the delivery of health care due in considerable part to the efforts to build and, over time, revise the Oregon Health Plan (OHP). The goals of this waiver application will expand upon this broad foundation.

The Oregon Health Plan is uniquely indispensable for children, currently serving as a lifeline of coverage to two out of five kids and youth across the state. (According to the Kaiser Family Foundation, in 2019 36.8% of the state's children are on Medicaid/CHIP, as are 49% of Oregon's children with special health care needs). Therefore, any policy changes made to OHP will continue to have an outsized effect on children. With this in mind, OPS applauds numerous provisions of the waiver proposal that will advance health equity, expand access to care, address social determinants of health (SDOH), and do more to strengthen children's health care. At the same time, we call attention to the State's proposals to continue waiving Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit and three months of retroactive coverage, and look forward to working with the state toward a resolution where these critical protections are part of Oregon's Medicaid program. We also want to draw attention to the importance of continuing to expand the capacity of Medicaid oral health and mental health services for children and youth, domains where our State services and access must be improved.

Oregon's pediatricians enthusiastically support the following components of this waiver application:

- **Continuous enrollment for children until age six, and 2-year continuous enrollment for all older than six:** Continuous coverage is enormously beneficial for children and the

9155 SW Barnes Road, Ste. 933 • Portland, OR 97225 • 503-334-1591 • [www.oraap.org](http://www.oraap.org)



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

clinics that provide their care. Research demonstrates that disruptions in Medicaid coverage are common, and this leads to periods of uninsurance, delayed care, and less preventive care.<sup>1</sup> Moreover, children of color are more likely to experience "churning" on and off Medicaid coverage.<sup>2</sup> Moving to uninterrupted coverage during the first five years of life and for two years subsequent to that will have an enormous, positive effect on the ability of children to maintain coverage, courses of treatment, and relationships with their medical homes and specialty and subspecialty care. Moreover, it will help address health inequities caused by churn among families of color.

- **Expedited enrollment for those with SNAP benefits:** This will not only decrease the burden on families applying for different programs, but has the potential to reduce administrative costs to the State, making this a "win-win" policy for Oregon and children and families.<sup>3</sup>
- **Covering all individuals regardless of immigration status:** As pediatricians, we acutely understand the connection between a parent's health and well-being with that of their children. Healthy parents have healthier children, and healthier parents are better equipped to care for and meet the needs of their children. Conversely, parents in poor physical or mental health may not be able to meet their children's needs, and increased family stress caused by ill health or unpaid medical bills can directly affect children. Building on the success of "Cover All Kids," moving to "Cover All People" will help ensure that parents, other caregivers, and extended family are covered by OHP and can receive needed care. This is particularly important right now as many adult immigrants are uninsured and work in jobs where the current pandemic has exposed them to considerable health risk.<sup>4</sup>
- **Providing coverage during life transitions and climate events:** These important steps will ensure that OHP is there for children and families when it is needed most. Of note, extending OHP coverage to youth in the juvenile justice system will provide much-needed care for a population that is at high risk and faces many barriers to reaching full

---

<sup>1</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>

<sup>2</sup> <https://ccf.georgetown.edu/2021/10/08/macpac-research-shows-closing-the-continuous-coverage-gap-for-kids-is-within-reach/>

<sup>3</sup> <https://www.cbpp.org/sites/default/files/atoms/files/9-9-20health2.pdf>

<sup>4</sup> <https://www.shvs.org/wp-content/uploads/2021/10/State-Funded-Affordable-Coverage-Programs-for-Immigrants.pdf>



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

potential, including exposure to adverse childhood experiences (ACEs) as well as unmet physical and mental health needs.<sup>5</sup>

- **Extending OHP coverage at existing income levels to youth with special health care needs (YSCNH) to age 26:** As stated in the waiver amendment application, "[m]any of these [YSCNH] are from communities of color, LGBTQAI+, members of Tribes in Oregon and have experienced homelessness, Intellectual and Developmental Disability (IDD) or poverty." This coverage extension at 305% FPL to age 26 will help with YSCNH transition preparation and ensure continuity of care during this critical time.
- **Providing SDOH services to vulnerable populations in transition:** Focusing on individual and family needs such as housing, transportation, food assistance, and employment supports are a recognition that so much of health care happens outside the medical setting. Health starts in our homes, schools, workplaces, neighborhoods, and communities, and providing these supports will have a significant impact on outcomes for children and their families.
- **Investments in community-based organization (CBO) infrastructure and capacity building as well as statewide health equity initiatives.** Such initiatives will help the state build its capacity to address service needs in places where families live, and better address root causes of health inequities.
- **A "comprehensive accountability structure" to address health inequities, ensure member/provider satisfaction, and protect member access to and quality of care.** Through better monitoring and data collection, this will help OHP identify coverage gaps, address health equity needs, and improve outcomes and satisfaction with the program. Moreover, it is important to note that when examining network adequacy for children, their access to *pediatric* primary, medical subspecialty, and surgical specialty care is paramount. Children are a unique population, and the care they require is unique. Children and adults have significantly different patterns of illness, injury, and death, and children have distinct needs in regard to their anatomic, physiologic, developmental, and psychological characteristics. Access to an adult physician or specialist must not substitute for care by pediatricians or pediatric specialists when measuring network adequacy.

---

<sup>5</sup> <https://publications.aap.org/pediatrics/article/146/1/e20201755/37020/Advocacy-and-Collaborative-Health-Care-for-Justice>



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

However, OPS highlights two provisions of the waiver amendment application that should be resolved:

**Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit is a critical protection and its full inclusion in the OHP would safeguard Oregon children now and for years to come.** EPSDT is a cornerstone of federal Medicaid protection that guarantees all Medicaid-eligible children are screened to assess and identify problems early, and ensures the provision of medically necessary health services to correct or ameliorate those identified health problems.<sup>6</sup> EPSDT is designed to address a broad range of child health needs, including preventive care; physical and mental health; oral, hearing and vision care; habilitative care; and social and emotional development. EPSDT ensures health issues for children are not only identified early *but also appropriately treated*. This protection is critically important for children and youth with special health care needs as well as children in low-income families, who have higher rates of a number of health conditions (such as asthma, heart conditions, hearing problems, digestive disorders, and elevated blood lead levels).<sup>7</sup>

While EPSDT has been historically waived under Oregon's Medicaid program, many children may indeed have had all their health needs met. However, it is not known how many Oregon children have not received timely medically necessary treatment because their needed care was not included in the OHP Prioritized List of Health Services. Returning the protection of EPSDT to Oregon's Medicaid program—in place for Medicaid-eligible children in every other U.S. state—would give Oregon the accountability and responsiveness to ensure that needed care for children occurs, both now and into the future. EPSDT will comprehensively safeguard children's health care in Oregon and protect future children enrolled in OHP. We encourage the state to reexamine this waiver amendment provision with the goal of including all EPSDT services in the OHP program.

We also acknowledge the national health and economic research opportunity that Oregon's unique decades-old EPSDT waiver has created in comparing measurable health outcomes for kids in Oregon with A) those in other states rigorously following EPSDT requirements; and/or B) services delivered in Oregon both under the current system and with EPSDT. If EPSDT is formally reinstated to Oregon's Medicaid

---

<sup>6</sup> <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>

<sup>7</sup> Woolf, S, Laudan A, et al. *How are Income and Wealth Linked to Health and Longevity?* Urban Institute, April 2015. Available at: <https://www.urban.org/sites/default/files/publication/49116/2000178-How-are-Income-and-Wealth-Linked-to-Health-and-Longevity.pdf>



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

program, there would be statewide comparison information available before and after its adoption that might determine system and pediatric population impact. Analyzing historical data with future comprehensive Medicaid EPSDT coverage would help the State and CCOs better understand what pediatric services are now more widely covered and used, benefits and challenges, as well as noting changes to clinical operations.

- **Three months of retroactive Medicaid coverage is essential and must also not be waived.** This longstanding protection—one not offered in the private market but explicitly included in Medicaid—ensures that health care expenses for three months prior to the Medicaid application date are also covered, provided the enrollee would have been eligible for Medicaid. This is particularly important for families who may lose coverage from an employer or face a sudden illness or injury. Eliminating retroactive eligibility could deter beneficiaries from seeking needed care for fear they would be responsible for medical bills they cannot afford. This can result in higher medical costs in the long-term as Medicaid beneficiaries delay seeking care. It could also result in increased rates of uncompensated care as physicians, hospitals, and pharmacies—many of whom may have agreed to provide acutely-needed services even before ensuring Medicaid coverage was secure—are not reimbursed for (some of the) services they have already provided.
- **The proposed drug exclusion raises questions about children's prescription drug coverage:** While we understand the state's concerns over increased costs associated with prescription drugs and appreciate that children will be exempted from the proposed closed formulary, we first question this approach for adults. It is not clear what process would be in place for adults to obtain needed medication should the single drug in a closed formulary not work for that patient. Moreover, we support the medically informed use of prescription drugs with limited or inadequate evidence of clinical effectiveness from coverage. For children, two federal laws, the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) have resulted in enormous strides in our understanding of the safe and effective use of medicine in children, with a significant increase in drug labeling for the pediatric population. However, off-label use of medication in children remains an unfortunate, but necessary component of pediatric practice, as roughly one-half of drugs still have no FDA-approved labeling for their use in children. For special child populations, such as preterm and full-term neonates, infants and children



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

younger than two years, and children with chronic or rare diseases, off-label use of drugs is significant and beneficial.<sup>8</sup>

Finally, we call attention to two specific areas that the waiver application and subsequent OHP services should prioritize for children: oral health and mental/behavioral health treatment, beyond screening.

- **Oral health:** CCOs are responsible for providing oral health services, however children in Oregon continue to suffer in obtaining needed oral health care. A recent study published by Oregon Health and Sciences University found that 40% of Medicaid-enrolled children in our state did not receive any dental services in 2018. Moreover, only 45% of Black Medicaid-enrolled children received dental services that year.<sup>9</sup> Pediatric services like topical fluoride varnish are included in Medicaid benefits, but access is very difficult through dental and primary care offices. OPS hopes to work with OHA and community partners to improve primary care oral health screenings and rates of preventive services.
- **Mental/behavioral health:** As was also commented upon by our partners at the Children's Institute in their 12/16/21 Waiver letter, the American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association recently declared a national emergency in child and adolescent mental health. Exacerbated by the pandemic and the ongoing struggle for racial justice, pediatricians are caring for children suffering from soaring rates of depression, anxiety, trauma, loneliness, and suicidality. While the waiver amendment application includes an increased focus on mental/behavioral health, we believe this or future waiver amendments can go further to advance children's health in this domain.

OPS especially highlights the importance of addressing solutions to aiding growth of child mental health professional services through supporting workforce training, financial incentives, and recruitment in underrepresented cultural populations; , integrated pediatric mental health services in primary care; and comprehensive systems of behavioral health care.

---

<sup>8</sup> <https://publications.aap.org/pediatrics/article/133/3/563/32274/Off-Label-Use-of-Drugs-in-Children>

<sup>9</sup> [https://static1.squarespace.com/static/5d97a4561a002c5b8061d827/t/5e334de678d5f55da08d8733/1580420589070/ocf\\_dental\\_brief\\_200122\\_FINAL.pdf](https://static1.squarespace.com/static/5d97a4561a002c5b8061d827/t/5e334de678d5f55da08d8733/1580420589070/ocf_dental_brief_200122_FINAL.pdf)



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

Thank you for the opportunity to provide comments on this Medicaid waiver amendment; we hope the thoughts of Oregon's pediatricians will be considered as amendments to this proposal. If you have questions for our organization or concerns, please contact me at [julie.scholz@oraap.org](mailto:julie.scholz@oraap.org).

Sincerely,

A handwritten signature in black ink that reads "Julie Scholz". The signature is written in a cursive, flowing style.

Julie Scholz, MBA - Executive Director  
On behalf of the Oregon Pediatric Society

**Name – Christine Kirk, Public Policy and Government Relations Manager**

**Contact information - 503-881-9571, [christine.kirk@oya.oregon.gov](mailto:christine.kirk@oya.oregon.gov).**

**Organization - Oregon Youth Authority – Corrections services for adjudicated and convicted youth.**

**Public Comments for - APPLICATION FOR RENEWAL AND AMENDMENT Oregon Health Plan 1115  
Demonstration Waiver - Draft Application for Public Comment 12/1/2021**

**Date – January 7, 2022**

### Summary

The Oregon Youth Authority is grateful for the opportunity provide comment to the 1115 demonstration waiver. OYA fully supports increased transition supports for youth and young adults in our care, but is not able to support differentiating between OYA and DOC facilities for how coverage is provided for those committed to OYA’s care. Benefits for OYA youth or young adults should be limited to transition services, not full custody episodes.

The Waiver doesn’t articulate our close-custody versus detention very well. We would strongly support the waiver’s ask for youth maintaining OHP in detention, but would not want that for close custody, with the exception of pre-release transition planning. This would put us on par with DOC for the proposal, not detention. It appears that there could simply be some confusion in terms, by using juvenile corrections, which is not defined here nor used. Language usage causes confusion on what is meant, and also causes it to appear that categories of youth, such as convicted youth housed in OYA, or those within OYA over age 19, are left out completely in this plan. Recommendations are provided below to remedy these gaps. The system nuances are better identified when speaking of the adult system and we would recommend modeling the language more after adults, with the exception of detention coverage.

Specific comments -

**Page 18 – With this demonstration authority, Oregon will specifically: a) Retain benefits and/or extend full OHP Plus Medicaid benefits to all youth otherwise eligible for Medicaid upon entering the juvenile correction system throughout the duration of their involvement in juvenile corrections.**

The Oregon Youth Authority is supportive of access to OHP for transition purposes to maintain continuity of care. This includes entering the juvenile justice system (which is detention, not corrections), and other transition points. The statement “throughout the duration of their involvement” would mean covering all OHP eligible services provided by in house medical staff. OYA does not believe that switching OYA youth in correctional facilities to a OHP care model, for their entire care is prudent or responsible. Youth receive medical care from OYA medical or contracted medical specialists within OYA facilities. OYA pays for regular external care. If a youth is admitted to a hospital, OHP covers those costs. While this section detail isn’t explicitly stating that current OYA medical services structure will change to an OHP funded model, OYA wishes to call out, that replacement of current services and standards of care within, to an OHP model is not appropriate.

OYA concerns are as follows if the statements here mean that internal OYA care would be managed within an OHP model or CCO.

- 1) Negative impact to current OYA Medical Services level of care – unlikely youth will receive the same level of care they are receiving at OYA currently.
  - a. Youth come in with severe issues that need to be immediately addressed upon admission. These issues are not always covered by OHP while the youth was in the community because OHP only covers medical conditions that are on the prioritized list.
- 2) Eligibility to be up to date on youth medical status
  - a. How would this function in the facility?
  - b. Would the CCO's be managing youth care vs. our internal OYA Health Services staff? Youth would have to be transported, every time, to health care providers that work in the CCOs and this would be a burden on facilities.
    - i. Concerns with losing that OYA Health Services care oversight and level of care. We provide health care services that are medically necessary and not always covered under the OHP prioritized list.
  - c. Administrative concerns for having to bill OHP for care youth received – this would be a substantial administrative burden to OYA and would result in the need for additional staffing.
  - d. Some providers refuse to take the OHP rates and can choose who they will and will not accept, especially for specialized providers in rural areas.

OYA would prefer that we keep the OYA Health Services in the facility as is but can use this new eligibility to cover services we aren't able to cover to be able to set up youth transitioning out of our care to have providers identified, appointments scheduled and prescriptions continuing without lapse upon release.

Note the term juvenile corrections system is a bit confusing – what does that mean? OYA provides corrections services, but youth enter into detention or jail, may be committed to OYA or DOC, and then housed at OYA. OYA is the only juvenile corrections entity in Oregon, but there are others that house and detain youth (committed crime before 18, adjudicated in juvenile court or convicted in adult court prior to 20, and under the age of 25 when in a correctional facility). We welcome the opportunity to partner with OHA to develop understandable consistent language that captures intent and creates clear implementation.

### **Page 53 - Youth in custody of Juvenile Corrections placed in secure facilities**

The secure facilities that may house youth are detention, jail (if over 18 awaiting pretrial for a crime committed before 18), a close-custody facility, and a camp or transitional facility run by OYA. All need to be included. In addition, youth can be convicted in adult court. They are committed to DOC but temporarily housed with OYA. The language needs to be inclusive of convicted youth. In addition, youth in OYA can be there up until their 25<sup>th</sup> birthday. The juvenile language must be inclusive of the age of all in custody. If this is not possible, the adult sections of the waiver need to include what the court sees as a youth in the care of the Oregon Youth Authority and sheriff's. It may be more appropriate to limit this section to pretrial and create a new section for OYA, that mirrors what is written for DOC.

**Adjust language to:**

**Description** - Youth in custody (pre- and post- adjudication and conviction) of detention, jail and Juvenile close-custody, camps and transition facilities and reside in a detention, jail or juvenile close-custody, camp or transitional facility or detention facility, such as those managed by the county juvenile departments, county sheriff's or Oregon Youth Authority and local or county juvenile department, who either enter with current OHP enrollment or become enrolled while in custody.

**Standards and Methodology** - Youth must be residing in a detention, jail, or close-custody, camp or transition facility under the jurisdiction of the Oregon Youth Authority, sheriff or county/local juvenile departments. Eligibility is determined pursuant to 42 CFR as implemented through the Oregon Administrative Rules Section 410, Division 200. The child must be considered a juvenile by the courts and under the age of 25 19, meet the income standards for the eligibility determination group, and meet the non-financial eligibility criteria based on the program. Eligibility will be determined through the use of community- based application assistors or trained agency staff using the Oregon Eligibility (ONE) system. The exception will be for youth in the legal custody of Child Welfare. Child Welfare youth will continue to assign OHP eligibility using the ORKids system. When applicable, notification of OHP eligibility and CCO enrollment will be communicated to the receiving CCO via the 834-enrollment file followed by subsequent community provider assignments.

**Projected # of Individuals** 580 130 individuals, annually (It is unclear where 130 would come from. This number seems small if looking to all the youth entering detention and releasing, those ageing out of detention and awaiting trial in jail, and all of those going into and outside of OYA care (that could be both committed to OYA and DOC).

#### **Adults incarcerated and in custody of the Department of Corrections**

As noted above, there are youth that are incarcerated as adults and committed to the custody of the Department of Corrections that are temporarily assigned to OYA. These youth may spend 100% of their custody time with OYA. This section should be amended to read DOC and OYA both, to be inclusive to all populations. Otherwise convicted youth risk being left out of this all together and they have significant transition needs due to their length of incarceration.

It is specifically this section, as written only for DOC, that should be mirrored for OYA close-custody, camp and transition facilities, as opposed to OHP coverage within facilities for their entire commitment. This section better matches for OYA than the previous juvenile section. This would increase the numbers served within this section to include those in OYA facilities.

**Page – 71- 72**

#### **Youth in custody of Juvenile Corrections placed in secured facilities Full OHP benefit package –\**

- What does juvenile corrections mean? Detention, close-custody, camp or transition facility of OYA? What about jail? The lack of clarity makes this waiver very difficult to understand and ensure all youth have access to equal services.
- OYA cannot support in custody youth being transported by someone other than OYA for outside medical appointments.
- Does this mean that they are limited to the OHP benefit package in a close-custody facility? Does this mean a CCO has to provide the service not OYA medical staff? Does this mean that they have to be transported out of a facility for care? OYA cannot support limits to care within

facilities, a new billing model for services other than transition within facilities, nor outside transportation or increased transportation costs.

**Page 72 – Youth Transition to Adulthood 17-26 Special healthcare needs.**

- Please provide clarity in who this pertains to and if includes those in secure facilities.

**Page 64 – Oregon Health Plan Coordination Benefit Package for individuals in custody**

- OYA fully supports this section. This further indicates that the language on page 53 should be adjusted to align with this model. Possibly add a section for youth that are committed to OYA or DOC and temporarily housed at OYA, separating out OYA from the pre-trial status' and DOC housed adults.

**Page 69 Changes to Benefits by Population**

- Recommend that a mirror section to “Adults incarcerated and in the custody of the Department of Corrections” be created for adjudicated youth committed to OYA and convicted adults committed to DOC and housed in OYA.
- Youth in custody of Juvenile Corrections placed in secured facilities – This section would be best limited to those in detention and jail. Then create a new section as noted above, so OYA has mirror language to DOC, vs pre-trial detainee status.



January 6, 2022

Oregon Health Authority

Re: Comment on 1115 Demonstration Waiver Concept Papers

Submitted online via: [1115.WaiverRenewal@dhsosha.state.or.us](mailto:1115.WaiverRenewal@dhsosha.state.or.us)

To our partners at the Oregon Health Authority:

On behalf of Project Access NOW (PANOW), I write to express our gratitude for your work on the 1115 Waiver Demonstration concept papers. PANOW is a non-profit in the tri-county area with a mission to improve our communities' health and well-being by creating access to care, services, and resources for those in need. We offer a suite of programs that promote access to care and social services, regardless of an individual's insurance status or type. Across PANOW programs, clients are low-income, from immigrant populations, non-English-speaking, and/or undocumented. **Today roughly 65% of our clients identify as Black, Indigenous, or people of color. Over 90% of the staff are bilingual and/or bicultural and roughly 60% are first- or second-generation immigrants, reflecting the communities the organization serves.**

We have read the policy concept papers and are in support of much of the strategies you propose. Specifically, we want to show our support of and recommendation for a few strategies within the following concept papers:

### [Ensuring Access to Health Insurance for All People In Oregon](#)

We are supportive of each of the strategies outlined, in particular:

- *Strategy 2: Two-year continuous OHP enrollment for people age six and up, even if their income changes*

Through support and active implementation of policy change, such as the Affordable Care Act and Cover All Kids, **Project Access NOW has partnered with the state and others to enroll over 19,000 individuals in health insurance over the last 3 years, most of whom identify as Black, Indigenous, or people of color.** Over the past year, the temporary federal rules that ceased mandatory annual verification of income and other eligibility criteria has meant individuals can remain insured, have access to preventive services, and not worry that a change in employment means loss of access to healthcare. These protections have been especially valuable as the pandemic continues to evolve, resulting in a quickly changing and unpredictable social and economic landscape.

As an organization working every day with the communities most affected by these challenges, we believe this strategy would help extend the benefits we've seen during the pandemic and avoid the churn that often happens when people move, an application gets lost in the mail, or due to

translation and administrative challenges. **Language barriers and missing paperwork should not be a reason eligible people do not have access to healthcare.** Not only is this unjust, but costly as well. According to research from the National Institute of Health, nationally the value of uncompensated health care services provided to persons who lack health insurance is roughly \$35 billion annually.

- Strategy 3: A fast, easy way to get enrolled in OHP for people who apply for SNAP  
During 2019-20 Project Access NOW partnered with DCBS to enroll individuals in unemployment benefits who were already seeking eligibility for OHP. Through this program we were able to cross-enroll individuals, improving the efficiency of not only non-profit staff time, but the individual's time, and minimizing potential trauma associated with asking personal questions about income, etc for multiple applications.
  - **Recommendation:** include OHP enrollment for other public programs beyond SNAP such as unemployment benefits and WIC.
  - **Recommendation:** Ensure the ONE system is capable of supporting cross-enrollment of programs, minimizing burden on application assisters system wide and avoiding duplication of questions for clients/patients.

### Improving Health Outcomes by Streamlining Life and Coverage Transitions

We are supportive of each of the strategies outlined, in particular:

- Strategy 3: Providing social supports to members experiencing life transitions  
Since 2016, Project Access NOW has partnered with the CCOs in the tri-county area to administer health-related service dollars for the CCO's members, including during the 2020 and 2021 heat waves, 2020 Oregon Wildfire emergencies, and pandemic housing crisis. The CCO determines who and what good is "in scope" and PANOW acts as the third-party administrator to connect the member with the item/service identified, often within hours of the request. Since its inception, PANOW has facilitated the delivery of over \$22 million in health-related services (such as emergency housing, transportation, and food assistance) in collaboration with our CCO partners. **This method of HRS dollar distribution is highly efficient because the collaborative model funds more than just the administrative process; it pays for the resource directly and avoids the lengthy, burdensome, and often unsuccessful referral process normally associated with accessing these services.**
  - **Recommendation:** It is important that the difference between funding for the maintenance and operation of the tool that supports referrals to a service/good and funding the cost of the actual good itself is clarified. In the current concept paper, both the "linkages" to a social resource (transportation or community-based food) **and** the resource itself are listed as options the CCO can pay for. Given the ease and low cost associated with referring relative to paying for a good/service, it is likely that referring out to another entity will be incentivized rather than paying for the good/service itself. If we are to ensure people have access to the services they need to get and stay healthy, investment in the referral alone – without payment for the underlying resource – will likely not in fact improve outcomes.

- **Recommendation:** *It will be important to articulate if Medicaid – CCOs – are meant to develop the infrastructure/staffing to support these transitions or if this can be outsourced to another CBO, with support from the Medicaid system. CBOs can and should be integrated into this process as they not only have the connections and built trust with clients but also in many cases (like ours) have already developed the infrastructure, networks, and workflows to access these resources efficiently.*

- **Strategy 4: Covering more providers outside the medical model**

In the context of today’s racial/ethnic disparities in both COVID-19 cases and vaccination rates, the role of the CHW has become increasingly important, but often does not fit within the classical medical model for lack of mentorship, appropriate supervision, and financial incentive to enter the field. Many CHWs are left isolated, underutilized, or cannot stay employed due to lack of a living wage, at the same time that we watch disparities widen.

- **Recommendation:** *Ensure the roles articulated in the concept paper – Traditional Health Workers, Community Health Workers, navigators – are covered at a livable wage rate to promote the quality and quantity of these positions in our state. Expanding infrastructure so CHWs can provide services directly to OHP members and support for capacity building cannot be overstated. Engaging folks from rural communities and people of color should be a top priority moving forward as community members feel safe when they see health care workers that look like them.*
- **Recommendation:** *If payors are required to focus on equity (and supporting THWs specifically), indicating where these funds come from is imperative. Building infrastructure, sustainable payments to these types of roles, and credentialing is a necessary step in implementation that is currently missing. It should be clear that this work is resourced as part of a CCOs global budget and/or separate funding needs to be earmarked for these services.*

- **Strategy 5: Invest in CBOs/health equity spending**

We understand the 1115 Waiver renewal is an integral part of a statewide strategy designed to center equity. However, we are concerned that multiple layers of additional administration are potentially being built “to support infrastructure for health equity investments.” There is a vast network of CBOs, Regional Health Equity Alliances, and CCO Community Advisory Councils in existence currently. CBOs have been a leading voice in the fight for health equity and equal access to health care. CBOs also have substantial trust in the community and are best positioned to provide culturally- and linguistically- appropriate outreach to communities, particularly those who are not currently engaged in the healthcare system. If CBOs are the last to receive the “trickle down resources” from the Waiver, our state will fail to support the individuals most at risk of poor health outcomes. This has implications for Oregon’s post-pandemic economic recovery, our ability to return to “normal,” and [Oregon’s goal of eliminating health inequities by 2030.](#)

- **Recommendation:** *We encourage the use of existing forums/channels, such as CCO Community Advisory Councils (CACs) and/or Regional Health Equity Coalitions, to drive community-level investment to avoid creating additional administrative overhead, and to ensure the largest investment can reach those who need it: the clients served by the CBOs.*



- *Recommendation: Consider creating learning space for CBOs that have established themselves in the healthcare space to leverage connection and partnership with health systems in support of younger/newer CBOs.*

We recognize you are submitting concept papers on behalf of all Oregonians and are grateful for the work you are doing to hear a variety of perspectives. We look forward to continuing to be a partner in helping achieve equity.

Thank you,

Carly Hood-Ronick MPA, MPH  
Executive Director



## **Patients Rising Now's Comments on Oregon's 1115 Waiver and Impact on Access**

The FDA's Accelerated Approval Program provides a path for earlier approval of drugs being developed to treat serious diseases and address unmet medical need. The process allows the use of a surrogate endpoint—an indirect marker of clinical benefit that allows the drug to be approved and in the hands of patients earlier, while the company continues to conduct post-marketing “confirmatory trials” to establish the drug’s benefits. It is important to understand that the FDA has processes in place to remove the drug from the market in case clinical benefit is not established with confirmatory trials.

### **Oregon's 1115 Waiver Will Block Much-Needed Access to These Drugs**

Oregon is asking to waive a key criterion that requires coverage for all FDA-approved drugs under the Medicaid Drug Rebate Program. If the waiver is approved, Oregon's Medicaid program would have a closed formulary for all adults, meaning there may only be one drug for each therapeutic class included in the formulary—a common restrictive strategy followed by commercial health plans. The decision for formulary inclusion would be based on the drug's price and the rebate being offered by the manufacturer. There are no exceptions or protected drug classes—unlike the closed formulary demonstration program that has been piloted by Tennessee Medicaid. Additionally, there is no mention of a process for enrollees to seek coverage for drugs not included in the formulary.

Oregon excludes coverage for children from its waiver request, undermining its stated justification of a waiver for a program for adults. The waiver gives Medicaid the power to decide which drugs have limited clinical benefit or “no incremental clinical benefit” compared to other drugs in the same class, even if they are approved by the FDA—this includes drugs that have received accelerated approval. This means that the Oregon Health Authority, may undermine and question the rigorous scientific and regulatory drug approval processes implemented by the FDA for the sake of cost savings.

Importantly, the proposed restrictive closed formulary will create access barriers for patients with chronic and debilitating conditions seeking prescription drugs and in turn have an adverse effect on their health outcomes. Patients Rising strongly opposes the implementation of such a restrictive program for Medicaid beneficiaries in Oregon—employing such policies will barricade patient access to innovative, life-altering treatment options.

Sincerely,

A handwritten signature in black ink that reads "Terry M. Wilcox". The signature is written in a cursive, flowing style.

Terry Wilcox  
Co-Founder & Executive Director, Patients Rising Now



PacificSource Community Solutions  
PO Box 5729, Bend, OR 97708-5729  
800.431.4135  
CommunitySolutions.PacificSource.com

January 7, 2022

Health Policy and Analytics, Medicaid Waiver Renewal Team  
Oregon Health Authority  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

Delivered electronically: [1115Waiver.Renewal@dhsola.state.or.us](mailto:1115Waiver.Renewal@dhsola.state.or.us)

**RE: PacificSource Community Solutions Comments on 2022-2027 § 1115 Medicaid Demonstration Waiver Draft Application**

Dear Ms. Hatfield:

The PacificSource companies are independent, not-for-profit health insurance providers based in Oregon. We serve over 500,000 commercial, Medicaid, and Medicare Advantage members in four states. PacificSource Community Solutions (“PacificSource” or “we”) is the contracted coordinated care organization (CCO) in Central Oregon, the Columbia Gorge, Marion & Polk Counties, and Lane County. Our mission is to provide better health, better care, and better value to the people and communities we serve.

Thank you for the opportunity to provide comment on the Oregon Health Authority (“Authority”) draft application for the next § 1115 demonstration waiver with the Centers for Medicare and Medicaid Services (“CMS”). As with our previous correspondence to the Authority regarding the draft concept papers, we divided our comments into sections for ease of use and navigation.

**Table of Contents**

Opening Comments .....	2
Comments on Sections .....	4
Section I. Program Description.....	4
Section II. Waiver and Expenditure Authority .....	10
Section III. Eligibility .....	11
Section IV. Benefits and Cost Sharing .....	11
Section V. Delivery System and Payment Rates .....	12
Section VI. Finance and Budget Neutrality .....	12
Section VII. Implementation Plan .....	12
Section VIII. Evaluation Plan .....	13
Section IX. Quality Strategy .....	15
Section X. Strategies to Align with Tribal Partners’ Priorities .....	15
Section XI. Public Notice .....	16

## Opening Comments

In our initial comment letter to the Authority dated June 22, 2021 (first comment letter), we pointed out how Oregon pioneered the approach to serving Medicaid members. It is worth reiterating here that in the state's 2016 waiver renewal, the application noted that "Oregon's current [waiver] began groundbreaking health system transformation through the coordinated care organization model." The CCO model, the application noted, "is more financially sustainable and has already accrued significant savings to the federal government[.]" More importantly, the collaborative approach has allowed Oregon to address key health indicators, like decreased emergency room visits and hospital admissions for short-term diabetes complications, while increasing member satisfaction and primary care access. As the Authority continues this successful demonstration, we must not lose sight of the fact that at its core, the Oregon Health Plan must deliver timely, cost-effective health care for Oregonians.

In addition to taking on responsibility for physical, oral and behavioral health care, this pioneering program also tasks CCOs with broad responsibility for addressing social determinants of health for members of the Oregon Health Plan. Addressing social determinants of health mirrors our commitment to provide better health, better care, and better value to the people and communities we serve. We carry out this commitment by establishing local health councils, who govern our work as a CCO and also make community-driven reinvestment decisions. While we helped stand up these health councils, we only retain one seat out 15, meaning that we do not exert control over the direction of community investments made by the health councils. Investment funds derive from our decision as a nonprofit to cap margins at two percent, freeing resources for community investment. We also share half of the Quality Incentive Metric funds with the health councils, who may use the funds to make additional investments in the community. Investments made by the health councils may be rooted in addressing issues adjacent to the Oregon Health Plan, but can potentially benefit the entire community. Consider the following:

- Through our support of and under the strategic direction of the Columbia Gorge Health Council, the local community has made over than \$11 million in key investments focusing on housing, food, transportation and mobility; equitable access to health care and services, fostered social connection and communication, and supported services for vulnerable youth.<sup>1</sup>
- Similarly, over the course of ten years the Central Oregon Health Council invested over \$35 million in such initiatives as permanent supportive housing, integrating primary care and behavioral health care, increasing access to fresh foods, and establishing crisis stabilization centers.<sup>2</sup>

Adding up these shared savings and the health council portion of the quality incentive metric funds, we can point to over \$100 million in community investments over the course of ten years.

---

<sup>1</sup> See Columbia Gorge Health Council, *Programs We Support* (available at <https://www.cghealthcouncil.org/programs-we-support/>); Central Or. Health Council, *Community Investment Profile* (available at [https://cohealthcouncil.org/wp/apps/uploads/2020/02/community-inves\\_44347887.pdf](https://cohealthcouncil.org/wp/apps/uploads/2020/02/community-inves_44347887.pdf)).

<sup>2</sup> See Central Or. Health Council, *Community Investment Profile* (available at [https://cohealthcouncil.org/wp/apps/uploads/2020/02/community-inves\\_44347887.pdf](https://cohealthcouncil.org/wp/apps/uploads/2020/02/community-inves_44347887.pdf)); *Funded Initiatives* (available at <https://cohealthcouncil.org/funded-initiatives/>).

This brings us to concerns about how the application characterizes to the extent CCOs invest in their local communities. Throughout the application, the Authority argues that CCOs have not markedly increased spending on “health related services,” noting that on average 0.7% may be attributable to HRS.<sup>3</sup> As we noted in our first letter, CCOs can only administer health-related services under the strictures developed by the Oregon Health Authority. We observed then that a number of requirements established by the Authority can make health-related services expensive and cumbersome to administer, as well as impede broader use or adoption of health-related services. While these requirements are well intentioned (like requiring a tie to a treatment plan), we noted that they can have unintended consequences. Providers that become well versed with health-related services maximize use of these funds, but other providers may not have the staff or inclination to access these funds. This can have unintended, inequitable outcomes. Perhaps outside of the waiver process, the Authority may convene a truly collaborative effort with CCOs and other stakeholders to examine and make recommendations on HRS spending.

Furthermore, we noted in our first comment letter that while CCOs do their best to administer health-related services in a manner consistent with regulations, CCOs find out months after an expenditure whether such expenditure qualifies for favorable treatment by the Authority. Lastly, because health-related services (including community-based health-related services) require a high degree of compliance, CCOs devote considerable administrative supports to assisting communities in navigating these requirements. For the PacificSource CCOs, we have seen our community shared savings model operate in a manner that achieves the objectives of community-based health-related services with less administrative cost and more community decision-making.

Thus, while 0.7% may be an accurate representation of spending that meets HRS regulatory requirements to be counted as such, this figure does not broadly account for all the community investments CCOs undertake.

Providing timely, cost-effective health care is a complex undertaking, and Medicaid managed care is indeed complex. Through this application, the Authority proposes to take on matters far outside of the conventional direct medical care delivered and paid for by CCOs. In our first comment letter, we touched on the “Oregon Way” of policy development – that is to say, a collaborative approach with a multitude of stakeholders and the public. We noted that the Oregon Way works not only across regions and sectors, but also across the branches of government. In that first comment letter, we stated it was crucial that the Authority involve state agency partners like the Oregon Housing and Community Services Department, the Department of Environmental Quality, and county and city governments. For example, in order for the state’s Alcohol and Drug Policy Commission to develop a strategic plan to reduce Oregon’s substance use disorder rate through prevention and recovery, no less than eleven agencies assisted the Commission in inventorying the current system for addressing substance use prevention and treatment.<sup>4</sup>

---

<sup>3</sup> See Or. Admin. R. 410-141-3735.

<sup>4</sup> See Or. Alcohol & Drug Pol. Comm., *2020-2025 Oregon Statewide Strategic Plan* 68 (available at [https://www.oregon.gov/adpc/SiteAssets/Pages/index/Statewide%20Strategic%20Plan%20Final%20\(1\).pdf](https://www.oregon.gov/adpc/SiteAssets/Pages/index/Statewide%20Strategic%20Plan%20Final%20(1).pdf)).

We understand now that at least some interagency work is underway, so we would ask the Authority to take into account how state services provided by multiple agencies will be delivered seamlessly for Oregonians. For example, portions of the expanded waiver clearly impact the mission of the Oregon Housing and Community Services Department (OHCS), who administer several programs meant to address homelessness prevention. We believe that the Authority and the OHCS should ensure that the involvement of the health care system in homeless prevention does not create “wrong doors” or barriers to Oregonians seeking assistance. Likewise, the application should be clear how when youth and adults in custody receive health care through the corrections systems, or through the health care system to prevent the kinds of system overlap that can lead to gaps in coverage.

Finally, we foresee great challenges ahead in building and sustaining a capable workforce that delivers direct health care to Oregon Health Plan members. We expect to see an emergency funding package for behavioral health providers introduced in the 2022 short legislative session in Oregon, but those efforts will need sustained action to maintain the workforce. As we develop metrics that focus on vulnerable members, those metrics will place further stress and demand on providers. None of us – the CCOs, the Authority, or other community partners – can realize the lofty goals of the demonstration waiver without skilled professionals in the community to carry out the work.

## Comments on Sections

### Section I. Program Description

On [page 5](#) of the draft application, regarding the research hypotheses, we agree with the Authority that measuring improvements in care delivery may provide a better picture than measuring savings.

On [page 6](#) of the draft application, we believe that the Authority missed an opportunity to highlight the significant social determinants of health initiatives that CCOs perform. In addition to the work we outlined above on page 2 regarding community-driven investment, CCOs have knitted together community resources through the Connect Oregon initiative.<sup>5</sup> Connect Oregon acts as a network of health and social service providers, ensuring that CCOs and community-based organizations can connect CCO members with needed services. Likewise, the application could have highlighted the work CCOs accomplish through individualized care management – i.e., directly working with members to connect them to housing, food, transportation, and utilities; following through with medical needs like filling prescriptions, and helping arrange for health care appointments or to find behavioral health, dental and medical providers. Our teams frequently tailor a care plan and approach with members based on individual needs.

On [page 10](#) of the draft application, regarding the effect of state controls over the cost of growth in federally-regulated Medicare Advantage plans, we raise again – as we did in our initial comment letter – that it is unclear how the Authority can make changes in the Medicare Advantage market that would have the effect of controlling cost growth in that market. Federal

---

<sup>5</sup> Connect Oregon, (available at <https://oregon.uniteus.com/>)

law preempts states from regulating Medicare Advantage plans, with the exception of chartering the entities that may offer the plans and regulating those entities' financial solvency.<sup>6</sup> Given that contract requirements are established and enforced by CMS, and payments come substantially from federal funding, it seems unlikely that CMS will also waive regulations to allow the Authority to establish substantive regulation over Medicare Advantage plans.<sup>7</sup> It seems unreasonable to expect that Oregon could effect a reduction in Medicare Advantage plan spending that would accrue to the federal government.

On page 15 of the draft application, as an initial matter, we believe that maximizing coverage in the Oregon Health Plan is impacted as much by ensuring that currently-eligible people enroll in coverage, as it is broadening the criteria for eligibility. We support public-private partnerships like the one with 300 organizations and 1,500 individual assisters to support members in enrollment.<sup>8</sup> As the Authority considers how to bolster its capacity to determine eligibility, funding can allow community partners to take on the work of navigating the Oregon Health Plan enrollment process or timely transition members to commercial coverage if the person no longer may receive Oregon Health Plan benefits.

On page 16 of the draft application, we note in support of continuous enrollment that this change may allow members with complex treatment needs to establish a plan before they face potential disenrollment. Members must arrive at a place of trust with their providers, and care managers must take the time to learn a member's prioritized need and goals. For example, continuous enrollment would assist CCOs with members presenting with severe and persistent mental illness, members with substance use disorders, and members with chronic medical needs or unmet oral needs.

On page 17 of the draft application, we believe that as part of a comprehensive plan to ensure that people in the custody of an institutional system retain Oregon Health Plan benefits, the Authority also consider robust data sharing and coordination processes. Planning in parallel with the policy ask, and building on the successes of data sharing in other contexts, will help ensure that this idea succeeds in practice.

On page 20 of the draft application, we believe that the intent of the request is to ensure that a youth with special health care needs would automatically transition from youth benefits to adult benefits. If that is the case, we support efforts that would make the transition for this vulnerable population more seamless.

On page 21 of the draft application, we remain unclear on what basis the Authority will determine eligibility for services. Setting and determining eligibility could potentially extend benefits to hundreds of thousands of Oregon Health Plan members. We would ask that the Authority establish a broad-spectrum workgroup, including CCOs and community, to establish practical eligibility criteria.

---

<sup>6</sup> See 42 C.F.R. § 422.402.

<sup>7</sup> See Nat'l Ass'n of Ins. Commissioners, *White Paper on Regulation of Medicare Private Plans* 20 (Sept. 10, 2008) (available at [https://www.naic.org/documents/committees\\_b\\_senior\\_issues\\_medpp\\_white\\_paper\\_final.pdf](https://www.naic.org/documents/committees_b_senior_issues_medpp_white_paper_final.pdf)).

<sup>8</sup> Or. Health Auth., *Oregon Health Plan Certified Community Partners* (available at <https://www.oregon.gov/oha/HSD/OHP/Pages/Community-partners.aspx>).

On page 22 of the draft application, CCOs in rural areas may not be able to marshal transportation resources for members in ways that may be practicable in urban areas. For instance, because in Oregon local jurisdictions regulate the practices of transportation network companies (TNCs; i.e., ridesharing), many cities may not even allow the practice within their limits. Only three jurisdictions in the state contain mass transit districts considered by the American Public Transportation Association as “larger transit agencies” – Portland, Salem and Eugene.<sup>9</sup> This means that in rural areas, CCOs may need to rely more on non-emergent medical transportation, which do not benefit from the efficiencies of scale that public transit or broadly-available TNC coverage may offer, and are thus an expensive option to provide transportation. CCOs may also be in a position to have to deny benefits for transportation in rural areas. We believe the application should acknowledge that real challenges may exist in the cost-effective provision of this benefit in rural areas.

On page 28 of the draft application, we first want to draw attention to our earlier note concerning community-driven investment. The premise contained within the application – that changes to the capitation model are needed because CCO spending has not markedly changed – depends on a narrow interpretation of health-related services spending. CCOs engage community partners in a variety of ways including Quality Incentive Metrics performance activities, investments in clinical programs, ways to increase access to non-clinical goods and services, and broad-based community-based investments. Not all of these qualify as “health related services,” but they do create meaningful ways of involving broad stakeholders in how CCOs prioritize their work. We recommend that we build upon or adapt the committees, workgroups and partnerships CCOs currently support to further the objectives listed in the bullets on pages 28 and 29.

On page 29 of the draft application, we have a number of questions about how the base budget is to be calculated under the concept in the application. Overall, we note that the draft application does not speak to the actuarial soundness of the base budget or the budget trending forward. More particularly, five-year-old data may be pretty stale; consider the state of the economy and the health care sector in 2016. If older historical data establishes the rates, the capitation process runs the risk of insufficient funding, necessitating more dramatic adjustments to adjust to present-day needs. Utilizing data that reflects membership during the federally-declared public health emergency similarly skews the data. Next, extending the base rate out over two biennia places extreme significance on what assumptions the Authority selects as part of historic trend. Furthermore, considering how frequently Oregon and the federal government make changes to benefits, policy and program changes, it seems likely that the assumptions may have to be adjusted to be appropriate for the projection period. Generally the Oregon Health Plan membership population provides reasonably predictable historical data on which to base budgets. However, five years may be too long of a time period to make inferences, even if the goal is increased stability.

Finally, the second bullet notes that the budget would include HRS spending over a period of five years. We would note that unless the budget takes into account year over year spending,

---

<sup>9</sup> See *Amer. Pub. Trans. Ass'n*, Oregon Transit Links (available at <https://www.apta.com/research-technical-resources/public-transportation-links/oregon/>).

using five years of historical data on HRS could result in less funding. We should also note that a “predictable” budget for social determinants of health services would likely entail a capitated rate to CCOs for a member’s needs. CCOs will have the task of balancing costs that go to behavioral health, physical health, prescription drugs, and community investments.

The majority of our comments on the community investment collaboratives may be found on page 9 of this comment letter. However, here we do wish to raise a question with respect to how a recent Oregon law affected this application. Under Oregon law, a “global budget” is the “total amount established prospectively by the Oregon Health Authority to be paid to a CCO for the delivery of, management of, access to and quality of the health care delivered to members of the CCO.”<sup>10</sup> In 2021, the Oregon Legislative Assembly enacted House Bill 3353, which directs CCOs to spend “up to three percent” of its global budget on among other things, programs or services that improve health equity – which we should point out may be well beyond what the health care community traditionally considers health related services.<sup>11</sup> It is unclear from the application whether or not the Authority plans to prospectively pay CCOs this percentage as directed by state law, or if a CCO that did not spend three percent or more on items enumerated in the legislation would see an upward adjustment to the global budget to account for Oregon law. Finally, we do request clarification if it is the Authority’s view that House Bill 3353 affects the actuarial soundness of rates.

On page 30 of the draft application, regarding the proposal to trend the base rate forward in a predictable way over five years, we can envision a scenario where the Authority establishes the CCO global budgets utilizing data from a five-year span, then informing rates in the upcoming five-year span. This results in potentially an 11-year window between adjustments. For context, this idea would be akin to using pre-CCO era data to inform next year’s rates. This long timespan has the potential for the base data to be very different from the projection period, requiring many adjustments along the way.

In terms of the request to trend the base budget at the statewide health care cost growth target, it is worth noting that the cost growth target program contains relief valves for “justified” variations in health care cost growth beyond the 3.4% target. This is essential to acknowledge for the base budget, because wholly unanticipated events could occur years out. For example, the ongoing COVID-19 pandemic drove dramatic increases in demand for certain types of health care services. This demand, along with a multitude of other pressures, has led health care providers – those providing behavioral, dental, or physical health care – to resign in greater numbers amidst ‘Great Resignation,’ so success in recruiting and retaining staff has become essential. As salaries increase to maintain enough providers, CCOs could well experience cost growth exceeding 3.4%. A budget that is fixed at a 3.4% rate of growth will need more than targeted rate adjustments.

Turning to the portion of the request that details a commercial-type, closed formulary approach, we agree that the Authority should pursue permissions that seek to lower the cost of

---

<sup>10</sup> Or. Rev. Stat. § 414.025.

<sup>11</sup> 2021 Or. Laws ch. 467, § (2)(a). The bill does not direct all 3% toward health equity, but also requires spending out of that 3% on community programs addressing social determinants of health, diversifying care locations, and enhanced payments to certain providers and support staff that can make certain demonstrations.

prescription drug spending in Oregon. However, we would ask for clarification that the Authority is not requesting through the waiver permission to establish a preferred drug list (PDL). The concept of a PDL does not address the prodigious increase in pharmaceutical prices, will not realize as much savings due to rebates – especially if rebates accrue to the Authority versus CCOs – and do not address the rise of specialty and professionally administered drugs in Medicaid pharmacy spend.

The idea of considering a more evidence-based approach to cover prescriptions that have moved to market via the Food and Drug Administration's accelerated approval pathway appears reasonable. We believe that by limiting coverage for pharmaceuticals not granted approval through the traditional approach, Oregon can ensure that it allocates precious public resources to pharmaceuticals with a clear demonstrable clinical benefit. We request that the Authority clarify the request to review coverage to those pharmaceuticals where the FDA granted accelerated approval, but the drug in question has not yet gone through required postmarketing clinical studies.<sup>12</sup> This would incentivize the completion of those studies without foreclosing future coverage of a prescription drug that proves to be clinically effective.

Finally, if the Authority moves forward with the request in the application regarding a closed formulary and does not request the evidence-based approach discussed above, we ask if the Authority will remove the prescription drug spending from the value-based payment calculations, given that the state would occupy the field of prescription drug management.

On page 37 of the draft application, regarding the Authority's goal to redistribute power to communities in setting metrics, we believe that providers who closely serve community members affected by health inequities should also be given due consideration for inclusion on this potential Health Equity Quality Metrics Committee. Additionally, going back to our general comments on page 4 that state and local government partners should be consulted on the development of the demonstration waiver, we wonder if representation by other agencies who have parallel responsibilities should also provide input on these equity metrics.

In terms of the proposal to close gaps in equity by tailoring metrics to subpopulations, we believe that such focus, while well intentioned, can also place undue pressure on the communities being uplifted by the measured work. Oregon clearly experiences wide and deep disparities amongst our racial groups, but in stratifying the downstream metrics by race and ethnicity and that CCOs must meet the improvement targets for each race/ethnicity in order to receive our quality pool dollars, the Authority risks creating scenarios where communities receive pressure by CCOs in an effort to earn full payout. We can collectively learn from the Authority's rollout of the COVID-19 vaccine metric in 2020 to inform experiences in setting metrics to advance health equity. In undertaking the efforts necessary to meet the vaccine metric, we worked through historic distrust of health care and government systems among the populations we needed to reach – particularly the Black/African American, Native American/Alaska Native, and Pacific Islander communities. While community partners, health care entities and CCOs worked diligently to address access needs and to promote vaccination, historic and present trauma complicated the work.

---

<sup>12</sup> See 21 C.F.R. § 314.510.

We also worked through privacy concerns; because people within certain communities have close and even familial relationships, some culturally-specific organizations and community leaders were hesitant to discuss vaccine status of fellow community members. This hindered the success of certain outreach efforts (e.g., individual phone calls).

On pages 38-39 of the draft application, the Authority seeks to create “community investment collaboratives” (CICs). In our first comment letter, we raised a number of concerns about the formation, structure, and governance of what was then termed “health equity zones.” While we appreciate the Authority fine-tuning its original concept, we nonetheless wish to raise a number of concerns again and ask for clarification.

First, in our first comment letter to the Authority we believed that the proposal to create health equity zones appeared to create a “parallel, possibly siloed process that could undermine existing efforts to meaningfully engage with the communities we serve.” In this application, the request is that Oregon receive federal investment to “support capacity-building” among CICs. One could infer from the application that in supporting capacity building among CICs, the Authority wishes to support existing entities that can serve the role as convener and investor in communities. In the next paragraph though, the application discusses how CICs might leverage existing organizations, implying that the CICs may be new organizations. We would ask for more clarity regarding whether the Authority will turn to existing organizations to fulfill the role of CIC, or if the Authority will insist on parallel organizations within communities.

The Authority, CCOs, and Community Advisory Councils have invested considerable time and resources into developing and executing the community health assessments and the community health improvement plans. The assessment and the plan to meet the issues must improve population health outcomes through collaboration and investment, reflect the needs and priorities of the entire community, and reduce the burden on stakeholders and community members who participated in similar efforts.<sup>13</sup> With all the effort that has gone into this important work, to burden community members with another round of planning and development seems inapposite to the Authority’s current goals.

If indeed the intent of the application is to utilize federal investment to foster new organizations, the issues we raised in our first comment letter regarding funding and accountability still apply. In our first comment letter, we noted that CCOs like PacificSource rightly remain accountable for effective program administration and metrics. Administering federal public funds takes adherence to many regulations and guidance. It is a necessary burden, but a burden nonetheless. It takes time and organization to meet such a burden, and when working with communities it also takes significant facilitation. Thus, it is unclear if CICs will also be accountable to the Authority, or if the CCOs in the area will nonetheless remain responsible for accountability. Are the CICs meant to govern the local work of a CCO? Given that the application contemplates CICs managing part of the CCO expenditures on health equity under state law, we also question whether the community advisory councils will lose responsibility for

---

<sup>13</sup> See Or. Health Authority, *CCO Guidance: Community Health Assessments and Community Health Improvement Plans 1* (October 17, 2019) (available at <https://www.oregon.gov/oha/HPA/dsi-tc/CHACHPTechnicalAssistance/CCO-Guidance-CHA-CHP.pdf>).

oversight. If not, we request clarity for how the Authority envisions community advisory councils' and CICs' roles vis-à-vis each other.

In terms of funding, we noted in our first comment letter that the health equity zones appeared related to the accountable communities of health (“ACH”) model utilized in Washington State to address health care and social-needs related projects.<sup>14</sup> We believe ACHs appear to blend attributes of the four health councils PacificSource helped stand up in our communities and the CCOs as they exist in Oregon. Given that we have a model to look to for guidance, we ask the Authority to detail how inclusion of CICs in Oregon adds to the system built up over a decade. How would CICs remain sustainable? Are there governance issues inherent in layering the CICs into the current framework, if that is the intent? Will the Authority, local government or the CCOs be responsible for oversight and accountability? Will funds directed to CICs be excluded from the CCO rate development process? Will capacity building for the CICs include reporting to the Authority? How would the CICs account for actions designed to further equity objectives?

Answers to these questions are warranted because if history is an indication, CCOs may eventually be responsible for funding a greater or total portion of the CICs. We observed when reviewing the description of the health system transformation in Oregon (page 7-8 of the draft application) the mention of the patient-centered primary care home (PCPCH) model. We recognize that model fulfills a vision of better health, care and lower costs for our members. Initially, the PCPCH model received support from various federal pilot projects, like the Comprehensive Primary Care model, and time-limited supplemental payments under the Affordable Care Act.<sup>15</sup> However, the 2019 CCO 2.0 contracts contained requirements for increased support of PCPCHs and by 2020, providers subscribed to the model received reimbursement by the CCOs primarily through the global budget.

The questions we raise should not imply we see no value in community-driven investments in health equity. Far from it – as we have discussed, we live this value every day in the responsibilities we carry out in the CCO service areas' community governance model we serve. Instead, we believe true success in this space will arise from more organic community involvement and decision-making. We do not see any incongruence between the Authority setting general standards and challenging communities to meet those standards as a way to receive federal investment.

## Section II. Waiver and Expenditure Authority

We have no specific comments on this section.

---

<sup>14</sup> We note that the ACH model in Washington state derives its funding through a State Innovation Model Round Two Test Grant; due to legislative changes in the state and challenges associated with self-sustaining funding, Washington state will likely need to apply for another 5-year tranche of federal funding to maintain the ACH model.

<sup>15</sup> Or. Health Auth., *Patient-Centered Primary Care Home Program: Payment Incentives* (available at <https://www.oregon.gov/oha/HPA/dsi-pcpch/Pages/Payment-Incentives.aspx>).

### Section III. Eligibility

On [page 53](#) of the draft application, we would reiterate our earlier general concern about ensuring seamless and efficient delivery of state services in partnership with other units of government.

### Section IV. Benefits and Cost Sharing

On [page 66](#) of the draft application, in terms of determining which members may receive transition supports, we believe it is important to understand how the Authority will establish specific eligibility criteria it will apply and the amount/nature of documentation a member must supply in order to show eligibility. We remain unclear if the Authority intends to adjudicate eligibility in the same manner it plans to do in terms of income eligibility, or if more up-front work would be necessary.

Relatedly, the eligibility criteria also determine how many members may receive these proposed transitory benefits. Later in the application, the Authority estimates that nearly 375,000 members may be eligible for housing, food, transportation and employment assistance due to their status of being “at risk” of homelessness. This estimate may vary greatly depending on how the Authority counts those “at risk” of becoming homeless, and what an at-risk member must prove to show eligibility. Depending on how the Authority counts “at risk,” the estimated number of members eligible for services may be greatly higher. This accuracy in measuring and counting extends to the estimated number of members vulnerable to climate events. In Oregon, climate events such as flooding, wildfire, extreme heat, and drought have increased in frequency.<sup>16</sup> These events affect rural and urban members of the Oregon Health Plan alike, sometimes simultaneously. Without an understanding of how to measure the criteria, it is possible that this request covers far more than the 129,549 members thought to be eligible for benefits.

On [page 68](#) of the draft application, we would reiterate our comment earlier concerning transportation resources. Turning to the climate supports proposal, we note that as a CCO, we delivered on supporting our members’ acute needs during Oregon’s recent spate of wildfires. On an ongoing basis, we also use diagnosis data to identify those members who are at highest risk of adverse events due to extreme weather and adverse weather conditions, such as smoke, so that we can conduct outreach and connect those members to supports that keep them safe and their conditions well-managed. We applaud the Authority including these supports in the waiver application. We do believe the application should have objective criteria in place to determine which of these services effectively address health inequities, lower costs and lead to better health outcomes.

On [page 75](#) of the draft application, we would reiterate here that it is important to understand more detail about the assessment tools utilized to determine whether an individual is at risk of homelessness, or vulnerable to extreme climate events; i.e., who administers the assessment, how responsible parties share the information with others, how will the benefit itself be administered, etc.

---

<sup>16</sup> See Dalton, M.M., and E. Fleishman, Oregon Climate Change Research Institute, Ore. State. Univ., *Fifth Oregon Climate Assessment* 31-79 (2021) (available at <https://blogs.oregonstate.edu/occri/oregon-climate-assessments/>).

On [page 76](#) of the draft application, we had raised in our first comment letter several barriers to fully realizing the potential of traditional health workers that could be addressed, whether in this particular waiver or through some other policymaking mechanism. We agreed then that traditional health workers need stable funding, but there are considerable barriers to traditional health workers operating in the community and receiving Medicaid funding for their services. The Authority could clarify or address certificate of approval requirements and supervision requirements. Next, coordinated care organizations and community-based traditional health workers may have different expectations about the requirements necessary to accept heavily regulated Medicaid funds in a sustainable payment model—including background checks, insurance, treatment plans, documentation, etc. While removal of the treatment plan requirement certainly helps facilitate the delivery of services, the change also needs to be part of a larger re-examination of traditional health worker regulation.

Additionally, we request clarification on how the Authority understands the term “recovery peer,” as it is used in this portion of the waiver application. Oregon law creates specialized pathways for those individuals working as family support specialists, peer support specialists, peer wellness specialists, and youth support specialists.<sup>17</sup> We presume that recovery peer would encompass those peer specialists whose scope of work includes assisting individuals in their recovery from behavioral health and substance use disorders, but would request confirmation.

Finally, it was our understanding that the state’s Traditional Health Worker Commission recommended enhancements to the waiver which, in our review, do not appear to have been integrated into the application. It is our understanding that the Commission made recommendations on all the types of traditional health workers licensed in Oregon, but the application only references recovery peer traditional health workers.

On [page 77](#) of the draft application, please see our comments on page 8 of this letter regarding a more evidence-based approach to covering prescription drugs approved through accelerated pathways.

#### Section V. Delivery System and Payment Rates

On [page 80](#) of the draft application, please refer to our comments on the proposals regarding the capitated budget starting on page 6.

On [page 82-83](#) of the draft application, please refer back to our comments on page 5-6 of this comment letter.

#### Section VI. Finance and Budget Neutrality

We have no specific comments on this section.

#### Section VII. Implementation Plan

Our only comments on this section of the draft application have to do with the implementation of the community investment collaboratives. The implementation schedule for years one through three includes funding for “equity infrastructure” supports. We take this to mean funding for

---

<sup>17</sup> Or. Rev. Stat. §§ 414.025(10), (20)-(21) & (27).

community investment collaboratives, but it could also refer to the community-based capacity building mentioned earlier in the application. We request clarification on this point; we believe that an implementation plan must include a realistic timeline for when community investment collaboratives would be ready to deliver investments and demonstrate accountability.

### Section VIII. Evaluation Plan

We wish to bring up a few general comments about this section before we raise specific concerns with the evaluation plan. We acknowledge that the measures for evaluating the demonstration's effectiveness depend on the results of the negotiation between CMS and the Authority. This creates difficulty in providing feedback on the methods and measures, of which CCOs like us must understand and meet. At the very least, we believe that the Authority should have included conceptual logic models for each hypothesis to facilitate testing and review in this public comment period.

We also observed that the Authority planned to rely on surveys as one of the primary tools for evaluating the demonstration. Surveys require sizeable resources to carry out, and can become even more costly if surveyors experience reduced response rates.<sup>18</sup> Surveys may also need multiple methods of follow-up (SMS, e-mail, regular mail, telephone), and will likely need to be crafted in culturally and linguistically appropriate ways to fully understand how the demonstration project may or may not be reducing health inequities. Effective surveys also need to account for comparisons by containing sampling methods that allow for comparison by race/ethnicity or other characteristics of interest (i.e., over-sampling). We believe that surveys will themselves require funding to maximize effectiveness and accuracy. This is particularly true if the Authority intends on utilizing community-based organizations to conduct the surveys. The Authority may have to take on even more capacity building and direct support of organizations surveying communities.

Without funding of community surveys, we believe that results may not illuminate whether or not a particular aspect of the demonstration waiver made a difference. Surveys without adequate support may be designed in a way that do not minimize response bias or other forms of sampling bias. For example, surveying individuals with landlines and with few address changes might yield much different results than if a survey uses SMS communications and surveys those with frequent address changes.

Additionally, we wish to make one more general note on evaluating social determinants of health spending and the impact on members. Funding to address social determinants of health will always be finite, largely determined by federal matching funds and the state's General Fund. No social program can comprehensively assist the entirety of the Oregon Health Plan community. This leads to an issue with measurement – because of the finite nature of existing efforts to address social determinants of health, it may be extraordinarily difficult to understand the true scope of the need because current efforts necessarily triage who may be supported and the nature of the support provided. To truly address social determinants of health, the Authority

---

<sup>18</sup> See Kennedy & Hartig, Pew Research Center, *Response rates in telephone surveys have resumed their decline* (Feb. 27, 2019) (available at <https://www.pewresearch.org/fact-tank/2019/02/27/response-rates-in-telephone-surveys-have-resumed-their-decline/>).

must expand its thinking to capture the true extent of the need in all CCO regions, rather than focusing on HRS spending.

On page 95 of the draft application, the Authority makes the statement that wishes to gauge how policies outlined in the waiver application will “improve care coordination and integration through continuous coverage and the use of transition support packages (outside of traditional covered services) to improve how care is delivered to members.” The revised evaluation areas, however, do not clearly show how they relate back to improved care coordination, integration or care delivery. We believe it may be worth re-phrasing the evaluation question to create a testable goal. One possible approach may be to ask “Does continuous coverage improve how care is delivered to members?”

On page 96 of the draft application, we recommend that the evaluation area drafted for focus areas number two be re-drafted to better test the question presented; namely, that community-driven decision making will reduce health inequities.

Regarding focus area number three, we wish to raise several concerns. First, as a point of clarification, we ask if the Authority meant that instead of “operationalizing incentive metrics to evaluate the impact of those changes on reducing health inequities,” the plan consists of developing an equity-driven process that would first define the metrics before taking the step of making the metrics operational. After all, we understand that the Authority may pursue state legislation in 2023 to create a new equity-focused metrics committee. More to the point, we believe that members of the community must collectively consider and select metrics that take into account historical injustices in health care and resulting health inequities. We noted earlier in our comment letter how we wished to avoid creating scenarios that placed undue pressure on communities to conform to health care service; without well-developed metrics that very scenario might come to pass.

On page 100 of the draft application, relating to Hypothesis 1, we ask if the Authority will clarify that “HRS investments” does not constitute a method or measure of testing the hypothesis.

We believe that in order to fully evaluate Hypothesis 1, the Authority will need to collect and analyze data regularly. We are cognizant that the Authority will need to implement the data collection system required under 2021 House Bill 3159.<sup>19</sup> Does the Authority intend to evaluate the hypotheses in the demonstration waiver through the use of the data collected under the authorization granted by that act? Or will the Authority be able to piece together data from multiple sources? We raise this point because we do not believe that the CMS core measures would provide the kinds of information necessary to evaluate how the hypotheses unfold in practice. In particular, it is not our understanding that the CMS core measures do not comprehensively or accurately portray health status. If measuring health status becomes key to understanding whether or not health inequities decreased in Oregon due to this demonstration, then the Authority may need different data.

Regarding Hypothesis 2, we would reiterate our comments above regarding the use of surveys. In our estimation, Hypothesis 2 may prove difficult to determine whether the measured outcome

---

<sup>19</sup> 2021 Or. Laws ch. 549.

is influenced by more consistent data collection or by policy changes (namely, in the development of metrics). The Authority will need to develop robust and strict controls to draw a direct connection between provider billing practices and quality improvement efforts through metrics.

On page 101 of the draft application, relating to hypothesis one we agree that kindergarten readiness is a laudable goal – but it may not be a method or measurement that proves the hypothesis that earlier Oregon Health Plan enrollment may result in greater quality of life. Kindergarten readiness may serve as an indicator that earlier health interventions do improve children’s quality of life, but one might not necessarily be able to draw that conclusion from empirical data. We would suggest that the Authority re-draft the measure to better draw a direct connection between continuous enrollment and health outcomes.

Relating to hypothesis two, we wish to point out that CCOs do not simply offer health care services alone. Setting aside the community investments CCOs make, CCOs provide care and community coordination, case management, intensive care treatment services (that require care coordination with community partners), coordination with the Oregon Department of Human Services with key population members, and so on. We believe that the hypothesis must acknowledge that Oregon is building on a successful program of collaboration and community health, and the hypothesis must clearly demonstrate that the packages of social determinants of health supports improve health outcomes as compared with that current baseline.

We also question how the Authority intends to measure the effectiveness of improved integration and stabilization. A successful transition might be measured quantitatively, through a period of years, but it is unclear how long a period of time equals a successful transition. The potential measures of a successful transition include self-reported measures of stability and security, but depending on how and when the questions are asked, the Authority could receive mixed results. Plus, self-reported measures would need to take into effect the work beyond health care services that CCOs already provide to ensure a more accurate measure of change. Finally, in line with our other comments, we think the Authority needs to take into account the effect workforce shortages may have on the demonstration evaluation. Here, time to first appointment with certain providers (especially behavioral health providers) may not be affected in any directly measurable way by continuous coverage. Indeed, more utilization of behavioral health services may end up increasing the time to first appointment, if the behavioral health workforce is not bolstered.

## Section IX. Quality Strategy

We have no specific comments on this section.

## Section X. Strategies to Align with Tribal Partners’ Priorities

On page 140 of the draft application, we generally support the request to remove prior authorization for American Indians and Alaska Natives. The application notes challenges with treatment for substance use disorders for enrolled tribal members. For our part, we do not require prior authorization for medication-assisted treatment and counseling for substance use disorder. We would note that when the Oregon Legislative Assembly took up prior authorization

changes in the 2021 legislative session, it did not make any substantive changes to the prior authorization requirements for any Oregon Health Plan members.<sup>20</sup>

We support the conversion of the Special Diabetes Program for Indians (SDPI) to a Medicaid benefit; this move would both ensure sustainability of the program and also recognize the sovereignty and self-determination of tribal nations and how they want to address this important health issue.

Likewise, we support the inclusion of tribal-based practices as a covered benefit. We do believe the application must include provisions to create a payment methodology for reimbursement of tribal traditional health workers, a class of traditional health worker created by House Bill 2088 (2021). We also have questions on who will assure the Authority that services were offered and utilized by Oregon Health Plan members within tribal communities, and what constitutes the most appropriate funding source for carrying out these practices.

While we support in principle the request to offer a social determinants of health payment for currently unreimbursed services, the proposal must be structured in such a way that the end result preserves sovereignty, promotes accountability, and can be accomplished without undue administrative burden.

#### Section XI. Public Notice

We have no specific comments on this section.

---

Please do not hesitate to contact me with any questions or comments. Thank you for your time and consideration.

Sincerely,



Erin Fair Taylor, MPH, JD  
Vice President of Medicaid Programs  
PacificSource Community Solutions  
[erin.fairtaylor@pacificsource.com](mailto:erin.fairtaylor@pacificsource.com)

---

<sup>20</sup> See 2021 Or. Laws ch. 154 (Enrolled House Bill 2517).



# PARTNERSHIP TO FIGHT CHRONIC DISEASE

January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Oregon Health Plan 1115 Demonstration Waiver Application for Renewal

*Submitted online*

Dear Ms. Hatfield:

We appreciate the opportunity to provide comments on the Oregon Proposed 1115 Medicaid Waiver (proposed Waiver). We applaud the intended focus to advance health equity mentioned throughout the proposed Waiver, but many changes proposed will have the opposite effect and pose serious risk of harm to highly vulnerable individuals. Accordingly, we write to share our serious concerns in opposition to the proposed Waiver. We urge to reject the highly controversial care limitations included within the proposed waiver and instead work to preserve the much-needed access protections for Medicaid beneficiaries afforded under federal law.

The Partnership to Fight Chronic Disease (PFCD) is an internationally recognized organization of patients, providers, community organizations, business and labor groups, and health policy experts committed to raising awareness of the number one cause of death, disability, and rising health care costs: chronic disease.

Six in ten adults living in Oregon have at least one chronic condition and many have more than one. The prevalence of chronic conditions is even higher among people covered by Medicaid



# PARTNERSHIP TO FIGHT CHRONIC DISEASE

than in the general population.<sup>1</sup> Those covered by Medicaid are among the state’s most vulnerable residents and depend upon affordable access to the care and treatments they need to maintain their health and independence. Medical and prescription drug coverage provided through Medicaid is a lifeline for thousands of individuals and families in Oregon. Protecting that coverage and the access to comprehensive medical services and treatment are of paramount importance and should dominate discussions of reforms that place that access at risk. For these reasons, we urge you to reject the proposed Waiver and instead work in favor of protecting Medicaid coverage and access while avoiding discriminatory practices that will exacerbate health disparities in the state.

## **Discriminatory Aspects of Waiver, Particularly Affecting People Living with Disabilities**

We reassert, by reference here, the concerns expressed and recommendations made in the letter submitted to you by the Oregon Disability Rights Center, of which PFCD is a signatory. Accordingly, we limit our comments to additional concerns we have with the proposed Waiver.

The proposed Waiver represents a dangerous departure from the protections afforded Medicaid beneficiaries under federal law, particularly relating to access to medicines people depend upon to maintain their health.

## **Denying Coverage of Prescription Medicines Harms People Living with Chronic Conditions**

The proposed Waiver includes provisions to limit adult beneficiary access to medicines severely by instituting “commercial-style” formularies with as few as one drug per class. Enabling Medicaid health plans to only cover one prescription drug per therapeutic class ignores the diversity and complexity of medical needs represented within the Medicaid population, the heterogeneity of treatment effects among different individuals, and the need for choices to promote optimal health among Medicaid beneficiaries. As such, the proposal if implemented disproportionately and negatively affects people living with multiple chronic conditions, those with complex treatment regimens, including many living with disease-related disabilities. The prevalence of multiple chronic conditions is almost twice that among adults aged 18-64 years on Medicaid—approaching 30 percent--than their peers on private insurance or uninsured.<sup>2</sup> The proposed Waiver cites to Medicare to support adoption of such restrictive formularies, but does not acknowledge the additional protections that of Medicare requiring comprehensive

---

<sup>1</sup> [Prevalence and Medical Costs of Chronic Diseases Among Adult Medicaid Beneficiaries - American Journal of Preventive Medicine \(ajpmonline.org\)](#)

<sup>2</sup> [Prevalence of Multiple Chronic Conditions Among US Adults, 2018 \(cdc.gov\)](#)



# PARTNERSHIP TO FIGHT CHRONIC DISEASE

drug coverage within six protected therapeutic classes of medicines or the availability of beneficiary choice among multiple, competing drug coverage options that enables people to choose coverage that best fits their needs.

## **Denying Access to Accelerated Approval Drugs Harms the Seriously Ill**

New medicines approved through FDA's accelerated approval pathway have made novel therapeutics, developed in response to significant unmet medical needs, available to people with serious or life-threatening conditions. Without these treatments, people suffering from rare cancers, genetic conditions, or HIV/AIDS would face avoidable disease progression, preventable disability, and premature death. People living with serious or life-threatening conditions dependent on Medicaid for access to accelerated approval medications are arguably among Medicaid's most vulnerable populations and reforms aimed at restricting access to treatments should be viewed with those significant vulnerabilities foremost in mind. CMS has already rejected such a state waiver proposal<sup>3</sup> and issued a letter to state Medicaid programs asserting the requirement to cover accelerated approval drugs<sup>4</sup>--for these important health reasons. Imagine if Oregon's waiver were adopted during the midst of the HIV/AIDS crisis and denied beneficiaries access to antivirals approved using accelerated approval that led death rates from HIV/AIDS to drop precipitously?

A recent economic analysis,<sup>5</sup> found that access to accelerated approval drugs for the seriously ill has had very limited impact on Medicaid costs. Specifically, accelerated approval drugs accounted for less than 1 percent of Medicaid spending consistently every year 2007-2018 and amounted to 1.3% of the growth in total Medicaid spending over that timeframe.

Unfortunately, judgments of value often fail to consider the full benefits associated with health improvements – critically important considerations given the linkages between health and economic mobility and their combined impact on promoting economic opportunity, particularly for communities of color, people living with disabilities, and others facing discrimination that limit opportunities. Seven in 10 adults covered by Oregon Medicaid are working in the state.<sup>6</sup> Preserving their access to the comprehensive coverage that federal law currently requires and Oregon provides will enable those adults to continue working while managing their health

---

<sup>3</sup> [MA revised eval design \(vet annuity disregard\) approval letter Signed.pdf \(medicaid.gov\)](#)

<sup>4</sup> [Medicaid Drug Rebate Program Notice \(Medicaid.gov\)](#)

<sup>5</sup> [Limiting Medicaid Access to Accelerated Approval Drugs: Costs and Consequences](#)

<sup>6</sup> [Medicaid in Oregon \(kff.org\)](#)



## PARTNERSHIP TO FIGHT CHRONIC DISEASE

effectively. Supporting upward economic mobility by promoting better health and affordable access to care is a foundational aspect of Medicaid coverage. The proposed Waiver violates that central tenant and puts seriously ill Oregonians at significant risk of harm.

We urge you to reject the proposed Medicaid waiver and preserve the access protections afforded low-income Medicaid beneficiaries in Oregon.

Respectfully submitted,

Candace DeMatteis, JD MPH  
Policy Director



**Joyce Rogers**  
Vice President  
US Policy and Public Affairs  
Pfizer Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017  
Email: [joyce.rogers@pfizer.com](mailto:joyce.rogers@pfizer.com)

January 6, 2022

**VIA ELECTRONIC DELIVERY**

Mr. Patrick Allen  
Director, Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Re: Comments of Pfizer Inc. Regarding Draft Application for Renewal and Amendment Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen,

Pfizer, Inc. (“Pfizer”) appreciates the opportunity to comment on the Oregon Health Authority’s (OHA) proposed renewal and amendment of its Section 1115 waiver (“proposed 1115 waiver”). Pfizer is committed to saving and improving lives through the development of medicines and vaccines, applying the latest science and technology to meet the most demanding healthcare challenges of today. Pfizer believes that the proposed 1115 waiver would jeopardize the ability of Medicaid beneficiaries—among the neediest of patients—to access life-saving therapies, among other troubling outcomes.

Pfizer is particularly concerned by the OHA’s proposal to implement a closed formulary and exclude drugs approved via FDA’s accelerated approval pathway—which the proposal calls “drugs with limited or inadequate evidence of clinical efficacy.”<sup>1</sup> Pfizer agrees with other commenters, including the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and the Biotechnology Innovation Organization (“BIO”), that these proposals fail to meet certain basic requirements for Medicaid waivers under Social Security Act (“SSA”) section 1115,<sup>2</sup> and thwart the Congressional intent underlying the Medicaid rebate statute,<sup>3</sup> which reflects a pact

---

<sup>1</sup> Oregon Health Authority, Oregon Health Plan, Section 1115 Demonstration Amendment Draft Application for Public Comment (Dec. 1, 2021), <https://www.oregon.gov/oha/hsd/medicaid-policy/pages/waiver-renewal.aspx> (“Waiver Request”).

<sup>2</sup> Codified at 42 U.S.C. § 1315.

<sup>3</sup> Codified at 42 U.S.C. § 1396r-8.

between government and industry to provide deep rebates in exchange for patient access. Further, the proposed formulary exclusions (even if allowable) would block access to therapeutic advances for serious and life-threatening conditions approved as safe and effective by the FDA for the most vulnerable and neediest group of patients.

## **I. The Commonwealth’s Proposal Fails to Satisfy the Requirements for Section 1115 Waivers.**

Pfizer shares the objections raised by PhRMA, BIO, and other organizations that OHA’s proposal falls outside the scope of waivers allowed by section 1115 and upends key requirements of the Medicaid rebate statute. First, the proposal flies in the face of PhRMA v. Thompson, in which the D.C. Circuit held that SSA section 1115 does not authorize waivers of the Medicaid rebate statute.<sup>4</sup> Second, such a waiver would destroy an essential element of the legislative compromise codified by Congress in the Medicaid rebate statute. Under the rebate statute, manufacturers of innovator drugs pay deep rebates to Medicaid programs, in exchange for Medicaid beneficiaries receiving the drug coverage protections. For innovator drugs, the statute provides Medicaid programs with a price net of the rebate that is at least as low as the manufacturer’s best price to any commercial customer. In fact, the price to Medicaid is often lower than any commercial customer’s price, because the Medicaid rebate statute guarantees Medicaid at least a 23.1% discount on most innovator drugs and an additional rebate that pays dollar-for-dollar the amount by which the average manufacturer price of the drug increases faster than the inflation rate.<sup>5</sup> Many cases have held that when a statute reflects such a legislative compromise, the interpretation of the law should uphold the compromise—not tear it apart.<sup>6</sup> As other commenters have argued, OHA’s proposal would fall short of section 1115 waiver requirements in other significant ways. For example, the proposal is not, in fact, a demonstration, test, pilot, or study—it does not involve any investigation of the impacts on healthcare outcomes, access, delivery, or secondary healthcare costs—but instead represents a mere benefits cut, which is not a permissible subject for a section 1115 waiver.<sup>7</sup>

Other commenters have also addressed the concerns for patient access under the proposal as well as the need for OHA to use the many tools already at its disposal (rather than this problematic proposed 1115 waiver). These themes are explored in more depth in the remainder

---

<sup>4</sup> 251 F.3d 219, 222 (D.C. Cir. 2001) (“Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r–8’s [the Medicaid rebate statute’s] rebate provision or the requirement that Medicaid beneficiaries contribute no more than a ‘nominal’ amount to the cost of medical benefits they receive.”).

<sup>5</sup> Specifically, the Medicaid rebate for innovator drugs equals the higher of the drug’s average manufacturer price (AMP) minus the drug’s best price, or the mandated minimum percentage discount based on product type (23.1 percent for most innovator drugs, 17.1 percent for clotting factors and drugs approved only for pediatric indications, and 13 percent for non-innovator/generic drugs). An additional dollar-for-dollar rebate, referred to as the CPI Penalty, is also required for price increases greater than the inflation rate (and applies to both innovator and non-innovator drugs).

<sup>6</sup> See, e.g., *General Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992) (upholding statutory provisions necessary to “preserve[] the delicate legislative compromise that had been struck by [prior] laws”).

<sup>7</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994) (“[Section 1115] requires that the state project be an ‘experimental, demonstration or pilot’ project. The statute was not enacted to enable states to save money or to evade federal requirements but to ‘test out new ideas and ways of dealing with the problems of public welfare recipients.’”).

of this comment, in keeping with Pfizer’s support for policies that appropriately promote patient access to prescribed products. We also explain below how granting OHA’s request would be inconsistent with FDA’s authority to grant accelerated approvals.

## **II. OHA’s Proposal Would Jeopardize Access for the Neediest Patients and Block Coverage of Cutting-Edge Treatments for Life-Threatening Conditions.**

### **A. The Proposal Would Exclude Important Medicines That Have Met FDA Standards of Safety and Efficacy**

OHA proposes to “[a]dopt a commercial-style closed formulary with at least one drug available per therapeutic class” and to “[e]xclude from the formulary drugs with limited or inadequate evidence of clinical efficacy,”<sup>8</sup> under sections 3a and 3b of its waiver request, respectively.

Regarding closed formularies, studies suggest that allowing more choice of medications has positive results for patients, including lowering the chances of drug interactions and adverse events, and increasing the efficacy of treatment.<sup>9</sup> Years of research have also shown that limiting formularies correlates to poor medication adherence outcomes.<sup>10</sup> Studies featuring Medicaid recipients with severe health conditions indicate that in many instances, these restrictions can result in negative health outcomes and other outcomes without generating program savings or other intended benefits (and sometimes increasing overall state costs).<sup>11</sup>

Regarding drugs with “limited or inadequate clinical efficacy,” OHA defines this term “as when one or more of the following conditions exist”:

- “Primary endpoints in clinical trials have not been achieved;
- Only surrogate endpoints have been reported;

---

<sup>8</sup> Waiver Request at 30-31.

<sup>9</sup> See, e.g., DiMasi, “Competitiveness in follow-on drug R&D: a race or imitation?” 10 Nat. Rev. Discov. 23-27 (Jan. 2011); Turner et. al, “Parsing Interindividual Drug Variability: An Emerging Role For Systems Pharmacology,” 7 Wiley Interdiscip. Rev. Syst. Biol. Med. 221-41 (2015); Mullins et. al, “Persistence, Switching, And Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, And Citalopram,” 25 Pharmacotherapy 660-67 (2005).

<sup>10</sup> See, e.g., Happeet. al, “A Systematic Literature Review Assessing The Directional Impact Of Managed Care Formulary Restrictions On Medication Adherence, Clinical Outcomes, Economic Outcomes, And Health Care Resource Utilization,” 20 Manag. Care Spec. Pharm. 677-84 (2014).

<sup>11</sup> See, e.g., USC Schaffer, “Medicaid Access Restrictions on Psychiatric Drugs: Penny-Wise or Pound Foolish?” (Feb. 2015), <http://healthpolicy.usc.edu/documents/USC%20Issue%20Brief%20No.%202%20Final.pdf> (indicating increased incarceration rates associated with certain access restrictions); Lu, et. al, “Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness,” 48 Medical Care 4 (Jan. 2010) (finding that while a prior authorization policy in Maine Medicaid was associated with a marked decrease in rates of initiation of bipolar treatments associated with reduction in initiation of nonpreferred agents, the policy had no discernable impact on rates of switching therapy among patients currently on treatment); Farley, et al., “Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications,” 30 Clinical Therapeutics 1524 (April 2008) (showing, for a group of Medicaid patients with schizophrenia who were subject to a prior authorization policy for atypical antipsychotic medications, significant increases in per member per month outpatient expenditures far exceeded the associated savings in a typical antipsychotic expenditures).

- Clinical benefits have not been assessed;
- The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives.”<sup>12</sup>

This language (contained in section 3b of the waiver request) reflects OHA’s misguided attempt to target for exclusion drugs that enter the market through FDA’s accelerated approval pathway.<sup>13</sup> This statutory pathway authorizes FDA to approve a product that treats “a serious or life threatening condition . . . upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit . . . taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative therapies.”<sup>14</sup>

Under the law, FDA must find “substantial evidence” of the drug’s effectiveness, and the applicant must have conducted one or more “adequate and well-controlled studies,”<sup>15</sup> just like drugs approved outside this pathway. Indeed, medicines approved through the accelerated pathway are those that FDA has determined meet the key requirements of safety and efficacy, and that FDA believes should be approved on an expedited basis because they are needed to treat “serious and life-threatening” diseases and conditions.

Existing literature supports this characterization. Researchers at Tufts University, for example, found that drugs cleared through FDA’s expedited review process “offered larger health gains, compared to drugs approved through conventional review processes.”<sup>16</sup> Notwithstanding these health benefits, OHA wishes to target these drugs for formulary exclusion.

While accelerated approval drugs represent the cutting edge of treatment—and meet the exacting FDA approval standards required under law—the proposal would permit OHA to exclude these drugs from coverage on the grounds, for example, that their clinical benefit was established through studies that rely on surrogate endpoints.<sup>17</sup> This exclusion criterion reflects OHA’s misunderstanding of the nature and purpose of validated surrogate endpoints. Under the Food, Drug, and Cosmetic Act (FDCA), FDA can base an accelerated approval “upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the

---

<sup>12</sup> *Id.* at 10.

<sup>13</sup> *Id.* (“Many drugs coming to market through the FDA’s accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints.”).

<sup>14</sup> 21 U.S.C. § 356.

<sup>15</sup> 21 U.S.C. § 355.

<sup>16</sup> James D. Chambers et al., “Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process,” 36 Health Affairs 1408-1415 (Aug. 2017), <http://content.healthaffairs.org/content/36/8/1408.abstract>.

<sup>17</sup> The Commonwealth also includes another criterion, “Primary endpoints in clinical trials have not been achieved.” This criterion is somewhat confusing, since primary endpoints are endpoints that FDA deems essential to establish effectiveness, thus it is not clear that any approved drugs exist for which “primary endpoints in clinical trials have not been achieved.” *See, e.g.*, FDA, Draft Guidance for Industry, Multiple Endpoints in Clinical Trials, at 2 (January 2017).

condition and the availability or lack of alternative treatments.”<sup>18</sup> FDA explains in its guidance that the accelerated approval process requires “that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. This judgment does not represent either a ‘lower standard’ or one inconsistent with section 505(d) of the act [i.e. FDA criteria for refusing applications, including the “substantial evidence” standard].”<sup>19</sup> FDA is the expert agency for determining products’ safety and efficacy, including those receiving accelerated approvals. CMS should not undermine its sister agency by allowing OHA to second-guess FDA by broadly rejecting coverage for products used for their FDA-approved indications.

If the waiver were granted, it would allow OHA to exclude many drugs that received accelerated approval and that thousands of patients, including Oregon Health Plan beneficiaries, depend on for the treatment of severe and life-threatening conditions.

In addition to noting the serious risks for patients who rely on these innovative medications, it is worth pointing out additional problems with OHA’s exclusion criteria. For example, the proposed criterion that “[c]linical benefits have not been assessed” actually does not apply to any FDA approved drug (under either the accelerated or traditional pathways); the criterion is a misguided attempt to target drugs that have been approved based on clinical studies using surrogate endpoints to predict a clinically meaningful benefit. Also, the criterion that that “drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives” is overly broad and could in fact be applied by OHA to exclude from coverage almost any drug. U.S. law does not require a demonstration of “incremental benefit” for product approval. Instead, drugs are approved if they are “safe and effective,” whether the drug receives approval under the traditional or the accelerated pathway.

#### B. An Exceptions Process is No Panacea

The proposal would allow patients to obtain excluded drugs through an exceptions process. However, exceptions procedures for non-formulary drugs, like utilization management restrictions for on-formulary drugs, can lead to a decrease in patient adherence and an increase in overall system cost and inefficiencies. Such burdensome administrative processes can deter or prevent patients from taking medication altogether. Moreover, several studies conducted with Medicaid beneficiaries suggest other ways in which utilization management controls like prior authorization can backfire—for example, by increasing certain costs of outpatient care that outweigh the per-member savings gained by limiting drug utilization.<sup>20</sup> Even where utilization

---

<sup>18</sup> 21 U.S.C. 356(c)(1)(A).

<sup>19</sup> FDA, “New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval,” 57 Fed. Reg. 58942, 58944 (Dec. 11, 1992).

<sup>20</sup> Farley, et al., “Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications,” 30 *Clinical Therapeutics* 1524 (April 2008) (“Among patients with schizophrenia, the PA policy was associated with a \$19.62 per member per month (PMPM) decrease in atypical antipsychotic expenditures and a \$2.20 PMPM increase in typical antipsychotic expenditures (both,  $P < 0.001$ ). Among the same patients with schizophrenia, however, the reduction in atypical antipsychotic expenditures was accompanied by a \$31.59 PMPM increase in expenditures for outpatient services ( $P < 0.001$ ).”).

management is successful in switching patients to lower-cost sales channels or lower-tier medications, such changes do not always result in greater cost savings overall.<sup>21</sup>

Clinical judgement exercised within the bounds of accepted medical practice ought to take precedent over a payer’s cost considerations in decisions about an individual’s care. This is especially true because there is no conclusive evidence that administrative barriers such as prior authorization or step therapy reduce long-term health care costs—and such restrictions may in fact result in higher costs due to possible adverse reactions or other treatment that may be required as the result of nonadherence. For these reasons, applying a blanket exclusion restriction to FDA approved therapies used for their approved indications, not to mention cutting-edge therapies approved through accelerated approval, and forcing patients and providers to rely on an exceptions process to access medically necessary drugs would be a step in the wrong direction, creating new barriers for patients rather than supporting prescriber decision making and pioneering drug development. Pfizer believes that existing utilization management tools provide OHA sufficient control over pharmacy spending. Given the limitations noted above, we believe these tools ought to be applied efficiently and judiciously, in a manner consistent with sound policy and the framework of existing law.

### **III. Granting OHA’s request would be inconsistent with FDA’s authority to grant accelerated approvals.**

Congress explained how it envisioned FDA’s role in the extensive “findings” and “sense of Congress” provisions included in Section 901 of the Food and Drug Administration Safety and Innovation Act (FDASIA), a bipartisan reform in 2012 that amended the federal Food Drug and Cosmetic Act (FDCA) to codify the accelerated approval pathway. Congress addressed both how it saw FDA’s role as a steward of medical innovation as well as the importance of the expedited approval framework to realizing FDA’s duty and purpose:

[FDA] serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation’s strategy to address serious or life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs. [. . .] FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate.<sup>22</sup>

FDA has recognized this statutory mandate through public statements, such as in a 2015 white paper in which FDA declared: “finding effective treatments for rare diseases is a public health priority, and FDA has brought to bear all of its drug review and technical assistance tools

---

<sup>21</sup> See, e.g., Martin, et. al, “Impact of a Novel Cost-Saving Pharmacy Program on Pregabalin use and Health Care Costs,” 22 J. Managed Care & Specialty Pharmacy 132 (Feb. 2016).

<sup>22</sup> Pub. L. 112–114, title IX, §901(a), July 9, 2012, as amended by Pub. L. 114-255, div. A, title III, §3101(b)(1), Dec. 13, 2016, 130 Stat. 1156.

to assist the development of new treatments for these conditions.”<sup>23</sup> FDA also acknowledged that Congress built on this framework through the passage of the 21<sup>st</sup> Century Cures Act:

With [21<sup>st</sup> Century Cures,] great progress has been made towards our shared goal of advancing regulatory science so that we can continue to speed the discovery, development, and delivery of medical products to prevent and cure disease and improve health while sustaining the evidence framework that enables assurance to the public of the safety and effectiveness of medical products.<sup>24</sup>

As these sources indicate, FDA’s role as contemplated by Congress is to apply FDA’s technical expertise to speed the development and approval of safe and effective medicines—including drugs that treat serious conditions and fill an unmet need. FDA exercises tools for regulatory flexibility in service of this mission. Congress has recognized that it is because of FDA’s expertise that FDA is able to use these tools to promote (and not hamper) the development and approval of safe and effective medicines.

OHA’s proposed section 1115 waiver request would undercut FDA’s role, by substituting the judgement of OHA for that of FDA.<sup>25</sup> We think that Congress never would have intended such an outcome, as it would conflict with the statutory framework Congress devised under FDCA and its amendments.

As courts have described, section 1115 allows CMS to exercise its own wisdom to determine whether a state experiment in social services programs and benefits should be allowed: Congress “intended that the Secretary would ‘selectively approve[]’ state projects,” and gave the HHS Secretary “plenary authority to reject State projects and to require States to modify projects to make them more consistent with federal requirements, less likely to harm recipients, and more likely to further the goals of the Social Security Act.”<sup>26</sup>

Moreover, OHA’s proposed 1115 waiver would violate a core principle of statutory interpretation—that where potential conflicts exist between two federal statutes, one should adopt “the interpretation that preserves the principal purposes of each.”<sup>27</sup> If the two laws cannot be reconciled, courts generally give effect to the “later-enacted, more specific statute.”<sup>28</sup> Here, OHA’s proposed 1115 waiver would usurp FDA’s authority and contradict the aims of FDCA in creating a cutting-edge legal framework for the exercise of FDA technical expertise.

---

<sup>23</sup> FDA White Paper, FDA and Accelerating the Development of New Pharmaceutical Therapies, 7-8 (March 23, 2015).

<sup>24</sup> 21<sup>st</sup> Century Cures Act; Making Progress on Shared Goals for patients, FDA Commissioner Dr. Robert M. Califf, FDA Voice, December 13, 2016.

<sup>25</sup> Waiver request at 9 (“Massachusetts seeks the ability to use its own rigorous review process, in partnership with the University of Massachusetts Medical School, to determine coverage of new drugs and to guarantee that patients access clinically proven, efficacious drugs.”).

<sup>26</sup> Beno v. Shalala, 30 F.3d 1057, 1069 (9th Cir. 1994)(internal citations omitted).

<sup>27</sup> See, e.g., SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc., 211 F.3d 21, 27-28 (2d. Cir. 2000).

<sup>28</sup> Hawaii v. Trump, 859 F.3d 741, 778 (9th Cir. 2017).

\*\*\*

Again, Pfizer appreciates the opportunity to comment on OHA's proposed 1115 waiver renewal and amendment application. If you have questions or need additional information, please contact Tom Brownlie at [thomas.brownlie@pfizer.com](mailto:thomas.brownlie@pfizer.com).

Joyce Rogers

A handwritten signature in cursive script that reads "Joyce Rogers".

Vice President  
U.S. Policy and Public Affairs

December 20, 2021

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Re: Comments on Oregon’s Application for Renewal and Amendment of Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) writes to share its concerns with the proposal to amend the Oregon Health Plan (“OHP”) to adopt a commercial-style closed formulary approach that would potentially exclude a vast number of Food and Drug Administration (“FDA”)-approved drugs (“Proposed Amendment”).<sup>1</sup> The Proposed Amendment is included in the Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver (“Application”)<sup>2</sup> that was posted for public comment by the Oregon Health Authority (“OHA”) on December 7, 2021.

PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA has a long-standing interest in promoting Medicaid members’ access to quality care and is concerned that Oregon’s proposal to waive sections of the Medicaid drug rebate statute to implement the Proposed Amendment will reduce and ration access to lifesaving medicines.

We understand that the state of Oregon faces considerable challenges in ensuring residents have access to quality, affordable health care, and PhRMA remains committed to ensuring that needed medicines are accessible for Medicaid members. Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity, and inclusion are essential to the discovery of new medicines and that people of all ethnic and racial backgrounds should have equitable access to treatment. As such, we are heartened to see the state’s commitment to improving equitable access to health care within Medicaid by addressing health equity and social determinants of health. However, Oregon’s proposal to waive

---

<sup>1</sup> OHA, Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver 30–32 (as revised Dec. 7, 2021). In the Application, OHA also proposes to, among other things, extend its existing OHP Medicaid Demonstration Waiver for an additional five years, effective as of July 1, 2022. PhRMA’s comment letter addresses only the Proposed Amendment that would waive “§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)” in order to adopt a commercial-style closed formulary approach and exclude from the formulary drugs with limited or inadequate evidence of clinical efficacy. PhRMA takes no position with respect to the other components of OHA’s Application.

<sup>2</sup> Id. at 1.

“§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)” to allow the state to impose a closed formulary and exclude drugs “with limited or inadequate evidence of clinical efficacy” does not promote those objectives; relies on flawed models to assess clinical/cost effectiveness that undervalues the lives of vulnerable populations; exacerbates health inequity; and fails to satisfy requirements for approval under Social Security Act (“SSA”) § 1115.<sup>3</sup> The Proposed Amendment will impede access to medically necessary drugs for more than 700,000 Oregonians<sup>4</sup> and raises serious concerns about the long-term impact on some of the sickest and poorest individuals in need of medical assistance. Moreover, the Proposed Amendment is ill-advised for both legal and policy reasons and should be withdrawn from the Application.

Our comments follow the outline below:

- I. The Proposed Amendment Does Not Meet the Requirements for Approval Under Social Security Act § 1115**
  - A. Waiving the Medicaid Rebate Statute’s Drug Coverage Requirements Would Not Promote Medicaid Objectives**
  - B. The Medicaid Rebate Statute Is a Package Deal that Cannot Be Torn Apart by a Selective Waiver of Its Coverage Requirements Alone**
  - C. A Closed Formulary Initiative is Not an “Experimental, Pilot, or Demonstration Project” Authorized Under Section 1115**
  - D. The Proposed Amendment Lacks Sufficient Details to Provide a Meaningful Opportunity for Public Comment**
- II. Cost Containment Tools to Control Pharmacy Expenditures are Currently Available Under Section 1927 and Other Provisions**
- III. Restricting Medicaid Drug Coverage Would Exacerbate Existing Health Inequities**
- IV. The Proposed Amendment Ignores Research Showing that Closed Formularies Hurt Patients, Lower Adherence, and Do Not Reduce Health Care Costs**

---

<sup>3</sup> Social Security Act (SSA) § 1115.

<sup>4</sup> May 2021 Medicaid and CHIP Enrollment Highlights, CMS (2021) <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html>.

## **I. The Proposed Amendment Does Not Meet the Requirements for Approval Under Social Security Act § 1115**

Oregon’s Proposed Amendment fails to satisfy the requirements of the SSA in several important respects. First, the Proposed Amendment would not meet the requirement that a Section 1115 demonstration program be “likely to assist in promoting [Medicaid] objectives.”<sup>5</sup> Allowing a wholesale waiver of the drug coverage requirements in the rebate statute would not promote this objective, but would instead reduce members’ access to needed medications and affect their health adversely. Second, waiving the Medicaid rebate statute’s coverage requirements alone (without waiving the requirements for manufactures to pay rebates) would impermissibly tear apart the legislative bargain reflected in the statute.<sup>6</sup> A state’s coverage obligations are not severable from manufacturer rebates, and Oregon’s proposal would violate the statutory covenant enshrined in the Medicaid rebate statute by doing so. Third, the Proposed Amendment fails to specify how it will serve as an “experimental” or “demonstration” project as required under Section 1115. The Proposed Amendment appears to impermissibly propose a series of cost cutting measures without research metrics to determine if the additional flexibilities the state is requesting further the core objectives of the Medicaid program. Finally, the Proposed Amendment lacks sufficient details to provide a meaningful opportunity for public comment.

### **A. Waiving the Rebate Statute’s Drug Coverage Requirements Would Not Promote Medicaid Objectives**

Any Section 1115 demonstration project must be “likely to assist in promoting the objectives of [Medicaid].”<sup>7</sup> Oregon proposes to waive “§1902(a)(54) insofar as it incorporates §1927(d)(1)(B)” in order to establish a closed formulary. The closed formulary would not comply with the rebate statute’s more patient-protective prescription drug coverage standards. The Proposed Amendment contains limited information on how drugs would be excluded from the formulary, but it appears that a drug could be excluded for two different reasons: (1) to reduce the number of drugs in a class to one so that “manufacturers could be offered an essentially guaranteed volume in exchange for a larger rebate”; or (2) because a drug has “limited or inadequate evidence of clinical efficacy.”<sup>8</sup> Neither of these rationales advance the objectives of the Medicaid statute.

Based on the SSA’s language and structure, the U.S. Department of Health and Human Services (“HHS”) and the courts agree that “the core objective of the Medicaid Act is to furnish health-care coverage to the needy.”<sup>9</sup> Indeed, the U.S. Court of Appeals for the D.C. Circuit confirmed in 2020 that “the principal objective of Medicaid is providing health care coverage.”<sup>10</sup> Allowing a wholesale waiver of the drug coverage requirements in the rebate statute would reduce members’ access to medicines and adversely affect their health in two ways: directly, by

---

<sup>5</sup> SSA § 1115(a).

<sup>6</sup> SSA § 1115(a).

<sup>7</sup> SSA § 1115(a).

<sup>8</sup> Application at 30-31.

<sup>9</sup> See *Philbrick v. Azar*, 397 F.Supp.3d 11 (D.D.C. 2019); *Gresham v. Azar*, 363 F. Supp. 3d 165, 176 (D.D.C. 2019) (noting that the HHS Secretary “refers to the provision of medical care to eligible persons as ‘Medicaid’s core objective.’”); see also SSA § 1901 (describing the purpose of the Medicaid program as enabling states to furnish “medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services,” as well as “rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care”).

<sup>10</sup> See *Gresham v. Azar*, 950 F.3d 93, 99 (D.C. Cir. 2020).

permitting the State to cut back on drug coverage; and indirectly, by eliminating or curtailing manufacturers' incentive to participate in the Medicaid Drug Rebate Program ("MDRP")—a program that has successfully provided Medicaid members "access to the same range of drugs that the private patients of their physicians enjoy"<sup>11</sup> since its start in 1991.

The direct damage from the waiver is also disturbing—and easy to anticipate—because the impact of closed formularies that restrict drug access for vulnerable populations has already been extensively studied. Notably, these studies show that restricting access to drugs results in non-adherence or poor adherence to prescribed medication regimens; worsened health outcomes; and higher, long-run costs, both to Medicaid and other state and local programs.<sup>12</sup> Medicaid patients, compared to those with other types of insurance, have higher rates of complex and chronic health conditions that often require access, without delay, to a broad range of medicines as prescribed by their physicians in order to achieve optimal therapeutic results,<sup>13</sup> thereby amplifying the detrimental effects of a closed formulary.

Moreover, given how broadly the Proposed Amendment defines drugs with "limited or inadequate evidence of clinical efficacy," allowing the Medicaid formulary to exclude these drugs could deny Medicaid members access to many vital and innovative drugs. According to the Proposed Amendment, "[l]imited or inadequate clinical efficacy may be defined as when one or more of the following conditions exist:

- Primary endpoints in clinical trials have not been achieved.
- Only surrogate endpoints have been reported.
- Clinical benefits have not been assessed.
- The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives."<sup>14</sup>

The suggestion that this is a small group of medicines with doubtful benefits because, according to the Proposed Amendment, the 21<sup>st</sup> Century Cures Act ("Cures Act") expedited drug approvals "by reducing the level of evidence required for drugs to reach the market,"<sup>15</sup> and Medicaid members will not suffer from losing access to these drugs, is incorrect. To mention just one example of the types of drugs that Oregon could exclude under the "limited or inadequate clinical efficacy" label, the last category in this list would include not just accelerated approval drugs, but *most drugs*, because FDA's drug approval framework does not require evidence of an "incremental benefit" over existing therapies for a demonstration of safety and efficacy. Drugs are approved in this country if they are shown to be safe and effective—that is what the law demands and accordingly, what FDA requires manufacturers to demonstrate.

---

<sup>11</sup> H.R. Rep. No. 101-881 at 96-97 (1990), reprinted in 1990 U.S.C.C.A.N. 2017, 2108-09.

<sup>12</sup> We summarize the research in section IV of this letter.

<sup>13</sup> MACStats: Medicaid and CHIP Data Book at Exhibit 43, MACPAC (December 2019), <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf>.

<sup>14</sup> Application at 31.

<sup>15</sup> *Id.*

To the extent Oregon suggests that the Cures Act amended the statutory standards for approval and coverage, these suggestions are wrong. All approved/licensed drugs are subject to the same standards of safety and efficacy for approval/licensure, and nothing in the Cures Act changed or diluted FDA's strict approval standards. Indeed, the Cures Act “ensure[s] that our country remains on the forefront of medical innovation while maintaining the gold standard for approvals of medical products.”<sup>16</sup> In fact, research has shown that drugs approved through expedited review “offered larger health gains, compared to drugs approved through conventional review processes,”<sup>17</sup> suggesting that FDA has prioritized drugs that offer the most significant health advances. If Oregon intended to refer to drugs approved under the accelerated approval pathway when discussing the Cures Act, as further discussed below, these drugs are subject to the same standards of safety and efficacy as all other FDA-approved drugs.

Denying Medicaid members access to these therapies would adversely affect their health—potentially in very serious and disturbing ways—and turn Medicaid into a second-class healthcare program whose members would lack the same access to treatment innovations “that the private patients of their physicians enjoy.”<sup>18</sup> This is the opposite of promoting Medicaid objectives. In fact, HHS previously rejected the state’s request to proceed with the Prioritized List of Healthcare Services (“the List”) based on explicit cost-effectiveness ratios derived from quality-adjusted life years (“QALYs”). Among other objections, one of the major concerns that HHS cited was the potential for the List to discriminate against people with disabilities. The conclusion that Oregon’s closed formulary proposal, with an admitted focus on limiting access to innovative drugs that may warrant accelerated review from FDA, would not promote Medicaid objectives is even stronger given that the courts explicitly require consideration of “the impact of [the state’s] project on the persons’ the Medicaid Act ‘was enacted to protect.’”<sup>19</sup>

The Proposed Amendment’s impact cannot be written off as a necessary consequence of reducing Medicaid costs in order to keep the program sustainable. Under current law, states may create Medicaid formularies, but may exclude a drug from their formulary only if the drug’s labelling or certain compendia establish that the drug has no “therapeutic advantage in terms of safety, effectiveness, or clinical outcome” compared to “other drugs included in the formulary.”<sup>20</sup> Even then, the state must permit members to access otherwise-excluded drugs by following the state’s rules for prior authorization.<sup>21</sup>

Oregon seeks to waive these requirements, requesting to close its formulary and make coverage decisions in each therapeutic class based on whether manufacturers have offered sufficiently “favorable rebate agreements.”<sup>22</sup> This approach is nothing more than cost-based rationing for the most vulnerable among us, and thus is starkly out of step with Section 1927’s “therapeutic advantage” requirement. Moreover, Oregon requests to presumptively exclude drugs approved by the accelerated pathway unless and until the state deems the drug’s price sufficiently

---

<sup>16</sup> July 9, 2015 Congressional Record, House at E1036 (statement of Rep. Pallone).

<sup>17</sup> James D. Chambers et al., *Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process*, 36 HEALTH AFFAIRS 1408, 1408 (2017).

<sup>18</sup> H.R. Rep. No. 101-881 at 96-97 (1990).

<sup>19</sup> *Wood v. Betlach*, 922 F. Supp.2d 836, 848 (D. Az. 2013) (quoting *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9<sup>th</sup> Cir. 2011)).

<sup>20</sup> SSA § 1927(d)(4)(C).

<sup>21</sup> SSA § 1927(d)(4)(D). The state must, for example, respond to prior authorization requests within 24 hours. SSA § 1927(d)(5)(A).

<sup>22</sup> Application at 30.

low or the drug's cost-effectiveness sufficiently high. The Proposed Amendment undercuts the value of drugs approved through the accelerated pathway, commenting that many of them "have not yet demonstrated actual clinical benefit and have been studied in clinical trials using only surrogate endpoints."<sup>23</sup> This, however, misconstrues the very purpose and nature of accelerated approval.

The Federal Food, Drug, and Cosmetic Act ("FDCA") makes clear that accelerated approval does not alter the statutory standard for new drug approval, and accelerated approval requires "substantial evidence" of clinical benefit.<sup>24</sup> Accordingly, the FDA has emphasized that accelerated approval drugs "meet FDA standards for safety and efficacy" and "must meet the same statutory standard for approval" as all other FDA-approved drugs.<sup>25</sup> The standard of evidence thus does not change; only the type of evidence that is evaluated differs from traditional approval. Accelerated approval permits FDA to approve drugs for a "serious or life-threatening condition" based on a determination that the drug has an effect on a surrogate or other endpoints that is "*reasonably likely to predict* clinical benefit."<sup>26</sup> Indeed, research has shown that drugs approved through the accelerated pathway "offered larger health gains, compared to drugs approved through conventional review processes."<sup>27</sup> This suggests that accelerated approval has expedited the availability of drugs that offer substantial health gains. Denying Medicaid members access to these therapies would adversely affect their health—potentially in very serious and disturbing ways—and would send the message that Medicaid is a second-class healthcare program.

Moreover, the proposal does not explain how drug costs will be assessed or how formulary decisions will be made, depriving the public of a meaningful opportunity to comment on Oregon's proposed changes to a program that has long protected access to medically necessary drugs. Oregon merely states that it "will ensure pharmacy protections for members, so that Oregon's closer management of pharmacy costs does not negatively impact member access to the spectrum of safe and effective drugs to treat various conditions."<sup>28</sup> This open-ended and ill-defined promise is not sufficient to guard against the harms presented by a closed formulary.

Section 1115 allows states to enact many types of program adjustments, including policies that may limit coverage in some respects, as long as the demonstration advances Medicaid objectives. *What states cannot do, however, is "prioritize[] program savings" without even acknowledging—much less weighing—"the consequences of lost coverage."*<sup>29</sup> To the contrary, the state and the Secretary of HHS ("Secretary") "must obviously consider the impact" of the state's proposed demonstration on the individuals that Medicaid "was enacted to protect."<sup>30</sup> And

---

<sup>23</sup> Id. at 31.

<sup>24</sup> Federal Food, Drug, and Cosmetic Act ("FDCA") § 506(e)(2) (referencing FDCA § 505(d)).

<sup>25</sup> Janet Woodcock & Peter Marks, Delivering Promising New Medicines Without Sacrificing Safety and Efficacy, FDA (last modified Aug. 27, 2019), <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/delivering-promising-new-medicines-without-sacrificing-safety-and-efficacy>.

<sup>26</sup> FDCA § 506(c) (emphasis added); Accelerated Approval, FDA (last modified Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>.

<sup>27</sup> See James D. Chambers et al., Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process, 36 HEALTH AFFAIRS 1408, 1408 (2017).

<sup>28</sup> Application at 32.

<sup>29</sup> *Stewart v. Azar*, 366 F. Supp. 3d 125, 149 (D.D.C. 2019) (emphasis added).

<sup>30</sup> *Newton-Nations v. Betlach*, 660 F.3d 370, 380 (9th Cir. 2011).

in this case, the impact cannot reasonably be written off as a necessary consequence of reducing Medicaid costs in order to keep the program sustainable.

The summary of research on the effects of formulary restrictions on vulnerable populations in sections III and IV of this letter shows that these restrictions are actually likely to *increase* these members' total healthcare costs, as the savings from curbing access to drugs are typically offset (or more than offset) by increased costs of hospitalizations, emergency room visits, physician visits, and other non-drug costs. Moreover, these unintended, but predictable, consequences must be factored into decisions about whether hoped-for savings from benefit cuts are actually likely to materialize and help to promote Medicaid sustainability—or instead to backfire and hurt members' health without generating overall Medicaid savings.<sup>31</sup>

Congress enacted the Medicaid rebate statute to ensure that members would “have access to the same range of drugs that the privately insured patients of their physicians enjoy.”<sup>32</sup> Oregon's request for a closed formulary would undermine this vision, especially with respect to new drugs approved under the accelerated pathway. Oregon's proposal “hinders the provision of health coverage to the needy” by jeopardizing Medicaid members' access to care and putting them on unequal footing with their counterparts in private plans or in Medicare.<sup>33</sup> The proposal is thus contrary to the objectives of the Medicaid statute.

#### **B. The Medicaid Rebate Statute Is a Package Deal that Cannot Be Torn Apart by a Selective Waiver of Its Coverage Requirements Alone**

Although the Proposed Amendment does not indicate whether the state is willing to give up the statutory Medicaid rebates it currently receives under Section 1927 of the SSA, Oregon's request for a closed formulary seeks to waive Section 1927 via a waiver of Section 1902(a)(54), to allow exclusion of covered outpatient drugs broadly, as well as “drugs with limited or inadequate evidence of clinical efficacy,” including accelerated approval drugs specifically.<sup>34</sup> We thus understand Oregon to be seeking continued manufacturer rebates under federal law (in addition to any supplementary rebates negotiated by the state) despite excluding drugs from coverage. This request for a waiver of drug coverage requirements under Section 1927(d)(4), without also waiving the state's access to mandatory rebates under the MDRP, is flatly inconsistent with the Medicaid rebate statute.

The Centers for Medicare & Medicaid Services (“CMS”) cannot waive the Medicaid rebate statute's coverage requirements while leaving in place the requirement for manufacturers to pay rebates on Medicaid utilization. Such a one-sided waiver would breach the careful legislative

---

<sup>31</sup> See, e.g., *Wood v. Betlach*, 992 F. Supp. 836, 850 (D. Ariz. 2013) (finding that CMS acted arbitrarily and capriciously in approving an 1115 demonstration increasing beneficiary copayments where a declaration that plaintiffs submitted to CMS showed that “extensive research on cost sharing for the poor has shown that copayments are not an effective Medicaid cost-saving measure for states” due to higher drug copayments leading members to use fewer drugs and more emergency room and inpatient hospital care, but CMS “made [no] effort to address Plaintiffs' administrative objections that copayments are not an effective cost-saving measure”).

<sup>32</sup> H.R. Rep. No. 101-881 at 96-97 (1990) (emphasis added).

<sup>33</sup> See *Gresham v. Azar*, 363 F. Supp. 3d 165, 178 (D.D.C. 2019).

<sup>34</sup> Application at 30-31.

bargain Congress created in the Medicaid rebate statute, described by Congressman Henry Waxman, a key sponsor, as a “government-industry compact.”<sup>35</sup> As CMS has explained:

[D]rug manufacturers must pay statutorily-defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.<sup>36</sup>

The rebate statute’s legislative history similarly emphasizes that the statute links manufacturer rebate obligations and Medicaid coverage obligations:

The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require states that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.<sup>37</sup>

Congress thus required states to cover all products of a manufacturer with a Medicaid rebate agreement (with specified exceptions), to ensure member access to the full range of drugs that are available to privately insured patients. Accordingly, the statute purposely coupled the rebate requirements on manufacturers with the coverage requirements on states. The standard Medicaid Rebate Agreement between CMS and each manufacturer that participates in the MDRP also emphasizes this bargain: it details manufacturers’ obligations to calculate and pay rebates, and recognizes that manufacturers must be able to rely on states fulfilling their end of the statutory bargain (and to enlist CMS’s assistance if a state does not fulfill its coverage obligations).<sup>38</sup>

As the Supreme Court has emphasized, “strict adherence to the language and structure of [an] Act is particularly appropriate where . . . a statute is the result of a series of carefully crafted compromises.”<sup>39</sup> Many cases similarly hold that when a statute reflects a legislative bargain, it

---

<sup>35</sup> Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce, H. Hrg. 103-61, 103rd Cong. 453 (1993) (statement of Rep. Waxman).

<sup>36</sup> 78 Fed. Reg. 4594, 4631 (Jan. 22, 2013) (emphasis added). The rebate statute’s legislative history similarly emphasizes this compact: “Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.” H.R. Rep. No. 101-881 at 96-97 (1990) (emphasis added).

<sup>37</sup> H.R. Rep. No. 101-881 at 96-97 (1990) (emphasis added).

<sup>38</sup> Medicaid Rebate Agreement § VI(a) (“A State’s failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act [establishing a notice and hearing process for CMS to stop or reduce payments to State Medicaid programs that are out of compliance with their State plan obligations]”).

<sup>39</sup> *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 748 n.14 (1989).

must be interpreted to uphold that bargain, not tear it asunder.<sup>40</sup> Applying this principle here, the rebate statute is a package—with benefits and obligations for both manufacturers and Medicaid—and CMS cannot authorize a state to keep the benefits of the package, but jettison its coverage responsibilities. The Proposed Amendment that Oregon seeks—which would expand its power to restrict coverage—would thwart the core objective of the rebate statute, undermining the compact between states and manufacturers.

CMS fully recognizes this statutory compact, as demonstrated by its decision to deny a Section 1115 waiver amendment request from Massachusetts to establish a closed formulary and exclude coverage of “accelerated approval pathway” drugs.<sup>41</sup> On June 27, 2018, CMS rejected this part of Massachusetts’s request on the grounds that it “would have allowed the State to continue to collect manufacturer rebates under Section 1927, while enabling the state to exclude certain drugs from coverage,” thereby rupturing the statute’s careful balance.<sup>42</sup> That same day, CMS issued a Program Notice emphasizing that Medicaid programs may not exclude coverage for a drug merely because it was approved under FDA’s accelerated pathway. By definition, these are “drugs for serious conditions that fill an unmet medical need,” which have, to FDA’s satisfaction, shown promising results on surrogate or intermediate clinical endpoints that are “reasonably likely to predict a real clinical benefit.”<sup>43</sup> A drug that has received FDA approval, accelerated or otherwise, “meets the definition of [a] covered outpatient drug” under Section

---

<sup>40</sup> See, e.g., *General Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992) (upholding statutory provisions necessary to “preserve the delicate legislative compromise that had been struck by [prior] laws”); *Mohasco Corp. v. Silver*, 447 U.S. 807, 826 (1980) (“We must respect the compromise embodied in the words chosen by Congress. It is not our place simply to alter the balance struck by Congress . . . .”); *Rodriguez v. Compass Shipping Co.*, 451 U.S. 596, 612 (1981) (“[In] interpreting the intent of Congress in fashioning various details of this legislative compromise, the wisest course is to adhere closely to what Congress has written”); *Villarreal v. R. J. Reynolds Tobacco Co.*, 839 F.3d (11th Cir. 2016) (elevating general notions of purpose over statutory text “disregards the processes of [legislative compromise] and, in the end, prevents the effectuation of congressional intent”) (citation omitted); *United States v. Taylor*, 487 U.S. 326, 336 (1988) (“the purposes of the Act and the legislative compromise it reflects [must be] given effect”); *American Mining Congress v. EPA*, 824 F.2d 1177, 1187 (D.C. Cir. 1987) (courts “must be loathe to tear asunder” the process of legislative compromise).

<sup>41</sup> MassHealth Section 1115 Demonstration Amendment Request (Sept. 8, 2017), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-pa3.pdf>. PhRMA notes that on January 8, 2021, despite having rejected the Massachusetts closed formulary request in 2018, CMS approved a Medicaid demonstration amendment from Tennessee that authorized the use of a closed formulary. See CMS Demonstration Approval: TennCare III (Project Number 11- W-00369/4), CMS (as amended Jan. 20, 2021), <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tn-cms-aprvl.pdf>. As detailed in PhRMA and many stakeholder comments to CMS on Tennessee’s demonstration amendment, CMS does not have the legal authority under the SSA to approve the Tennessee amendment. PhRMA’s Comments on Tennessee’s “TennCare III” Medicaid Demonstration (Project Number 11-W-00369/4), [https://1115publiccomments.medicaid.gov/jfe/file/F\\_3DkgKMhfPUCv6Gh](https://1115publiccomments.medicaid.gov/jfe/file/F_3DkgKMhfPUCv6Gh). CMS has since reopened implementation of the demonstration amendment in response to litigation involving the approval and solicited a new round of public comments on the amendment. See *McCutchen et al v. Becerra et al*, No. 21-cv-01112, Government’s Unopposed Motion to Hold in Abeyance (D.D.C. Aug. 11, 2021) (asking to hold the case in abeyance while CMS “opens the federal comment period on the Medicaid demonstration approval challenged in this lawsuit and reconsiders the challenged decision.”); CMS, 1115 TennCare III - Approval STCs, [https://1115publiccomments.medicaid.gov/jfe/form/SV\\_9zWXfvSDSRtLxAy](https://1115publiccomments.medicaid.gov/jfe/form/SV_9zWXfvSDSRtLxAy).

<sup>42</sup> Letter from Tim Hill, Acting Director, Ctr. for Medicaid & CHIP Services, to Daniel Tsai, Assistant Sec’y, MassHealth, at 2 (June 27, 2018) [hereinafter “CMS Response to Massachusetts”], <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-aprvl-jun-2018.pdf>.

<sup>43</sup> Accelerated Approval, FDA (last modified Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>; see also 21 U.S.C. § 356(c).

1927(k), meaning that “the drug must be covered by state Medicaid programs if the manufacturer has an applicable signed Medicaid national drug rebate agreement.”<sup>44</sup>

**C. A Closed Formulary Is Not a Permissible “Experimental, Pilot, or Demonstration Project” Under Section 1115**

Section 1115 authorizes the Secretary to approve “experimental, pilot, or demonstration project[s].”<sup>45</sup> Approved demonstrations must not only serve the objectives of the Medicaid program, but must also be designed and intended to learn and/or demonstrate something new. Oregon’s proposal fails to specify how it will serve as an “experimental” or “demonstration” project as required under Section 1115. The Proposed Amendment appears to propose using a closed formulary as a cost-cutting measure without associated research metrics to determine if such a change would further the core objectives of the Medicaid programs, which is not permissible under Section 1115.

As the courts have explained,

[t]he purpose of these [Section 1115] demonstrations, which give states additional flexibility to design and improve their programs, is to *demonstrate and evaluate policy approaches* such as: expanding eligibility to individuals who are not otherwise Medicaid or CHIP eligible; providing services not typically covered by Medicaid; using innovative service delivery systems that improve care, increase efficiency . . .<sup>46</sup>

Similarly, as the Ninth Circuit explained in *Beno v. Shalala*:

[SSA § 1115] requires that the state project be an experimental, demonstration or pilot project. *The statute was not enacted to enable states to save money or to evade federal requirements but to test out new ideas and ways of dealing with the problems of public welfare recipients.* Thus, the Secretary must make some judgment that the project has a research or a demonstration value. *A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement . . . the Secretary must make at least some inquiry into the merits of the experiment—she must determine that the project is likely to yield useful information or demonstrate a novel approach to program administration.*<sup>47</sup>

The Ninth Circuit applied this reasoning in *Newton-Nations v. Betlach* and found CMS’s approval of an Arizona demonstration increasing Medicaid copayments to be arbitrary and capricious.<sup>48</sup> Notably, the court questioned whether the initiative could have research or demonstration value given that “Plaintiffs’ public health expert stated that over the last 35 years,

---

<sup>44</sup> Medicaid Drug Rebate Program Notice, State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway, CMS (June 27, 2018), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf> (emphasis added).

<sup>45</sup> SSA § 1115(a).

<sup>46</sup> See *Nazareth Hosp. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 747 F.3d 172, 181 (3d Cir. 2014) (emphasis added); *Cooper Hosp. / Univ. Med. Ctr. v. Burwell*, 179 F. Supp. 3d 31, 50 (D.D.C. 2016), *aff’d sub nom. Cooper Hosp. Univ. Med. Ctr. v. Price*, No. 16-5165, 2017 WL 2347695 (D.C. Cir. May 9, 2017) (quoting the Third Circuit).

<sup>47</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

<sup>48</sup> *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011).

a number of studies have looked at the effects of cost sharing on the poor” and that “[t]he administrative record contains no finding from the Secretary that Arizona’s demonstration project will actually demonstrate something different than the last 35-years’ worth of health policy research.”<sup>49</sup>

A large body of research exists on how restrictions affect vulnerable populations, similar to the cost-sharing research cited in *Newton-Nations*. The topic has already been extensively studied. Section IV of this letter provides a detailed summary of that body of research—which shows that imposing formulary restrictions on vulnerable populations generally produces adverse effects on members’ health; increases the risks of justice system contacts and other social problems; and increases overall healthcare costs, as beneficiary care increasingly shifts from outpatient drugs to hospitalizations and emergency room visits.

Nothing in the Proposed Amendment suggests that the requested waiver would advance knowledge of the impact limiting access to medicines for the needy. The most this demonstration could possibly achieve would be to replicate the negative outcomes found in the existing literature. This is not research, but a “simple benefits cut,”<sup>50</sup> with a wholly predictable outcome, and is therefore inconsistent with Section 1115’s purpose.

#### **D. The Demonstration Amendment Lacks Sufficient Detail to Provide a Meaningful Opportunity for Public Comment**

Following years of concern about the transparency of Section 1115 demonstration approvals, the Affordable Care Act amended Section 1115 to require greater transparency and opportunity for public comment relating to proposed demonstrations that would affect “eligibility, enrollment, benefits, cost-sharing, or financing.”<sup>51</sup> Pursuant to this mandate, CMS issued regulations requiring a public notice and comment process at the state and federal levels meeting basic transparency standards specified in the regulations. Oregon has, in accordance with those regulations, released a draft Application for public comments, which includes the Proposed Amendment. The Application leaves out crucial details, however, and thus fails to satisfy the requirement for a “comprehensive description of the demonstration application or extension to be submitted to CMS that contains a sufficient level of detail to ensure meaningful input from the public.”<sup>52</sup>

In several important areas, Oregon has provided only vague outlines of the Proposed Amendment. These rough sketches are insufficient for the public to understand the state’s intentions or to provide “meaningful” comments on the proposal’s risks and benefits. The following are only some of the many examples of underspecified proposal elements:

- 42 C.F.R. § 431.408 requires a “hypothesis and evaluation parameters of the demonstration,” and Oregon’s Proposed Amendment clearly falls short of this requirement.<sup>53</sup> While Oregon offers hypotheses for the other changes proposed in the

---

<sup>49</sup> Id. at 381 (emphasis added).

<sup>50</sup> *Beno v. Shalala*, 30 F.3d at 1069.

<sup>51</sup> SSA § 1115(d)(1).

<sup>52</sup> 42 C.F.R. § 431.408(a)(1)(i).

<sup>53</sup> Id. § 431.408(a)(1)(i)(D).

- Application, it offers no hypotheses or evaluation parameters for the impact the Proposed Amendment.
- More explanation is needed of the statement that Oregon “will ensure pharmacy protections for members, so that Oregon’s closer management of pharmacy costs does not negatively impact member access to the spectrum of safe and effective drugs to treat various conditions.”<sup>54</sup> This brief statement is less than a “comprehensive description” of the initiative that “contains a sufficient level of detail to ensure meaningful input from the public,” as Oregon provides no explanation of the types of protections it envisions to ensure access to safe and effective drugs.<sup>55</sup>
  - The description of how the closed formulary would be developed and the types of drugs that could be excluded (e.g., drugs labeled as having “limited or inadequate clinical efficacy” or an even broader group) is also insufficient to ensure meaningful public input. Oregon states only that it will “use its own rigorous review process to determine coverage of new drugs and to prioritize patient access to clinically proven, effective drugs,”<sup>56</sup> but describes nothing further about what that rigorous review process would entail.
  - We are further concerned that the listing of drug categories ostensibly having “limited or inadequate clinical efficacy” actually includes a broad and vitally important group of drugs, and the description of these drugs in the Proposed Amendment may cause confusion about the scope of potential formulary exclusions and thereby prevent meaningful stakeholder comments on the closed formulary proposal.

## **II. Cost Containment Tools to Control Pharmacy Expenditures are currently Available Under Section 1927 and Other Provisions**

In exchange for substantial guaranteed rebates, state Medicaid programs must cover most outpatient drugs with certain statutory exceptions. States have access to numerous cost containment tools to control or manage access and encourage responsible and cost-effective use of medicines within the Medicaid program. In 2019, Medicaid prescription drug spending in Oregon was found to be only 3.3% of total Medicaid spending, due in part to manufacturer rebates and other cost containment tools.<sup>57</sup> If Oregon seeks increased leverage to negotiate higher rebates from manufacturers, Oregon should use the cost containment tools available under the drug rebate statute before taking such drastic action to remove drugs from coverage.

Section 1927 already offers multiple policy levers through which states can control inappropriate drug utilization and reduce drug spending. Among other tools, states have the authority to exclude a drug from their formulary if the drug’s labelling or certain compendia establish that the drug has no “therapeutic advantage in terms of safety, effectiveness, or clinical outcome” compared to “other drugs included in the formulary.”<sup>58</sup> In view of this existing authority,

---

<sup>54</sup> Application at 32.

<sup>55</sup> See 42 C.F.R. § 431.408(a)(1)(i); Application at 32.

<sup>56</sup> Application at 31.

<sup>57</sup> The Facts About Medicaid in Oregon, PhRMA, [https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/OR-One-Pager\\_19.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/OR-One-Pager_19.pdf).

<sup>58</sup> SSA § 1927(d)(4)(C).

Oregon’s request for a closed formulary suggests an intent to exclude coverage for medications that *do* have a “therapeutic advantage” over other drugs.

In outlining the parameters for prescription drug coverage in the Medicaid program, Congress enacted comprehensive provisions designed to protect patients. If Oregon wants to establish a formulary, it should do so through existing authority in the Medicaid drug rebate statute. Yet it has chosen not to do so. Instead, the Proposed Amendment seeks to create a “closed formulary” that would exclude a wide range of drugs without making the clinical determinations required under the SSA, effectively vitiating formulary safeguards established by Congress for the protection of members. Doing so is not “likely to assist in promoting the objectives of title XIX” of the SSA and fails to meet a basic requirement of Section 1115.<sup>59</sup>

The cost containment tools available to states under SSA §1927 include the following:

- States may impose prior authorization requirements on any drug, provided they respond to prior authorization requests within 24 hours and dispense a 72-hour supply of the requested drug in an emergency;<sup>60</sup>
- States may exclude or restrict coverage of any drug that is not prescribed for a “medically accepted indication” (defined as FDA-approved indications plus off-label uses supported by specified compendia),<sup>61</sup>
- States may impose restrictions authorized by an agreement with the drug manufacturer, also known as the Medicaid Drug Rebate Agreement;<sup>62</sup>
- States may exclude or restrict coverage of any drug used for certain listed purposes (e.g., anorexia, weight loss, weight gain, to promote fertility, for cosmetic purposes, etc.);<sup>63</sup>
- States may create Medicaid formularies and exclude a drug from a Medicaid formulary if: (a) the drug’s labeling or certain compendia establish that the drug “does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome” over a drug included on the formulary, (b) there is a publicly-available written explanation of the basis for the exclusion, (c) the excluded drug is available with prior authorization, and (d) certain additional requirements relating to the committee that develops the formulary are satisfied;<sup>64</sup>
- States “may impose limitations, with respect to all . . . drugs in a therapeutic class, on the minimum or maximum quantity per prescription or on the number of refills, if . . . necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under [the Medicaid statute];”<sup>65</sup> and

---

<sup>59</sup> SSA § 1115(a).

<sup>60</sup> SSA § 1927(d)(1)(A),(5).

<sup>61</sup> SSA § 1927(d)(1)(B)(i).

<sup>62</sup> SSA § 1927(d)(1)(B)(iii).

<sup>63</sup> SSA § 1927(d)(1)(B)(ii),(2).

<sup>64</sup> SSA § 1927(d)(4).

<sup>65</sup> SSA § 1927(d)(6).

- States may create PDLs, which are lists of drugs that are not subject to prior authorization and are not “formularies” that must satisfy the rebate statute’s requirements for formularies, and may demand supplemental rebates as the price for including a drug on the PDL.<sup>66</sup>

The leverage provided to states by these measures is so great that as of June 2021, 47 states (including Oregon) and the District of Columbia had supplemental rebate programs that allowed them to collect extra rebates above and beyond the large rebates required by the rebate statute.<sup>67</sup>

Oregon may also rely on voluntary, value-based payment arrangements for Medicaid drug purchasing. Value-based arrangements can improve member outcomes, reduce medical costs, and reduce the cost of medicines. These arrangements can improve member access to medicines while supporting better health outcomes and reducing hospitalizations and other medical costs. Value-based contracting arrangements should be tailored carefully to address the medication involved and the members and disease conditions they seek to treat. Such arrangements have already been explored in other states including Colorado<sup>68</sup>, and Michigan,<sup>69</sup> and are currently being implemented in Oklahoma,<sup>70</sup> Washington,<sup>71</sup> and Louisiana.<sup>72</sup> Value-based agreements for Medicaid members must be voluntary, however, given that a statutory minimum rebate is already in place. In other words, the arrangements must be effected through a supplemental rebate agreement. Voluntary, value-based agreements could include:<sup>73</sup>

- Outcomes-based arrangements, which tie costs or discounts to member outcomes;
- Conditional treatment continuation arrangements, which typically are conditioned on meeting short-term treatment goals;
- Indication-based pricing arrangements, where the net price varies based on the indication for treatment;

---

<sup>66</sup> PhRMA v. Meadows, 304 F.3d 1197 (11<sup>th</sup> Cir. 2002); PhRMA v. Thompson, 362 F.3d 817, 823-24 (D.C. Cir. 2004).

<sup>67</sup> Medicaid Pharmacy Supplemental Rebate Agreements, CMS (June 2021), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxsupplemental-rebates-chart-current-qtr.pdf>.

<sup>68</sup> “CMS Oks Colorado’s waiver for Medicaid value-based purchasing”. Modern Healthcare, (February 2019) <https://www.modernhealthcare.com/article/20190225/NEWS/190229950/cms-oks-colorado-s-waiver-for-medicaid-value-based-purchasing>

<sup>69</sup> Nicholas Fiore et al. *Novel State Payment Models for Prescription Drugs: Early Implementation Successes and Challenges*. Duke Margolis Center for Health Policy, (September 2019). <https://healthpolicy.duke.edu/sites/default/files/2020-07/Novel%20State%20Payment%20Models%20Final%20Revised%20091219.pdf>

<sup>70</sup> Reck, Jennifer. Oklahoma Signs the Nation’s First State Medicaid Value-Based Contracts for Rx Drugs, National Academy for State Health Policy (NASHP) (September 25, 2018). <https://www.nashp.org/oklahoma-signs-first-medicaid-value-based-contracts-for-rx-drugs/>

<sup>71</sup> “AbbVie Wins Hep C contract with Washington State in Latest ‘Netflix’ Deal,” BioPharma Dive, April 26, 2019. <https://www.biopharmadive.com/news/abbvie-wins-hep-c-contract-with-washington-state/553576/>

<sup>72</sup> Gee, Rebekah. *Louisiana’s Journey Toward Eliminating Hepatitis C*, Health Affairs Blog, (April 1, 2019).

<sup>73</sup> Comer, Ben. “Six Drug Pricing Models Have Emerged to Improve Product Access and Affordability.” PwC, (September 2019).

<https://www.pwc.com/us/en/industries/health-industries/library/6-drug-pricing-models.html>.

- Regimen-based pricing arrangements, where the net price of a medicine decreases when a member must take additional medication to make the treatment more effective; and
- Expenditure cap arrangements, which limit the cost of medicine per member to a negotiated threshold.<sup>74</sup>

The availability of a wide array of alternative cost containment mechanisms, many of which are being explored in other states, demonstrates that Oregon’s proposed authorization for a closed formulary is fiscally unnecessary, in addition to being harmful to OHP members.

### **III. Restricting Medicaid Drug Coverage Would Exacerbate Existing Health Inequities**

Since the start of the COVID-19 pandemic, roughly one in four Americans have been laid off or lost their job due to the pandemic. Financial insecurity during this time has affected the ability of many to pay for necessities, with 44% of respondents stating in a recent poll that they have used money from savings/retirement to pay bills, and 35% stating that they have received food from a food bank/organization since the start of the pandemic.<sup>75</sup> The economic instability brought on by the pandemic has increased Medicaid rolls nationwide. Oregon’s Medicaid program has experienced a 24.16% jump in enrollment (+260,000 members) since March 2020, and it is estimated that over 300,000 current members may lose eligibility during the redetermination process once federal pandemic Public Health Emergency provisions expire.<sup>76</sup>

Due to concerns about the pandemic, 41% of adults have avoided or delayed routine or emergency/urgent care.<sup>77</sup> The prevalence of delaying or avoiding care is higher among Black (60% higher) and Hispanic (50% higher) adults than non-Hispanic White adults and higher still among indigenous populations. These disparities demonstrate that the pandemic has had harmful effects on the social, economic, and health care-related outcomes among lower-income and racially/ethnically-diverse groups.

Predating the COVID-19 pandemic, there have been myriad longstanding and intersecting systemic, social, and structural barriers that have impeded equitable access to medicines. Research clearly shows that social determinants of health impact life-long health care outcomes.<sup>78</sup> Additionally, patients respond differently to treatment because of a number of factors, such as genetics, age, sex, socioeconomic status, drug-drug interactions, diet, environment, and co-

---

<sup>74</sup> Trusheim MR, Cassidy WM, Bach PB. Alternative State-Level Financing for Hepatitis C Treatment—The “Netflix Model”. *JAMA*. 2018;320(19):1977–1978.

<sup>75</sup> Hamel L, Lopes L, Munana C, Artiga S. KFF/The Undeclared Survey on Race and Health. Kaiser Family Foundation. Oct 2020. <https://www.kff.org/report-section/kff-the-undeclared-survey-on-race-and-health-main-findings/#ExecutiveSummary>.

<sup>76</sup> <https://stateofreform.com/featured/2021/10/oha-says-as-many-as-300000-enrollees-may-come-off-the-oregon-health-plan-once-the-public-health-emergency-ends/>.

<sup>77</sup> Czeisler MÉ, Marynak K, Clarke KE, et al. Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns — United States, June 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1250–1257.

<sup>78</sup> Reno R, Warming E, Zaugg C, Marx K, Pies C. Lessons Learned from Implementing a Place-Based, Racial Justice-Centered Approach to Health Equity. *Matern Child Health J*. 2021 Jan;25(1):66-71.

morbidities. This means that treatments that are the best option for some individuals are not as effective for others.<sup>79</sup>

In addition, underserved populations are often treated later for many diseases, such as certain cancers<sup>80</sup> and asthma. Therefore, timely access to provider-recommended medicines is central to reversing that trend, improving health outcomes, decreasing avoidable health care utilization and costs,<sup>81</sup> and reducing mortality.

As such, Oregon's Proposed Amendment to implement a closed formulary would not serve the state's other laudable goals of advancing health equity. Instead, it would curtail any bridging of health care gaps by creating yet another layer of bureaucracy, impeding equitable access to necessary medications. A recent study suggests that restrictive benefit designs are associated with reduced medication adherence and negative clinician outcomes.<sup>82</sup> Moreover, a restrictive, closed formulary would undervalue patient preferences and medication needs made in consultation with their physicians and the priorities and health care needs of diverse populations in Oregon. As a result, patients with chronic and other conditions may lose access to their current treatments or experience disruptions in care.

America's biopharmaceutical companies maintain frontline commitment to developing more treatments and vaccines not just for COVID-19, but also for thousands of other debilitating and life-threatening conditions including those like Alzheimer's disease,<sup>83</sup> certain cancers,<sup>84,85</sup> and many other common chronic and rare diseases. There are a number of conditions disproportionately impacting communities of color, including sickle cell disease and metachromatic leukodystrophy in African American and Hispanic populations, and lupus and sarcoidosis across indigenous communities. Patients of color with rare diseases face extraordinary challenges and experience a disproportionate burden in accessing care.

The state's proposed intent to exclude from its formulary drugs "with limited or inadequate evidence of clinical efficacy" is especially problematic with respect to the assignment of "value" of medicines. Measurements accounting for "clinical efficacy" often obscure the distinct needs of disadvantaged populations, including communities of color, by rendering judgments about value based on "average" study results, which often reflect primarily White populations and ignore diversity in preferences and other factors that impact health, such access to care, education, and literacy.

---

<sup>79</sup> McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines?. *PharmacoEconomics* (2021).

<sup>80</sup> Halpern MT, Holden DJ. Disparities in timeliness of care for U.S. Medicare patients diagnosed with cancer. *Curr Oncol.*2012;19(6):e404-e413.

<sup>81</sup> Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care.* 2005 Jun;43(6):521-30.

<sup>82</sup> Park Y, Raza S, George A, Agrawai R, Ko J. The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review. *JMCP.* August 2017; 23 (8). <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.23.8.893>.

<sup>83</sup> 2020 Alzheimer's disease facts and figures. *Alzheimer's and Dementia.* <https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12068>.

<sup>84</sup> Cancer Stat Facts: Prostate Cancer. SEER. <https://seer.cancer.gov/statfacts/html/prost.html>

<sup>85</sup> Multiple Myeloma Research Foundation. <https://themmrf.org/multiple-myeloma/black-patients/>.

For example, the value of a lifesaving treatment for Black patients can be automatically valued up to 10% less than for White patients due to biased value metrics such as the quality-adjusted life year or QALY.<sup>86</sup> Most Medicaid patients contend with chronic and rare disease management that requires regular assessments by a provider to determine the type of medicine and dosage that works best. Anything other than an open formulary, free from value constraints, runs the risk of ignoring important patient differences and overriding physician-patient decisions about the best course of treatment for any patient population, but most especially for those served by Medicaid.

Implementing a closed formulary could have the unintended consequence of widening health disparities at a time when Oregon residents are still dealing with the continued effect of the pandemic, and previous and possible pandemic-induced health conditions.

We applaud the state on its other proposals in the amendment to improve health equity, which may be more effective at improving health equity than a closed formulary. Such other measures include improvement of quality metrics and data collection and reporting designed to incentivize systems-level changes that advance equity and address domains for which no current metrics exist. The COVID-19 pandemic has underscored disparate data collection and reporting practices across states and even by the federal government. A key opportunity to improve health outcomes among Oregon's Medicaid population is to promote standards in the collection and reporting of data, including social determinants of health data, that can be applied across the health system, using granular definitions to reflect diversity within broad categories of race and ethnicity, ensuring data collection in a culturally sensitive manner, while safeguarding against misuse of personally identifiable data.

We recommend that improvements in data collection and reporting involve strong engagement with experts, community leaders (e.g., historically black colleges and universities and community health centers), and patients themselves to understand and test which social determinants of health data are most important to collect, and in what manner to collect them. We also encourage efforts to collect and use health data to consider the intersection between different social and demographic factors. Many populations experience more than one source of disadvantage at a time which can have multiplicative impacts on an individual's life experiences.<sup>87</sup>

Additionally, there are opportunities to leverage existing data to better inform health care use and outcomes across important subpopulations, particularly as they relate to health disparities. For example, CMS publicly reports select information to inform health disparities among the Medicare and Medicaid populations that could be readily expanded to better understand inequities in diagnosis and treatment by adding measures of recommended screenings and use of medicines.

We also applaud the state's intent to collaborate with community-based organizations on strategies to improve health equity. We have mutual interest in empowering traditional and non-traditional, community-based partners to align with the health sector towards addressing health

---

<sup>86</sup> Broder, M, Ortendahl, J. Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research. 2021. <https://blogs.heart.org/2021/08/is-cost-effectiveness-analysis-racist/>.

<sup>87</sup> Nick G, Schloss K, Lekas HM, et al. A Social Determinants Perspective of the Intersection of Ageism, Racism, and Social Isolation During COVID-19. Behavioral Health News. Jan 1, 2021. <https://behavioralhealthnews.org/a-social-determinants-perspective-of-the-intersection-of-ageism-racism-and-social-isolation-during-covid-19/>.

inequity and social determinants of health across the continuum, from birth to adulthood. Community-based organizations are integrated with and understand the specific needs of the communities they serve, which is critical to successfully engaging and reaching underserved areas. These organizations can recommend approaches most likely to resonate with their communities.

In April 2019, PhRMA created the Collaborative Actions to Reach Equity (“CAREs”) grant program, which has since awarded nearly \$400,000 to community organizations, institutions, and individuals who have a mission to advance health equity. The PhRMA CAREs grant program aims to address health inequities through partnership with community-led organizations to support local and national activities and research, driving meaningful change on the ground by addressing pressing issues, such as maternal mortality, access to COVID-19 treatments and vaccines, disparities in medication use/access, and bias in seeking health care.

Bridge-Pamoja, a CAREs grant recipient located in Portland, Oregon,<sup>88</sup> is a network of faith-based leaders and culturally specific organizations dedicated to addressing unique needs of African and African American communities through grassroots and community-based efforts. To combat the COVID-19 pandemic, Bridge-Pamoja aims to break down barriers to the uptake of COVID-19 vaccines within local African and African American communities using a three-pronged approach: 1) partnering with state officials to track how many Africans and African Americans successfully complete doses of COVID-19 vaccines; 2) monitoring how the state government partners with Black-led organizations (including houses of worship) to perform outreach to the African and African American communities regarding COVID-19 vaccination; and 3) hosting virtual forums with Black community and faith leaders to address the successes and challenges of the state’s COVID-19 vaccination outreach process.<sup>89</sup> Through these efforts, Bridge-Pamoja has helped to create an environment that fosters relationships of trust through reliable messengers.

This is just one example of the type of impact on-the-ground organizations can have to improve health equity. As the state continues to consider meaningful actions to improve health equity, we are happy to discuss solutions to a shared goal in addressing health equity—solutions that do not impair access to necessary and much-needed medicines for Medicaid patients, but that promote and provide opportunities to thrive.

#### **IV. The Proposed Amendment Ignores Research Showing that Closed Formularies Hurt Patients, Lower Adherence, and Do Not Reduce Health Care Costs**

Oregon’s Proposed Amendment threatens the health of Medicaid members by limiting access to a host of medicines and imposing significant restrictions in creating a closed formulary. Medicaid members are more likely to be in fair or poor health and have complex and chronic health conditions that often require access to a broad range of medicines compared to those with

---

<sup>88</sup> <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/FINAL-CARES-Awardees-Overview-Rev.pdf>.

<sup>89</sup> PhRMA Covid-19 Collaborative Actions to Reach Equity (CAREs) Grant: Spurring Ideas for a More Equitable Future Available at: [https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/COVID-19\\_Community\\_Action\\_Health\\_Equity\\_Grant\\_RFP.pdf](https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/COVID-19_Community_Action_Health_Equity_Grant_RFP.pdf).

private insurance.<sup>90</sup> If Oregon chooses to adopt the Proposed Amendment, OHP members will have no other options if the formulary does not include a needed medication. The direct damage from a closed formulary is easy to anticipate—and highly concerning—in view of the extensive research documenting the consequences of restricting access to prescription drugs. Importantly, these studies show that access restrictions reduce adherence to prescribed medication regimens, worsen health outcomes, and drive up long-run costs, both to Medicaid and other state and local programs.

Oregon’s proposal to restrict access to one drug per class would ration care and deny members access to a diverse range of treatment options that would best suit their health, biology, and preferences. Research has found that allowing patients and doctors a choice of medicines can increase efficacy of treatments, lower incidence of adverse events, and lower the chances of drug interactions.<sup>91,92,93</sup>

We offer here a small sampling of the many studies that underscore the important role that a *choice* of medicines plays in improving patient outcomes. Without access to multiple drugs in a class, including the latest formulations, physicians are hindered in their ability to effectively treat or manage patients’ medical conditions.

- A *New England Journal of Medicine* study found that patients who had capped benefits were more likely to have higher blood pressure and cholesterol levels compared to those without capped benefits.<sup>94</sup>
- For patients with depression, many studies have shown that a substantial number of patients who fail to respond to first-line selective serotonin reuptake inhibitors will achieve a clinically meaningful response when switched to another drug in the same class.<sup>95,96,97</sup>
- New formulations of HIV medicines that combine up to four medicines with different mechanisms have increased adherence and worked to avoid drug resistance, further reducing additional health care costs.<sup>98,99,100</sup>

---

<sup>90</sup> MACStats: Medicaid and CHIP Data Book, MACPAC (December 2019), <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf>.

<sup>91</sup> Joseph A. DiMasi & Laura B. Faden, Competitiveness in Follow-On Drug R&D: A Race or Imitation?, 10 NATURE REVIEWS DRUG DISCOVERY 23 (2011).

<sup>92</sup> Richard M. Turner et al., Parsing Interindividual Drug Variability: An Emerging Role for Systems Pharmacology, 7 WILEY INTERDISCIPLINARY REVIEWS: SYSTEMS BIO. & MED. 221 (2015).

<sup>93</sup> C. Daniel Mullins et al., Persistence, Switching, and Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, and Citalopram, 25 PHARMACOTHERAPY 660 (2005).

<sup>94</sup> John Hsu et al., Unintended Consequences of Caps on Medicare Drug Benefits, 354 NEW ENG. J. MED. 2349 (2006).

<sup>95</sup> Michael E. Thase et al., Citalopram Treatment of Fluoxetine Nonresponders, 62 J. CLINICAL PSYCHIATRY 683 (2001).

<sup>96</sup> Michael Bauer & Andreas Baumgartner, Fluoxetine-Induced Akathisia Does not Reappear After Switch to Paroxetine, 57 J. CLINICAL PSYCHIATRY (1997).

<sup>97</sup> C. Daniel Mullins et al., Persistence, Switching, and Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, and Citalopram, 25 PHARMACOTHERAPY 660 (2005).

<sup>98</sup> Jeannette R. Ickovics et al., Consequences and Determinants of Adherence to Antiretroviral Medication: Results from Adult AIDS Clinical Trials Group Protocol 370, 7 ANTIVIRAL THERAPY 185 (2002).

<sup>99</sup> David R. Bangsberg et al., A Single Tablet Regimen Is Associated with Higher Adherence and Viral Suppression than Multiple Tablet Regimens in HIV+ Homeless and Marginally Housed People, 24 AIDS 2835 (2010).

<sup>100</sup> Jean B. Nachega et al., Lower Pill Burden and Once-Daily Antiretroviral Treatment Regimens for HIV Infection: A Meta-Analysis of Randomized Controlled Trials, 58 CLINICAL INFECTIOUS DISEASES 1297 (2014).

- A systematic literature review of nearly 100 studies concluded that “formulary restrictions were most frequently negatively correlated” with desirable outcomes, including a consistent negative effect on medication adherence.<sup>101</sup> Medication non-adherence can have serious health consequences, and may cost the U.S. economy up to \$300 billion annually in “avoidable” health care expenditures, as discussed in a 2017 *New England Journal of Medicine* article.<sup>102</sup>
- A closed formulary involves “one size fits all” determinations about clinical efficacy and cost-effectiveness, determinations that inevitably fail to accommodate the diverse needs of a heterogenous patient population like Oregon’s Medicaid population, which includes pregnant women, people with significant disabilities, and parents who face only acute or mild-to-moderate chronic health conditions. A recent study found that, if the Oregon Medicaid program implemented rigid cost-effectiveness criteria for a set of chronic conditions treated with long-term drug regimens, up to 100% of affected members would need to change their current prescriptions.<sup>103,104</sup>
- The evidence shows “a clinical and economic advantage to utilizing newer versus older drugs.” However, drug access restriction programs have been shown to drive “an increase in the age of drugs prescribed for Medicaid beneficiaries versus non-Medicaid patients.”<sup>105</sup> By further limiting coverage for the newest, most innovative medicines under a closed formulary, Oregon would be telling its most vulnerable citizens that they don’t deserve full access to cutting-edge therapies.
- For curative hepatitis C antivirals, a 2016 study concluded that Medicaid policies allowing only certain members to access those drugs were “*more costly and less effective than unrestricted, full-access strategies.*”<sup>106</sup>
- A study published in *The American Journal of Public Health* found that formulary restrictions for Medicaid members in Arizona living with rheumatoid arthritis had unintended consequences including increasing hospitalizations by 50% and costing an additional \$900 per patient annually.<sup>107</sup>

---

<sup>101</sup> Laura E. Happe et al., A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization, 20 J. MANAGED CARE PHARM. 677 (2014).

<sup>102</sup> Zullig, LL, Bosworth, H, Engaging Patients to Optimize Medication Adherence, 3 NEJM CATALYST (2017).

<sup>103</sup> Impact Analysis of ICER Formulary Implementation in Medicaid, XCENDA, [https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/icer-medicaid-analysis\\_march-2019.pdf?la=en&hash=03590A12822FB95144692F0BF6FFF846E2E26F1A](https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/icer-medicaid-analysis_march-2019.pdf?la=en&hash=03590A12822FB95144692F0BF6FFF846E2E26F1A) (last visited Dec. 12, 2021).

<sup>104</sup> Applying Icer Assessments In Oregon Could Limit Patients’ Access To Medicines, XCENDA, <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Applying-ICER-Assessments-Oregon-Fact-Sheet.pdf> (last visited Dec. 15, 2021). The conditions studied were: multiple sclerosis (100% of prescriptions would need to be changed), rheumatoid arthritis (84%), non-small cell lung cancer (42%), and asthma (52%).

<sup>105</sup> Frank R. Lichtenberg, The Effect of Access Restrictions on the Vintage of Drugs used by Medicaid Enrollees, AM. J. MANAGED CARE (2005).

<sup>106</sup> Alexis P. Chidi et al., Economic and Public Health Impacts of Policies Restricting Access to Hepatitis C Treatment for Medicaid Patients, 19 VALUE HEALTH 326-34 (2016) (emphasis added).

<sup>107</sup> Tricia J. Johnson & Stephanie Stahl-Moncada, Medicaid Prescription Formulary restrictions and Arthritis Treatment Costs, 98 AM. J. PUBLIC HEALTH 1300 (2008).

- A 2015 review conducted by the University of Southern California noted the following research findings regarding Medicaid access restrictions on psychiatric drugs:<sup>108</sup>
  - Medicaid formulary restrictions for members with severe mental illness result in few drug cost savings, worse member outcomes, higher overall Medicaid spending, and increased incarceration rates.
  - Restricting access to antidepressants drove a 17% increase in the likelihood of hospitalization for a mental health condition; as a result, there was no evidence of overall Medicaid savings from the access restriction.
  - Restricting access to schizophrenia and bipolar medicines increased inpatient and total costs to the Medicaid program by 10 to 23%, without lowering pharmacy costs.

As these findings demonstrate, closed formularies inhibit individualized patient care by limiting access to the specific drug—or combination of drugs—that will most effectively treat or manage the patient’s conditions.

Section 1115 is intended to foster state experimentation by allowing for “experimental, pilot, or demonstration projects.” In light of the robust evidence base summarized above, there is nothing for Oregon to “test” or learn by developing a closed formulary: the literature is rife with examples of the negative consequences that flow from restrictions on member access to prescription drugs. As the Ninth Circuit Court of Appeals explained more than 25 years ago, a Section 1115 project must have a “research or a demonstration value”; a “simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement.”<sup>109</sup>

In this case, Oregon’s proposed “benefits cut” may actually *increase* total Oregon health care spending, given the evidence that limiting members’ access to needed drugs will lead to worse health outcomes and, therefore, greater utilization of other health care services, such as emergency visits and hospitalizations. As it is, Section 1927 affords states ample opportunities to impose appropriate safeguards around prescription drug utilization, as set forth in section II of this letter.

\* \* \* \* \*

We understand that states face a considerable challenge in ensuring residents have access to quality, affordable health care, and recognize Oregon’s desire for flexibility and the imperative to reduce costs throughout OHP. PhRMA remains committed to helping Medicaid members access needed medicines so that every member, in consultation with their physician, has access to therapies that can improve their quality of life. The Proposed Amendment’s closed formulary approach represents a step backwards in pursuit of that goal. This policy definitively fails to promote the objectives of the Medicaid program, as demonstrated by the robust literature

---

<sup>108</sup> Dana Goldman & Seth Seabury, Medicaid Access Restrictions on Psychiatric Drugs: Penny-wise or Pound-Foolish?, USC SCHAEFFER (February 1, 2015), <https://healthpolicy.usc.edu/research/medicaid-access-restrictions-on-psychiatric-drugs-penny-wise-or-pound-foolish/>.

<sup>109</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

demonstrating the negative effects of restrictions on prescription drug access. Closed formularies constrain physician discretion, undermine patient-centered care, and heap additional administrative burdens on patients and providers. The ultimate result is lower medication adherence, worse patient health outcomes, widened health disparities, and higher overall costs for the Medicaid program.

As Congress and HHS continue to work with states to achieve these goals, the basic compromise of Section 1927 must remain in place, as it serves the dual goals of cost-control and access to treatment in the Medicaid program. Unwinding this statutory bargain is not permitted by the law and would undercut the quality of patient care and is unnecessary in light of the significant flexibility states have under existing law. Medicaid costs and broader state fiscal issues need to be addressed holistically. For these reasons, we strongly urge Oregon to withdraw its Proposed Amendment from the Application.

Thank you for the opportunity to comment on this important matter. We welcome the opportunity to continue this conversation with the state. Please contact Joanne Chan at [jchan@phrma.org](mailto:jchan@phrma.org) or Dharia McGrew at [dmcgrew@phrma.org](mailto:dmcgrew@phrma.org) if you have any questions related to this issue.

Sincerely,



Dharia McGrew  
Director, State Policy



Joanne Chan  
Assistant General Counsel/Head of State Legal Affairs, Law



**VIA EMAIL**

[1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Ms. Hatfield,

Pacific Northwest Bleeding Disorders (PNWBD), Hemophilia Federation of America (HFA) and the National Hemophilia Foundation (NHF) hereby submit the following comments in response to the Oregon Health Authority's proposed revisions to the Section 1115 Demonstration Waiver for the Oregon Health Plan (OHP).

***Who We Are***

PNWBD, HFA, and NHF are non-profit organizations representing individuals with bleeding disorders nationwide. Our missions are to ensure that persons with inherited bleeding disorders such as hemophilia have timely access to quality medical care, therapies, and services, regardless of their financial circumstances or place of residence.

***About Bleeding Disorders***

Hemophilia is a rare, genetic bleeding disorder affecting about 20,000 Americans that impairs the ability of blood to clot properly. Without treatment, people with hemophilia bleed internally. This is sometimes due to trauma but can also simply result from everyday activities. Bleeds can lead to severe joint damage and permanent disability, or even – with respect to bleeds in the head, throat, or abdomen – death. Related conditions include von Willebrand disease, another inherited bleeding disorder that is estimated to affect more than three million Americans.

Patients with bleeding disorders have complex, lifelong medical needs. They depend on prescription medications (clotting factor or other new treatments) to treat or avoid painful bleeding episodes that can lead to advanced medical issues. Current treatments are highly effective and allow individuals to lead healthy and productive lives. However, these therapies are also extremely expensive, costing anywhere from \$250,000 to \$1 million or more per year depending on the severity of the disorder and whether complications such as an inhibitor are present. As a result, low-income individuals and families coping with bleeding disorders are at great risk if they lack affordable health insurance. Medicaid provides essential coverage for this segment of the bleeding disorders population.

PNWBD, HFA, and NHF remain committed to ensuring Oregon's Medicaid program provides quality and affordable health coverage. We appreciate the focus the Authority has placed on equitable access to healthcare in its 1115 Demonstration Waiver. In addition, the Authority's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over will help eliminate existing gaps in coverage.

However, the waiver request also contains other proposals that would undermine access to care for patients with bleeding disorders. PNWBD, HFA, and NHF are concerned with the proposed closed formulary for adult beneficiaries, which would make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries and waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one, as both proposals would significantly jeopardize access to care for patients we represent.

As a result, our organizations offer the following comments and suggested changes for the 1115 Demonstration Waiver request.

### ***Continuous Eligibility***

PNWBD, HFA, and NHF support the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six.

Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. It likewise increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>1</sup> Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>2</sup> Continuous eligibility will help reduce these negative health outcomes.

### ***Closed Formulary***

PNWBD, HFA, and NHF oppose the proposal to transition to a closed formulary for adult beneficiaries. Limiting access to medications is extremely harmful to the bleeding disorders community, putting patient health at risk and potentially raising overall medical costs for this population.

Prescription drugs used in the treatment of bleeding disorders vary considerably in important respects including mechanism of action, method and frequency of administration, half-life, and immunogenicity. **No generic alternatives exist for clotting factor and non-factor therapies for hemophilia and the various products are not therapeutically equivalent or interchangeable.** These characteristics make an individual's response and tolerability for a specific product unique.

For these reasons, the treatment guidelines developed by [NHF's Medical and Scientific Advisory Council \(MASAC\)](#) specifically recommend that individuals retain access to the full range of FDA-approved bleeding disorder products. The council (composed of physicians, scientists, medical professionals, and government agency representatives) warns that limiting access through the use of restrictive drug formularies negatively impacts access to quality care for persons with bleeding disorders and should be avoided, since delays or disruptions in treatment are tantamount to a denial of medically necessary care.

As a result, restricting OHP drug benefits to a closed formulary could greatly harm the health of persons with hemophilia or other bleeding disorders. It also could negatively impact the patient-provider relationship by limiting the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to a state agency. A robust and open formulary needs to be part of OHP so that patients can fully benefit from advancements in treatments and access the medications their doctor determine to be most effective for them.

Additionally, the Authority's proposal to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through FDA's accelerated approval processes, would also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new and beneficial treatments have been approved through an accelerated approval process. All patients enrolled in Medicaid through OHP should have the opportunity to access these treatments as they could extend or greatly improve their quality of life.

Finally, we note that the Authority's proposal does not include any appeals process for patients to access non-formulary medications, nor does it guarantee that patients who are stable on their current therapies may remain on their existing regimen even if their medication is subsequently excluded from the formulary. PNWBD, HFA, and NHF are disturbed that the proposal omits such basic protections – while reiterating that a closed formulary would endanger patient health, even if the state were to take the rudimentary step of providing an appeals process or exemptions for certain classes of drugs.

### ***Retroactive Coverage***

PNWBD, HFA, and NHF are likewise concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind, and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. Eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients diagnosed with a serious illness, such as bleeding disorders, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid enrollees were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>3</sup> Without retroactive eligibility, enrollees could then face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals when conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care because of the waiver.<sup>4</sup>

Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. Our organizations oppose the continued limitations to retroactive coverage and encourage the state to expand retroactive coverage to include all Medicaid beneficiaries.

### ***EPSDT Benefit***

PNWBD, HFA, and NHF are opposed to OHP's restrictions on Medicaid coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT).

As you know, the purpose of the EPSDT benefit is to ensure that children under age 21 receive all medically necessary care, regardless of whether it is a covered benefit under the State Plan. However, excluding medically necessary care simply because it does not fall under OHP's prioritized list of services greatly threatens access to care for non-prioritized services that can be critically important to children with bleeding disorders. Potential examples could include periodontal disease (line 492), disorders of synovium (line 503), post-thrombotic syndrome (line 519), hematoma/ear (line 553), thrombotic disorders (line 582), and synovitis and tenosynovitis (line 589).

While your agency has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. For example, children of color are enrolled in Medicaid at disproportionately higher rates<sup>5</sup> and as mentioned before, are also more likely to be affected by gaps in coverage.<sup>6</sup> These children will thus be disproportionately affected by the limitations to the EPSDT benefit.

PNWBD, HFA, and NHF support the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

Please feel free to contact either of our organizations as listed below with any questions or additional information related to these comments.

Sincerely,



Madonna McGuire Smith  
Executive Director  
Pacific Northwest Bleeding Disorders  
[m.mcquiresmith@pnwbd.org](mailto:m.mcquiresmith@pnwbd.org)



Sonji Wilkes  
Vice President for Policy and Advocacy  
Hemophilia Federation of America  
[s.wilkes@hemophiliafed.org](mailto:s.wilkes@hemophiliafed.org) 303-887-2600



Nathan Schaefer, MSW  
Vice President, Public Policy  
National Hemophilia Foundation  
[nschaefer@hemophilia.org](mailto:nschaefer@hemophilia.org) 917-755-2483

---

<sup>1</sup> Osorio, Aubrianna. Alker, Joan, “Gaps in Coverage: A Look at Child Health Insurance Trends”, Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)

<sup>2</sup><https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.

<sup>3</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

<sup>4</sup> Virgil Dickson, “Ohio Medicaid waiver could cost hospitals \$2.5 billion”, Modern Healthcare, April 22, 2016. (<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>5</sup> Brooks, Tricia. Whitener, Kelly. “At Risk: Medicaid’s Child-Focused Benefit Structure Known as EPSDT,” Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. EPSDT-At-Risk-Final.pdf (georgetown.edu)

<sup>6</sup> Osorio, Aubrianna. Alker, Joan, “Gaps in Coverage: A Look at Child Health Insurance Trends”, Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)

January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

*Submitted electronically via Oregon.gov/1115WaiverRenewal*

**RE: Oregon Section 1115 Oregon Health Plan (OHP) Draft Waiver Application for Renewal and Amendment**

Dear Director Allen and Director Vandehey,

As the statewide advocacy and political voice for Planned Parenthood's two Oregon affiliates (Planned Parenthood Columbia Willamette and Planned Parenthood of Southwestern Oregon), Planned Parenthood Advocates of Oregon (PPAO) submits these comments regarding Oregon Health Authority's (OHA) draft waiver extension and amendment application for the Oregon Health Plan (OHP) demonstration program. In its draft application, Oregon is seeking to implement several changes to the program, with the main overarching goal of advancing health equity. These changes include implementing 24-months continuous eligibility for OHP enrollees age 6 and older, providing transitional social determinants of health (SDOH) services to vulnerable populations, and implementing a closed prescription drug formulary and excluding certain drugs, among others. As a trusted sexual and reproductive health (SRH) care provider, educator and advocate, we appreciate the opportunity to provide input on this draft application.

Planned Parenthood is a safety net provider for the populations in Oregon most in need of health services. Planned Parenthood operates 11 health centers across the state of Oregon and serves as a leading health care provider, educator and advocate of high-quality, affordable health care for women, men, non-binary individuals, and young people. Our health centers range in size and location from small rural clinic practices to larger metropolitan clinics. Every year, our health centers provide affordable birth control, lifesaving cancer screenings, testing and treatment for STIs, abortion, and other essential care to more than 60,000 patients annually. Approximately 50% of Planned Parenthood's patients use Medicaid coverage or other state-funded programs to access affordable, preventive care and are therefore likely to be affected by Oregon's draft application.

Medicaid is a vital part of the health care system and plays a major role in ensuring access to essential primary and preventive care services. Medicaid is critical to improving the health and well-being of individuals and families with low incomes across Oregon and the rest of the nation. In particular, Medicaid is a crucial program for people of reproductive age, enabling them to access necessary SRH and maternal health services. Approximately 1 in 5 women of reproductive age use Medicaid,<sup>1</sup> and

---

<sup>1</sup> Adam Sonfield, "Why Protecting Medicaid Means Protecting Sexual and Reproductive Health," Guttmacher Institute (Mar. 9, 2017), available at <https://www.guttmacher.org/gpr/2017/03/why-protecting-medicaid-means-protecting-sexual-and-reproductive-health#>.

roughly two-thirds of adult women enrolled in Medicaid are in their reproductive years.<sup>2</sup> For nearly half of women giving birth, Medicaid is the source of coverage for essential care, including prenatal and delivery care; recent data found that in 25 states 40 percent or more of births are covered by Medicaid.<sup>3</sup> Finally, the program is the largest payer of reproductive health care coverage in the country,<sup>4</sup> paying for 75 percent of publicly-funded family planning services.<sup>5</sup>

Because women make up the majority of Medicaid enrollees, they will be disproportionately affected by Oregon's draft application. In particular, Medicaid coverage of family planning services and supplies helps individual's health, lives, educational success, and economic empowerment. Moreover, due to racism and other systemic barriers that have contributed to income inequality, women of color disproportionately comprise the Medicaid population and will be further impacted by the draft application; 31 percent of Black women and 27 percent of Hispanic women are enrolled in Medicaid, compared to only 16 percent of white women.<sup>6</sup>

Due to Medicaid's outsized role for people of color, Medicaid is essential in narrowing health disparities and improving access to care for their communities. Indeed, research shows that Medicaid expansion has contributed to such reductions in racial disparities in health coverage, in particular for Black and Hispanic individuals.<sup>7</sup> In addition, Medicaid expansion is associated with decreased disparities in some health outcomes for communities of color, including in infant and maternal health.<sup>8</sup>

As the political and advocacy voice for Oregon's two Planned Parenthood affiliates and for SRH, PPAO takes every opportunity to comment on Medicaid program features that increase or decrease access to care and impact people with Medicaid. Accordingly, our comments will address the following proposals:

- 24-months continuous eligibility for enrollees ages 6+;
- investing in social determinants of health (SDOH) transition services for vulnerable populations;
- the continued waiver of retroactive coverage; and
- implementing a closed formulary for adult OHP enrollees and excluding drugs with limited or inadequate evidence of clinical efficacy.

---

<sup>2</sup> "Medicaid's Role for Women," Kaiser Family Foundation (Mar. 28, 2019), available at <https://www.kff.org/medicaid/fact-sheet/medicaids-role-for-women/>.

<sup>3</sup> In Oregon, Medicaid covers 43 percent of births, see Births Financed by Medicaid, Kaiser Family Foundation, available at <https://www.kff.org/medicaid/state-indicator/births-financed-by-medicaid/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>.

<sup>4</sup> Usha Ranji, "Medicaid and Family Planning: Background and Implications of the ACA," Kaiser Family Foundation (Feb. 3, 2016), available at <https://www.kff.org/womens-health-policy/issue-brief/medicaid-and-family-planning-background-and-implications-of-the-aca/>.

<sup>5</sup> Adam Sonfield et al., "Public Funding for Family Planning, Sterilization and Abortion Services, FY 1980-2006," Occasional Report, New York: Guttmacher Institute, No. 38. (Jan. 2008), available at <https://www.guttmacher.org/sites/default/files/pdfs/pubs/2008/01/28/or38.pdf>.

<sup>6</sup> *Supra* note 1, "Why Protecting Medicaid Means Protecting Sexual and Reproductive Health."

<sup>7</sup> Madeline Guth, et al., "Effects of the ACA Medicaid Expansion on Racial Disparities in Health and Health Care," Kaiser Family Foundation (Sep. 30, 2020), available at <https://www.kff.org/report-section/effects-of-the-aca-medicaid-expansion-on-racial-disparities-in-health-and-health-care-issue-brief/>.

<sup>8</sup> *Id.*

PPAO applauds OHA's commitment to advancing health equity through many of the requested changes in the draft waiver application. However, the policies around retroactive coverage and prescription drugs do not achieve the draft waiver's goal of advancing health equity. Therefore, PPAO urges OHA to remove these program features and proceed forward with the draft waiver application without them.

**I. Twenty-four months continuous eligibility is an important program feature that increases access to care and can improve health outcomes for people with Medicaid, and OHA should proceed forward with this program feature.**

Continuous eligibility is vital to ensuring that Medicaid coverage, such as OHP coverage, is stable, continuous, and accessible for eligible individuals. Continuous eligibility keeps people enrolled in Medicaid for at least 12 months regardless of changes in their income. This policy has been shown time and again to reduce the likelihood that Medicaid enrollees will lose their affordable health insurance coverage due to small fluctuations in income or burdensome administrative requirements.<sup>9</sup> For example, a variety of Montana stakeholders, including health care providers and the state's Medicaid agency, have noted the benefits of this feature, which include: (1) stabilizing coverage, especially for seasonal workers; (2) improving continuity of care, particularly for preventive care services; and (3) saving on Medicaid administrative costs.<sup>10</sup>

Continuous eligibility is particularly important in ensuring access to essential SRH services for at least 12 months. Crucially, time is of the essence when accessing critical SRH services. Being unable to access SRH care can result in not only missed appointments, but also unintended pregnancies, undiagnosed STIs, and life-threatening cancers. People who utilize birth control and regular STI testing, including parents, cannot afford to be without Medicaid temporarily even for a few days time, let alone being without it for a month or longer; such a disruption in coverage could have enormous consequences on an individual's present and future health and lives, including educational and work commitments.

Moreover, continuous eligibility ensures that individuals who may experience income fluctuations or are unable to keep up with burdensome paperwork requirements, are also able to stay current on their medications and other health needs. A study by the Government Accountability Office (GAO) reinforces this positive effect, finding that enrollees covered by Medicaid for a full year reported fewer difficulties in obtaining necessary medical care and prescription medicine compared to those who were covered between one and eleven months.<sup>11</sup>

In addition to comprehensive SRH services, PPAO underscores that the continuous eligibility feature is particularly important for people who currently qualify for OHA's pregnancy eligibility group and have recently given birth. As Oregon has not adopted the American Rescue Plan's state option to extend Medicaid postpartum coverage to a full year after delivery, continuous eligibility ensures continuity of

---

<sup>9</sup> Jennifer Wagner and Judith Solomon, "Continuous Eligibility Keeps People Insured and Reduces Costs," Center on Budget and Policy Priorities (May 4, 2021), available at <https://www.cbpp.org/research/health/continuous-eligibility-keeps-people-insured-and-reduces-costs>.

<sup>10</sup> "Federal Evaluation of Montana Health and Economic Livelihood Partnership (HELP): Draft Interim Evaluation Report," Social & Scientific Systems: Prepared for CMS (Jul. 22, 2019), available at <https://www.medicaid.gov/medicaid/downloads/mt-fed-eval-draft-interim-eval-rpt.pdf>.

<sup>11</sup> "Medicaid: States Made Multiple Program Changes, and Beneficiaries Generally Reported Access Comparable to Private Insurance," Government Accountability Office (Nov. 2012), available at <https://www.gao.gov/assets/gao-13-55.pdf>.

care during the critical postpartum period for OHA women and birthing people. Based on Centers for Disease Control and Prevention (CDC) data, up to 33 percent of pregnancy-related deaths occur between one week to one full year after childbirth.<sup>12</sup> Indeed, the Oregon Maternal Mortality and Morbidity Review Committee (OMMMRC) found several factors contributing to maternal deaths in the state, including: (1) inadequate access and missed opportunities to health care and medical services; (2) inadequate access to wrap-around services; (3) inadequate resources and missed screening opportunities for mental health and substance use disorder (SUD); (4) possible implicit biases toward homelessness, tobacco/drug abuse, mental illness, low income, alcohol abuse, etc.; (5) histories of intimate partner violence (IPV); and (6) untreated childhood physical and emotional trauma.<sup>13</sup>

Given the ongoing maternal health crisis, it is necessary that comprehensive Medicaid coverage enable individuals to seek diagnosis, treatment, and monitoring for chronic health conditions, especially in the postpartum period, when individuals are at elevated risk for experiencing pregnancy-related complications that could lead to death.<sup>14</sup> Providing 24 months of continuous eligibility for these individuals means they would be able to continue accessing care from the same health care professionals that have served them throughout their pregnancies and who have the best sense of their health needs and risks. This would have the biggest positive impact on populations most impacted by maternal death in Oregon, including Black and Hispanic women.<sup>15</sup>

Finally, PPAO agrees with OHA that the continuous eligibility feature will be especially important after the public health emergency (PHE) ends in the United States. Nationally, enrollment in the Medicaid program increased by 16.2% from February 2020 to May 2021, and this increase is reflected in every state.<sup>16</sup> As OHA notes in the draft application, implementing continuous eligibility is an effective method to preserve the coverage continuity gains that were achieved during the pandemic through the continuous coverage requirement in the Families First Coronavirus Response Act (FFCRA).<sup>17</sup> Maintaining this continuity of coverage is crucial to prevent eligible OHP enrollees from losing coverage after the PHE ends.

Given the importance of 24 months of continuous eligibility in increasing access to timely SRH and maternal health services, in particular for people of reproductive age and women of color, PPAO supports this program change and urges OHA to proceed forward with it in their application to CMS.

---

<sup>12</sup> “Vital Signs: Pregnancy-related deaths,” CDC (May 7, 2019), available at <https://www.cdc.gov/vitalsigns/maternal-deaths/index.html>.

<sup>13</sup> “Oregon Maternal Mortality and Morbidity Review Committee Biennial Report,” OHA (Jan. 1, 2021), available at [https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/DATAREPORTS/SiteAssets/Pages/Maternal-Mortality-Morbidity-Review-Committee/2020\\_MMRC%20First%20Biennial%20Report%20FINAL%204.1.21.pdf](https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/DATAREPORTS/SiteAssets/Pages/Maternal-Mortality-Morbidity-Review-Committee/2020_MMRC%20First%20Biennial%20Report%20FINAL%204.1.21.pdf).

<sup>14</sup> “Extend Postpartum Medicaid Coverage,” The American College of Obstetricians and Gynecologists, available at <https://www.acog.org/advocacy/policy-priorities/extend-postpartum-medicaid-coverage>.

<sup>15</sup> *Supra* note 11, “Oregon Maternal Mortality and Morbidity Review Committee Biennial Report.”

<sup>16</sup> Bradley Corallo and Avirut Mehta, “Analysis of Recent National Trends in Medicaid and CHIP Enrollment,” Kaiser Family Foundation (Oct. 29, 2021), available at <https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/>.

<sup>17</sup> FFCRA, § 6008(b)(3).

## II. Investing in SDOH transition services for vulnerable populations will improve health outcomes, and OHA should proceed forward with these program features.

The social determinants of health, defined by the World Health Organization (WHO) as the “conditions in which people are born, grow, live, work, and age, and the wider set of forces and systems shaping the conditions of daily life” have become a frequently discussed concept in the areas of health and social services.<sup>18</sup> Accounting for up to 90 percent of a person’s health status, SDOH are far-reaching, and include factors such as safe and affordable housing, access to education, public safety, the availability of healthy foods, local emergency/health services, and environments free of harmful toxins.<sup>19</sup> PPAO emphasizes that while sometimes SDOH are discussed, researched, and pursued independently from racism, discrimination, and inequality, they are, in fact, intertwined. Indeed, SDOH are mostly responsible for health inequities and they are “shaped by the distribution of money, power and resources at global, national and local levels.”<sup>20</sup>

PPAO supports OHA’s initiative to provide housing, health-related transportation, and food assistance, among other SDOH transition services, to vulnerable populations and urges OHA to proceed forward with these program features.

- A. *Housing access is vital to improving health outcomes, in particular for women of reproductive age and people of color and therefore, OHA should proceed forward with providing transitional housing services, including rental assistance or temporary housing.*

Among SDOH, significant research and data show that homelessness and housing instability (frequently moving, falling behind on rent, facing eviction) are detrimental to one’s health. The health impacts of homelessness and housing instability are myriad:

- People who are chronically homeless face substantially higher morbidity in both physical and mental health,<sup>21</sup> as well as increased mortality.<sup>22</sup>
- Unstable housing situations can cause individuals to experience increased hospital visits, lead to loss of employment and employer-provided health insurance benefits, dramatically increase the risk of an acute episode of a behavioral health condition, including relapse of addiction in adults, and are associated with increased likelihood of mental health problems in children.<sup>23</sup>

---

<sup>18</sup> “Social determinants of health,” World Health Organization, available at [https://www.who.int/health-topics/social-determinants-of-health#tab=tab\\_1](https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1).

<sup>19</sup> “Social Determinants of Health,” Healthy People 2030, Office of Disease Prevention and Health Promotion, Department of Health and Human Services, available at <https://health.gov/healthypeople/objectives-and-data/social-determinants-health>.

<sup>20</sup> *Id.* at “Social Determinants of Health,” World Health Organization.

<sup>21</sup> David L. Maness and Muneza Khan, “Care of the Homeless: An Overview,” *Am Fam Physician* (Apr. 2014), available at <https://www.aafp.org/afp/2014/0415/p634.html>.

<sup>22</sup> Colette L Auerswald, et al., “Six-year mortality in a street-recruited cohort of homeless youth in San Francisco, California,” *PeerJ* (Apr. 14, 2016), available at <https://peerj.com/articles/1909/>.

<sup>23</sup> See Will Fischer, “Research Shows Housing Vouchers Reduce Hardship and Provide Platform for Long-Term Gains Among Children,” Center on Budget and Policy Priorities (Oct. 7, 2015), available at <https://www.cbpp.org/research/research-shows-housing-vouchers-reduce-hardship-and-provide-platform-for-longterm-gains>; see also Linda Giannarelli et al., “Reducing Child Poverty in the US: Costs and Impacts of Policies Proposed by the Children’s Defense Fund,” Urban Institute (Jan. 2015), available at <https://www.urban.org/sites/default/files/publication/39141/2000086-Reducing-Child-Poverty-in-the-US.pdf>.

- When systemic barriers force people with low incomes to spend too much of their income on their rent, they cannot afford to pay for health care. In fact, many renters delay needed medical care because they are unable to afford it.<sup>24</sup>
- People who are evicted from their homes, or even threatened with eviction, are more likely to experience health problems such as depression, anxiety, and high blood pressure than people with stable housing.<sup>25</sup> This exacerbates the heightened risk women, particularly women of color, have for experiencing depression,<sup>26</sup> anxiety,<sup>27</sup> and high blood pressure.<sup>28</sup>

Crucially, stable housing has consistently been shown to lead to improved health outcomes, particularly among individuals who have past experiences with housing insecurity. These improved health outcomes include reduced psychological distress, intimate partner violence (IPV), behavior issues, and sleep problems.<sup>29</sup>

It is also important to note that access to stable housing is vital for women and the LGBTQ+ communities. That is because women and the LGBTQ+ community are more likely to face economic insecurity at all stages of their lives, due to ongoing employment discrimination, overrepresentation in low-wage jobs, difficulty accessing affordable and comprehensive health care, and greater responsibilities for unpaid caregiving. As a result, housing assistance is vital for these individuals and their families.

Indeed, data show how critical housing is for people of reproductive age in obtaining needed SRH services. The Kaiser Family Foundation conducted a study evaluating access to reproductive health care

---

<sup>24</sup> “Renters Report Housing Costs Significantly Impact Their Health Care,” Enterprise (Apr. 3, 2019), available at [https://www.enterprisecommunity.org/news-and-events/news-releases/2019-04\\_renters-report-housing-costs-significantly-impact-their-health-care](https://www.enterprisecommunity.org/news-and-events/news-releases/2019-04_renters-report-housing-costs-significantly-impact-their-health-care); see also Munira Z. Gunja et al., “How the Affordable Care Act Has Helped Women Gain Insurance and Improved Their Ability to Get Health Care.” Commonwealth Fund (Aug. 10, 2017), available at <https://www.commonwealthfund.org/publications/issue-briefs/2017/aug/how-affordable-care-act-has-helped-women-gain-insurance-and> (noting that even though health insurance coverage gains through the Affordable Care Act have reduced the share of women skipping or delaying care because of costs, in 2016, 38 percent of women age 19 through 64 still reported not getting the health care they needed because of costs).

<sup>25</sup> Alison Bovell & Megan Sandel, “The Hidden Health Crisis of Eviction,” Children’s Health Watch Blog (Oct. 5, 2018), available at <http://childrenshealthwatch.org/the-hidden-health-crisis-of-eviction/>.

<sup>26</sup> Paul R. Albert, “Why is depression more prevalent in women?,” 40 J. Psychiatry Neurosci. 219-221 (Jul. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4478054/> (noting the higher prevalence of major depression in women than in men); National Institutes of Health, Office of Research on Women’s Health, “Women of Color Health Data Book” p. 147 (Oct. 2014), available at <https://orwh.od.nih.gov/sites/orwh/files/docs/WoC-Databook-FINAL.pdf> (more women seek treatment for depression than men, though white, non-Hispanic women are more likely to receive treatment for depression than Latinx and Black women).

<sup>27</sup> “Anxiety Disorders,” Office on Women’s Health (last updated Jan. 30, 2019), available at <https://www.womenshealth.gov/mental-health/mental-health-conditions/anxiety-disorders> (reporting that women are twice as likely as men to get an anxiety disorder in their lifetime and noting that more American Indian/Alaskan Native women have generalized anxiety disorder than women of other races and ethnicities).

<sup>28</sup> *Id.* at “Women of Color Health Data Book” p. 121 (noting that Black women experience high blood pressure at a higher rate than Latinx or white, non-Hispanic women).

<sup>29</sup> “Follow-Up Family Options Study: Long-Term Housing Subsidies are Most Effective Intervention for Homeless Families,” National Low-Income Housing Coalition (Oct. 31, 2016), available at <http://nlihc.org/resource/follow-family-options-study-long-term-housing-subsidies-are-most-effective-intervention> (finding long-term subsidies had a range of positive impacts on adult and child well-being).

for women with low incomes in five communities across the United States and found that in each of the communities, a shortage of affordable housing (among other SDOH) resulted in women prioritizing food and shelter above preventive health care and family planning.<sup>30</sup> Planned Parenthood also conducted a survey assessing the SDOH-related needs of women of reproductive age and found the following:

- Women living at or below 300 percent of the federal poverty level (FPL) have high and varying SDOH-related needs, including access to stable housing.<sup>31</sup> In fact, more than two-thirds of women say it is very or somewhat hard to pay for basics, such as housing.<sup>32</sup>
- While the types of social needs varied, housing/having a steady place to live and support with utilities (such as heating and electricity) were among the most commonly reported.<sup>33</sup>
- Black, Asian/Pacific Islander, and Hispanic women of reproductive age are more likely to report needing SDOH-related support, with Black women reporting the highest need for support in almost all areas.<sup>34</sup>

Finally, as evidenced by the data from Planned Parenthood’s study, people of color are disproportionately affected by homelessness and housing insecurity, and addressing this SDOH is critical for these groups. In Multnomah County alone, Black people face a greater risk of homelessness, making up 16.1% of the homeless population—more than double their share of the general population in the county, which is 7.2%.<sup>35</sup>

Given the importance of housing as an SDOH that is integral to one’s health and wellbeing, PPAO urges OHA to move forward with providing transitional housing services, including rental assistance or temporary housing.

- B. Transportation is necessary to enable individuals to get to and from their appointments and will increase access to SRH care, and therefore, OHA should proceed forward with providing health-related transportation for eligible OHP enrollees.*

Transportation, including non-emergency medical transportation (NEMT), is essential for many individuals enrolled in the Medicaid program and increases access to care. In FY2018 alone, there were over 60 million NEMT ride-days (days in which a Medicaid enrollee had at least one NEMT ride).<sup>36</sup>

---

<sup>30</sup> Usha Ranji, et al., “Beyond the Numbers: Access to Reproductive Health Care for Low-Income Women in Five Communities,” Kaiser Family Foundation (Nov. 14, 2019), available at <https://www.kff.org/report-section/beyond-the-numbers-access-to-reproductive-health-care-for-low-income-women-in-five-communities-executive-summary/>.

<sup>31</sup> “What about Her? — Assessing Social Determinants of Health Among Women of Reproductive Age,” Planned Parenthood Federation of America (2020), available at [https://www.plannedparenthood.org/uploads/filer\\_public/33/97/33976d5a-f402-4b14-ab68-671aa58a0f00/210115-hcip-sdoh-what-about-her-update-v2.pdf](https://www.plannedparenthood.org/uploads/filer_public/33/97/33976d5a-f402-4b14-ab68-671aa58a0f00/210115-hcip-sdoh-what-about-her-update-v2.pdf).

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* (finding that Black women of reproductive age report the highest need for SDOH support in all surveyed areas except for intimate partner violence, where non-Hispanic white women report the highest rate of need for support).

<sup>35</sup> Latisha Jensen, “Black Residents of Multnomah County Face a Greater Risk of Homelessness,” Willamette Week (Jan. 6, 2021), available at <https://www.wweek.com/news/2021/01/06/black-residents-of-multnomah-county-face-a-greater-risk-of-homelessness/>.

<sup>36</sup> “Mandated Report on Non-Emergency Medical Transportation,” MACPAC (Jun. 2021), available at <https://www.macpac.gov/wp-content/uploads/2021/06/Chapter-5-Mandated-Report-on-Non-Emergency-Medical-Transportation.pdf>.

It is vital to note that many families with low incomes have lower vehicle ownership rates and less access to reliable transportation.<sup>37</sup> In addition, transportation barriers are often cited as barriers to accessing care, leading to rescheduled or missed appointments, delayed care, and missed or delayed medication use.<sup>38</sup> Notably, data from Iowa indicates that women, people of color, and younger people are significantly more likely to report a transportation barrier.<sup>39</sup>

In particular, transportation barriers can affect people's access to health care services. These barriers may result in missed or delayed health care appointments, increased health expenditures and overall poorer health outcomes. Many individuals with low incomes do not have access to affordable transportation to get to and from medical appointments. For them, transportation issues can be a major barrier to needed health care, including receiving necessary postpartum contraception, pregnancy tests, Pap smears, and tests for sexually transmitted infections.

As transportation access has outsized importance in increasing access to timely SRH care, PPAO urges OHA to move forward with providing health-related transportation services in addition to the already provided NEMT services.

- C. Access to healthy and nutritious foods is another important SDOH to improve health outcomes and therefore, OHA should proceed forward with providing food assistance services, including links to the Supplemental Nutrition Assistance Program (SNAP).*

Importantly, extensive research has found that food insecurity is associated with poorer health outcomes.<sup>40</sup> Adults who experience food insecurity are also more likely to report lower health status overall than those with high food security.<sup>41</sup> This includes: (1) women of color, who already have less access to healthy food,<sup>42</sup> safe housing, and basic health care due to the intersections of structural

---

<sup>37</sup> Mobility Challenges for Households in Poverty, FHWA (2014), available at <https://nhts.ornl.gov/briefs/PovertyBrief.pdf>; Wolfe, M.K., McDonald, N.C., and Holmes, G.M., "Transportation Barriers to Health Care in the United States: Findings from the National Health Interview Survey, 1997-2017," Am. J. Public Health (Jun. 2020), available at <https://pubmed.ncbi.nlm.nih.gov/32298170/> (finding that Hispanic people, those living below the poverty threshold, Medicaid recipients, and people with a functional limitation had greater odds of reporting a transportation barrier after controlling for other sociodemographic and health characteristics).

<sup>38</sup> Samina T. Syed, et al., Traveling Towards Disease: Transportation Barriers to Health Care Access, J Community Health (Dec. 13, 2014), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265215/pdf/nihms646723.pdf>.

<sup>39</sup> Suzanne Bentler et al., "Non-Emergency Medical Transportation and the Iowa Health and Wellness Plan," University of Iowa Public Policy Center (Mar. 1, 2016), available at [https://ppc.uiowa.edu/sites/default/files/nemt\\_report.pdf](https://ppc.uiowa.edu/sites/default/files/nemt_report.pdf).

<sup>40</sup> Craig Gundersen and James P. Ziliak, "Food Insecurity and Health Outcomes," Health Affairs (Nov. 2015), available at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0645>.

<sup>41</sup> Christian A. Gregory and Alisha Coleman-Jenson, "Food Insecurity, Chronic Disease, and Health Among Working-Age Adults," United States Department of Agriculture (July 2017), <https://www.ers.usda.gov/webdocs/publications/84467/err-235.pdf?v=4606.4>.

<sup>42</sup> Treuhaft, Sarah & Karpyn, Allison, "The Grocery Gap: Who Has Access to Healthy Food and Why It Matters," PolicyLink & The Food Trust (2010), available at [http://thefoodtrust.org/uploads/media\\_items/grocerygap.original.pdf](http://thefoodtrust.org/uploads/media_items/grocerygap.original.pdf).

racism, inequality, sexism, classism, xenophobia, and other systemic barriers; and (2) LGBT people, who are more likely than non-LGBT people to experience food insecurity.<sup>43</sup>

Research shows that SNAP reduces poverty and food insecurity, and that over the long-term, these impacts lead to improved health and economic outcomes, especially for those who receive SNAP as children.<sup>44</sup> SNAP plays a critical role in addressing hunger and food insecurity in the communities of people of color<sup>45</sup> and the LGBTQ+ community.<sup>46</sup>

Access to healthy and nutritious food is an essential SDOH and as such, PPAO urges OHA to move forward with its initiative to provide food assistance services, including linkages to SNAP, to vulnerable populations in need.

### **III. Retroactive coverage increases access to timely SRH care, and PPAO urges OHA to reinstate this program feature for all OHP enrollees.**

As OHA is aware, federal law and policy requires states to pay for covered services provided to individuals during the three month period prior to the date of applying for Medicaid coverage, provided that the individual would have been eligible during that period.<sup>47</sup> This provision helps safeguard enrollees' continuous access to care when there are delays in determining eligibility. PPAO underscores that retroactive coverage has been a requirement of the Medicaid program since 1972; waivers of retroactive coverage are a departure from this long-standing requirement.

Retroactive coverage is critical to reducing individuals' medical debt, as well as financial strain on the health care system that stems from uncompensated care. When individuals have coverage, they are more likely to be able to receive the care they need in a timely manner, which enables the health care system to treat conditions before they become more serious and more costly. PPAO also underscores the importance of retroactive coverage during the COVID-19 pandemic, which has seen enormous increases in Medicaid enrollment<sup>48</sup> due to the ongoing employment and income fluctuations many individuals are experiencing.<sup>49</sup> Ensuring access to timely care for all Medicaid enrollees is more important than it has ever been.

---

<sup>43</sup> Brown, Taylor N.T., et al., "Food Insecurity and SNAP Participation in the LGBT Community," The Williams Institute (Jul. 2016), available at <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Food-Insecurity-and-SNAP-Participation-in-the-LGBT-Community.pdf>.

<sup>44</sup> "Chart Book: SNAP Helps Struggling Families Put Food on the Table," Center on Budget and Policy Priorities (Nov. 7, 2019), <https://www.cbpp.org/research/food-assistance/chart-book-snap-helps-struggling-families-put-food-on-the-table>.

<sup>45</sup> "SNAP Helps Millions of African Americans," Center on Budget and Policy Priorities (Feb. 26, 2018), available at <https://www.cbpp.org/research/food-assistance/snap-helps-millions-of-african-americans>; "SNAP Helps Millions of Latinos," Center on Budget and Policy Priorities (Feb. 26, 2018), available at <https://www.cbpp.org/research/food-assistance/snap-helps-millions-of-latinos>.

<sup>46</sup> Rooney, Caitlin, et al., "Protecting Basic Living Standards for LGBTQ People," Center for American Progress (Aug. 2018), available at <https://cdn.americanprogress.org/content/uploads/2018/08/10095627/LGBT-BenefitCuts-report.pdf>.

<sup>47</sup> 42 U.S.C. § 1396a(a)(34); 42 C.F.R. § 435.914.

<sup>48</sup> *Supra* note 16, "Analysis of Recent National Trends in Medicaid and CHIP Enrollment."

<sup>49</sup> Paul Shafer, et al., "Medicaid Retroactive Eligibility Waivers Will Leave Thousands Responsible for Coronavirus Treatment Costs," Health Affairs (May 8, 2020), available at <https://www.healthaffairs.org/doi/10.1377/hblog20200506.111318/full/>.

Timely access to care is particularly relevant in the context of family planning care, as only a few days without contraception can result in an unintended pregnancy. Moreover, STIs that go untested and untreated can spread throughout communities and cause lifelong problems, including infertility and pelvic inflammatory disease.<sup>50</sup> Urinary tract infections are one of the most common infections women experience and are easily treatable, but without treatment, can result in emergency room care, which can cost a state nearly \$1,500 per patient.<sup>51</sup>

In addition, data shows that retroactive coverage has positively impacted individuals in states that have kept this feature in their Medicaid programs. In New Hampshire, in one 16-month period, 4,567 Medicaid expansion individuals benefited from the policy, which paid more than \$5 million for their medical expenses.<sup>52</sup> Conversely, data show that the absence of retroactive coverage has increased financial burdens for people with low incomes, as well as safety net providers that serve those individuals. In Indiana, nearly 14 percent of the parent and caretaker relatives eligibility group needed retroactive coverage, and individuals in this group incurred medical costs averaging \$1,561 per person.<sup>53</sup> These costs would have been paid for by Medicaid if retroactive coverage was in place.<sup>54</sup> Finally, sixteen percent of providers in Indiana experienced increases in the provision of uncompensated care after retroactive coverage was waived.<sup>55</sup>

Retroactive coverage also bolsters critical provider participation in the Medicaid program as providers know in advance that they will be adequately compensated, which means that patients are better able to meaningfully access care. Medicaid programs are already faced with provider shortages, with more than two-thirds of states reporting difficulty in ensuring provider participation in Medicaid.<sup>56</sup> Provider shortages are particularly acute for people who can get pregnant, as states are especially challenged in recruiting OB/GYNs. A report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that Medicaid managed care plans had extreme provider shortages, with only 42 percent of in-network OB/GYN providers able to offer appointments.<sup>57</sup>

---

<sup>50</sup> Chlamydia: Fact Sheet, Centers for Disease Control and Prevention (Jan. 23, 2014), available at <https://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm>.

<sup>51</sup> Nolan Caldwell, et al., “How Much Will I Get Charged for This?” Patient Charges Top Ten Diagnoses in the Emergency Department,” Plos One Journal (Feb. 27, 2013), available at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0055491>.

<sup>52</sup> Conditionally Approved Waiver of Retroactive Coverage, NHDHHS (Dec. 21, 2015), available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/health-protection-program/nh-health-protection-program-premium-assistance-retro-cov-waiver-submission-12212015.pdf>.

<sup>53</sup> Letter to Director McGuffee, CMS (Jul. 29, 2016), available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>.

<sup>54</sup> *Id.*

<sup>55</sup> Harris Meyer, “New Medicaid Barrier: Waivers ending retrospective eligibility shift costs to providers, patients,” Modern Healthcare (Feb. 9, 2019), available at <https://www.modernhealthcare.com/article/20190209/NEWS/190209936/new-medicaid-barrier-waivers-ending-retrospective-eligibility-shift-costs-to-providers-patients>.

<sup>56</sup> “States Made Multiple Program Changes, and Beneficiaries Generally Access Comparable to Private Insurance,” Government Accountability Office (Nov. 2012), available at <http://www.gao.gov/assets/650/649788.pdf>; “Access to Care: Provider Availability in Medicaid Managed Care,” Department of Health and Human Services, Office of the Inspector General (Dec. 2014), available at <http://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

<sup>57</sup> *Id.*

Yet, despite the shortages of OB/GYN providers, people who can get pregnant often rely on their OB/GYN providers as their main source of care.<sup>58</sup> Any policy, including the current lack of retroactive coverage, that reduces the availability of SRH providers in the Medicaid program can cause longer wait times for appointments and delays in accessing critical SRH. Due to the unique way women and people who can get pregnant experience the health care system, delays in access to OB/GYNs and other SRH providers can also impact their access to the broader health care system and result in them lacking access to other essential primary and preventive care. Sufficient provider participation is essential to ensure Oregon's success in improving health care delivery systems. Indeed, health care coverage is meaningless if patients are unable to receive care from quality providers in a timely manner.

For all the reasons set forth above and retroactive coverage's importance to accessing timely SRH care, PPAO urges OHA to reinstate retroactive coverage for all OHP enrollees.

**IV. A closed prescription drug formulary for OHP adults and exclusion of certain drugs limits patient choice, including for contraceptives, and therefore, OHA should not proceed forward with these program features.**

In the draft application, OHA seeks to implement a closed prescription drug formulary for OHP adults, with only at least one drug per therapeutic class. In addition to the closed formulary, OHA seeks to use its own review process to determine coverage of new drugs for OHP enrollees. OHA states that through this process, Oregon could "avoid exorbitant spending on high-cost drugs that are not medically necessary."<sup>59</sup> PPAO strongly urges OHA to not proceed forward with these program features, as these changes are not waivable under Section 1115 and they dramatically narrow enrollee choice and access.

First, PPAO notes that Congress ensured that Medicaid enrollees have broad access to outpatient prescription drugs. Except for a very limited set of drug classes, state Medicaid programs cannot outright deny coverage of drugs produced by manufacturers participating in Medicaid's Drug Rebate Program. Section 1396r-8 of the Medicaid Act outlines these requirements for state Medicaid programs, including those that govern the development and use of a formulary.<sup>60</sup>

Second, modifications to prescription drug policy should be developed to benefit patients, with a focus on decreased costs and a commitment to robust access and choice. OHA's closed formulary and proposed drug exclusions fail to offer sufficient safeguards to ensure that enrollees, including people who can get pregnant who benefit from a wide array of birth control choices, will continue to have access to the prescriptions that work for them. These changes also set a harmful precedent wherein drug cost is weighed more heavily than health care needs, absent patient input.

Importantly, many patients require significant trial and error to find the therapeutics best suited to their needs. This is particularly true for contraceptive care. For these patients, a closed formulary could be

---

<sup>58</sup> *Id.*

<sup>59</sup> Application for Renewal and Amendment: Oregon Health Plan 1115 Demonstration Waiver, OHA (Dec. 1, 2021), available at <https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf>.

<sup>60</sup> 42 U.S. Code § 1396r-8.

particularly disruptive, given that access to the drug or device that works for them would not be guaranteed.

Finally, not only is it vital to safeguard enrollee access; ensuring that people have access to the contraceptive that works best for them reaps many benefits. A majority of women who access care through publicly funded family planning providers said birth control has allowed them to take better care of themselves or their families (63 percent), complete their education (51 percent), support themselves financially (56 percent), or keep or get a job (50 percent).<sup>61</sup> Furthermore, greater access to all approved Food and Drug Administration (FDA) contraceptive methods<sup>62</sup> would help improve health outcomes for pregnancy-related illness, injury, and death, especially for people who have medical conditions that may be exacerbated by pregnancy.<sup>63</sup> Implementing a closed formulary and restricting access to FDA-approved contraception will likely lead to worse health outcomes for all enrollees who need access to contraception of their choice.

Further, PPAO also strongly urges OHA to not adopt a closed formulary for HIV treatment medications, for the following reasons:

HIV is a highly individual disease. Different people living with HIV have different treatment needs based on their specific medical history and the resistance(s) to medication that may have developed in their bodies. As a result, people living with HIV and their healthcare providers need maximum flexibility to select an HIV treatment regimen that is right for them.

HIV disproportionately impacts people who are also experiencing challenges such as homelessness, mental illness, and/or substance-use disorder. Members of this population may need simpler, more manageable HIV treatment regimens (e.g., single-tablet regimens) to remain adherent to their medications, but closed formularies can restrict access to those regimens by not factoring social determinants of health into decision-making on coverage.

Utilization-management techniques used in a closed-formulary approach, such as prior-authorization requirements, can cause abandonment of treatment, especially for those already at risk of falling out of care. For people living with HIV, in particular, the consequences can be disastrous: Medication non-adherence can lead not only to poor health outcomes, but also to permanent resistance to a drug or entire class of drugs.

People who are living with HIV and in successful treatment cannot transmit the virus through sex. However, if people fall out of care, as utilization management can cause them to do, they can spread HIV to their sexual partners. Adherence is, therefore, a public-health issue as well as an individual one.

---

<sup>61</sup> Jennifer J. Frost and Laura Duberstein Lindberg, "Reasons for using contraception: Perspectives of US women seeking care at specialized family planning clinics," *Contraception*, Vol. 87, Issue 4 (Apr. 2013), available at <https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/j.contraception.2012.08.012.pdf>.

<sup>62</sup> Birth Control Guide, Food and Drug Administration, available at <https://www.fda.gov/media/99605/download>.

<sup>63</sup> Megan L. Kavanaugh and Ragnar Anderson, "Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers," New York: Guttmacher Institute (Jul. 2013), available at <http://www.guttmacher.org/pubs/health-benefits.pdf>.

For all these reasons, it is considered best practice to ensure access to HIV treatment medications, even within a closed-formulary approach. This is why antiretrovirals are designated as a drug class “of clinical concern” within Medicare Part D, requiring Part D plans to cover all drugs within that class (rather than only two or more drugs, as for most classes). It’s also why the federal agencies responsible for ending the HIV epidemic direct states to “design their prescription drug formularies to minimize potential barriers presented by utilization management techniques so that Medicaid...beneficiaries can readily access all [HIV] regimens.”<sup>64</sup> Several states, including California, Colorado, and Illinois, have gone so far as to codify in statute protections from utilization-management techniques for Medicaid members living with HIV.

Oregon currently includes all U.S. Food and Drug Administration-approved HIV drugs on its Preferred Drug List, and the above-average health outcomes of Oregonians living with HIV reflects such public policies. Ensuring access to HIV treatment medications bolsters not just Oregon’s efforts to end the HIV epidemic, but the state’s commitment to eliminating health inequities as well, because Black, Latinx, and Indigenous Oregonians are more likely to be living with HIV, and more likely to experience poor HIV health outcomes (e.g., viral non-suppression). We hope that Oregon will remain aligned with best practice and the state’s own strategic goals by committing in its 1115 waiver application to maintain open access to HIV treatment medications.

For all the reasons set forth in this section, we strongly urge OHA to not proceed forward with the closed formulary and exclusion of certain drugs through OHA’s review process.

**V. PPAO urges OHA to consider how open access to safety net providers and other community providers will create meaningful change for patient access and provider burden.**

An important aspect of increasing access to and utilization of quality preventative and SRH care is patients being able to go to a trusted provider of their choice and where it is convenient for them. Planned Parenthood affiliates are contracted with the majority of coordinated care organizations (CCOs) in Oregon, but not all. When patients arrive at Planned Parenthood health centers needing urgent reproductive health care, they are often unable to serve them if they are not contracted with their CCO plan. Or, Planned Parenthood provides necessary care without reimbursement. In the past six months, Planned Parenthood Columbia Willamette served close to 400 patients who were covered by a CCO plan not contracted with them.

Ensuring there is ‘no wrong door’ for patient care is vital for patients to receive timely care, especially if they have traveled outside their community and cannot easily access alternate providers in a timely manner. Similar barriers occur when a patient’s plan changes to one which is not contracted with Planned Parenthood. Health center staff are often informing patients of a change in coverage and, if the new CCO is not contracted, their limited ability to offer patient care. This is wasteful for staff and stressful for patients.

Open access to safety net providers and other community providers would create meaningful change for patient access and provider burden. These services are often low cost yet carry high cost implications if

---

<sup>64</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf>

not addressed in a timely manner. Claims data from these visits would inform CCOs of where patients are accessing care, and which providers they are choosing for specific services. This open access could even encourage new contracts with diverse providers.

**VI. PPAO agrees with OHA that advancing health equity is paramount, and supports OHA in proceeding forward with several other equity-driven requests in the draft application and notes the importance of provider choice for OHP enrollees.**

Advancing health equity is paramount in transforming the OHP program to effectively serve people with low incomes, including people of color, in Oregon. As discussed in detail in this comment letter, due to longstanding systemic barriers to economic advancement, these populations are disproportionately enrolled in the Medicaid program and experience worse health outcomes on several measures. To meaningfully address access to care and improve health outcomes for people with low incomes, including women of color, a comprehensive equity-driven approach must be taken.

OHA has included several requests and changes in the draft application to advance health equity. In addition to the proposals discussed at length in this letter, PPAO notes its support for the following proposals that increase access to care and ensure continuity of coverage for critical populations:

- providing continuous eligibility for children until their 6th birthday;
- providing an expedited OHP enrollment path for people who apply for SNAP benefits;
- retaining benefits and/or extending full OHP Plus Medicaid benefits to justice-involved individuals;
- providing transitional employment support services for vulnerable populations and benefits for people impacted by climate disasters and at high-risk for extreme weather;
- expanding the infrastructure needed to support access to services using providers outside the medical model, including personal health navigators and doulas; and
- investing in provider and community-based organizations' (CBO) infrastructure and capacity building.

Taken together with the other program features discussed in detail in this letter, these features provide a strong foundation to meaningfully make progress on health equity for Oregonians. PPAO urges OHA to move forward with these program features and work with community-based reproductive health care providers when implementing these changes.

\*\*\*

Thank you for the opportunity to comment on the OHP draft waiver application. OHA has put forward a comprehensive approach in addressing health equity through several program features, which would have an outsized impact on women of color, in this draft application. Planned Parenthood urges OHA to move forward with seeking 24-months continuous eligibility for OHP enrollees ages 6 and over and investing in SDOH transition services for vulnerable populations, along with several other features. However, Planned Parenthood strongly urges OHA to reinstate retroactive coverage for all OHP enrollees and not proceed forward with the prescription drug policy changes proposed in the draft application. The continued waiver of retroactive coverage and prescription drug policy proposals undermine OHA's goal of advancing health equity by decreasing access to care and limiting patient choice.



Planned Parenthood Advocates of Oregon

If you have any questions about the issues raised in this letter, please do not hesitate to contact An Do, Executive Director, at [an.do@ppaoregon.org](mailto:an.do@ppaoregon.org).

Respectfully submitted,

An Do  
Executive Director  
Planned Parenthood Advocates of Oregon

**Providence Health & Services**

4400 N.E. Halsey St., Building 2

Suite 599

Portland, OR 97213

[www.providence.org/oregon](http://www.providence.org/oregon)



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Oregon Health Authority  
500 Summer Street NE, E65  
Salem, OR 97301

Via email: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

RE: 1115 Medicaid Waiver application

To Whom It May Concern:

Providence appreciates the opportunity to provide feedback on the Oregon Health Authority's application for the 1115 Medicaid Demonstration Waiver for years 2022-2027. Providence is committed to the continued success of the coordinated care model and broader health care transformation efforts in Oregon. Since the establishment of Coordinated Care Organizations, our operational and clinical leaders have actively participated on six coordinated care organization boards, supported innovation efforts statewide, and currently serve as the patient-centered medical home for nearly 53,000 Oregon Health Plan members. In the Portland-metro area Providence is fully accountable for more than 55,000 Health Share of Oregon members.

Providence shares the Authority's goals of creating a more equitable system of care and ensuring the most vulnerable in our state have consistent access to high-quality, affordable health care. In achieving this end, we request the OHA consider the following and move forward in a manner that maintains the integrity of the Oregon Health Plan and continues to build on our success.

**Medicaid is one of our state's most critical safety-net programs, it is essential we preserve the viability of this foundational program.**

Providence strongly supports private and public efforts to transition away from fee-for-service, but we must ensure that the proposed value-based global budget is actuarially sound and predictable. Building the new benefits and health related services into the budget will require annual adjustments, which should only be prospective to preserve the stability of the system.

Specific to the social determinants of health benefits, it will be important to establish these benefits in a way that doesn't jeopardize the long-term sustainability of the OHP. The need for these services is immense, and Medicaid should not bare sole responsibility for developing solutions. Oregon deserves a strategic, thoughtful, stratified solution with partnership from other public agencies.

At Providence, all of our primary care clinics use a standardized SDOH screening tool to identify needs for housing, food insecurity, utilities, and transportation. Patients with positive screens are offered a referral to the community resource desk, a partnership with local community-based organizations, and connected to services and resources. Food insecurity is the number one challenge patients are facing, with housing concerns continuing to increase.

Providence is collaborating with CCOs, community-based organizations and other health systems to develop local infrastructures to meet the needs of the communities we serve. The system that OHA establishes should not jeopardize the current or ongoing system and structures that are in place. To ensure we are not duplicating resources and making measured progress toward our intended outcomes, Providence recommends that the OHA develop shared, state-wide outcome measures to monitor progress at scale.

**Waiver proposals should build off the existing structure, reinforcing systematic, long-term change.**

The CCO model is based on the premise that local leadership and community engagement will elevate the issues most needed in each community. Rather than further segmenting important conversations around equity and social determinants of health, the OHA should reinforce structures that integrate community voices into permanent systems and structures.

An important area for integration into permanent CCO structures includes the Community Investment Collaboratives. As a mission driven organization committed to responding to the needs of our community, we work directly with community leaders to guide decision making. Specifically, Providence partners with community organizations, CCOs and health systems in each community to do Community Health Needs Assessments and develop Community Health Improvement Plans. Providence utilizes a local Service Area Advisory Council, comprised of hospital leadership and community members, to elevate the voices of community in our strategies to ensure our community health investments are caring for the needs of our most vulnerable populations. In order to make the CICs most effective long-term, Providence suggests collaborative efforts around community investment. This would be a model that includes providers and health care systems to ensure shared strategies that maximize new, significant investments.

**Maintain the established incentive metrics structures, with the inclusion of community members and a health equity focus, to ensure that the entire health care system makes strategic improvements together, at-scale.**

The Quality Incentive Program is the cornerstone to the success of the CCO program. Rather than completely dismantling this program, Providence would recommend that health equity measures be incorporated. This may include breaking down existing metrics and evaluating success based on BIPOC data for incentive measures, as OHA has done successfully with COVID measures. Patient-centered primary care homes have established models and can be a great partner in this work. We would also suggest adding individuals to the existing committee to elevate the voice of community rather than removing operational and clinical experts.

**Behavioral health needs renewed focus and commitment to further health system integration.**

The waiver is an opportunity to strengthen the behavioral health system and expand proven models that help Medicaid members access timely services, particularly in a primary care setting. The behavioral health system in Oregon is collapsing and OHA should ensure that options to first stabilize, then innovate and transform the behavioral health system are optimized in the waiver. The absence of behavioral health concepts further puts the behavioral health system at risk.

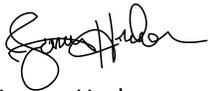
Providence requests that OHA consider the following for this waiver application:

- House Bill 3353 (2021) requires CCOs to dedicate 3% of their global budget to address health inequities and behavioral health. The waiver application includes health inequities but does not follow the statute in requesting waiver authority for behavioral health.

- OHA should develop a dedicated behavioral health proposal that includes federal funding for co-located behavioral health services, integrated psychiatric emergency services and community collaboration like the CAHOOTS model.
- There are not sufficient Psychiatric Residential Treatment Services (PRTS) beds in Oregon. While we understand the critical needs of the Child Welfare population, prioritizing beds for Child Welfare is an insufficient band aid likely to lead to catastrophic consequences for other children, including longer wait times in hospitals and emergency departments. Rather than forcing more competition for beds, we recommend exploring options to staff unstaffed beds, develop rates that equitably reimburse residential behavioral health care with other areas of health care, and developing a functioning bed registry to track the number and availability of beds.

Thank you for the opportunity to provide feedback. We look forward to additional opportunities to discuss this important issue.

Sincerely,



James Harker  
Chief Executive, Population Health  
Providence Health & Services



Jonathan Cascino  
Director, Medicaid Program  
Providence Health & Services



Thursday, December 9<sup>th</sup>, 2021

To: Oregon Health Policy Board  
Attention: David Bangsberg MSc, MD, MPH  
C/O: Tara Chetock, Oregon Health Authority  
[tara.a.chetock@dhsosha.state.or.us](mailto:tara.a.chetock@dhsosha.state.or.us)

From: Josh Balloch  
AllCare Health  
1701 NE 7<sup>th</sup> St  
Grants Pass, OR 97526  
[josh.balloch@allcarehealth.com](mailto:josh.balloch@allcarehealth.com)

Written public comment to the Oregon Health Policy Board for the December 7<sup>th</sup> 2021 meeting --  
RE: Draft Application for the 1115 Medicaid Waiver

Chair Bangsberg and members of the Oregon Health Policy Board,

AllCare Health is currently reviewing the 157-page publically available waiver application, and will be submitting formal comments soon. However, before those comments are completed, I wish to raise concern about this draft waiver's failure to comply with legislative direction, as outlined in HB 3353.

In 2020, when Oregon faced a massive budget shortfall because of the COVID pandemic, likely resulting in hundreds of millions of dollars taken from the Medicaid delivery system, many of us realized the impending negative impact on Oregon Health Plan members and providers. To minimize this impact, a strategy was created to use the 1115 Oregon Medicaid Waiver to leverage more federal dollars being directed into the Oregon Medicaid System. By allowing Coordinated Care Organizations to spend 3% of their funding on health equity improvements and upstream Social Determinants of Health investments, we could then provide significant health improvements for OHP members and the community as a whole. This strategy required that those funds count as "medical expenditures", ensuring the sustainability of those investments.

In late 2020, a coalition comprised of local equity groups, providers, Community Advisory Councils, and legislators, established a consensus that created House Bill 3353 (*Reference: <https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB3353>*). HB 3353 outlines a blue print for the 1115 Oregon Medicaid Wavier request in 2022, giving the Oregon Medicaid System more flexibility on spending Medicaid dollars. More importantly, it created local accountability for CCOs investing in the delivery system, in a way that meaningfully serves members and the communities as a whole.

During the 2021 session, the collation was focused on attaining comprehensive bi-partisan and bi-cameral support for HB 3353. The bill had four chief sponsors (Two Democrats and Two Republicans) and 22 regular sponsors (12 House Democrats; 6 House Republicans; 3 Senate Democrats and 1 Senate Republican). The broad legislative support resulted in the bill passing overwhelmingly (57-0 in the House; 19-10 in the Senate). This is the similar to the broad support enjoyed by the legislation that created the CCOs in 2011/2012.



This bi-partisan legislative support gives added credibility to Oregon's waiver request and demonstrates that funding and flexibility for Medicaid is a non-partisan core issue in Oregon. This is significant when Oregon is again seeking to be a national trailblazer for Medicaid.

Unfortunately, the Oregon Health Authority's Draft Waiver Proposal fails to match the language or the intent of HB 3353. The bill explicitly says CCOs are to "spend" their global budgets on specific investments. (*Reference: Section 2(1)(a) of HB 3353*). Instead, the OHA's draft application, in direct contravention of legislative intent, tells CCOs to give money to a newly formed third party that would "grant out" funds without CCO accountability.

The OHA's draft waiver request seemingly ignores the legislative directive to cause CCOs, at the local level, to be responsible for engaging the whole community in making health investments. (*Reference Section 2(3)(a) & (b) of HB 3353*). The waiver request also rejects the legislators' bi-partisan intent for accountability, by allowing a siloed, third party equity entity to make funding decisions. HB 3353 clearly states that expenditures "be approved by the coordinated care organization's community advisory council."

Another concerning aspect of the draft waiver is the misunderstanding of HB 3353's general operation. The bill specifically and intentionally outlines that unless the OHA can insure CMS will include the 3% expenditures as medical expenses **AND** is fully funded by the increased federal reimbursement, then the CCOs can "spend up to" 3%. Legislators made clear it is not a "shall spend", unless specific requirements are met (*Reference: Section 4 of HB 3353*).

Many of the accountability measures that were included in HB 3353, aimed at ensuring that community voices were present during the creation of spending strategies in an effort to hold both CCOs and the OHA accountable, were not included in the 1115 Draft Waiver. The bill states that in order for these dollars to be counted as this 3%, they have to be part of "a plan developed in collaboration with, or directed by, members of organizations or organizations that serve local priority populations that are underserved in communities served by the coordinated care organization." In short, the plan the CCOs use for investments (i.e. Community Health Improvement Plan or Health Equity Plan) must include voices from priority and underserved populations within the service region, in the development of that plan. (*Reference: Section 2(3)(a) of HB 3353*). Within HB 3353, there is clear direction that these investments must demonstrate "practice-based or community-based evidence", giving CCOs the flexibility they need in order to find innovative solutions in partnership with new community organizations, likely to serve smaller populations among the underserved communities. These requirements were included in the Bill as part of the discussion with RHECs and should apply to the full 3%, but the Draft Waiver only applies this to the third party equity silos. (*Reference: Section 2(3)(b) of HB 3353*).

There are many other conflicts between the current draft waiver proposal and HB 3353. This letter is only intended to highlight the most urgent concerns about the draft 1115 proposal, which I and other members of the coalition wish to bring to your attention.

The Oregon Health Policy Board must be informed of these concerns, as failure to follow both the language and intent of HB 3353 will create significant issues and unnecessary confusion. The lack of



alignment between the waiver and HB 3353, which is referenced many times in the waiver, will generate uncertainty when the Centers for Medicare and Medicaid (CMS) review Oregon's request. Confusion at CMS will make it difficult to obtain the flexible and sustainable funding Oregon needs to address health inequities by 2030. Failure to follow the language and intent of HB 3353 also disenfranchises partners, such as regional health equity commissions and community advisor councils, which supported and helped pass the bill. Importantly, creating a third party equity silo, will very likely fail to win the endorsement from many of HB 3353's bi-partisan supporters. Divisions in the federal Oregon Congressional delegation could create a reason for CMS to label the waiver as "partisan" and to reject it.

Many community members in our region are thoroughly disappointed about the current direction of this waiver. Concerns about third party equity silo concepts have been shared with the OHA many times, yet meaningful changes have not been made.

To be clear, AllCare is extremely supportive of incorporating more diverse voices and having community accountability to ensure that health needs of all people are being met. Our concern is that these third party equity silos create bifurcated efforts that are unsustainable in a "grant-based" system.

Based on our experience, the number one issue with a CCO's ability to support sustainable equity investments within the community, is the lack of a true global budget; not an absence of desire by our Community Advisory Councils, our CCO Board of Governors, or any of the locally-based organizations with whom we partner.

Our request to you, the Oregon Health Policy Board, is that you ask the OHA to make meaningful changes to Oregon's 1115 Waiver Request, in the following areas:

- 1.) Removal of the third party equity silos, replaced with bi-partisan concepts laid out in HB 3353, as written and supported by over 80% of the legislature.
- 2.) Make clearer the request that the identified 3% of investments in health equity and SDOH be recognized as Medical expenditures. This is key to making these investments sustainable.
- 3.) Make clearer a request for full federal funding of these important upstream investments.

HB 3353 was a significant bi-partisan accomplishment during a contentious legislative session. It is important that the negotiated cooperation of the stakeholders and legislators and their significant achievement is not squandered in this application to the Federal Government. Thank you for you considering this sincere request for the changes necessary for the waiver application to appropriately reflect House Bill 3353 and the will of the People of Oregon.

If you would like to discuss this further please feel free to call me anytime (503-508-5868).

Sincerely,

Josh Balloch  
AllCare Health  
Vice-President of Health Policy



January 3, 2022

To whom it may concern:

I am writing on behalf of Cascade AIDS Project (CAP) and the undersigned organizations to submit public comment on Oregon's draft 1115 Medicaid Demonstration Waiver application.

Founded in 1985 as a grassroots response to the AIDS crisis, CAP is now the oldest and largest HIV-services provider in Oregon. We and our allies are deeply concerned by the proposal in Oregon's draft application to adopt a closed formulary approach, and **we urge the state to commit in the application to maintaining open access to HIV treatment medications.**

Although we understand the reasons for adopting a closed formulary, this approach is not appropriate for HIV treatment medications, for a number of reasons:

- (1) HIV is a highly individual disease. Different people living with HIV have different treatment needs based on their specific medical history and the resistance(s) to medication that may have developed in their bodies. As a result, people living with HIV and their healthcare providers need maximum flexibility to select an HIV treatment regimen that is right for them.
- (2) HIV disproportionately impacts people who are also experiencing challenges such as homelessness, mental illness, and/or substance-use disorder. Members of this population may need simpler, more manageable HIV treatment regimens (e.g., single-tablet regimens) to remain adherent to their medications, but closed formularies can restrict access to those regimens by not factoring social determinants of health into decision-making on coverage.
- (3) Utilization-management techniques used in a closed-formulary approach, such as prior-authorization requirements, can cause abandonment of treatment, especially for those already at risk of falling out of care. For people living with HIV, in particular, the consequences can be disastrous: Medication non-adherence can lead not only to poor health outcomes, but also to permanent resistance to a drug or entire class of drugs.
- (4) People who are living with HIV and in successful treatment cannot transmit the virus through sex. However, if people fall out of care, as utilization management can cause them to do, they can spread HIV to their sexual partners. Adherence is, therefore, a public-health issue as well as an individual one.

**Chief Executive Officer**

Tyler TerMeer, PhD

**Board of Directors**

**President**

Karol Collymore  
Nike

**Vice President**

William E. Spigner  
Nike

**Secretary**

Miguel Villarreal  
Kaiser Permanente

**Treasurer**

Edwin Kietzman  
Smart Foodservice  
Warehouse Stores

**Member at Large**

Kris Young  
Nike

**Tracy A. Curtis**

Wells Fargo Bank

**Eric Garcia**

Multnomah County

**Daniel Guilfoyle**

Native American Youth &  
Family Center (NAYA)

**Andy Jamison-LeGere**

OnPoint Community Credit  
Union

**Jordan Olson**

Community Volunteer

**Rhodes Perry**

Rhodes Perry Consulting, LLC

t > 503 223 5907

f > 503 223 6437

capnw.org

520 Northwest Davis Street, Suite 215 Portland, Oregon 97209

For all these reasons, it is considered best practice to ensure access to HIV treatment medications, even within a closed-formulary approach. This is why **antiretrovirals are designated as a drug class “of clinical concern” within Medicare Part D, requiring Part D plans to cover all drugs within that class** (rather than only two or more drugs, as for most classes). It’s also why the federal agencies responsible for ending the HIV epidemic direct states to “design their prescription drug formularies to minimize potential barriers presented by utilization management techniques so that Medicaid...beneficiaries can readily access all [HIV] regimens.”<sup>1</sup> Several states, including California, Colorado, and Illinois, have gone so far as to codify in statute protections from utilization-management techniques for Medicaid members living with HIV.

Oregon currently includes all U.S. Food and Drug Administration-approved HIV drugs on its Preferred Drug List, and the above-average health outcomes of Oregonians living with HIV reflects such public policies. Ensuring access to HIV treatment medications bolsters not just Oregon’s efforts to end the HIV epidemic, but the state’s commitment to eliminating health inequities as well, because Black, Latinx, and Indigenous Oregonians are more likely to be living with HIV, and more likely to experience poor HIV health outcomes (e.g., viral non-suppression). We hope that Oregon will remain aligned with best practice and the state’s own strategic goals by **committing in its 1115 waiver application to maintain open access to HIV treatment medications.**

Sincerely,

Jonathan Frochtz wajg  
Public Policy & Grants Manager, CAP



<sup>1</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf>



**BY ELECTRONIC DELIVERY**

January 7, 2022

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**RE: Application for Renewal and Amendment Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

The Rare Access Action Project, (RAAP) appreciates the opportunity to comment on the Oregon Health Authority's (OHA) proposed renewal and amendment of its Section 1115 waiver for the July 1, 2022- June 30, 2027, demonstration period. RAAP agrees with OHA's focus to maximize continuous and equitable access to coverage and supports OHA's goal to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon.

RAAP, however, is concerned that OHA's proposals seeking the authority to implement a closed formulary and limit coverage of drugs approved under the FDA's accelerated approval pathway will have the opposite result. On its face, RAAP understands why Oregon seeks these new authorities, however, these policies are penny wise pound foolish because, if implemented, these policies will have the opposite impact of the state's intent. That is, these policies will reduce access to life saving therapies magnifying the health equity divide amongst Medicaid patients and between other Oregon residents.

The Health Equity Committee, a subcommittee of OHPB seeks to promote elimination of health disparities for all people in Oregon, "eradicating health inequities by 2030." Rather than making progress toward this goal, Oregon's proposed closed formulary would likely create additional health disparities for rare disease patients, especially those who are also part of racial and/or ethnic minority



group and face substantial burdens that can cause economic hardship, difficulty accessing care, and poorer health outcomes for themselves and caregivers.

Using accelerated approval as a proxy for high drug costs to Oregon's Medicaid program is misguided. Accelerated approval concerns require accelerated approval solutions that account for the importance of this pathway to rare disease patients. They cannot be solved with solutions designed to resolve drug pricing challenges that would, ultimately, disincentivize research and development and slow the availability of novel drugs to patients with rare diseases.<sup>1</sup>

RAAP is a registered 501(c)(4) non-profit organization that is a coalition of life sciences and patient stakeholders that explore creative policy solutions to address structural issues in access and coverage. Our priority is to help ensure rare disease patients have access to the care and treatments they need and submits the following comments consistent with that objective.

## **Background: Rare Diseases and Orphan Products**

The [Orphan Drug Designation Program](#) provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than [200,000 people in the US](#), or that affect more than 200,000<sup>2</sup> persons but are not expected to recover the costs of developing and marketing a treatment drug. Rare diseases include more familiar conditions, such as cystic fibrosis, Lou Gehrig's disease, and Tourette's syndrome, as well as less familiar conditions, such as Duncan's Syndrome, Madelung's disease, and acromegaly/gigantism. These conditions are complex and often not well understood, which causes great challenges to the diagnosis and treatment as well as research efforts.

[Rare disease treatments](#) range from curing the disease, modifying how the disease functions, or treating the symptoms. Truly curative treatments are rare. Disease-modifying therapies target the underlying pathology of a disease to prevent it from

---

<sup>1</sup> FDA's Accelerated Approval Pathway: A Rare Disease Perspective, National Organization for Rare Disorders (NORD®), June 11, 2021.

<sup>2</sup> Department of Health and Human Services, Food and Drug Administration (FDA). Office of Orphan Drug Development. <https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-orphan-products-development>. Accessed March 13, 2021.



worsening. Symptomatic treatments seek to temper symptoms or to maintain physical, emotional, and mental functioning.

Only 5% of rare diseases have a treatment approved by the Food and Drug Administration (FDA) and for one-third of individuals with a rare disease, it can take between one and five years to receive a proper diagnosis. Patients with rare diseases often seek treatment in clinics where the condition has never been seen before and have symptoms that are absent, masked, misunderstood, or confused, which often leads to delayed diagnosis further complicating the patient's and family's arduous journey. Half of all patients diagnosed with a rare disease are children, and as many as 3 in 10 children with a rare disease<sup>2</sup> will not live to see their 5th birthday<sup>3</sup>.

Many of these patients rely on the CHIP and Medicaid federal safety net programs for healthcare services such that changes to these programs must be carefully analyzed and appreciated so as to not cause more harm than good, which RAAP fears is the case with this waiver request.

### **Recent Advancements in Rare Disease Treatments**

The Orphan Drug Act and the Food and Drug Administration Safety Innovations Act (FDASIA) are clear examples of Congress' recognition of the significant disease burden that rare disease patients face. Each of the Act's provisions create greater incentives towards therapeutic development for these diseases. Specifically, the [FDA Guidance Document](#) and the accelerated approval provisions of FDASIA in section 506(c) of the FD&C Act allow the FDA discretion to grant accelerated approval to:

*. . . a product for a serious or life-threatening disease or condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the<sup>3</sup> availability or lack of alternative treatments<sup>4</sup>.*

---

<sup>3</sup> Slade, A., Isa, F., Kyte, D., Pankhurst, T., Kerecuk, L., Ferguson, J., Lipkin, G., & Calvert, M. (2018). Patient reported outcome measures in rare diseases: a narrative review. *Orphanet journal of rare diseases*, 13(1), 61. <https://doi.org/10.1186/s13023-018-0810-x>

<sup>4</sup> Department of Health and Human Services, Food and Drug Administration (FDA). Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics <https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf>



According to the FDA Guidance,<sup>5</sup>

*. . . a surrogate endpoint used for accelerated approval is a marker - a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Likewise, an intermediate clinical endpoint is a measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality (IMM).*

*The FDA bases its decision on whether to accept the proposed surrogate or intermediate clinical endpoint on the scientific support for that endpoint. Studies that demonstrate a drug's effect on a surrogate or intermediate clinical endpoint must be "adequate and well controlled" as required by the FD&C Act.*

### **Challenges in Rare Disease Clinical Trials: FDA in Best Position to Balance**

Clinical trials for rare disease drugs overall engage more investigative sites to recruit fewer patients and typically have longer trial durations, reflecting the difficulties of patient supplants the judgment of the individual patient/family and their treating physician with that of State Medicaid agencies. The FDA is best positioned to balance the challenges of rare disease clinical trials and the unmet medical need in particular as it relates to rare disease situations.

According to Samiya Luthfia Khaleel, Senior Research Analyst with the Tufts Center for the Study of Drug Development<sup>6</sup>, patient recruitment and retention is one of the many challenges in rare disease research complicated by the paucity, often scattered nature of the disease patient population and because 50 percent of rare diseases affect the pediatric population identification and enrollment.<sup>78910</sup>Coverage,

---

<sup>5</sup> Department of Health and Human Services, Food and Drug Administration. Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. <https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf>. Accessed March 13, 2021.

<sup>6</sup> Tufts Center for the Study of Drug Development, *Impact Report Analysis & Insight into Critical Drug Development Issues*. Vol. 15, No. 1, Tufts University, 2013.

<sup>7</sup> Khaleel, Samiya Luthfia. Rare Disease Patient Recruitment and Retention. <https://www.clinicalleader.com/doc/rare-disease-patient-recruitment-and-retention-0001>. Accessed March 13, 2021.

<sup>8</sup> Tufts Center for the Study of Drug Development, *Impact Report Analysis & Insight into Critical Drug Development Issues*. [https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5d2490ae0072ee0001a1a198/1562677423360/summary\\_julyaugust\\_2019.pdf](https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5d2490ae0072ee0001a1a198/1562677423360/summary_julyaugust_2019.pdf). Accessed March 13, 2021.

<sup>9</sup> Tambuyzer E. Rare diseases, orphan drugs and their regulation: questions and misconceptions. *Nat Rev Drug Discov*. 2010;9(12):921–9.

<sup>10</sup> Sharma A, et al. Orphan drug: Development trends and strategies. *J Pharmacy and Bioallied Sciences*. 2010;2(4):290–9.



access and rebate policy should not be based on completion of the FDA confirmatory trial in the case of orphan designated, accelerated approval products. Such a policy is contrary to the established FDA regulatory approval process in the case of orphan designated accelerated approval products that are specifically designed for the FDA to weigh the public interests of safety and efficacy with the unmet medical needs in particular scenarios. Such a proposed policy supplants the judgment of the individual patient/family and their treating physician with that of State Medicaid agencies.

Access restrictions on FDA approved accelerated approval products without understanding the drug development circumstances can undermine the intention of the orphan drug development policies established by Congress and implemented by the FDA that have allowed for the advancements and innovation in so many rare diseases over the years. The FDA, as indicated in the [FDA Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologic](#), is in the best position to balance public welfare needs to further demonstrate safety and efficacy, the unmet medical need in the context of the particular rare disease, and the challenges and unique complexities of confirmatory studies for rare diseases,

*FDA recognizes that certain aspects of drug development that are feasible for common diseases may not be feasible for rare diseases and that development challenges are often greater with increasing rarity of the disease. FDA will continue to apply flexibility in these situations to address particular challenges posed by each disease.*<sup>11</sup>

### **RAAP Believes that OHA’s Proposals Violate Existing Law**

Oregon seeks the ability to more closely manage pharmacy costs in its Medicaid program, through a two-part strategy. First, the state wishes to adopt a commercial style closed formulary approach, which ostensibly means that the state could only cover a single drug per therapeutic class. Second, Oregon seeks new flexibility under this waiver to exclude drugs approved under FDA’s accelerated approval pathway that the state deems to have limited or inadequate clinical efficacy under its closed formulary approach. RAAP believes that both proposals violate current law, specifically the Medicaid Drug Rebate Program.<sup>12</sup>

---

<sup>11</sup> Department of Health and Human Services, Food and Drug Administration. Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. <https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf>. Accessed March 13, 2021.

<sup>12</sup> Social Security Act (SSA) §1927.



Specifically, on June 27, 2018, the Centers for Medicare & Medicaid Services issued State Release No. 185 (Release) reminding states of their legal obligations to cover all drugs that meet the statutory definition of covered outpatient drugs, including those drugs approved under the FDA’s accelerated approval pathway.<sup>13</sup> Specifically, the Release states “that a drug approved by the Food and Drug Administration (FDA) under its “accelerated approval” pathway, which is the approval program authorized under section 506(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA),<sup>14</sup> must be covered by state Medicaid programs, if the drug meets the definition of “covered outpatient drug” as found in Section 1927 of the Social Security Act (the Act).”<sup>15</sup> Therefore, Oregon’s two part strategy to manage formulary costs via a closed formulary and limited coverage of accelerated approval drugs violates the parameters of the Medicaid Drug Rebate Program.

Finally, CMS denied the Massachusetts’ closed formulary proposal because the state would have also preserved statutory rebates. While CMS noted it would consider proposals to institute a closed formulary in Medicaid, they mentioned it would only consider such a proposal if the state agrees to forgo the federal mandatory rebates available through the federal Medicaid rebate program. Oregon has not included this in their proposed waiver application, and therefore is more likely to also be rejected by CMS in its current form.

### ***SSA § 1115 Waivers Do Not Override the State’s Obligations Under the Medicaid Drug Rebate Agreement***

Section 1115 of the Social Security Act (SSA) gives the Secretary of Health and Human Services authority to approve experimental, pilot, or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program. The purpose of these demonstrations, which give states additional flexibility to design and improve their programs, is to demonstrate and evaluate state-specific policy approaches to better serve Medicaid populations.<sup>16</sup> The statute provides that waivers must set forth an “experimental, pilot, or demonstration project,” that, in the judgment of the Secretary, is “likely to assist in

---

<sup>13</sup> CMS State Release No. 185, June 27, 2018.

<sup>14</sup> <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm>

<sup>15</sup> CMS State Release No. 185, June 27, 2018.

<sup>16</sup> <https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html>



promoting the objectives of title XIX [i.e., the Medicaid program].”<sup>17</sup> RAAP believes that 1115 waivers, in order to better serve Medicaid patients, should demonstrate improved access and/or better outcomes and fails to see how Oregon’s two part strategy achieves either of these objectives.

Specifically, the State has not specified a research proposition that it seeks to test. It proposes only to cut costs by restricting coverage of covered outpatient drugs that it would otherwise be required to cover under SSA § 1927. As stated above, SSA § 1115 demonstration projects must test innovative approaches aimed at furthering the objectives of the Medicaid program, for example, by enhancing quality of care or promoting efficient administration. A demonstration project may not operate as a mere benefit cut with no actual experimental value.

Additionally, a waiver of compliance with SSA § 1927 fails to promote the objectives of title XIX, which was enacted by Congress to provide medical care to the needy and medically needy.<sup>18</sup> By denying access to otherwise-covered and potentially life-saving therapies, the State would do precisely the opposite. Congress enacted SSA § 1927 in order to guarantee that “[s]tates that elect to offer prescription drugs ... cover all the products of any manufacturer that agrees to provide price rebates.”<sup>19</sup> If CMS were to approve a waiver of compliance that enables a state to avoid its drug coverage obligations under SSA § 1927, the agency would undermine the primary objective of SSA § 1927, as stated by Congress itself. On top of this, the State would fail to ensure that “Medicaid beneficiaries have access to the same range of drugs that the private patients or their physicians enjoy,” as intended by Congress.<sup>20</sup> CMS has confirmed this with numerous communications to other states and in State Releases.

### **OHA’s Two-Part Strategy to Manage Drug Spend Hinders Access to Innovative Therapies Jeopardizing the Quality of Care For Medicaid Patients**

RAAP has concerns that a waiver of compliance with SSA § 1927’s coverage requirements will restrict access to medically necessary drugs. Below we highlight

---

<sup>17</sup> SSA § 1115(a).

<sup>18</sup> Staff of H. Comm. on Ways and Means, 89th Cong., Summary of Major Provisions of H. R. 6675, The “Social Security Amendments of 1965” 1 (Comm. Print 1965).

<sup>19</sup> Id.

<sup>20</sup> H. Rep. No. 101-881, at 96-97 (1990).



only a few examples in which excluding accelerated approval medications is detrimental to rare patients.

Since the introduction of the AAP, more than 250 drugs have received accelerated approval, with roughly 42 percent representing drugs that treat rare diseases or conditions and 65 percent for oncology treatments. Over 25 million Americans suffer from rare diseases, which are particularly likely to be serious and life-threatening diseases with unmet medical needs. Of the 7,000 rare diseases that have been identified, more than 90% of them have no FDA-approved treatment.

As you know, with smaller, ultra-rare populations, traditional clinical trials would delay or halt progress for years while waiting for enrollment. Such a policy could have a disproportionate impact on the future rare patient access to these therapies. Many facets of rare diseases make them particularly difficult to study in clinical trials targeting direct clinical benefit.<sup>21</sup> “[D]eveloping drugs for rare disease can be challenging due to specific rare disease characteristics such as small heterogeneous patient populations, long time-frames for disease progression, a poor understanding of disease natural history, and a lack of prior clinical studies.”<sup>22</sup> This makes accelerated approval a particularly important tool for the development of treatments for rare diseases.

For example, Sanfilippo syndrome could provide you with an important analogue to understand the importance of accelerated approval on development of pediatric rare diseases. This syndrome is akin to Alzheimer’s disease in children. Children with Sanfilippo syndrome are born with a genetic abnormality so their bodies cannot break down heparan sulfate, a natural cellular product that needs to be recycled. Accumulation of excess heparan sulfate is toxic to both the body and the brain. Almost all children born with this syndrome die before adulthood. Currently, there are no approved therapies for Sanfilippo syndrome, nor are there any approved surrogate biomarkers. If use of the heparan sulfate level in cerebrospinal fluid were to be recognized as a biomarker that reflects underlying disease activity, a number of therapeutic programs that currently are at risk for never being approved could be advanced.<sup>23</sup> However, once a treatment is developed, and

---

<sup>21</sup> Emil D. Kakkis et al., *Recommendations for the Development of Rare Disease Drugs Using the Accelerated Approval Pathway and for Qualifying Biomarkers as Primary Endpoints*, 10:16 Orphanet J. of Rare Diseases 1, 1 (2015), available at <https://ojrd.biomedcentral.com/track/pdf/10.1186/s13023-014-0195-4.pdf>.

<sup>22</sup> U.S. Food & Drug Admin., CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint (Jan. 14, 2021), <https://www.fda.gov/media/88907/download>

<sup>23</sup> Emil D. Kakkis, Aduhelm’s accelerated approval offers a promising roadmap for rare neurological diseases (July, 2021). <https://www.statnews.com/2021/07/07/accelerated-approval-aduhelm-promising-roadmap-rare-diseases/>



approved through the accelerated pathway, the Oregon Medicaid program under this waiver request could deny access to patients.

Pediatric neuromuscular therapies, lysosomal disorder medicines, gene therapies, and many other rare pediatric and adult medications—all these important advances could be denied to patients under this waiver, even though they are FDA approved, and must meet rigorous standards for that label and approval none-the-less.

\*\*\*

Thank you for the opportunity to submit comments on the Oregon Health Plan's Section 1115 Demonstration Waiver Renewal and Amendment application. We strongly urge the state to work with the rare patient community to ensure new policies do not severely jeopardize patient access to care, given our belief that Oregon Health Plan can achieve its objectives without any waiver of §1927.

Sincerely,

Michael Eging  
Executive Director  
Rare Access Action Project



**BY ELECTRONIC DELIVERY**

January 7, 2022

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**RE: Application for Renewal and Amendment Oregon Health  
Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

The Rare Disease Company Coalition (RDCC) appreciates the opportunity to provide comments on the state of Oregon's application for a section 1115 Demonstration Waiver. We appreciate the state's intention to be responsive to the community feedback and request the state consider our serious concerns with the potential impact of the demonstration waiver on the discovery and development of new medicines, particularly on treatments and cures for patients with rare diseases who currently have limited or no treatment options.

In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people. There are 7,000 identified rare diseases that impact an estimated 25 to 30 million Americans. These diseases are devastating and often life-threatening: 80 percent of rare diseases are genetic in origin, 50 percent impact children, and 30 percent of those children will not live to see their 5th birthday. While only 7 percent of rare diseases have an FDA-approved treatment, the 20 life science companies comprising the RDCC are committed to continuing to change these statistics by discovering, developing, and delivering rare disease treatments for patients. Our goal is to inform policymakers of the unique challenges—and promises—we face in taking these rare disease drugs from research through development, approval, manufacturing, to delivery to patients. Collectively, Coalition members invested over \$4.5 billion in R&D in 2020; have brought 36 treatments to market to date, the majority of which are first-to-market therapies; and are presently working on more than 225 rare disease development programs, many of which would be first-to-market therapies if approved. We are focused on working to meet the needs of rare disease patients with currently limited or no treatment options.

The RDCC has significant concerns with the Oregon Health Authority's (OHA) request to establish a closed formulary for the state's Medicaid program that could limit coverage to one drug for each therapeutic class and would exclude drugs approved via the Accelerated Approval pathway. We believe a closed formulary is not in the best interest of patient health, particularly for patients with rare disease, and that this proposal would curtail innovation in the discovery and

development of new treatments. We believe this could potentially deny Medicaid patients access to important medical advances.

Our specific concerns are as follows:

**Oregon's 1115 Demonstration Waiver would impact innovation for rare disease treatments and cures**

Rare diseases present specific challenges - such as small population sizes, or slow, irreversible, and variable disease progression - that make it difficult to study in some cases using clinical measures as endpoints. The Accelerated Approval pathway is a critical tool, well-suited to recognize these unique circumstances. If these drugs are not covered by state Medicaid programs thereby limiting patient access, manufacturers have little incentive to pursue research and development in rare diseases, as an already small (rare) population becomes smaller.

Oregon's approach simply does not align with the intent of the Accelerated Approval pathway to expedite access to rare disease treatments for patients with serious conditions, especially for diseases that have limited or no treatment options. We are concerned about the impact to these patients and the broader impact on the entire rare disease community, regardless of payor, because we believe the OHA 1115 Demonstration Waiver would effectively disincentivize and curtail research and development for the treatment of certain rare diseases. Ultimately, this approach would punish patients who are forced to suffer as their disease progresses while continuing to wait for a treatment. For example, the Accelerated Approval pathway can be credited for changing the trajectory of scientific advancement for HIV/AIDS and for oncology. We also note that a significant proportion of rare disease patients are children who are on Medicaid and while the Oregon waiver would maintain an open formulary for children, we note that these children would potentially lose access to these drugs when they reach adulthood.

**Oregon's 1115 Demonstration Waiver would undermine the intent of the Accelerated Approval pathway and FDA's role as the sole arbiter of determining safety and efficacy**

We believe that subjecting medicines that are approved via the FDA Accelerated Approval pathway to additional scrutiny based on their pathway for approval undermines the purpose of the Accelerated Approval pathway and disregards its benefits to patients with unmet medical needs, including those with rare diseases. Targeting Accelerated Approval therapies could deprive patients who suffer from certain conditions the important, safe, and effective therapies they need. In many cases, these therapies are the only effective course of treatment for their disease.

By law (21 U.S.C. § 356(e)(2)), the FDA must find "substantial evidence of effectiveness" to approve any drug, including drugs approved via the Accelerated Approval pathway. The Accelerated Approval pathway is a targeted and robust, science-based pathway established by Congress and the FDA to speed the availability of new therapies to patients with serious conditions,<sup>1</sup> especially when there are no available alternatives, while preserving the FDA's

---

<sup>1</sup> Serious condition is defined as: "...a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is

rigorous standards for safety and effectiveness. In 1992, the FDA established a new expedited pathway to speed approval of medicines that treat serious conditions and address an unmet need, later codified by Congress in 1997.<sup>2</sup> In 2012, Congress passed the Food and Drug Administration Safety Innovations Act (FDASIA) that amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow the FDA to reinforce and enhance the Accelerated Approval pathway in FDASIA and encouraging broader applicability for rare disease.<sup>3</sup> The Accelerated Approval pathway has been credited with significant advances in the treatment of life-threatening diseases where patients have limited or no treatment options. Historically, this pathway has been used primarily for oncology drugs with 174 oncology accelerated approvals through June 30, 2021.<sup>4</sup> In fact, from 2010-2020, 85 percent of the agency's accelerated approvals have been for oncology indications.<sup>5</sup> We believe this can be a critical pathway for rare diseases as well.

The FDA's Accelerated Approval pathway is a well-established, proven, regulated path forward for certain drugs that rely on the use of surrogate or intermediate clinical endpoints to determine the effectiveness of a therapy. Surrogate endpoints are imperative to getting rare disease treatments to patients as there is limited disease knowledge and small populations so determining a clinical endpoint is rarely feasible. Congress, the FDA, and the scientific community have all recognized the important role of surrogate endpoints as relevant and reliable biomarkers to assess effectiveness in certain circumstances, particularly for slowly progressing, debilitating diseases where verification of clinical benefit may take many years.<sup>6</sup>

Both Congress and the FDA have been clear in affirming that accelerated approval does not diminish or compromise FDA's stringent approval standards. Notably, the FDA has maintained that prescription drugs and biologics approved under the Accelerated Approval pathway must meet clinically meaningful endpoints and that the benefits of the treatment must outweigh the risks of treatment, finding that *"Approval...requires ... that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. This judgment does not represent either a "lower standard" or one inconsistent with section 505(d) of the act, but rather an assessment about whether different types of data show that the same statutory standard has been met."*<sup>7</sup>

The FDA has noted that the Accelerated Approval pathway "ensure[s] that therapies for serious

---

persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one." 21 CFR 312.300(b)(1); <https://www.fda.gov/media/86377/download>

<sup>2</sup> <https://www.govinfo.gov/content/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf>

<sup>3</sup> <https://www.govinfo.gov/content/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>

<sup>4</sup> CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint (As of June 30, 2021). Accessed December 22, 2021. <https://www.fda.gov/media/151146/download>

<sup>5</sup> See Friends of Cancer Res., Optimizing the Use of Accelerated Approval 3(2020) ("FOCR Report"), [https://friendsofcancerresearch.org/sites/default/files/2020-11/Optimizing\\_the\\_Use\\_of\\_Accelerated\\_Approval-2020.pdf](https://friendsofcancerresearch.org/sites/default/files/2020-11/Optimizing_the_Use_of_Accelerated_Approval-2020.pdf) (stating that 84% of accelerated approval drugs from 2010 to 2019 were for oncology indications); CDER Drug and Biologic Accelerated Approvals, supra note 72 (stating that FDA has granted 253 accelerated approvals as of December 31, 2020, of which 9 were approved after June 30, 2020 and 7 were for oncology drugs); see also Julia A. Beaver & Richard Pazdur, "Dangling" Accelerated Approvals in Oncology, 384 New Eng. J. of Med. e68(1), 1 (May 2021) ("[A]pproximately 85% of accelerated approvals in the past 10 years have been granted in oncology.").

<sup>6</sup> <https://www.fda.gov/news-events/fda-voices/delivering-promising-new-medicines-without-sacrificing-safety-and-efficacy>

<sup>7</sup> 57 Fed. Reg. at 58944.

conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks."<sup>8</sup> The Agency has also emphasized that the accelerated approval procedures "are intended to provide expedited marketing of drugs for patients suffering from such [serious or life-threatening] illnesses when the drugs provide meaningful therapeutic advantage over existing treatment"<sup>9</sup> and that "it is in the public interest to make promising new treatments available at the earliest possible point in time for use in life-threatening and serious illnesses."<sup>10</sup>

Oregon's interest in making determinations that would deny coverage for drugs "with limited or inadequate evidence of clinical efficacy" based on the state's own review process is particularly troublesome. We believe it is inappropriate for OHA to substitute its own judgement for determinations related to clinical efficacy of drugs that have been reviewed and approved by the FDA. The FDA remains the gold standard for drug safety and efficacy. Moreover, Oregon's efforts to supplant FDA authority go beyond just excluding Accelerated Approved drugs. Oregon's request would seek to exclude drugs with "no incremental clinical benefit within its therapeutic class, compared to existing alternatives." FDA's drug approval framework does not require evidence of an "incremental benefit" over existing therapies for a demonstration of safety and efficacy. Overall, such an approach implies that Oregon is better suited to review drugs than the scientists and disease experts at the FDA. Establishing such a framework undermines the important, independent authority of the FDA as the sole arbiter of safety and efficacy.

### **Closed formularies are not in the best interests of rare disease patients with limited to no treatment options**

We have great concerns that Oregon's proposal to cover as few as one drug per therapeutic class would seriously jeopardize the health of patients and would hinder access to quality of care for the most vulnerable patients, especially those with rare, life-threatening diseases. For many therapeutic classes, such restrictions could leave impacted Medicaid beneficiaries without access to the physician-prescribed medicine deemed most appropriate. Given the heterogeneity within patient populations and the advancement of precision medicine, providing access to a wide variety of drug options is foundational to appropriate patient care. One formulary agent may not produce the intended therapeutic outcome or have the same side effects across patient types which could be detrimental to Medicaid patients in Oregon, particularly those with rare diseases. The Oregon approach would also provide fewer protections for Medicaid beneficiaries. For example, it does not provide any access protections or require its closed formulary to adhere to the Essential Health Benefits benchmark standards. We also note this approach would not align with the interests of CMS in consistency across programs – specifically Medicaid and Medicare – given the Medicare Part D coverage requirement of at least 2 drugs per drug category/class.

### **Oregon's 1115 Demonstration waiver is not consistent with foundational Medicaid policies.**

---

<sup>8</sup> FDA. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics. May 2014

<sup>9</sup> 57 Fed. Reg. 58942.

<sup>10</sup> 57 Fed. Reg. at 58944

The Medicaid Drug Rebate program represents a carefully balanced compromise made by Congress under the Omnibus Reconciliation Act of 1990 to ensure the federal government has access to the lowest available price for covered outpatient prescription medicines – via a statutorily mandated rebate – while also ensuring that manufacturers’ products would be accessible to Medicaid recipients if medically necessary and subject to statutorily defined access restrictions. The Oregon demonstration waiver would disrupt this long-term, successful Medicaid policy that has facilitated access to medicines for beneficiaries with a fiscally prudent approach.

We note that severely limiting beneficiary access to physician-prescribed medicines in the Medicaid program has already been rejected by the Centers for Medicare and Medicaid Services (CMS). In 2017, the Commonwealth of Massachusetts proposed a closed formulary with at least one drug per class, with the intent to exclude drugs approved through the FDA’s Accelerated Approval process. These policies were firmly rejected by CMS, indicating that a state cannot simply opt out of the Medicaid Rebate Program, and not provide access to “covered outpatient drugs” for which a manufacturer has a signed National Rebate Agreement.<sup>11</sup> Of note, the same day that CMS responded to the Massachusetts waiver amendment, the agency issued “State Release No. 185,” which underscored the fact that drugs approved through the FDA’s expedited approval processes “must be covered by state Medicaid programs, if the drug meets the definition of “covered outpatient drug” as found in Section 1927 of the Social Security Act”<sup>12</sup> and the Manufacturer has a signed Medicaid National Rebate agreement. We believe these policies demonstrate continued support by CMS for patient access to medicines facilitated by the Medicaid Drug Rebate Program.

### **This approach would not promote the elimination of health disparities nor the achievement of health equity**

OHA’s approach to establish a closed formulary for adults and to not cover drugs approved via the Accelerated Approval pathway is in direct conflict with the state’s purported goal of the 1115 Demonstration waiver: “to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon.” The Health Equity Committee, a subcommittee of the Oregon Health Policy Board (OHPB) was tasked with coordinating and developing policy that proactively promotes the elimination of health disparities and the achievement of health equity for all people in Oregon and the state has a goal of “eradicating health inequities by 2030.” This is an admirable goal for the state, as 27% of the state’s population is considered low-income, below 200% of the Federal Poverty Level. However, rather than making progress toward Oregon’s goal of eradicating health disparities, Oregon’s proposed closed formulary would likely create additional health disparities for rare disease patients, especially those who are also part of racial and/or ethnic minority group. Without the ability to have coverage of a medicine that may not be included in Oregon’s closed formulary, these issues will be exacerbated and could result in poor health outcomes and increased costs of care, rather than achieving the state’s goals of eliminating health disparities and the achievement of health equity for all people in Oregon. Individuals with rare diseases tend to report common concerns that result from being underserved, such as a long road to diagnosis, limited treatment

---

<sup>11</sup> CMS letter to Asst. Secretary Tsai, MassHealth, June 27, 2018.

<sup>12</sup> CMS State Release No. 185, June 27, 2018.

options, and a need for research to better understand their medical condition.<sup>13</sup> Rare diseases are disproportionately prevalent among some racial and ethnic minority groups. These patients may also face greater disease burden, earlier age of disease onset, and/or complex sets of comorbidities that limit the safety and effectiveness of older treatment options. We believe the Oregon approach sends a message to patients with high unmet needs that their lives are not worth the investment; we strongly oppose that sentiment.

### **Oregon's 1115 Demonstration Waiver would have a limited budgetary impact**

Historical claims analysis suggests that a closed formulary would not be likely to yield significant savings to OHA. From 2007 to 2018, Accelerated Approval drugs account for less than 1% of overall Medicaid spending while often representing the only treatment options available for beneficiaries.<sup>14</sup> The same analysis continues to conclude that “[l]imiting Medicaid coverage for accelerated approval drugs would have a devastating impact on patients benefiting from these treatments while having a de minimis impact on spending.”<sup>15</sup>

Thank you for the opportunity to submit comments on the OHA's section 1115 Demonstration Waiver Renewal and Amendment application. The RDCC is greatly concerned about the impact of the proposed closed formulary provisions on the rare disease community and we respectfully request your reconsideration of this proposal.

Should you have any questions, please feel free to contact Patroski Lawson, Interim Executive Director of the RDCC at [patroski@kpmgroupdc.com](mailto:patroski@kpmgroupdc.com)

Sincerely,  
Patroski Lawson

---

<sup>13</sup> Barriers To Rare Disease Diagnosis, Care and Treatment In The US: A 30-Year Comparative Analysis, NORD 2020, [https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report\\_FNL-2.pdf](https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report_FNL-2.pdf)

<sup>14</sup> Am J Manag Care. 2021;27(6):e178e180. <https://doi.org/10.37765/ajmc.2021.88596>

<sup>15</sup> Am J Manag Care. 2021;27(6):e178e180. <https://doi.org/10.37765/ajmc.2021.88596>



January 7, 2022

Health Policy & Analytics  
Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St., NE, E65  
Salem, Oregon 97301

Dear Ms. Hatfield:

On behalf of REI Co-op, this is to endorse and amplify comments submitted in this matter by Bobby Cochran of the Rural Community Assistance Partnership. REI is an 84-year-old co-op dedicated to the proposition that time in, and access to, nature are fundamental to individual and societal well-being. We have a substantial presence in Oregon, with 800,000 members, 8 stores, 600+ employees and some 60+ vendor-partners. More relevant to this inquiry, REI has recommitted itself to promoting greater justice, equity and belonging in the nation's and each state's natural spaces.

How does this relate to public health? As OHA's concept paper on equity notes, "the evidence linking time outdoors with better mental health and social cohesion is substantial" (p. 15). REI is proud to have supported research that provides some of that evidence. Among the more telling conclusions is this:

According to the best available evidence, nature contact offers considerable promise in addressing a range of health challenges, including many, such as obesity, cardiovascular disease, depression, and anxiety, that are public health priorities. Nature contact offers promise both as prevention and as treatment across the life course. Potential advantages include low costs relative to conventional medical interventions, safety, practicality, not requiring dispensing by highly trained professionals, and multiple co-benefits. Few medications can boast these attributes.

"Nature Contact and Human Health: A Research Agenda," Howard Frumkin, et al., 31 July 2017, CID: 075001, <https://doi.org/10.1289/EHP1663>.

Mr. Cochran's observation is straightforward. As laid out in the draft Waiver Renewal, yes, delivering on OHA's equity goals will require addressing climate equity and resilience in under-served communities. The health effects of climate change are only growing more apparent and severe. But notably, there is preventative investment that can serve **both** the state's health and climate interests; namely, increasing the amount of, and access to, greenspace can ameliorate the impact of climate change both on the planet and on people's health. As Mr. Cochran suggests, this element of the community health equation can be addressed by adding to the Waiver's list of Climate Supports the simple goal of "increasing access to natural areas with shade." Per the Frumkin et al. paper, providing such nature-access – especially in under-served communities – can readily deliver multiple, meaningful co-benefits.

Respectfully submitted,

/s/ Marc Berejka  
Director, Community Advocacy & Impact

January 7<sup>th</sup>, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team

Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Medicaid 1115 Waiver

Currently there are six Regional Health Equity Coalitions (RHECs) in the state of Oregon that cover 11 out of the 36 counties, and the Confederated Tribes of Warm Springs, including urban, rural and frontier regions (see below “About Regional Health Equity Coalitions”). RHECs involvement in the Medicaid waiver process has been with community and health equity at the forefront because we work firsthand with historically underserved populations and see the impact of inequities in our communities. We believe that community is the ultimate accountability point.

We also keep seeing firsthand, as we know has been the case for centuries, the ways that systems create and deliver the outcomes they are designed to. <sup>1</sup>These systems and institutions have been created to benefit a select group of people over time, while communities of color experience avoidable inequities due to structural racism (Agénor, et. al, 2017), and without intentional structural changes we are bound to keep repeating and perpetuating these inequities.

Through the legislative session, the passage of HB 3353, and through the waiver proposal drafting process the RHECs have advocated for targeted financial investments in community health equity, as well as clear sideboards and accountability points for entities who comprise the system. In recent meetings we have heard the OHA waiver team say they support a statewide oversight committee and the community investment collaboratives (CIC) model. The RHECs also support these two important interventions, and we have submitted public testimony advocating for them because they were designed to specifically address health inequities because *current efforts and investments are not working for our communities*. While the OHA waiver team expresses support, there is no financial allocation in the concept papers of the proposal to reflect that commitment, including how sideboards and accountability from OHA, CCOs, and other entities will be measured. Without a strong independent point of accountability for the asks in HB 3353, it falls on us RHECs to continually keep knocking on the doors of those in power to make small changes.

**We ask for the following changes to reflect HB 3353’s work towards equity, and to demonstrate the necessary shifts in power and resources to address health inequities:**

- 1.) **The commitment from OHA to have a line item in CCO budgets for the 3% regardless of ‘additional’ future federal funding.** That funding needs to be accounted for in the CCOs annual rates and contract rate sheets. We seek a clear request that the identified 3% of investments in health equity and SDOH be recognized as medical expenditures, we see this as a key to making these investments intentional and sustainable.

---

<sup>1</sup> Agénor, M., Bailey, Z.D, Bassett, M.T., Graves, J., Krieger, N., Linos, N. (2017). Structural Racism and Health Inequities in the USA: Evidence and Interventions. *Lancet*, 389, pp. 1453-63.

Section 2(1)(a) of HB 3353 explicitly says, “Require a coordinated care organization to spend up to three percent of its global budget on investments:

“(A)(i) In programs or services that improve health equity by addressing the preventable differences in the burden of disease, injury or violence or in opportunities to achieve optimal health that are experienced by socially disadvantaged populations;

“(ii) In community-based programs addressing the social determinants of health;

“(iii) In efforts to diversify care locations; or

“(iv) In programs or services that improve the overall health of the community”

**The OHA’s draft application does not outline how these funds will be accounted for within the CCO budget.**

a. Please also include in the waiver concept that these funding allocations will be accounted for in the annual CCO rate development process (published here <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/OHP-Rates.aspx> ) and Contract Rate Sheets and that the funding available should be outlined in each CCO’s rate sheets.

b. The most current rates are published here: <https://www.oregon.gov/oha/HPA/ANALYTICS/OHPRates/Oregon-CY22-Rate-Certification-CCO-Rates-Final-20211001.pdf> )

2.) **The waiver concept papers also need to include that a state-level oversight committee**, as established by HB 3353, will be charged with overseeing the 3% global budget spend and that the state-level oversight committee be housed in the Oregon Health Authority Office of Equity and Inclusion, as called for in HB3353.

The RHECs have collectively participated in and co-developed many OHA housed committees, from committees charged with Community Health Improvement Plans, Rules Advisory Committees, the PartnerSHIP, and many others. These models, while asking for the labor of communities most impacted to make recommendations on possible solutions, ultimately the decision making and execution is left to the state. **We ask there be a distribution of power more representative of the work that shapes these decisions via clear policies, practices, and procedures as defined by the oversight committee.**

Section 3 (6) of HB 3353 The authority shall convene an oversight committee in consultation with the office within the authority that is charged with ensuring equity and inclusion. The oversight committee shall be composed of members who represent the regional and demographic diversity of this state based on statistical evidence compiled by the authority about medical assistance recipients. The oversight committee shall:

“(a) Evaluate the impact of expenditures described in subsection (2) of this section on promoting health equity and improving the social determinants of health in the communities served by each coordinated care organization;

“(b) Recommend best practices and criteria for investments described in subsection (2) of this section; and

“(c) Resolve any disputes between the authority and a coordinated care organization over what qualifies as an expenditure under subsection a (2) of this section.

- 3.) The way the regional Community Investment Collaboratives CIC model is being designed, is for them to be directed by organizations, or members of organizations, that serve local priority populations that are underserved in communities served by the coordinated care organization, and should also be funded by any additional federal funds that are leveraged for these services.
  - a. **Please clarify that Community Investment Collaboratives will be independently funded with additional funds leveraged from the federal government.**
  - b. **As independent entities they will communicate with the oversight committee and have clear dispute process in the event of a dispute between CCOs, the CICs, and OHA.**
  
- 4.) **Please clarify should the Federal Government allow duplicate investment from the CIC and CCOs, then the State wide Oversight Committee will resolve disputes between these entities.**

Please show your support in this effort in redesigning the system and shifting power and resources to communities through clearly outlined and responsible allocation of funds and accountability.

Sincerely,

Reina Estimo  
Rez Active representing Confederated Tribes of Warm Springs

Roberto Gamboa and Norma Ramirez  
Eastern Oregon Health Equity Alliance (EOHEA) representing Malheur & Umatilla Counties

Esther Kim  
Oregon Health Equity Alliance (OHEA) representing Clackamas, Multnomah & Washington Counties

Liliana Lachino  
Mid-Columbia Health Equity Advocates (MCHEA) representing Columbia Gorge Counties

Seynabou Niang  
Linn Benton Health Equity Alliance (LBHEA) representing Linn & Benton Counties

Annie Valtierra-Sanchez  
SO Health-E representing Jackson & Josephine Counties

### **About Regional Health Equity Coalitions**

Regional Health Equity Coalitions (RHECs) are autonomous, community-led, groups whose backbone organizations are non-governmental in nature. They work to identify the most pressing health equity issues in the state and find creative solutions to address root causes of barriers to health and wellness through policy, system and environment changes.

There are six RHECs in Oregon that represent 11 Oregon counties and the Confederated Tribes of Warm Springs, including urban, rural and frontier regions. There is RHEC representation for Confederated Tribes of Warm Springs, as well as the following counties: Linn, Benton, Multnomah, Washington, Clackamas, Hood River, Wasco, Jackson, Jefferson, Malheur and Umatilla.



January 7, 2022

**BY ELECTRONIC DELIVERY**

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer Street NE, E65  
Salem, OR 97301

Sent via email: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

**RE: Comments Regarding Oregon's Draft 1115 Medicaid Waiver Demonstration Renewal**

Dear Health Policy and Analytics Medicaid Waiver Renewal Team:

Sarepta Therapeutics, a leading biopharmaceutical company in precision genetic medicine for rare diseases, appreciates the opportunity to comment on Oregon Health Authority's (OHA) draft application for renewal of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver for the July 1, 2022 – June 30, 2027 demonstration period (1115 waiver application). While we appreciate OHA's stated intent to advance health equity, Sarepta has significant concerns that OHA's 1115 waiver application would do the exact opposite if implemented and exacerbate existing inequities impacting underserved populations by placing increased burden and access challenges on patients and caregivers, leading to poorer health outcomes. It would, in fact, put OHA's strategic goal to eliminate health inequities in the state by 2030 out of reach.

Specifically, under the pretext of "Paying for Population Health" in Section 3.3, Strategy 3 of the 1115 waiver application, OHA proposes to establish a closed prescription drug formulary that allows for exclusion of drugs with "limited or inadequate evidence of clinical efficacy." This approach very plainly targets exclusion of drugs approved through the Food and Drug Administration's (FDA) accelerated approval pathway – a pathway designed to address the urgent unmet medical needs of patients with serious and often life-threatening diseases – as a means to shift resources to prevention and health-related services, and to contain costs. Unfortunately, in doing so, this approach ignores the needs of the state's most vulnerable populations – including those with largely *unpreventable* rare, genetic diseases that are fatal, progressively debilitating, and lack treatment options. By the numbers, people living with rare disease collectively represent one of the largest underserved patient communities in the world. There are over 7,000 known rare diseases, 80% with genetic causes, that affect approximately 25-30 million people in the U.S., 50% of which are children. Only 5% of known rare diseases have an approved treatment. Accelerated approval may be the only hope for some of these patients to ever have a chance at a treatment that could slow or halt progression while reducing adverse impacts on their lives and those of their caregivers.

Under OHA's Section 3.3 Strategy 3, Oregon's most vulnerable patients would stand to lose access to drugs approved through the FDA's accelerated approval pathway and some therapies may never be developed, perpetuating health inequities for patients with rare, life-threatening conditions. This clearly

will not result in the economic model Oregon is striving for in a Medicaid program that focuses on rewarding health equity and improving health among underserved populations. Our specific comments and concerns are that OHA's approach:

1. Vitiates the accelerated approval pathway—a long-standing, science-based tool established by Congress and FDA to speed availability of life-saving therapies for otherwise intractable diseases with unmet medical needs—devaluing accelerated approval products and the lives of patients who depend on them;
2. Fails to meet requirements under the federal Social Security Act (SSA) section 1115 and Oregon's obligations under the Medicaid Drug Rebate Statute (SSA section 1927); and,
3. Falls far short of meaningful cost containment given drugs approved through this pathway are not a primary driver of Medicaid spending or its growth, particularly when weighed against significant potential harm to patients.

For these reasons, we respectfully urge OHA to withdraw Section 3.3, Strategy 3 from its 1115 waiver renewal application in order to stay true to its intent to drive down health disparities. Patients suffering from difficult and tragic diseases, especially where *prevention is not an option*, deserve a chance for better health outcomes with early access to treatment based on cutting-edge science.

\* \* \*

**1. Vitiates the accelerated approval pathway—a long-standing, science-based tool established by Congress and FDA to speed availability of life-saving therapies for otherwise intractable diseases with unmet medical needs—devaluing accelerated approval products and the lives of patients who depend on them**

**OHA's waiver undermines the accelerated approval pathway's purpose in providing timely patient access to safe and effective treatments for patients with high unmet need**

Thirty years ago, FDA created, and Congress subsequently codified, the accelerated approval pathway to expedite the availability of novel treatments that address urgent and unmet medical needs of patients with serious and often life-threatening diseases.<sup>1</sup> Under the accelerated approval pathway, FDA may approve a drug that demonstrates safety and efficacy in well-controlled clinical trials where efficacy is based on a surrogate endpoint that is reasonably likely to predict clinical benefit, rather than on a clinical outcome itself.<sup>2</sup> Post-marketing confirmatory trials are then required to verify and describe the predicted clinical benefit.<sup>3</sup> Importantly, drugs granted accelerated approval meet the same rigorous safety and efficacy standards that all medicines must meet<sup>4</sup> and therefore are not considered experimental, investigational or having met a lower evidentiary standard. The accelerated approval pathway has been used "primarily in settings in which the disease course is long and an extended period of time would be required to measure the intended clinical benefit of a drug."<sup>5</sup>

As FDA has noted:

[A]ccelerated approval has been used extensively in the approval of drugs to treat a variety of cancers and human immunodeficiency virus (HIV) disease where an effect on tumor growth or viral load can be assessed rapidly, but demonstrating an effect on

<sup>1</sup> FDA, New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58942 (Dec. 11, 1992).

<sup>2</sup> FDA, Accelerated Approval, <https://www.fda.gov/forpatients/approvals/fast/ucm405447.htm> (last updated Sept. 15, 2014).

<sup>3</sup> FDA, Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics. May 2014.

<sup>4</sup> 21 U.S.C. § 356(e)(2).

<sup>5</sup> Expedited Pathways Guidance at 15.

survival or morbidity generally requires lengthy and sometimes large trials because of the duration of the typical disease course.<sup>6</sup>

In these disease areas, accelerated approval has driven innovation and resulted in tremendous treatment advances over the past three decades. Recognizing the significant challenges in developing treatments for rare diseases, in 2012, Congress<sup>7</sup> reinforced its overwhelming, bipartisan support for the use of the accelerated approval pathway for rare diseases through the enactment of the Food Drug Administration Safety and Innovation Act (FDASIA), with the goal of bringing treatment options to rare disease patients, 95% of whom currently do not have any.<sup>8</sup>

FDASIA Section 901, “enhancement of accelerated patient access to new medical treatments,” both specifies the criteria for accelerated approval (including the fact that it does not relax FDA’s approval standards to which all medicines are held) and, as described in the findings provision, reflects the urgency and importance that Congress attached to this approval pathway:

"(a) FINDINGS; SENSE OF CONGRESS.—

"(1)FINDINGS.—Congress finds as follows:

"(C) ... [T]he FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

"(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

"(E) For these reasons, the [pre-FDASIA] statutory authority governing expedited approval of drugs for serious or life threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

"(2) SENSE OF CONGRESS.—It is the sense of Congress that the [FDA] should apply the accelerated approval and fast track provisions set forth in section 506 of the FDCA (21 U.S.C. 356), as amended by this section, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments."

The accelerated approval pathway saves valuable time for patients who cannot afford to wait. It provides an avenue for approval before confirmation of the evidence-predicted clinical benefit which could take

<sup>6</sup> Expedited Pathways Guidance at 15.

<sup>7</sup> Food and Drug Administration Safety Innovations Act (FDASIA). Section 901

<sup>8</sup> Kaufman, Petra, et al., “From Scientific Discovery to Treatments for Rare Diseases—A View from the National Center for Advancing Translational Sciences—Office of Rare Diseases Research,” Orphanet Journal of Rare Diseases, November 6, 2018. <https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0936-x>

many years, particularly for drugs that treat complex rare diseases with very small and heterogeneous patient populations and a long, variable disease course. Surrogate endpoints and the accelerated approval pathway are not used out of convenience, but as a necessity due to the realities of rare disease drug development.

We are deeply concerned that Section 3.3, Strategy 3 of OHA's waiver application, if implemented, could prevent Medicaid beneficiaries from accessing drugs approved through this carefully-constructed approval pathway, and could effectively turn Medicaid into a healthcare program whose beneficiaries lack access to "innovative new medicines to address unmet medical needs for serious or life-threatening diseases ... including those for rare diseases." It would, in effect, prevent our most vulnerable populations from obtaining the innovative and potentially lifesaving medicines that Congress has repeatedly worked to make available to them.

### **Duchenne muscular dystrophy exemplifies the necessity of the accelerated approval pathway**

Duchenne muscular dystrophy is a universally fatal, rare pediatric disease caused by an absence of dystrophin—a protein vital for muscle structure, function, and preservation. Without dystrophin, patients with Duchenne experience progressive muscle deterioration and weakness, irreversibly losing the ability to walk, feed themselves, and breathe unassisted over time. Premature death typically occurs in a patient's mid-to-late twenties. An unfortunate reality is that annually – in the U.S. alone – 400 patients are lost to the disease, nearly 400 lose the ability to walk, and hundreds more lose functions they will never regain – use of their arms to feed and dress themselves, use of their hands to play video games and text friends, or the ability to breathe without ventilatory support. While this trajectory is relentless and predictable, the rate of progression from patient to patient can be quite variable complicating drug development. And while treating patients with progressive diseases earlier may delay irreversible manifestations from occurring, trials may have extensive timelines when a direct clinical benefit is required to demonstrate evidence of effectiveness, especially when the rate of progression is slow. Without accelerated approval, children with Duchenne would otherwise suffer irreparable damage waiting years for verification of clinical benefit based on a validated clinical endpoint. Today, with the accelerated approvals of EXONDYS 51 in September 2016, VYONDYS 53 in December 2019, and AMONDYS 45 in February 2021, nearly 30% of the total Duchenne population has an exon-skipping therapy available that aims to restore dystrophin production and slow disease progression in different subpopulations.

### **OHA's proposal mischaracterizes the FDA accelerated approval pathway, which offers unique benefits and maintains FDA's rigorous approval standards**

The suggestion that drugs granted accelerated approval need "more rigorous review," and that the 21<sup>st</sup> Century Cures Act expedited drug approvals "by reducing the level of evidence required for drugs to reach the market,"<sup>9</sup> are demonstrably incorrect. The waiver application states that "current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be covered without being fully clinically proven." By law (21 U.S.C. § 356(e)(2), FDA must find "substantial evidence of effectiveness" to approve any drug,<sup>10</sup> specifically including drugs granted accelerated approval.<sup>11</sup> FDA and Congress have both made clear that neither FDASIA's accelerated approval provisions nor the 21<sup>st</sup> Century Cures Act diluted FDA's approval standards.

As FDA has explained:

<sup>9</sup> Oregon 1115 Medicaid Demonstration Waiver – Draft Application for Public Comment 12/1/2021.

<sup>10</sup> 21 U.S.C. § 355(d)(5).

<sup>11</sup> 21 U.S.C. § 356(e)(2) (the statute's accelerated approval provisions are not to be "construed to alter the standards of evidence" required for approval).

Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. For effectiveness, the standard is substantial evidence based on adequate and well controlled clinical investigations. For safety, the standard is having sufficient information to determine whether the drug is safe for use under conditions prescribed, recommended, or suggested in the proposed labeling. Under accelerated approval, FDA can rely on a particular kind of evidence, such as a drug's effect on a surrogate endpoint, as a basis of approval.<sup>12</sup>

FDA repeatedly made the same points in adopting the 1992 accelerated approval regulations. FDA specifically addressed whether drugs approved under this pathway meet the standards for Medicaid coverage. Responding to concerns that third-party payors could decline payment for drugs receiving accelerated approval because they have "attributes of investigational drugs," FDA disagreed and stated that:

The agency expects that, because drugs approved under the accelerated approval process meet the statutory standards for safety and effectiveness, they would be eligible for reimbursement under State Medicaid programs or other third-party plans. Drug products granted accelerated approval will not be, under the law, investigational...<sup>13</sup>

FDA similarly responded to concerns that the accelerated approval process was inconsistent with the substantial evidence requirement of section 505(d) of the Food, Drug, and Cosmetic Act:

Approval under this rule requires ... that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. This judgment does not represent either a "lower standard" or one inconsistent with section 505(d) of the act, but rather an assessment about whether different types of data show that the same statutory standard has been met.<sup>14</sup>

Further to this point, in a statement on October 17, 2017, FDA Commissioner Dr. Scott Gottlieb explained that "[FDA] sees] a product that goes through FDA's accelerated approval process as meeting the gold standard for approval" and that such drugs "meet a high hurdle for access to the market."<sup>15</sup>

In short, from 1992 to the present, Congress and FDA have repeatedly emphasized that therapies approved through the accelerated pathway must satisfy FDA's safety and effectiveness standards and must be covered by Medicaid in accordance with the Medicaid rebate statute. The 21st Century Cures Act was similarly designed to "ensure that our country remains on the forefront of medical innovation while maintaining the gold standard for approvals of medical products."<sup>16</sup>

### **Excluding drugs with only surrogate endpoint data ignores the science underlying accelerated approval**

In targeting exclusion of drugs when "only surrogate endpoints have been reported", OHA fails to recognize that surrogate endpoints may be more reliable than clinical endpoints in detecting a measurable

<sup>12</sup> FDA, Guidance for Industry, Expedited Programs for Serious Conditions —Drugs and Biologics at 7 (May 2014)

<sup>13</sup> 57 Fed. Reg. at 58945 (emphasis added). (referred to as "Expedited Pathways Guidance")

<sup>14</sup> 57 Fed. Reg. at 58944.

<sup>15</sup> FDA's Gottlieb Defends Accelerated Approval Pathway As Meeting Gold Standard, Watching For Access Limitations By Payors," Prevision Policy (Oct. 18, 2017).

<sup>16</sup> July 10, 2015 Congressional Record at E1036 (statement of Rep. Pallone) (emphasis added).

benefit in some situations because slow, variable disease progression and small patient numbers may confound results that rely on clinical endpoints. Increased understanding about the causes of disease enables the selection of more relevant and reliable biomarkers that are directly related to both disease pathophysiology and the mechanism of drug action. This allows for a more accurate assessment of whether a drug is likely to have a beneficial treatment effect in a given disease.

Specific to Duchenne, a growing body of scientific evidence supports the use of dystrophin as a surrogate endpoint. The sole cause of Duchenne is well understood to be a lack of dystrophin. Exon-skipping therapies act directly upon this root cause to restore dystrophin production. And dystrophin can reliably be quantified by a validated assay. In approving the first exon skipping product for Duchenne, FDA concluded that “the biochemical data strongly support the idea that low-level increases in dystrophin product are reasonably likely to predict clinical benefit.”<sup>17</sup> More recently, a team of independent clinical researchers conducted a study reinforcing the predictive value of dystrophin as a surrogate endpoint, demonstrating that dystrophin in very low quantities, as low as less than 1%, leads to an attenuated disease course, noting delayed time to loss of ambulation and declines in vital capacity and cardiac function, and improved survival compared to patients with no dystrophin.<sup>18</sup> Today’s surrogate endpoints, like dystrophin, are not a leap of faith but grounded in science.

### **Excluding drugs approved through accelerated approval denies patients' access to cutting edge treatments for which limited or no alternatives exist and exacerbates health disparities**

As written, Section 3.3, Strategy 3 could allow OHA to exclude not just accelerated approval drugs but most drugs, because the FDA's drug approval framework does not require evidence of an "incremental benefit" over existing therapies for a demonstration of safety and efficacy.<sup>19</sup> However, excluding accelerated approval drugs would particularly undermine the most vulnerable patients' access to FDA-approved treatments for rare diseases where no other treatments may exist.

As you appreciate, Medicaid is critical for people with rare diseases, especially children, half of whom rely on the program for the care and treatment they need. Oregon’s own researchers from the Oregon Health & Science University (OHSU) collaborated with the National Institute of Health’s National Center for Advancing Translational Science and concluded in an October 2021 published study that there is an “urgent and considerable need for earlier and accurate rare disease diagnosis and intervention to address medical management for rare disease patients.”<sup>20</sup> Creating barriers that prevent access to rare disease treatments approved through accelerated approval runs counter to OHSU’s conclusions and could have devastating consequences for the health and well-being of Medicaid beneficiaries.

OHA’s Section 3.3, Strategy 3 proposal would be particularly harmful to adults with rare diseases. The unfortunate reality is that only half of patients with a rare disease will reach adulthood. Many such patients wait years for an FDA approved treatment to ever be available, meaning a Medicaid patient diagnosed as a child may be an adult when a treatment finally receives FDA approval. Conversely, an Oregon Medicaid patient may be prescribed and taking an accelerated approval drug as chronic treatment through adulthood. As we interpret OHA’s proposal, adult Oregon Medicaid patients would be blocked from continuing to

<sup>17</sup> FDA, Center Director Decisional Memo. September 2016.

<sup>18</sup> De Feraudy Y, Yaou RB, Wahbi K, et al. Very low residual dystrophin quantity is associated with milder dystrophinopathy. *Ann Neurol* 2020;: 1-13.

<sup>19</sup> As noted earlier, the waiver request would define drugs with "limited or inadequate evidence of clinical efficacy" so that it would not just include accelerated approval drugs but also drugs "provid[ing] no incremental benefit within its therapeutic class, compared to existing alternatives."

<sup>20</sup> Tisdale, A., Cutillo, C.M., Nathan, R. *et al.* The IDEaS initiative: pilot study to assess the impact of rare diseases on patients and healthcare systems. *Orphanet J Rare Dis* 16, 429 (2021). <https://doi.org/10.1186/s13023-021-02061-3>

access this treatment on their 18<sup>th</sup> birthday or never access a future treatment because of their age. Such an approach to healthcare is discriminatory and unethical and sends a strong message to Medicaid patients that their lives are not worth treating. More so, it will perpetuate drastic and life-threatening situations for patients who may have no other treatment options.

### **Excluding accelerated approval drugs will discourage future innovation**

Excluding coverage for drugs approved under accelerated approval pathway will also discourage manufacturers from developing innovative therapies if substantial portions of the population will no longer be able to access those therapies after they are developed. This is especially true for rare diseases, as developing treatments for these diseases poses unique challenges,<sup>21</sup> and the potential rewards for innovation (and rewards for society, i.e., patient access) dwindle if the already-small patient population effectively gets smaller due to payors targeting novel treatments for coverage restrictions.

The accelerated approval pathway is a critical regulatory pathway that enables and encourages development of medicines for rare and ultra-rare diseases. It can serve as an important tool in the innovation cycle – enabling the development of the first treatment for a rare disease, providing patients access, and spurring additional investment and competition in the development of subsequent treatments. This is exactly what has unfolded in Duchenne. Sarepta invested approximately \$2 billion in research and development over more than a decade to advance our Duchenne exon-skipping RNA therapeutic pipeline, leading to the first FDA-approved treatment for Duchenne, EXONDYS 51, in 2016. Accelerated approval of EXONDYS 51 enabled not only Sarepta to reinvest our revenue and more back into developing additional and improved innovations for Duchenne patients (~2/3 of our budget is allocated to research and development year over year), but it also signaled to the broader industry that a viable regulatory pathway to approval exists for this complex, rare disease. The approval catalyzed unprecedented investment and innovation in Duchenne, leading to a transformed treatment landscape with 5 FDA-approved therapies, more than 30 treatments in the pipeline, including next-generation exon-skipping therapies, gene therapy and gene editing approaches, and over 25 companies in the space today.<sup>22</sup> Notably, of RNA therapies in development dystrophin is the most common target and Duchenne ranks among the most common diseases being studied for RNA and gene therapies.<sup>23</sup> The accelerated approval pathway can be credited for these advances and enabling the first step to forever changing the course of Duchenne. Formulary restrictions targeting accelerated approval drugs could disrupt this cycle, deter future development of treatments for deadly and otherwise serious diseases, limit choices for patients and their physicians, and hinder competition.

### **OHA's waiver thwarts the aims of the Food, Drug, and Cosmetic Act and undermines FDA's statutory role in determining drug safety and effectiveness**

As proposed, Section 3.3, Strategy 3 would thwart the goals of the Federal Food, Drug and Cosmetic Act (FDCA), which tasks FDA with applying its expertise to speed the development of medicines for serious

<sup>21</sup> For example, the FDA has noted that rare diseases create the following research challenges differing from other diseases: (1) "small populations, limited opportunity for study and replication in clinical trials"; (2) "highly heterogeneous collection of diseases" ("e.g., genetic disorders often characterized by wide range of severity, clinical presentation and rate of progression"); (3) "diseases are poorly understood" ("natural histories incompletely

described" and "diagnosis difficult"); (4) "most are serious or life-threatening, most have unmet medical needs" (thus "lack[ing] regulatory/drug development precedent"); (5) "endpoints, outcome assessment tools often lacking"; and (6) "many affect pediatric patients" (thus posing "additional ethical considerations and constraints"). "Rare Diseases and Clinical Trials," presentation by Anne Pariser, MD, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA (Nov. 4, 2014) at 6.

<sup>22</sup> PPMD. Duchenne Drug Development Pipeline. Accessed December 13, 2021. <https://www.parentprojectmd.org/duchenne-drug-development-pipeline/>

<sup>23</sup> American Society of Gene and Cell Therapy. Q3 2021 Quarterly Data Report. Gene, Cell & RNA Therapy Landscape. Available at: <https://asgct.org/global/documents/asgct-pharma-intelligence-quarterly-report-q3-2021.aspx>

diseases while maintaining its rigorous approval standards. As explained in the extensive findings and sense of Congress provisions of FDASIA 901 —

[FDA] serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

\* \* \*

...FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools.

\* \* \*

The [pre-FDASIA] statutory authority governing expedited approval...should be amended...to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

FDA has emphasized the importance of tools like the accelerated approval pathway in realizing FDA's statutory mandates. As a 2015 FDA white paper explained:

The statutory requirement for approving a new drug is that it be shown to be safe and effective. Effectiveness must be based on substantial evidence from adequate and well-controlled clinical investigations. This requirement usually means evidence from at least two adequate and well controlled studies, each convincing on its own, although a single study can be sufficient. The agency "exercise[s] the broadest flexibility in applying the statutory standard, while preserving appropriate guarantees for safety and effectiveness," as its regulations state...

\* \* \*

Nowhere is the use of flexibility in drug development more evident -and impactful - than in the case of rare, or "orphan," diseases that afflict a small percentage of the population ....[F]inding effective treatments for rare diseases is a public health priority, and FDA has brought to bear all of its drug review and technical assistance tools to assist the development of new treatments for these conditions."<sup>24</sup>

FDA's leaders have recognized that achieving this mission requires collaboration with FDA's sister agencies and Congress to speed the development of innovative treatments that meet FDA's exacting standards. As Dr. Robert Califf, FDA's Commissioner from 2016-17, explained:

With [the 21st Century Cures Act], great progress has been made towards our shared goal of advancing regulatory science so that we can continue to speed the discovery, development, and delivery of medical products to prevent and cure disease and

---

<sup>24</sup> FDA White Paper, FDA and Accelerating the Development of New Pharmaceutical Therapies, 7-8 (March 23, 2015).

improve health while sustaining the evidence framework that enables assurance to the public of the safety and effectiveness of medical products.

FDA now stands ready to work with Congress, our sister federal agencies and the medical products ecosystem to implement these important provisions as we continue to work on behalf of all Americans to protect and promote public health and promote innovation...<sup>25</sup>

OHA's Section 3.3, Strategy 3, if granted, would disrupt this statutory framework. Even though the FDCA already establishes a robust framework for FDA's expert review and approval of safe and effective medicines, the OHA suggests that drugs granted accelerated approval "would be ideal for more rigorous evaluation" and seeks "authority to limit [OHP's] formulary to exclude unproven or low-value drugs".<sup>26</sup> Further, OHA implies Oregon is more equipped to "use its own rigorous review process to determine coverage of new drugs and to prioritize patient access to clinically proven, effective drugs"<sup>27</sup> than the FDA.

Such an approach by Oregon would diminish FDA's statutory role as the expert gatekeeper entrusted by Congress to determine the safety and efficacy of new drugs and would limit FDA's effectiveness in speeding innovative treatments to seriously ill patients with unmet needs. Further, the review would be led by an organization (OHA) that has historically tried to block access to accelerated approval drugs. In 2017, OHA's Health Evidence Review Commission (HERC) assigned EXONDYS 51 to a newly created unfunded line of the Prioritized List, line 660, for "conditions for which certain treatments have no clinically important benefit" and then retracted this approach after Sarepta challenged Oregon's legal authority as it conflicted with federal drug coverage requirements.<sup>28</sup> OHA has demonstrated repeated skepticism regarding the clinical merits of drugs approved via the accelerated pathway, reflecting a strong bias, and as such will not conduct a review with the same objectivity as the rigorous review as executed by FDA in its approval of these drugs.

The requested waiver would also generate regulatory redundancy and inefficiency, as OHA would be carrying out functions that have already been assigned to—and already have been carried out by—a federal agency, effectively adding another layer of review for product developers. This is just the opposite of what a Medicaid demonstration should be doing; waivers should eliminate redundancy and create efficiency, streamlining processes of product review rather than adding costly and time-consuming new layers that further delay treatments from getting to patients.

Section 1115 cannot be interpreted to permit this waiver. When potential conflicts exist between two federal statutes, courts must apply "the familiar canon" of adopting "the interpretation that preserves the principal purposes of each."<sup>29</sup> If the two laws cannot be harmonized (and do not specifically address the

<sup>25</sup> 215 Century Cures Act; Making Progress on Shared Goals for Patients, FDA Commissioner Dr. Robert M. Califf, FDA Voice, December 13, 2016.

<sup>26</sup> Oregon 1115 Medicaid Demonstration Waiver – Draft Application for Public Comment 12/1/2021

<sup>27</sup> Oregon 1115 Medicaid Demonstration Waiver – Draft Application for Public Comment 12/1/2021

<sup>28</sup> In May 2018, OHA retracted EXONDYS 51's assignment recognizing "federal requirements set out in section 1927 of the Social Security Act (the federal Medicaid rebate law) and Oregon's 1115 Medicaid Demonstration Waiver, we are not going to pursue this approach further at this time." Oregon Health Authority. Prioritization of FDA-approved drugs on unfunded lines of the Prioritized List. May 14, 2018.

<sup>29</sup> SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc. 211 F.3d 21, 27-28 (2d. Cir. 2000). See also, *te c ., Vomado Air Circulation Systems, Inc. v. Duracraft Corp.*, 58 F.3d 1498, 1507 (10th Cir. 1995) ("Except to the extent that Congress has clearly indicated which of two statutes it wishes to prevail in the event of a conflict, we must interpret and apply them in a way that preserves the purposes of both and fosters harmony between them"); *Zenith Electric Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir.

resolution of conflicts), then courts give effect to the law that was enacted most recently or that more specifically addresses the matter at issue.<sup>30</sup>

These interpretive principles all dictate the same result here: Section 1115 must be interpreted to harmonize with the FDCA's accelerated approval provisions and this waiver request cannot be approved. To do otherwise would conflict with both the FDCA and the Medicaid rebate statute (which gives great weight to FDA approval decisions, requiring that State Medicaid programs generally cover rebated drugs when used for "medically accepted indications," including "any use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act").<sup>31</sup> There is no exception to this requirement for accelerated approval drugs: FDA applies a single overarching approval standard that all approved medicines must meet, regardless of whether they were approved via the traditional or accelerated pathway.

The principal purpose of Section 1115, which was enacted in 1962 and applies to programs authorized under six different titles of the Social Security Act, is allowing States to "test out new ideas and ways of dealing with the problems" of program beneficiaries.<sup>32</sup> Congress "intended that the Secretary would 'selectively approve[ ]' state projects" and the HHS Secretary "has plenary authority to reject State projects and to require States to modify projects to make them more consistent with federal requirements, less likely to harm recipients, and more likely to further the goals of the Social Security Act."<sup>33</sup> Thus, CMS is not obliged to grant a waiver that would undercut a sister agency's ability to carry out its statutory mission and harm beneficiaries who need access to safe and effective, FDA-approved new therapies. Section 1115 is a broad provision that does not deal with the matter at issue here and its purpose would not be implicated by denying this waiver; it is difficult to believe Congress ever envisioned Section 1115 being used for such a purpose. By contrast, this waiver would sharply limit FDA's ability to achieve the principal purposes of the FDCA's accelerated approval provisions—which were enacted in 2012, decades after the enactment of Section 1115, and are directly targeted by this waiver request. In these circumstances, Section 1115 cannot permissibly be interpreted as allowing the waiver OHA requests.

## **2. Fails to meet the requirements under the federal Social Security Act (SSA) section 1115 and Oregon's obligations under the Medicaid Drug Rebate Statute (SSA section 1927)**

**OHA's closed formulary approach and exclusion of accelerated approval drugs violates the principal tenets of the Medicaid drug rebate program and purpose of 1115 demonstration authority**

Beyond impermissibly setting up a conflict with the FDCA, Oregon intends to request CMS to waive the Medicaid rebate statute's drug coverage requirements (specifically, Social Security Act (SSA) § 1927(d)(1)(B)). The Medicaid rebate statute requires drug manufacturers to pay large rebates on Medicaid utilization of their products, in exchange for state Medicaid programs covering that product subject only to the "permissible restrictions" specified in the rebate statute. In 2018 guidance to state Medicaid programs, the CMS reinforced "drugs that are granted 'accelerated approval' are drugs approved by FDA under section 505(c) of the FDCA [Federal Food, Drug and Cosmetic Act], and are able to satisfy the definition of covered outpatient drug, and if used for a medically-accepted indication, then the drug must

---

1999) (same); *FMC Corp. v. Control Solutions, Inc.*, 369 F. Supp.2d 539, 571 (E.D. Pa. 2005) (statutes in conflict should be interpreted to preserve "principal purpose" of each, but no conflict between two statutory regimes existed where "the EPA regulations do not explicitly require copying [in violation of the Copyright Act] of the original and pioneer label and the applicable statutes and regulations here do not intimate such a result"); *IRIS Corp. v. Japan Airlines InYI Co.*, 2009 WL 3245910, \*4 (E.D. N.Y. 2009) (following the SmithKline framework of preserving the "principal purposes" of two conflicting statutes).

<sup>30</sup> See, e.g., *Hawaii v. Trump*, 859 F.3d 741, 778 (9th Cir. 2017) ("a later-enacted, more specific statute generally governs over an earlier, more general one").

<sup>31</sup> Social Security Act § 1927(k)(6), (d).

<sup>32</sup> S. Rep. No. 1589, 87-h Cong., 2d Sess. 20, re printed in 1961 U.S.C.C.A.N., 1943, 1961.

<sup>33</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994) (citing S. Rep. 1589 at 20).

be covered by state Medicaid programs if the manufacturer has an applicable signed Medicaid national drug rebate agreement for participation in the MDRP [Medicaid Drug Rebate Program].”<sup>34</sup> OHA requests that CMS waive these coverage requirements and allow Oregon to establish a closed formulary without the safeguards the rebate statute requires of a Medicaid formulary. Oregon is pursuing this request, despite CMS’s denial of MassHealth’s<sup>35</sup> similar attempt to establish a closed formulary upon which Oregon modeled its 1115 waiver.

OHA’s waiver cannot be approved for several reasons:

First, SSA § 1927 (the Medicaid rebate statute) cannot be waived under Section 1115.<sup>36</sup> In *PhRMA v. Thompson*, a ruling that has never been overturned or questioned by later cases, the D.C. Circuit held that:

The Social Security Act, of which the Medicaid statute is a part, authorizes HHS to approve experimental "pilot" or "demonstration" projects that the Secretary determines are "likely to assist in promoting the objectives of [Medicaid]." [42 U.S.C.] § 1315(a) [Social Security Act § 1115(a)]. Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of [42. U.S.C.] Section 1396r-8's [SSA 1927's] rebate provision , . . . See id. § 1315(a)(1).<sup>37</sup>

Second, even if CMS could waive the requirements of the Medicaid rebate statute under section 1115, it still could not selectively waive the rebate statute's coverage requirements, while leaving in place the requirement for manufacturers to pay rebates. The rebate statute's legislative history emphasizes that the statute is a carefully-constructed package with inseparable parts:

The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.<sup>38</sup>

<sup>34</sup> CMS Medicaid Drug Rebate Program Notice, Release No. 185. State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway. June 27, 2018.

<sup>35</sup> CMS Response to MassHealth Regarding 1115 waiver demonstration request, June 27, 2018.

<sup>36</sup> SSA § 1115(a)(1) provides that, "[i]n the case of any experimental, pilot, or demonstration program which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid or certain other programs], in a State or States -- (a) the Secretary may waive compliance with any of the requirements of section 402, 454, 1402, 1602, or 1902 ... to the extent and for the period he finds necessary to enable such State or States to carry out such project."

<sup>37</sup> *PhRMA v. Thompson*, 251. F.3d 219, 222 (D.C. Cir, 2001) (emphasis added).

<sup>38</sup> H. Rpt. 101-881, 101st Congress, 2d Session (Oct. 16, 1990) (emphasis added).

Thus, the rebate statute is a "government-industry compact"<sup>39</sup> that purposely coupled the rebate requirements on manufacturers with the coverage requirements on States.<sup>40</sup> As the Supreme Court has emphasized, "strict adherence to the language and structure of an act is particularly appropriate where ... a statute is the result of a series of carefully crafted compromises."<sup>41</sup> Many cases reinforce this point, holding that a statute reflecting a legislative bargain must be interpreted to uphold that bargain.<sup>42</sup> The rebate statute is just such a legislative bargain and CMS cannot authorize a State to keep the benefits of the bargain without fulfilling its coverage obligations.<sup>43</sup>

Third, the waiver Oregon seeks does not meet the requirement that 1115 waivers must promote Medicaid objectives.<sup>44</sup> The Medicaid statute generally describes Medicaid's objectives as providing medical assistance to those whose income and resources are inadequate to meet the costs of such care.<sup>45</sup> Instead of enabling states to assist people who cannot afford necessary medical care, Section 3.3 Strategy 3 could restrict beneficiaries' access to medicines and adversely affect their health in two important ways: by permitting Oregon to cut back on drug coverage, particularly for innovative drugs approved through FDA's accelerated approval pathway; and by reducing manufacturers' incentive to develop innovative treatments in the future (and potentially by reducing their incentive to participate in the Medicaid rebate program) if the waiver were to be approved and then replicated in other states.

Congress meant for the Medicaid rebate statute to assure Medicaid patients access to "the same range of drugs as private patients of their physicians enjoy,"<sup>46</sup> and has repeatedly emphasized the vital role that innovative treatments that are granted accelerated approval play in this nation's healthcare. Section 3.3 Strategy 3 of OHA's waiver request conflicts with both of these goals and it would set back Medicaid objectives rather than promote them.

Finally, because section 1115 only permits "experimental, pilot, or demonstration projects," the courts require that these projects have legitimate research value—they must be designed to learn something new and not just to reduce spending or to replicate benefit cuts that have well-known effects. But there is nothing in the waiver request to suggest that OHA's closed formulary proposal is designed to generate knowledge or would do so. The closed formulary strategy with exclusions for accelerated approval drugs as described in section 3.3 appears to be positioned by OHA as a means merely to cut benefits and reduce spending.

---

<sup>39</sup> Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce, H. Hrg. 103-61, 103~d Cong. 453 (1993) (statement of Rep. Waxman).

<sup>40</sup> The standard Medicaid Rebate Agreement that implements the rebate statute, drafted by CMS shortly after the statute's enactment, thus details the manufacturer's obligations to calculate and pay Medicaid rebates and recognizes that manufacturers must be able to rely on CMS to enforce the statute's coverage obligations, providing that "a State's failure to comply with the drug access requirements of section 1927 shall be cause for the manufacturer to notify CMS and for CMS to initiate compliance action against the State." Medicaid Rebate Agreement § VI(a).

<sup>41</sup> *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 748 n.14 (1989).

<sup>42</sup> See, *te c .*, *General Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992) (upholding statutory provisions necessary to "preserve the delicate legislative compromise that had been struck by [prior] laws"); *Rodriquez v. Compass Shipping Co.*, 451 U.S. 596, 612 (1981) ("[in] interpreting the intent of Congress in fashioning various details of this legislative compromise, the wisest course is to adhere closely to what Congress has written."); *Mohasco Corp. v. Silver*, 447 U.S. 807, 826 (1980) ("We must respect the compromise embodied in the words chosen by Congress. It is not our place simply to alter the balance struck by Congress").

<sup>43</sup> The waiver request also fails to acknowledge that the rebate statute already gives States significant flexibility, permitting States to exclude or otherwise restrict coverage in a variety of circumstances.

<sup>44</sup> Social Security Act § 1115(a).

<sup>45</sup> Social Security Act § 1901.

<sup>46</sup> H. Rpt. 101-881 (Oct. 16, 1990).

**3. Falls far short of meaningful cost containment given drugs approved through this pathway are not a primary driver of Medicaid spending or its growth, particularly when weighed against significant potential harm to patients**

**Targeting accelerated approval drugs will not yield significant budget savings**

OHA presents its Section 3.3, Strategy 3 proposal as cost savings stating “the state could avoid exorbitant spending on high-cost drugs that are not medically necessary” but does not point to specific data identifying the impact of accelerated approval drugs on OHA’s budget. A recent publication sheds light on the budget impact of these drugs, demonstrating they are not a key driver of Medicaid spending. Data indicate that accelerated approval drugs account for less than 1% of annual Medicaid spending consistently year over year (2007-2018).<sup>47</sup> Notably, Medicaid spending on accelerated approval drugs did not increase but instead remained steady at 0.6-0.8 percent per year after 2012 passage of the Food and Drug Safety and Innovation Act (Section 901), which enhanced the accelerated approval pathway and encouraged its broader use for rare diseases. Over the 2007 to 2018 period, hospital spending contributed the most to Medicaid spending and its growth, accounting for nearly 30% of program expenses. Targeting accelerated approval drugs is misdirected as it will not yield meaningful savings for OHA but instead threatens to harm the state’s most vulnerable beneficiaries.

\* \* \*

For the reasons noted above, we respectfully request OHA to not move forward with Section 3.3 Strategy 3 of its 1115 waiver proposal to establish a closed prescription drug formulary and exclude accelerated approval drugs. As outlined, the accelerated approval pathway is a crucial and irreplaceable tool for diseases for which approval via the traditional pathway is not feasible for practical, scientific, or ethical reasons. If Section 3.3 Strategy 3 is implemented as proposed, OHA would not meet the objectives of their 1115 waiver proposal to achieve health equity and instead would further marginalize the state’s safety-net population, including patients with rare diseases and the disabled population. We hope OHA considers these implications and, instead, focuses on implementing policies that facilitate health equity, recognize FDA as the sole authority for determining safety and effectiveness of medical products, and uphold the purpose of the Medicaid drug rebate program which is to ensure all patients have access to FDA approved drugs for which their treating physicians deem medically necessary.

If you have questions, please contact me at [dberry@sarepta.com](mailto:dberry@sarepta.com) or 425-905-8377.

Sincerely,



Diane L. Berry, Ph.D.  
SVP, Global Policy, Government & Patient Affairs

Cc: Patrick Allen, Director of the Oregon Health Authority (OHA)

<sup>47</sup> Thorpe, K. and Holtz-Eakin D. Quantifying Impact of Accelerated Approval Drugs on Medicaid Spending. *American Journal of Managed Care*. 30 Mar 2021

**From:** [Haile McIntosh](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** Scared for my loved ones  
**Date:** Wednesday, January 5, 2022 8:34:33 PM

---

You don't often get email from haile.mcintosh@gmail.com. [Learn why this is important](#)

**Think twice** before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Interim Deputy Director Hittle,

I am writing to you regarding the Oregon 1115 Demonstration Waiver for the Oregon Health Program (OHP). My name is Haile McIntosh and I am a caregiver in Oregon who has clients and loved ones who have epilepsy. I am deeply concerned by the potentially life-threatening effects these proposals could have on them.

In agreement with Epilepsy Foundation Oregon, I will uplift and quote their concerns:

"We support Oregon's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over. Unfortunately, this waiver also contains multiple proposals that would undermine access to care and needed medications for people with epilepsy. We are very concerned with the new proposed closed formulary for adults, as well as Oregon's proposals to continue the waiver of retroactive eligibility, continue to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children over the age of one, and continue to use of a Prioritized List of services that relies, in part, on a quality-adjusted life year."

I am writing to say that I strongly Oppose transitioning to a Closed Formulary for adults. The implications that the state could offer and cover just one drug per therapeutic class is so dangerous. All of the people I know who have epilepsy take several different kinds of seizure medications and they are all critical to effectively managing their health. I know that this is common across the population of people who live with epilepsy. Limiting the availability and access to these medications could absolutely be devastating and life threatening to my loved ones, as they would not be able to afford all of the medications their bodies have become reliant on if some of them were no longer covered.

I strongly Oppose Continuing to Eliminate Retroactive Coverage.  
Again, to quote and agree with Epilepsy Foundation Oregon,

"Retroactive eligibility allows people with epilepsy who have either been newly diagnosed or need a new treatment regime to begin treatment right away, avoiding delays in lifesaving care and without the burden of medical debt while they work on eligibility paperwork."

I also Oppose Prioritized List and Use of Quality Adjusted Life Years and Restricting coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT).

I agree with the following statements presented by Epilepsy Foundation Oregon regarding my opposition:

"We urge OHP to abandon the use of the QALY and work with Disability Rights Oregon, Epilepsy Foundation Oregon, and other disability rights organizations to develop a better way to allocate scarce Medicaid dollars and care for people with disabilities in an equitable way."

"We strongly support the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit."

I am scared for my loved ones and angry and tired of the ways the state continues to display an interest in profit over care for human beings. With all the compassion you can muster up, please consider supporting continued life and essential, baseline care. This proposal is unacceptable. We are writing history and we have to be doing better.

Sincerely,

Haile McIntosh

January 7, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Ms. Hatfield:

Re: Comments in Support of Medicaid 1115 Demonstration Application

[Shift Health Accelerator](#) (“Shift”) supports the Medicaid 1115 Demonstration Application and, specifically, the requirement that coordinated care organizations (CCOs) allocate 1% of their global budgets to be directly administered by community investment collaboratives to address ongoing health inequities. Authentic health equity requires that the communities most directly impacted by legacies of racial discrimination, disinvestment, marginalization, and oppression have the power and resources to address the resulting negative consequences. This feature of the proposed 1115(a) demonstration waiver renewal – resulting from a long process of collaboration with regional health equity coalitions – goes beyond community voice and is an important step towards participatory decision making and health justice.

There is a long and unfortunate history of top-down, prescriptive, interventions to address community health issues. At best, these interventions are ineffective. More often, they have proven to be actively harmful, based on uninformed or biased understanding of the upstream causes of health disparities, and focusing on what can be easily measured or replicated rather than on what a community needs. Providing communities with control and resources to address the needs that they identify and prioritize, supporting solutions that they develop and buy into, allows agency, cultural intelligence, empowerment, and true community ownership of solutions.

Shift works explicitly in this space, supporting and uplifting community leaders and we see this effort leading the field nationwide to move toward equity and justice, specifically pertaining to health. We work in and with communities across the country, including in Oregon, and can attest to the imagination, resolve, and power of communities freed to address their health priorities. From our work, we have noticed that there is an active desire by community leaders to be empowered to make their own decisions and apply what they know to be best. Empowering these communities with not only the decision-making power, but also the financial capital is critical.

The proposed Medicaid 1115 Demonstration Application is an important step towards building health equity. It should be supported by Oregon’s leaders, and efforts to weaken the role of community investment collaborative should be opposed.

Sincerely,

Jen Lewis-Walden, Lisa Richardson, Zachary Travis, on behalf of Shift Health Accelerator



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

RE: 1115 Medicaid Demonstration Waiver Application for Renewal

Dear Ms. Hatfield:

We appreciate this opportunity to provide comments as the Oregon Health Plan (OHP) applies to the Centers for Medicare & Medicaid Services (CMS) for a new five-year 1115 Medicaid Demonstration Waiver.

Trillium Community Health Plan (TCHP) has been serving Oregon Health Plan members for over 20 years and currently serves as a Coordinated Care Organization (CCO) in Lane, part of Linn, and Western Douglas Counties as well as Clackamas, Multnomah, and Washington Counties. TCHP is supportive of the intent behind the waiver application to facilitate a more inclusive and holistic approach to drive health equity among the most vulnerable populations in Oregon. Below please find a section-by-section summary of our comments:

#### Maximizing continuous and equitable access to coverage

TCHP is supportive of continuous enrollment as it reduces churn and reduces the burden on families to re-enroll. We understand this would be a request for a longer continuous enrollment than other states that currently offer continuous coverage in CHIP or Medicaid, and it is our hope that the should the Center for Medicare & Medicaid Services (CMS) decline to grant this level of continuous enrollment, the state is open to alternative continuous enrollment options that would still move the Oregon Health Plan forward in reducing enrollment barriers. For example, 32 states currently offer continuous coverage for a duration of 12 months. We would be supportive of any movement towards an extension of continuous eligibility beyond what is currently allowed. Additionally, TCHP looks forward to working with the Oregon Health Authority on other opportunities for easing enrollment burdens, including enhanced flexibility for CCOs to communicate with our members.

#### Improving health outcomes by streamlining life and coverage transitions

TCHP is very supportive of the state's request to waive the federal rule preventing a person in custody from accessing Medicaid benefits. Offering Medicaid to eligible individuals prior to release from jail would provide necessary benefits and transition support for a vulnerable population. While TCHP would prefer continuous enrollment to facilitate continuity of care, we suggest that if CMS does not approve this request, the state

should consider requesting at least 30 days pre-release or presumptive Medicaid eligibility for justice-involved individuals as ten other states have done through 1115 waiver demonstrations.

Regarding the creation of a defined set of Social Determinants of Health (SDOH) services based on transition-related criteria and expansion of infrastructure beyond the medical model, TCHP is supportive of this opportunity. Working to address SDOH needs for members in transition is a current TCHP priority and we are supportive of increasing opportunities to continue to build capacity among delivery system partners and local Community Based Organizations to improve access to these services. TCHP supports shifting care from institutional settings to the community when possible. We look forward to better understanding payment structures and operational processes to ensure these proposals are successful and sustainable.

### Value-Based Global Budget

As a CCO, TCHP has been committed to investing up-stream to incentivize utilization of preventative care to improve the health of our members. We employ multiple strategies, including the use of Traditional Health Workers and case management teams to help our members access lower-cost interventions. While Trillium works to manage the risk of our membership, we believe the global budget process should also include risk mitigation mechanisms. We would suggest that risk mitigation be prospectively defined ahead of the five-year period and only reconsidered if the “base budget” is revised. However, we recommend avoiding risk mitigation strategies that are retroactive in nature and would prefer a risk mitigation mechanism that spans the entire length of the “rating period.”

While there are 16 CCOs and a single CCO's experience may have a fairly small impact on the statewide base data, a CCO has more leverage to drive up the regional factor for the geographical area in which they operate. At the same time, we think that in practice, CCOs are concerned with many priorities that align with OHA's goals, including making up-stream community investments, addressing the SDOH needs of our members, and reducing health inequities, all while managing near-term financial goals. CCOs are essentially under constant pressure to match or exceed the performance of other CCOs.

As a locally-based community-driven CCO, TCHP works closely with our community partners to advance SDOH and Equity investments in the communities we serve and we are supportive of opportunities to advance a budget model that increases sustainable community investments. Currently, TCHP works with our Community Advisory councils, and our consumer members to implement community investment strategies. Trillium's Innovation Fund has allowed Community Advisory Council consumer members to oversee a grant process investing in diverse strategies that align closely with the goals of our Community Health Improvement Plan and address health disparities identified in the Community Health Assessment, resulting in investments that improve access to care and services in our communities.

However, the proposed changes to CCO capitation rate development may result in unintended consequences if they don't reflect appropriate data. 42 CFR § 438.5(c) specifies that "States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates." Similar expectations can be found in the 2021-2022 Medicaid Manage Care Rate Development Guide and the ASOP 23 Section 3.2.b.1. This 1115 waiver proposal violates this rule and associated guidance, as well as the exception clause. When states request exceptions to this rule, they must set forth a corrective action plan to come into compliance, indicating such

exceptions are intended to be temporary rather than an intrinsic component of how the program sets capitation rates.

Changes in practice patterns and delivery systems, especially as we continue to rebound from the Public Health Emergency (PHE), as well as the additions of new policies and benefits to the Oregon Health Plan, creates a need for a more frequent incorporation of appropriate data. We support the state's intention to improve predictability and increase simplicity in the budget development process, but with such low industry margins, it is important to ensure CCO rates meet actuary soundness.

In calculating this base budget, we would be supportive of counting "health-related spending" as part of the medical load provided it can be done in an actuarially sound mechanism and certain caveats are considered in the assumptions. CCO involvement is critical in establishing the base budget, trends, and other rate components as they are developed. CCOs can help ensure that recent trends examining the downstream impacts of the PHE and rates are not negatively influenced by unique circumstances. For example, we may see lower utilization during CY20 and potentially higher-cost encounters as a result of delayed care or emergent care in ensuing years. Given these recent and ongoing anomalies, we would recommend that the "base budget" be reassessed every year for appropriateness, which would involve ongoing evaluation with CCO input.

We believe that in order to improve the sustainability of health equity investments, the appropriate funding should be loaded into the rates. Not doing so could pose significant adequacy issues, especially if unexpected events were to occur such as enhanced utilization as a result of economic recession, pandemic impacts or natural disasters. Additionally, it will be important to be mindful of impacts to our provider networks in this new budgeting model, as shifting priorities could create solvency challenges for an already challenged workforce.

#### Incentivizing Equitable Care

TCHP looks forward to working in collaboration with the state to help ensure we can build out clear and transformative metrics. Oregon's incentive metrics program has proven successful and over the course of our past Medicaid demonstrations. The incentive metrics program has helped engage the delivery system in driving members to evidence-based preventative care services and we look forward to continuing to enhance the program. However, we do want to ensure that incentives are not "cherry picked" to reward and steer members only to certain providers. Rather, the state should investigate how best to develop metrics and monitoring processes that enhance workforce development initiatives that incentivize development of a more representative workforce for the populations we serve.

#### Focused Equity Investments

TCHP supports efforts to address health inequities, and in particular supports care delivery in the community when possible, as it is our intention to build relationships and partner with community organizations to identify and address SDOH needs. We are proud of the work we have done as a CCO to build partnerships with local, community-based organizations and help build organization capacity for supporting our member's needs. While we want to be careful that new investments do not negatively impact capitation rates developed based on membership risk, we look forward to working with the state to continue to build capacity for addressing health inequities.

Thank you again for the opportunity to provide comment. We look forward to partnering with the Oregon Health Authority, local system partners, providers, and community organizations to continue to improve the Medicaid Delivery system in Oregon.

Sincerely,

A handwritten signature in black ink, appearing to read 'Courtney Johnston', with a stylized, cursive script.

Courtney Johnston  
Senior Director of Medicaid and Government Relations  
Trillium Community Health Plan

January 7, 2022

Paul Terdal  
700 NW Macleay Blvd  
Portland, OR 97210

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301  
By email: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Re: Public Comment on Oregon's Section 1115 Medicaid Demonstration Waiver Renewal Application

Dear Ms. Hatfield,

I am writing as a member of the public, and as the father of two Medicaid-eligible children with disabilities, to provide comment on Oregon's planned Section 1115 Medicaid Demonstration Waiver Renewal Application.

There are three critical fixes that should be included in Oregon's next waiver: removing the obsolete EPSDT waiver provision, renouncing the use of discriminatory Quality Adjusted Life Year (QALY) metrics in ranking services on the prioritized list, and ensuring that individuals with disabilities and significant health conditions do not face discrimination in accessing suicide prevention services.

**Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Waiver:**

Oregon is currently the only state in the country that reserves the right to withhold medically necessary care from children on Medicaid for the sole purpose of saving money, through the EPSDT waiver clause, which reads:

**3. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)  
Section 1902(a)(10)(A) and 1902(a)(43)(C)**

To allow the state to restrict coverage for treatment services identified during an EPSDT screening for individuals above age 1 to the extent that such services are not consistent with a prioritized list of conditions and treatments. (Applies to all Medicaid state plan populations, except population 23.)

This directly contradicts the U.S. Department of Health and Human Services explanation of EPSDT:<sup>1</sup>

“All medically necessary diagnostic and treatment services within the federal definition of Medicaid medical assistance must be covered, regardless of whether or not such services are otherwise covered under the state Medicaid plan for adults ages 21 and older.” (*emphasis added*)

---

<sup>1</sup> <http://mchb.hrsa.gov/epsdt/overview.html#1>

The Center for Medicaid and CHIP Services has further described EPSDT as follows<sup>2</sup>:

“In 1967, Congress introduced the Medicaid benefit for children and adolescents, known as Early and Periodic Screening, Diagnostic and Treatment (EPSDT). The goal of this benefit is to ensure that children under the age of 21 who are enrolled in Medicaid receive age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting. This broad scope supports a comprehensive, high-quality health benefit.”

The Oregon Department of Justice has published an opinion<sup>3</sup> asserting that this clause in the waiver permits Oregon to limit or exclude coverage of medically necessary care from children, even when those limits or exclusions specifically contradict CMS guidance, such as CMS guidance prohibiting “hard” limits on physical therapy visits for children.<sup>4</sup>

The State of Oregon has used this EPSDT clause to save money by withholding medically necessary care from needy children. Specifically, Oregon uses the prioritized list of health care services to determine which services are to be provided. Services that are “below the line” – or simply not recorded on the list at all – are withheld, regardless of individual determinations of medical necessity.

Over the past few months, I have met with a number of physicians and families on OHP who have struggled to access medically necessary care for their patients and children to learn about the human impact of Oregon’s EPSDT waiver.

Here are some findings and observations:

- Many of the condition / treatment pairs that are “below the line” are debilitating but treatable, and denying coverage can lead to significant harm. Some examples:
  - Selective mutism: untreated children cannot fully participate in school or community. HERC found that treatment was highly effective, but excluded coverage anyway because of an erroneous belief that the condition was insignificant to patients.
  - Chronic otitis media: physicians have advised us that they must wait until a child suffers actual hearing loss before they can get coverage of this condition.
  - Conduct disorder: low-income children on Medicaid who exhibit disruptive behavior are denied access to psychotherapy for this DSM-5 condition, resulting in a higher chance of incarceration.
  - Inpatient behavioral treatment for severe autism: while the prioritized list covers outpatient Applied Behavior Analysis (ABA) therapy as a treatment for autism, the list does NOT include any inpatient services. There are Oregon teens with severe autism

---

<sup>2</sup> <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html>

<sup>3</sup> Deanna Laidler, Sr. Assistant Attorney General, Oregon Department of Justice, to Darren Coffman, Director, Health Evidence Review Commission, “Mental Health Parity and Rehabilitative Therapies,” October 5, 2016

<sup>4</sup> CMS, EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents (“CMS EPSDT Guidance”), p.24, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html>

who require much more intensive, inpatient treatment to address self-injurious to aggressive behaviors – which are excluded from the list without regard to medical necessity. Some nationally ranked hospitals have begun refusing Medicaid patients from Oregon because of Oregon’s notorious refusal to pay for behavioral health treatment, and no Oregon hospitals have the necessary capabilities.

- Many physicians resort to “code games” to work around the prioritized list
  - For instance, coding “selective mutism” as “anxiety” or “depression”
  - This bypasses the list – defeating any intent at cost savings – while increasing bureaucratic burden
  - Obscures a patient’s true condition by disguising it as a coverable condition, making a patient’s medical history harder for future medical providers to follow and treat
  - Exposes physicians to risk of prosecution for fraud
- Oregon’s prioritized list places a high priority on coverage of common services for otherwise healthy people (routine dental exams) while deprioritizing rarer or more serious conditions for patients with disabilities.
  - Any “rare” condition that simply hasn’t been considered by HERC is automatically excluded (below the line) with no opportunity for a successful appeal
  - Palliative care (and even assisted suicide) are given a higher starting category weight (65 points) than life saving care (40 points)
- Priorities are set on the list without direct input from patients and families on values and preferences, resulting in strange or inappropriate decisions
  - Selective mutism and Pika were both scored below the line because HERC believed that the conditions had minimal impact on patients or that there was no need for treatment

Please refer to the attached issue briefs from Disability Rights Oregon on “How the Oregon Health Plan Discriminates” and “Oregon’s Unique EPSDT Waiver Allows OHP to Deny Medically Necessary Care to Children to Save Money” for more information.

Perhaps 30 years ago there was some policy justification for rationing care to low income children by withholding medically necessary care from them to save money – but not now. America has come a very long way since then in providing universal access to health care, especially for children, with a substantial expansion in Medicaid funding under the Affordable Care Act. It’s time for Oregon to catch up to the rest of the nation – and comply fully with EPSDT’s requirement to provide “all medically necessary diagnostic and treatment services ... regardless of whether or not such services are otherwise covered ... for adults ages 21 and older”.

<p><u>Recommendation:</u> The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.</p>
---

## Quality Adjusted Life Year (QALY) Metrics:

Oregon has consistently used discriminatory “Quality Adjusted Life Year” (QALY) metrics as a factor in ranking services on the prioritized list. QALY is a tool that estimates the value of a treatment according to years of additional life – discounted by the level of disability. This approach places a lower value on years of life for those with disabilities – such as my children – than on years of life for people without disabilities – and is inherently discriminatory.

Over the past six months, I have studied the Oregon Health Plan’s use of QALY metrics in detail, and have met with senior OHA leadership for input. Here are my initial observations:

- Oregon Health Authority records show that when the US Department of Health and Human Services directed Oregon NOT to use the QALY metric in 1992, on grounds that it violated the Americans with Disabilities Act, the HRC simply worked around this by voting to adopt essentially the same discriminatory results derived from the QALY-based formula.<sup>5</sup>
- Despite Federal guidance to the contrary, Oregon continued to use the QALY as an explicit input in the “cost effectiveness” factor in the prioritization formula until 2017
  - Most of the condition-treatment pairs now on the list continue to be ranked using the old QALY-based factor
- HERC continues to rely upon QALY-based cost effectiveness reports from ICER, NICE, and other organizations. When staff prepare summaries of those reports for the commissioners, they frequently cite and call attention to the QALY scores, as is clearly documented in meeting materials
- Other factors in the formula, such as “Impact on Health Life” closely resemble the QALY concept. When HERC commissioners vote on these factors, they do so immediately after reviewing staff briefings and reports with QALY scores

When the Oregon Health Plan ranks services on the prioritized list, using QALYs in any way, it engages in discrimination against individuals in violation of the Americans with Disabilities Act and contrary to the mission of the Oregon Health Policy Board to promote health equity.

**Recommendation:** The Waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, with a provision such as this:

**“Prohibition on Reliance on Discriminatory Measures.** The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per-quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”

---

<sup>5</sup> Bob DiPrete and Darren Coffman, “A Brief History of Health Services Prioritization in Oregon,” Oregon Health Authority, March 2007. <https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf>

## Non-discrimination in Suicide Prevention Services

Oregon also chooses to provide coverage for some services that aren't on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of physician assisted suicide, including counseling and lethal prescriptions.<sup>6</sup> OHP patients who have been denied coverage of potentially life-saving health services that were "below the line" have been advised by OHP that physician assisted suicide is a covered alternative to life saving care.<sup>7</sup> This sends a message to patients with disabilities or serious illness that they are not worth treating – but Oregon will pay to expedite their death.

It is ethically essential to ensure that any patients with disabilities or serious illness continue to receive full suicide prevention services, especially if they have been confronted with a denial of life-saving care due to the prioritized list. Physicians and CCOs should NOT assume that a disabled patient who has been denied access to care is making a "rationale" or reasonable choice to hasten the end of their lives without first providing the same range of suicide prevention services that any other member of the general public would receive.

### Recommendation:

The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for lethal drugs under Oregon's "Death with Dignity Act," will be provided with the same harm and suicide prevention services<sup>8</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to die by suicide because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.

Sincerely,

/s

Paul Terdal

### Attachments:

- DRO Issue Brief: Oregon's Unique EPSDT Waiver Allows OHP to Deny Medically Necessary Care to Children to Save Money
- DRO Issue Brief: How the Oregon Health Plan Discriminates

---

<sup>6</sup> Oregon Health Authority, "Prioritized List of Health Services," 2/1/2021, P. SI-1, "STATEMENT OF INTENT 2: DEATH WITH DIGNITY ACT."

<sup>7</sup> Susan Donaldson James, "Death Drugs Cause Uproar in Oregon. Oregon woman denied drugs for lung cancer, but offered assisted-death drugs." ABC News, 8/6/2008. (<https://abcnews.go.com/Health/story?id=5517492>)

<sup>8</sup> The term "harm and suicide prevention services" includes screening, diagnosis, psychiatric treatment, therapy, counseling, and other services whose purpose is the detection and treatment of suicidal ideation and tendencies and the causes thereof, including depression, mental disorders, and lack of access to rehabilitative and supportive care.

## Oregon's Unique EPSDT Waiver Allows OHP to Deny Medically Necessary Care to Children to Save Money

Under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called “Early and Periodic Screening, Diagnostic and Treatment” ([EPSDT](#)) to ensure that they receive “age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting.” Critically, the EPSDT provision requires comprehensive coverage of health services for children – *regardless of whether or not such services are otherwise covered* under the state Medicaid plan for adults ages 21 and older – to make certain that rationing is not imposed for this vulnerable population.

### Except in Oregon.

Oregon's Section 1115 Medicaid waiver includes a provision authorizing it to withhold medically necessary care from children over the age of 1 if it is “below the line” on its “Prioritized List” of health services:

*3. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Section 1902(a)(10)(A) and 1902(a)(43)(C) To allow the state to restrict coverage for treatment services identified during an EPSDT screening for individuals above age 1 to the extent that such services are not consistent with a prioritized list of conditions and treatments. (Applies to all Medicaid state plan populations, except population 23.) [Centers For Medicare & Medicaid Services Amended Waiver List and Expenditure Authority; Number: 21-W-00013/10 and 11-W-00160/10 Title: Oregon Health Plan \(OHP\)](#)*

Effective January 1, 2020, Oregon Health Plan covers [Prioritized List](#) lines 1 through 471. Any service that is “below the line” – numbered higher than 471 – is automatically excluded from coverage regardless of need, as is any service that isn't included anywhere on the list at all.

The Oregon Department of Justice has published an opinion asserting that this clause in the waiver permits Oregon to limit or exclude coverage of medically necessary care from children, even when those limits or exclusions specifically contradict CMS guidance, such as [CMS guidance](#) prohibiting “hard” limits on physical therapy visits for children. [Meeting Packet, April, 2016](#)

The purpose of the waiver – and of this EPSDT clause – is to save money by withholding medically necessary care from needy children. Some services for children that have been excluded because they fall below the line include: Selective Mutism – Medical / Psychotherapy (line 473), Conduct Disorder, Age 18 or Under (Line 479), Chronic Otitis Media (line 475).

Selective Mutism fell below the line and is excluded even though it scored high on effectiveness (4 out of 5), and even though Oregon's Health Evidence Review Commission (HERC) concluded that 80% of affected individuals would need care – because the category weight in [HERC's methodology](#) was low (Non Fatal condition = 20), and because HERC staff concluded that the “impact on healthy life” for a child unable to speak was very low (1 out of 10); that the impact on suffering was low (1 out of 5); and there was no impact to the general population for a child who is unable to communicate.

Conduct Disorder fell below the line and is excluded because the category weight is low (Non Fatal condition = 20) and because HERC staff rated effectiveness low (1 on a 0 to 5 scale). As a result, children and adolescents in Oregon with a conduct disorder who might have a chance of benefiting from professional counseling or psychotherapy are denied care and placed at much higher risk of incarceration in the juvenile justice system.

Chronic Otitis Media (recurrent ear infection) fell below the line and is excluded even though it scored medium on effectiveness (3 out of 5), and even though Oregon’s Health Evidence Review Commission (HERC) concluded that 80% of affected individuals would need care – because the category weight was low (Non Fatal condition = 20), and because HERC staff concluded that “impact on healthy life” for a child with chronic otitis media was low (2 out of 10), even though it can result in [severe complications](#) if left untreated, including permanent hearing loss and problems with speech and language development.

Prioritization of Selective Mutism, Conduct Disorder, and Chronic Otitis Media with [HERC Methodology](#):

Factor:	Selective Mutism (line 473)	Conduct Disorder (line 479)	Chronic Otitis Media (line 475)	Range:
Category Weight	20*	20*	20*	1 to 100
Impact on Healthy Life:	1	5	2	0 to 10
Impact on Suffering:	1	3	1	0 to 5
Population Effects:	0	2	0	0 to 5
Vulnerable Population:	0	2	0	0 to 5
Tertiary Prevention:	1	1	1	0 to 5
Effectiveness:	4	1	3	0 to 5
% Need for Service:	80%	70%	80%	0% to 100%
Total Score:	192	182	192	

\* Nonfatal Conditions, Where Treatment is Aimed at Disease Modification or Cure

For children whose families can afford commercial insurance plans, coverage of all three conditions is required under Oregon and Federal law as an “Essential Health Benefit” – insurers would face severe civil penalties for refusing to provide coverage.

**Oregon’s vulnerable youth deserve better. It is time to end this failed experiment relying on discrimination to ration care.**

Disability Rights Oregon (DRO)

For more than 40 years, DRO has served as Oregon’s federally authorized and funded Protection & Advocacy System. DRO is committed to ensuring the civil rights of all people are protected and enforced, including youth in correctional settings.

## Issue Brief: How the Oregon Health Plan Discriminates

The Oregon Health Plan (OHP) delivers Medicaid and EPSDT under a Section 1115 demonstration waiver ranking health care services in a prioritized list from most to least important. Only services over a certain line are funded regardless of individual determinations of medical necessity.

In 1992, Oregon submitted a waiver application relying on the quality-adjusted life year (QALY) to prioritize services for coverage that was denied by the U.S. Department of Health and Human Services as violating the Americans with Disabilities Act (ADA):

*“Our principal concern is that Oregon’s plan in substantial part values the life of a person with a disability less than the life of a person without a disability. This premise is discriminatory and inconsistent with the Americans with Disabilities Act.”* [New York Times, HHS Secretary Louis W. Sullivan, M.D.](#)

The waiver was later approved in 1993, after committing to changes for ADA compliance. Despite ADA concerns, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the quality-adjusted life year (QALY). Officially, Oregon excluded the survey-based QALY data that triggered denial of its initial waiver application in 1992. Yet, the voting members of Oregon’s Health Policy Commission have authority to override the results of non-QALY considerations, which they did in over 70% of the cases. The outcome for how care is valued and prioritized is the same:

*“Because most objective measures representing health outcomes were not allowed, the subjective collective judgment of the Commissioners became more of a factor. As a result, many of the public values on health that had been expressed through the community meetings, the telephone survey, and in public testimony were reflected through the application of Commissioner judgment in the final prioritization process.”* [Bob DiPrete and Darren Coffman, A Brief History Of Health Services Prioritization In Oregon.](#)

Today, the Health Evidence Review Commission (HERC) website explicitly describes the use of QALYs in its cost effectiveness framework, and it is embedded in the prioritization formula.

As reconstructed in 2008, Oregon’s [revised prioritization framework](#) emphasizes preventive services and chronic disease management in order to keep the “population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health.” This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. The process uses QALYs both explicitly – as a direct part of the formula – and implicitly, through QALY-based analyses of factors within the formula:

$$Score = \left( \begin{matrix} \text{Category} \\ \text{Weight} \end{matrix} \right) \times \left[ \begin{matrix} \text{Impact on Healthy Life} \\ + \text{Impact on Suffering} \\ + \text{Population Effects} \\ + \text{Vulnerability of Population} \\ + \text{Tertiary Prevention} \end{matrix} \right] \times Effectiveness \times \left( \begin{matrix} \% \text{ Need for} \\ \text{Medical} \\ \text{Services} \end{matrix} \right)$$

Under this category weighting scheme, preventative services start with a category weighting multiplier of 95 – more than double that of care to cure a fatal illness, with a weight of just 40, and nearly 5 times the weight of services for nonfatal conditions. As an example, a routine dental exam is considered preventative, so it has a weight of 95 – while an appendectomy to treat appendicitis, or surgery to remove a treatable cancer would have a weight of just 40.

After the category weight, five population and individual impact measures are summed together - Impact on Healthy Life (sometimes referred to as Impact on Health Life Years and reflecting QALY inputs); Impact on Suffering Population Effects; Vulnerability of Population Affected; and Tertiary Prevention. The scores for these five factors are proposed by the HERC Medical Director and confirmed or amended by a vote of HERC's Value-based Benefits Subcommittee. HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by the Institute for Clinical and Economic Review (ICER) as they vote.

The final two factors in the formula – effectiveness and need for medical services – are multiplied together into an “effectiveness” score. The “effectiveness” score is proposed by the HERC Medical Director based on a review of medical evidence and factoring in QALY-based cost effectiveness analyses and confirmed or amended by the HERC Evidence-based Guidelines Subcommittee with this QALY-based framework:

*“The cost of a technology will be considered according to the grading scale below, with “A” representing compelling evidence for adoption, “B” representing strong evidence for adoption, “C” representing moderate evidence for adoption, “D” representing weak evidence for adoption and “E” being compelling evidence for rejection:*

- *A = more effective and cheaper than existing technology*
- *B = more effective and costs < \$25,000/LYS or QALY > existing technology*
- *C = more effective and costs \$25,000 to \$125,000/LYS or QALY > existing technology*
- *D = more effective and costs > \$125,000/LYS or QALY > existing technology*
- *E = less or equally as effective and more costly than existing technology”*

[Prioritization of Health Services: A Report to the Governor, 2013](#), p. 24. (**Emphasis** added)

After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list.

Oregon also chooses to provide coverage for some services that aren't on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of physician assisted suicide, including counseling and lethal prescriptions. OHP patients who have been denied coverage of potentially life-extending health services that were “below the line” have been advised by OHP that physician assisted suicide is a covered alternative. (See for instance [“Death Drugs Cause Uproar in Oregon. Oregon woman denied drugs for lung cancer, but offered assisted-death drugs,”](#) ABC News, 2008)

**Below the line – examples of excluded services for disabilities:**

- Selective Mutism (psychotherapy recommended)
- Otosclerosis (hearing aid, cochlear implant or surgery options)
- Bell's Palsy (facial palsy, medication and physical therapy often recommended)
- Spastic Diplegia (form of cerebral palsy, physical therapy recommended)
- Personality Disorders Excluding Borderline and Schizotypal (psychotherapy recommended)

[Prioritized List of Health Services](#), Oregon Health Authority website.

**Oregonians deserve better. It is time to end this failed, discriminatory experiment.**

### **Disability Rights Oregon (DRO)**

**For more than 40 years, DRO has served as Oregon's federally authorized and funded Protection & Advocacy System. DRO is committed to ensuring the civil rights of all people are protected and enforced, including youth in correctional settings.**

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

**RE: Oregon's Draft Medicaid Demonstration 1115 Waiver Application**

Dear Ms. Hatfield,

The ALS Association of Oregon and Southwest Washington is concerned with the proposal by Oregon Health Authority to potentially restrict access for Medicaid patients to new ALS treatments. We request that you remove "Strategy 3" from the 1115 Medicaid Demonstration Waiver.

Our organization is the central source for services and education for people with Amyotrophic Lateral Sclerosis (ALS), their families, caregivers, and health care professionals in all of Oregon and the six counties of SW Washington. We provide a range of services: direct services to people with ALS including clinics, support groups, access to medical and speech equipment, funding cutting-edge research and generally connecting those whose lives have been impacted by ALS.

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. ALS robs people of their ability to walk, talk, eat and speak; it is always fatal disease with an average life expectancy for of 2-5 years from diagnosis. There is no current cure for ALS, and only a few drugs approved for treating various symptoms of ALS. The pipeline for ALS treatments depends on the FDA accelerated approval pathway, as ALS has a serious condition with unmet needs. Moreover, the short life expectancy of a person diagnosed with ALS makes every second count, whether in research, approval, access and treatment.

Stated plainly, there are very few reasons for people living with ALS and their families to be hopeful following diagnosis. The pipeline for new treatments is one thing they cling to, and the FDA accelerate approval process makes that hope real. Unfortunately, Oregon Health Authority's (OHA) draft 1115 Waiver application would create one more potential barrier for access if OHA determined that it would not cover a new, approved ALS drug. This would be crushing to a patient and family on Medicaid, already inundated with the challenges of coverage while facing a complex labyrinth of health care costs and administration in light of an impossible diagnosis.

While the ALS Association sympathizes with OHA's challenges in containing costs, focusing on the accelerate approval process as a mechanism for restricting access or reducing utilization is dangerously misplaced. The proposed language directly undermines the FDA's scientific approach for determining that a drug is safe and effective (and purports to replace it with a "rigorous state review process" which doesn't exist). Worse, the application specifically refers to accelerate approval drugs as drugs with "limited or inadequate evidence of clinical efficacy" which is plainly false and continues to undermine patients and the public's faith in scientific rigor. The purpose of the accelerated approval



**OUR VISION** Create a world without ALS.

**OUR MISSION** To discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

Main Office: 825 NE Multnomah St, Suite 940, Portland, Oregon 97232  
Phone 503.238.5559 • FAX 503.296.5590 • [www.alsa-or.org](http://www.alsa-or.org)

pathway is to benefit patients with conditions like ALS, where there are unmet medical needs and for those facing with rare diseases. It is NOT a shortcut for rigorous scientific review.

By law (21 U.S.C. § 356(e)(2)), FDA must find "substantial evidence of effectiveness" to approve any drug, including AA drugs. FDA and Congress have both made clear that neither FDASIA's accelerated approval provisions nor the 21<sup>st</sup> Century Cures Act diluted FDA's approval standards. There is no reason (nor evidence) that OHA current infrastructure, including Oregon's "Health Evidence Review Commission" or Pharmacy and Therapeutics Committee has the staff, expertise, resources to duplicate the FDA process. Any such review would be redundant, costing patients valuable time and options where treatments may be available.

Secondly, with rare disease, such as ALS, reducing access to drugs approved through the accelerated approval process won't provide meaningful savings for our state Medicaid program anyway (or at least OHA should demonstrate that it will). According to the American Journal of Managed Care, accelerated approval drugs have accounted for less than 1% of Medicaid spending consistently every year ([https://cdn.sanity.io/files/Ovv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC\\_06\\_2021\\_Thorpe\\_final.pdf](https://cdn.sanity.io/files/Ovv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC_06_2021_Thorpe_final.pdf)). Coupling the scientific rigor of the FDA process and the limited savings, there is no rational reason to seek authority to limit access to drugs for those with rare conditions or no other treatment options.

Further, the waiver application will create even more disparities in care and sends a message to Oregonians that those with high unmet need, rare conditions and needing access to new therapies are a lower priority for full Medicaid coverage. The disparity of care would only be magnified where people with ALS could access a new drug through a private insurance carrier, but low-income Oregonians seeking access through Medicaid may not (or worse, spend valuable time fighting a challenging prior authorization process while their condition continues to progress). While the value of accelerated approval drugs to our community is clear, has OHA provided evidence that excluding these drugs would result in savings to the state system? If not, this is a significant risk to patient access and their hopes and realization of better quality of life with no clearly established benefits flowing to the state.

On a broader scale, these types of proposals only further discourage innovation for diseases like ALS where the only viable pathway to bring a treatment to market is the accelerated approval pathway. With so many conditions where investment and research can provide a quicker (and already more certain) return on investment, OHA's application would only increase our community's challenges in finding researchers and companies who will focus on treatments for ALS.

On a final note, we are also concerned with the request for the state to create a closed formulary. Again, this change is counter to Oregon's purported goal of the 1115 waiver: "to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon." In addition to the few ALS treatment currently available, ALS patients rely on an array of drugs to deal with the myriad symptoms of a degenerative neurological condition. Medicaid patients should have access to the drugs their providers prescribe without OHA preliminarily determining which have more value.

OHA's Section 1115 demonstration amendment request to exclude new drugs approved under the FDA's accelerated approval pathway is misplaced and potentially significantly damaging for patients

with rare conditions and unmet needs. It could very likely lead to perverse disparities in care and limit options for ALS patients on state Medicaid.

We urge you to remove Strategy 3 from the waiver application.

Thank you,

A handwritten signature in black ink that reads "Lance Christian". The signature is written in a cursive, slightly slanted style.

Lance Christian  
Executive Director

Sarah Spansail, Chair, Jackson County Community Advisory Council

Thank you so much Jackie and hello Medicaid Advisory Committee members. My name is Sarah Spansail. I live in Medford and I am the chair of the Jackson County Community Advisory Council with Allcare.

While we support the extra focus on HealthEquity and other positive changes in the waiver, like children staying insured until the age of 6. I'm here today to speak in opposition to the draft waiver as written.

Uhm House Bill 3353 is seen as a way to increase the accountability of CCOs especially when it comes to supporting and serving those who are typically underserved. It's a way to continue to build on the community relationships we've already established, enabling us to create more sustainable and long-term projects in order to create real community transformation.

Unfortunately, the draft presented is siloing out dollars into a new undefined entity with no specific geographic or membership makeup. And while I understand some community partners were engaged in the drafting of the waiver and many of the changes in it are positive, it is disappointing that the community advisory councils were not invited to participate more deeply in the internal process and offer feedback. Our councils have been working hard to support the health of our communities for more than 7 years and have invested over \$ 1.2 million dollars in that effort. We've accomplished this through a collaborative process that ensures our OHP members, representatives like myself and others have an equal voice to our community partners. Our request to this community is that the draft 1115 waiver is changed to reflect House Bill 3353 as it is written and secondly as these changes are made to the waiver, OHA should work with our community advisory councils on these internal processes as we are important stakeholders. The flexibility and sustainability of these funds are critical to supporting otherwise underfunded programs that focus on the most vulnerable and underserved people in our communities, so please change the waiver and ensure that our community advisory committees are partners in that process. I appreciate your time. Thank you.

Patti Maloney, Soundview Medical Supply

My name is Patti Maloney, I work with Soundview Medical Supply. We are an incontinence supplier and we do a lot of business with beneficiaries who have CareOregon, OHP and the managed care programs.

I will be writing something up, but I wanted to put in a comment. Uhm because when you're putting in the waivers and there's a lot of talk about opening up care, the care inequity and, allowing people, the eligibility to be longer periods of time.

But we're really concerned about is the continued care and within the continued care is those can continued care requirements, especially during COVID, the 1135 waiver was very vague and it's it's pretty simple. It does say that sufficient health care items and services are available to meet the needs of individuals enrolled which is something that you had up on the OHA website, that also includes that providers you know who give these services are in good faith get reimbursed.

I'd like to drill down a little bit on that and talk about those requirements for the continued care. Uhm we work with with customers or beneficiaries that have permanent lifelong conditions and there was never anything in the language for the waivers about not being able to go to the doctor, the Telehealth was something that was talked about. But when you're talking about a population that is mentally or physically disabled, they really have to rely on somebody else to do those things for them.

The pandemic had things shut down. Certain things, their care providers could not bring them to appointments or have the ability to have a Telehealth appointment.

Uhm. We were unable to get these continued care requirements as renewals; they're considered prescriptions. Uhm doctors whose offices were closed so one of the things that I wanted to, and I will address. It is and I know you want to keep things under under the 2 minutes.

Oh, you're muted do you want me to stop?

It's just really they're looking at the requirements for the continued care and I think that falls right into you know the health equity.

Thank you.



January 7, 2022

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Director Allen,

Traverse Therapeutics, Inc. (Traverse) appreciates the opportunity to provide comments on Oregon Health Authority's draft Section 1115 waiver and applauds the state for its innovative approaches. However, if the waiver is submitted and approved by the Centers for Medicare and Medicaid (CMS) as proposed, Traverse is concerned about two provisions: 1) limiting drug access to patients for therapies approved through the Federal Food and Drug Administration's (FDA) accelerated approval pathway; 2) enacting a closed formulary. We urge the state to revise its waiver request and remove these provisions before formally submitting to CMS.

Traverse is a small biotechnology company based in San Diego, exclusively focused on identifying, developing, and delivering life-changing therapies to people living with rare disease. We have three approved products that are used by patients each day to treat rare nephrology and hepatology conditions. We also have late-stage research and development (R&D) programs with first-in-class potential for rare kidney conditions, and ongoing discovery efforts partnered with the National Institutes of Health (NIH) and leading patient advocacy organizations.

While millions of Americans have a rare disease or live with someone who does, the patient population living with any given rare disease is very small, even miniscule. By definition, rare disease patient populations are less than 200,000 people residing in the U.S., and in many cases are much smaller – one of our therapies serves under 100 U.S.-based patients. People with rare disease face unique challenges and often have very

**Traverse Therapeutics, Inc.**

3611 Valley Centre Drive, Suite 300, San Diego, CA 92130  
888-969-7879 | [traverse.com](http://traverse.com) | @TraverseRare    

limited treatment options.<sup>1</sup> The complex nature of rare diseases combined with small patient populations presents a unique set of challenges to developing treatments for rare diseases and facilitating their access. In fact, 95% of the approximately 7,000 known rare diseases still have no treatment available.<sup>2</sup> Yet, for the 5% of patients that have the hope that comes with an FDA-approved treatment for their condition, it is likely that treatment was approved via the accelerated approval pathway due to the unmet need and burden of the disease.

Travere writes to express concerns and ask the state to reconsider the following two provisions included in its draft waiver request:

**Limits to Drugs Approved Via Accelerated Approval Would Decrease Access for Rare Disease Patients That Already Have Very Limited Options**

Travere, and others, are deeply concerned about the state's proposal to use its own review process to determine coverage of new drugs. If this proposal moves forward, Oregon could exclude drugs approved through FDA's accelerated approval process from its formulary. This would be devastating for the state's rare disease community as "accelerated approval offers a valuable source of hope," according to the National Organization for Rare Disorders.<sup>3</sup> Additionally, the draft waiver proposes to use discretion of drugs when certain conditions, like only "surrogate endpoints have been reported." Surrogate endpoints are a crucial aspect of the FDA accelerated approval pathway that help allow patients access to life-changing medicine when there is an unmet need, without sacrificing safety and efficacy. In sum, Travere disagrees with the state's interpretation of the intent of the 21<sup>st</sup> Century Cures Act.

In 2018, CMS notes in *State Release 185* that these drugs must be covered by the Medicaid program if there is a signed Medicaid National Rebate Agreement, but it also reaffirms that these drugs go through the same rigorous approval as drugs through the traditional approval process. *State Release 185* notes,

"Drugs granted accelerated approval by FDA under the process described in 506(c) of the FDCA are approved under section 505(c) of the FDCA and must meet the same statutory evidentiary standards for safety and effectiveness as those granted traditional approvals. See section 506(e)(2) of the FDCA. Thus, as noted above, at the time a product is granted accelerated approval, FDA has based such an approval on a determination that the drug has an effect on a

---

<sup>1</sup> See, e.g., Gina Kolata, *'It Will Consume Your Life': 4 Families Take On Rare Diseases*, N.Y. TIMES, July 7, 2020, <https://www.nytimes.com/2020/07/07/health/rare-diseases.html>.

<sup>2</sup> Rare Diseases Clinical Research Network, National Institutes of Health, available at <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=126>.

<sup>3</sup> [https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report\\_Accelerated-Approval\\_FNL.pdf](https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf)

surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint other than survival or irreversible morbidity.”<sup>4</sup>

Drugs approved via the accelerated approval pathway are a lifeline for the more than 95% of rare disease patients that do not yet have access to an FDA-approved treatment. If Oregon moves forward with circumventing the FDA process, which is considered to be the “gold standard” for review and efficacy of drugs, there would likely be unequal treatment and worsened health outcomes for patients already dealing with serious, life-threatening diseases. More is explained in the extensive findings and sense of Congress provisions of the *Food Drug Administration Safety and Innovation Act*, §901:

“[FDA] serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation’s strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.”

Drugs approved through the accelerated approval pathway are subject to a demanding standard of review — demonstration of “substantial evidence” of effectiveness.<sup>5</sup> In fact, studies have found that certain drugs reviewed under the accelerated approval processes have offered greater medical gains than drugs reviewed through the FDA’s traditional, lengthier process.<sup>6</sup> Importantly, for drugs granted accelerated approval, post-approval confirmatory trials or studies are required as part of the regulatory process to verify and describe the anticipated clinical benefit.<sup>7</sup> If the confirmatory trial fails to verify benefit, the FDA has the authority to withdraw approval and has done so when needed.<sup>8</sup>

Furthermore, if the goal of this section of the waiver is to save costs or improve care, we believe that is misguided. According to Medicaid claims data from 2007 to 2018, accelerated approval drugs only accounted for less than 1 percent of Medicaid spending.<sup>9</sup> For the impacted families living with rare disease, “...downstream access concerns have emerged that could be chilling the appetite for investing in accelerated approval programs and [leave] patients without access to beneficial treatment,” according to the EveryLife Foundation for Rare Diseases.<sup>10</sup>

---

<sup>4</sup> *State Release 185*, CMS, June 27, 2018.

<sup>5</sup> 21 U.S.C § 355(d)(5).

<sup>6</sup> Chambers, et al., *Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved by Conventional Process*, Health Affairs Vol. 36, No. 8, 2017.

<sup>7</sup> FDA. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics. May 2014.

<sup>8</sup> FDA. Delivering Promising New Medicines Without Sacrificing Safety and Efficacy. FDA Voices: Perspectives from FDA Leadership and Experts. August 2019.

<sup>9</sup> <https://www.fightchronicdisease.org/sites/default/files/FINAL%20Quantifying%20Impact%20-%20White%20Paper%20v6.pdf>

<sup>10</sup> <https://everylifefoundation.org/events-schedule/scientific-workshop/>

## **Closed Drug Formularies Harm Rare Disease Patient Care**

Travere is also concerned about the state using a closed formulary approach and the impact that would have on rare disease patients that rely on Medicaid. If Oregon proceeds with covering one drug per therapeutic class, patient care and well-being would be severely compromised. It is not uncommon for rare disease patients to take multiple drugs to manage their condition. The decision on the best course of treatment should remain between the provider and patient, not the state's Medicaid program.

Medicaid is a lifeline for many rare disease patients and families. There could be many unintended consequences to the overall health of patients in Oregon if access is limited to only certain medications through a closed formulary approach. For example, medication adherence would likely decrease leading to worsened health outcomes.<sup>11</sup> Additionally, we believe a closed formulary approach will only further exacerbate disparities in care that could lead to delays and worsened health outcomes. We urge Oregon to reconsider this approach and prioritize rare disease patients living in the state.

## **Conclusion**

Travere strongly encourages the Oregon Health Authority to protect the core objectives of the Medicaid program and refrain from moving forward with the proposed outlined provisions above. Rare disease patients in the state rely on the Medicaid program for access to their needed treatments and care. We urge Oregon to revise its proposal before submitting to CMS and we look forward to working with you to advocate for better outcomes for all rare disease patients and families living in the state. If you have any questions, please do not hesitate to contact me or Rose Gallagher at 315-263-8463 or by email at [rose.gallagher@travere.com](mailto:rose.gallagher@travere.com).

Sincerely,



Christopher Porter  
Vice President  
Government Affairs and Policy  
Travere Therapeutics, Inc.

---

<sup>11</sup> <https://www.imcp.org/doi/pdf/10.18553/imcp.2014.20.7.677>

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
RE: 1115 Medicaid Demonstration Renewal Comments

Dear Oregon Health Authority:

Thank you for the opportunity to comment on the 1115 Medicaid Demonstration Renewal. Our names are Sadiya Muqueeth and Kristin Kovalik. We are writing in our capacities as Director of Community Health and Oregon Program Director at the Trust for Public Land (TPL). TPL has a long-standing commitment in Oregon, working for 40+ years to create parks and protect land for people. Our work extends from parks in Greater Portland and Bend, to large landscapes including the Columbia River Gorge and Steens Mountain. In addition, we are launching a three year Oregon Rural Schoolyard Program due to our success working with the Klamath Tribes on our Chiloquin Schoolyard project. We do this work with the recognition that our greenspaces have an impact on health, climate resilience, equity, and communities.

**Thus, we commend Oregon Health Authority's (OHA) inclusion of investment in social determinants of health,** with 1% of the global budget carved out to community investment collaboratives on health equity with citations to housing, climate, and other upstream factors. Retaining this investment will increase health equity across Oregon. In support of OHA's leadership in this work, we recommend:

1. OHA retain the requirement that CCOs invest at least 33% of the 3% of their global budgets with community investment collaboratives with flexible authority to invest in health equity. Community investments such as those in community led efforts significantly impact health and well-being.
2. OHA retain authority for expenditures on population health as healthcare investment in social determinants will have wide-ranging effects on myriad health outcomes.
3. OHA enhance opportunities for climate resilience through prevention not solely through response to disaster.

**Investment in Community Collaboration:** CCOs investments of their global budgets into community collaborative will generate distant and clear opportunities to improve health through community-led initiatives. Communities are experts in their contextual needs and priorities. Such decision making opportunities and cooperation mechanisms will strengthen the neighborhoods and social connectedness, a critical need in the context of an ever-evolving pandemic. Our work in Klamath County with the Klamath Tribes and numerous community partners including Oregon Health and Outdoors Initiative and Healthy Klamath Initiative serves as a principal example of this. For the past two years' students and community members in Chiloquin Oregon worked together to design a safe, multi-generational outdoor gathering space at Chiloquin Elementary School. The final design is reflective of the diverse culture and local priorities and needs. Private and public investments including funding from the Cascade Comprehensive Care (CCC)/Cascade Health Alliance (CHA), is supporting the creation of this green schoolyard which will also serve as a much needed public gathering space.

**Healthcare must invest in social determinants of health equity:** High healthcare costs and health inequities will continue to rise without intentional investment in social determinants of health such as education and climate change. We, therefore, recommend that OHA retain authority for expenditures on population health equity in the communities that need it most. Such investments in community-based efforts have wide-reaching intersectional ramifications. For example, in a study of 1,772 schools in Massachusetts, when controlling for race and household income, the increased level of greenness surrounding the schools was linked to reduction in chronic absenteeism. According to the study, an increase of 0.15 in the greenness index was associated with 25,837 fewer students

chronically absent every year (or a 2.6 percent reduction) (MacNaughton, 2017). Chronic absenteeism is associated with health outcomes across the lifespan.

These efforts may have significant implications for health care costs. Review studies find urban green space exposure consistently related to decreased mortality, reduced heart rate and violence, improved attention and mood, and increased or higher likelihood of physical activity (M. Kondo et al., 2018; Wolf et al., 2020). Systematic reviews find inverse relationships between greenness, measured through a normalized difference vegetation index (NDVI), and all-cause mortality (M. Kondo et al., 2018; Rojas-Rueda et al., 2019). Muller et al. (2019) studied 30 years of available data for all US counties and found that a \$100 increase in per capita investment in parks and recreation was associated with 3.4 fewer deaths per 100,000 people, suggesting that increased funding for parks could be considered a broader public health intervention (Mueller et al., 2019).

Analysis of data from Los Angeles projected that more than 164,000 years of life expectancy could be gained by addressing park needs in that city, with the majority of gains occurring among Black and Latinx residents (Yañez et al., 2020). Greenspace studies have also found protective associations with two leading risk factors for infant mortality, low birthweight and small for gestational age, with heightened effects among mothers in lower socio-economic positions (Ebisu et al., 2016). Kondo, et al. (2020)'s health impact assessment in The Lancet projected that 403 (95% interval 298–618) premature deaths could be prevented city-wide by attaining a 30% tree canopy cover by 2025, with the majority (244) of the deaths prevented in lower socio-economic census tracts (M. C. Kondo et al., 2020). If tree canopy increased by 5 percentage points in areas with non-tree vegetation alone, researchers projected an annual reduction of 302 deaths city-wide, with a monetary value of \$2.9 billion.

**Create opportunities for climate resilience through prevention not only disaster response:** The Waiver Renewal includes clear language on the health risks created by climate change as well as climate-related fires and extreme heat. However, the Waiver application frames climate support as a 'response to climate disasters'. This does not include specific authority to invest in climate resilience. With prevention serving as a central tenet of public health and healthcare, we recommend adding a bullet to the list of Climate Supports on p68 such as, "Increasing access to natural areas with shade."

In conclusion, we know that place-based inequities drive preventable health outcomes. The practice of community health is to address inequities through prevention and collaboration. This investment from OHA into communities will advance the health and well-being of communities, ensure they are more resilient to climate change, and place Oregon on a path to innovation and leadership against adaptive challenges that lie ahead. Thank you for your consideration of our comments.

Sincerely,

<b>Sadiya Muqueeth, DrPH, MPH</b> <b>Director of Community Health</b> The Trust for Public Land 100 M Street, Suite 7 Washington, D.C. 22202 <a href="mailto:Sadiya.Muqueeth@tpl.org">Sadiya.Muqueeth@tpl.org</a> 443.415.2029	<b>Kristin Kovalik</b> <b>Oregon Program Director</b> The Trust for Public Land 15 SW Colorado Ave., Suite 100 Bend, OR 97702 <a href="mailto:kristin.kovalik@tpl.org">kristin.kovalik@tpl.org</a> (541) 668-4390
--	---



8737 Colesville Road, Suite 400 | Silver Spring, MD 20910  
800-225-6872 | [info@tscalliance.org](mailto:info@tscalliance.org) | [tscalliance.org](http://tscalliance.org)

January 7, 2022

Interim Deputy Medicaid Director Dana Hittle  
500 Summer St. NE, E65  
Salem, OR 97301

Submitted via email to: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

Dear Interim Deputy Director Hittle:

The TSC Alliance appreciates the opportunity to comment on the Oregon 1115 Demonstration Waiver for the Oregon Health Program (OHP). This waiver contains multiple proposals that would be catastrophic to the rare epilepsy community, who rely on complex care management with as few unnecessary hurdles as possible. As there are many individuals within the rare epilepsy community with refractory epilepsy it is imperative that therapy options remain accessible to meet these serious unmet medical needs.

The TSC Alliance is a 501(c)(3) non-profit organization dedicated to finding a cure for tuberous sclerosis complex (TSC), while improving the lives of those affected. We drive research, increase care quality and access, inspire hope and advocate with and for all affected by the disease. TSC is a rare genetic disorder that can cause tumor growth in all the body's vital organs. Symptoms can include seizures, kidney failure, brain and lung tumors, autism spectrum disorder and severe learning disabilities. TSC is also the leading genetic cause of both epilepsy and autism.

As with many rare disease organizations, our constituents are left with minimal treatment options, if any. We are very concerned with the new proposed closed formulary for adults, as well as Oregon's proposals to continue the waiver of retroactive eligibility, and continue to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children over the age of one and continued use of a Prioritized List of services that relies, in part, on a quality-adjusted life year. Approval of these proposals eliminate options that give our loved ones hope and valuable time that many individuals desperately need to avoid irreversible damage, complications, and death.

**Hope no matter how complex**

Oregon's proposal would allow the state to exclude FDA-approved drugs entirely. Failure to allow already FDA-approved drugs for our community is ethically unacceptable and detrimental to those individuals living with epilepsy. By suggesting the state could offer just one drug per therapeutic class for our population will not only increase overall healthcare burden that many of these individuals face, these individuals and families will also experience higher hospitalizations, increased missed work for adults with epilepsy and caregivers, and decreased overall quality of life. Restricting appropriate medications and irresponsibly determining prescription practices outside of the physician – patient collaboration is harmful and can be avoided.

Additionally, Oregon proposes to continue to eliminate retroactive coverage for nearly all beneficiaries excluding those eligible through a disability pathway. Retroactive eligibility for our community is essential to expediting critical discovery and evaluations that if left untreated can lead to life altering and even fatal consequences. Furthermore, without this eligibility our community faces another burden of financial costs and delays that continue to widen the gap of healthcare disparities and access to care for our rare disease community. We are also concerned with the existence of the Prioritized List at all, and further concerned about the use of QALYs to determine who gets care. QALYs discriminate against people with disabilities by devaluing lives lived with disability.

Equally, we are opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnostic and Treatment. We strongly support the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit for Screening, Diagnosis and Treatment (EPSDT). As you are aware, management for most conditions do not solely focus on medications, especially those within our community where care is complex and multifaceted. In addition to seizures, subependymal giant cell astrocytoma (SEGA) is a slow growing tumor that can cause life-threatening complications by blocking the flow of fluid in the brain and remains a major clinical feature associated with TSC.<sup>1,2</sup> Given the complexity of tumor burden and location not all individuals are surgical candidates leaving these individuals with fatal complications. Devices such as Vagus Nerve Stimulation (VNS) and other medically appropriate devices that improve epilepsy are helpful to our population. 80% of those with TSC are affected by epilepsy and two-thirds are medically refractory. Early intervention is key to quality cognitive outcomes for those living with TSC. Limitations to services that are paramount in providing optimal evidence-based care for this population will further add to sub-optimal care for these families, especially those who are low-income.

The TSC Alliance appreciates the opportunity to comment on this proposal. We strongly hope that you consider our concerns so that those within the epilepsy and rare disease community can continue to obtain access to medications and services they need. If you have any questions or need further information, please do not hesitate to contact Chief Executive Officer, Kari Rosbeck, at [krosbeck@tsalliance.org](mailto:krosbeck@tsalliance.org) or Director of Medical Affairs, Ashley Pounders MSN, FNP-C, at [apounders@tsalliance.org](mailto:apounders@tsalliance.org).

Sincerely,



Kari Luther Rosbeck  
President and CEO



Ashley Pounders, MSN, FNP-C  
Director of Medical Affairs

#### References

1. Arroyo MS, Krueger DA, Broomall E, Stevenson CB, Franz DN. Acute Management of Symptomatic Subependymal Giant Cell Astrocytoma With Everolimus. *Pediatr Neurol.* 2017;72:81-85. doi:10.1016/j.pediatrneurol.2017.04.008
2. Northrup H, Krueger DA, Roberds S, et al. Tuberous sclerosis complex diagnostic criteria update: Recommendations of the 2012 international tuberous sclerosis complex consensus conference. *Pediatr Neurol.* 2013;49(4):243-254. doi:10.1016/j.pediatrneurol.2013.08.001



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

**Subject: Support for Oregon’s Draft Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Application**

Dear Director Allen:

Unite Us writes in strong support of Oregon Health Authority’s draft 1115 Waiver Renewal and Amendment application.

This comprehensive Waiver application appropriately recognizes that working upstream is the path of the equity agenda. The Waiver builds on Oregon’s innovative efforts made possible through previous Waivers and furthers Oregon’s commitment to health equity through important reforms, which include expanding covered benefits to include services that address social determinants, incentivizing CCOs to address upstream drivers of health through equity-focused quality metrics, and driving community-centric health investments and governance structures.

Unite Us believes the Waiver application could be further strengthened by recognizing and incorporating the ongoing and planned work of OHA, the CCOs, and community-based partners across the state to build the infrastructure required for community information exchange (CIE).

Over the last 2 years, significant statewide advancement has been made on CIE. These include smarter, more precise definitions of the term and greater awareness as to core components of CIE: shared statewide technology, community-driven governance across diverse sets of network partners, and data and reporting to support network maturation, population health initiatives, and policy and government budgeting decisions. CIE in Oregon, sustained with new long-term financing that maximizes federal drawdown, is now primed to be the shared infrastructure upon which many of the efforts outlined in this Waiver should be built.

In particular, Unite Us encourages OHA to:

- Recognize the CIE Workgroup established by OHA in December of 2021;
- Recognize CIE as the central infrastructure required to advance the equity agenda;
- Consider the overlaps of ongoing CIE work in Oregon with those proposed in this waiver, including existing CIE governance structures and the Community Investment Collaboratives; and
- Use this Waiver opportunity, coupled with administrative claiming opportunities, to communicate intent to build long-term sustainable financing of the CIE.



## **Background on Unite Us and Connect Oregon**

Since 2013, Unite Us has been the national leader in deploying community-wide care coordination infrastructure to meaningfully connect health and social care providers in a common ecosystem and to help address social determinants of health. Our goal is to ensure every individual, no matter who they are or where they live, can access the critical services they need to live happy and healthy lives.

We help community partners – payers and providers, private and public, large and small – work together in new ways to identify and address unmet social needs. To support these network partners, we have deployed our community engagement process in more than 42 states. Our coordinated care networks demonstrate that a robust, collaborative, and holistic community-wide approach to identifying and addressing unmet social needs not only improves individual health and quality of life, but also improves community health, reduces healthcare costs and utilization, and promotes health equity. Network partners leverage the Unite Us platform to securely share information required to coordinate care through closed-loop referrals. If enabled, partners are also able to streamline the billing and invoicing of services from CBOs to payers. A suite of data as well as centralized care coordination services make up the end-to-end solution available to network partners.

In Oregon, Connect Oregon is the network, powered by Unite Us, of organizations participating in community information exchange. Unite Us is currently contracted by 12 of the 16 CCOs to serve 35 of the 36 Oregon counties. In addition to the CCOs, health providers (including large systems and FQHCs), CACs, CBOs, and county-based programs are partners. Further, Oregon Health Leadership Council serves as statewide convener of the CCOs, and 211info operates as a coordination center for the network. OHA currently recognizes Connect Oregon as a Community Information Exchange (CIE).

Given these partnerships in place, the history and the trajectory of this work, and an expansive overlap in values and mission, Unite Us respectfully submits the following comments as a committed partner and advocate for the impact envisioned through OHA's waiver proposal.

**Unite Us is excited to support OHA's 1115 Waiver renewal and amendment which critically expands policy levers to incentivize and enable upstream health approaches focused on equity.** Among the provisions applauded, we highlight the following:

### **1. The Waiver supports individuals experiencing life transitions and disruptions through comprehensive SDOH-related benefits.**

Unite Us applauds OHA's expenditure authority requests for 1) CCOs, to provide covered SDOH services for populations experiencing transitional events, such as reentry from the criminal justice system or the impacts of extreme climate change, and for 2) community-based organizations (CBOs), to support their implementation capacity through infrastructure and capacity-building spending flexibility. These requests will lay the foundation for critical health reforms that emphasize and reward preventative, upstream approaches to care delivery.

Covered SDOH transition services will importantly help individuals more easily access expanded health-related services that meet their basic needs in areas such as housing, food, and employment assistance.

These SDOH benefits will help OHA standardize and streamline the delivery of services that address SDOH, which often reflect and reinforce entrenched health inequities. These benefits can ultimately be offered to additional populations beyond those experiencing life transitions and disruptions.

Importantly, this strategy will drive healthcare dollars to CBOs and community providers who have historically supported the whole-person health of Medicaid members without receiving reimbursement for their services. These dollars will drive sustainable funding and capacity for CBOs, targeting resources toward prevention and directly into communities where the most vulnerable and marginalized individuals often receive their care.

Unite Us works with CBOs on a daily basis. We applaud that this waiver acknowledges the disruption and change management that will be required of CBOs; this initiative presents a massive change to their normal workflows with the added benefit of Medicaid reimbursement. The implementation capacity funds for CBOs and aligned Community Investment Collaboratives (CICs) will be critical for supporting CBOs through this transition. These funds are essential for setting up the necessary infrastructure system that allows for tracking the delivery of services, payment and billing, reporting, and monitoring outcomes.

***To further strengthen this proposal, Unite Us recommends:***

Early CBO/Payer Alignment. We encourage OHA to ensure close collaboration with CBOs and community leaders when developing requirements for CBO participation, reimbursement, and reporting. This can help prevent undue administrative burden for community providers and to ensure the reimbursement process is not over-medicalized for CBOs that are not resourced to process and submit traditional medical claims. For example, OHA should ensure that their state reporting requirements for CCOs do not undermine the ability of CBOs to easily submit invoices for reimbursement. For example, California requires health plans to submit all data on Community Supports in standard encounter format, which forces plans to require traditional medical claims from CBOs so they can properly report back to the state. It's important to acknowledge that this transition will be difficult for CBOs operating with limited overhead spending, and so OHA's requirements should ensure that the transition to billing for social services is as simple and efficient as possible. CCOs should allow CBO providers to submit reimbursement requests in invoice form if that is the best process for them, and encourage use of an invoice portal as an alternative to traditional claims reporting.

In addition, OHA should ensure that vetting processes for CBO providers is distinct from the vetting process in place of medical providers. Background checks on CBO staff and other aspects of the traditional credentialing process may preclude important and trusted CBOs from participating in the initiative, and OHA should explore alternatives that are uniquely suited to vet CBOs.

Clear Standards to Drive Quality. In order to reduce duplicative efforts and minimize the number of systems and solutions that providers need to learn and adopt, SDOH transition services payments and infrastructure investments should build upon existing CIE efforts across the state, which include social needs screenings, closed-loop referrals, social care outcomes data collection and reporting functions.

OHA can ensure that all CIE solutions meet the same single set of standards to allow for standardized data collection and streamlined care coordination efforts across the state. Just as OHA has encouraged MMIS and APCD to align with REALD regulations as required by statute, so should that be encouraged with a CIE solution.

Establishing appropriate privacy, security and billing compliance requirements SDOH referral and reimbursement technology must also be emphasized here. Information exchange between partners must occur in order to ensure care coordination and the adoption of trauma-informed approaches to addressing health-related social needs; but this information sharing must occur pursuant to HITRUST Certification and compliance with HIPAA, 42 CFR Part 2, FERPA, and other pertinent regulations. The assurance of privacy and compliance enables the trust upon which any integrated solution is built and upon which equity is achieved.

Shared, Publicly-Sponsored, CBO Billing Systems. Billing systems adopted and/or procured by and/or for CBOs participating in reimbursement arrangements with CCOs should be seen as shared infrastructure. The burden should not be placed on CBOs nor community investment collaboratives that lack technical capacity to build and/or procure their own billing systems. Further, it is important for CBO payments to be linked to closed loop referral infrastructure in order to link outcomes with reimbursement and monitor population outcomes.

If viewed as shared infrastructure, OHA may consider an Advanced Planning Document (APD) as a mechanism for securing federal match funding (75-90%) for statewide CBO referral and reimbursement technology, while continuing to finance SDOH payments to CBOs via waiver requests. Continued federal investment in SDOH services combined with a publicly-privately funded foundational referral technology presents a sustainable strategy for financing such systems in the long-term – ensuring that individuals’ upstream needs are being met and that CBOs are being paid for their valuable services.

## **2. The Waiver aligns financial incentives in the healthcare delivery system to drive community health and health equity improvements.**

Unite Us celebrates OHA’s commitments in this waiver around redesigning financial incentives in the healthcare system to shift resources towards and reward prevention and population health. We applaud the regulatory and policy levers outlined, including a) value-based global budgets for CCOs, b) 3% allocation of CCO population health budgets towards health equity investments with 30% designated for community investment collaboratives, and c) flexibility around CCO’s ability to count health-related spending as part of their medical load when calculating MLR.

As described by OHA, Unite Us believes that these requirements/levers will “flip” financial incentives in Oregon’s healthcare delivery system – CCOs will be accountable for and rewarded by improvements in whole-person health outcomes, health equity, prevention, and care

coordination rather than being financially rewarded when members are sick and access more care.

Unite Us agrees with and celebrates OHA's recognition that entrenched inequities, power imbalances, and systemic racism in and resulting from the health system cannot be undone unless financial incentives link market power to health equity and community health improvements. At Unite Us, we're working with communities and our funded healthcare partners to shift investments upstream and into community health through community health infrastructure – we will continue supporting and elevating the efforts of OHA alongside our work in communities.

### **3. The Waiver holds CCOs accountable for health equity through quality metrics.**

Unite Us supports OHA's proposal to redesign the Oregon Health Plan Quality Incentive Program with dedicated upstream metrics focused on equity as well as to better integrate community member decision-making power through the new Health Equity Quality Metrics Committee (HEQMC).

In particular, Unite Us celebrates the new health equity upstream metric titled “Social Determinants of Health: Social Needs Screening and Referral,” which incentivizes more CCO members having their social needs acknowledged and addressed.

With this metric in place, OHA is building a comprehensive healthcare delivery system that seeks to address members' social determinants of health through population health and prevention strategies, which include connecting members to services that address their social needs.

The new upstream metrics, coupled with the new HEQMC, will enable OHA to iterate and improve its social determinant strategy in the long term.

OHA and the HEQMC should also consider the role of analytical tools to identify opportunities where proactive outreach could drive social care service delivery. Supported as a shared service and run out of OHA, risk scoring mechanisms and proactive human services outreach can be essential components of a forward-looking strategy to achieve health equity.

### **Conclusion & Unite Us Support for Oregon's Waiver**

This 1115 waiver will allow OR to implement innovative and long-lasting equity initiatives within the healthcare delivery system.

These proposals will drive sustainability for the CBO provider network, financially reward CCOs for delivering holistic care that keeps members healthy and in their communities, and incentivize more equitable outcomes with new quality standards.

We recommend that OHA continue to build upon efforts already underway across the state, including the CIE efforts and its governance approaches, to avoid conflicting solutions when possible.

If you have any questions or if there is any additional information Unite Us can provide, please do not hesitate to contact me at [read@uniteus.com](mailto:read@uniteus.com).

Thank you for the opportunity to submit comments, and for your continued leadership and support to provide more holistic and equitable care in Oregon and nationally.

Sincerely,

/s/ Read Holman

Read Holman  
Policy Director, Government and Regulatory Affairs  
Unite Us  
[read@uniteus.com](mailto:read@uniteus.com)



OFFICE OF THE DIRECTOR

Kate Brown, Governor

Oregon  
**Health**  
Authority

500 Summer St NE E20

Salem OR 97301

Voice: 503-947-2340

Fax: 503-947-2341

[www.Oregon.Gov/OHA](http://www.Oregon.Gov/OHA)

[www.health.oregon.gov](http://www.health.oregon.gov)

OFFICIAL WEBSITE NOTICE

Posting Date: August 27, 2015

## RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Wilsonville, Oregon on Thursday, July 30, 2015. The Committee considered in order of priority: the safety and efficacy of the drugs being considered, the ability of Oregonians to access effective prescription drugs that are appropriate for their clinical conditions and finally, substantial differences in costs of drugs within the same therapeutic class. Based upon the clinical information presented by staff<sup>i</sup> and all public comment offered,<sup>ii</sup> while considering the impact on special populations, the Committee makes the following recommendations for the Oregon Practitioner-Managed Prescription Drug Plan (PMPDP) or for any other preferred drug list established by the Oregon Health Authority:

### Drug Use Review Recommendations:

#### Ivacaftor PA Criteria

The Committee recommended updating the prior authorization (PA) criteria to include patients aged 2-5 years old with gating mutations and amended the proposed criteria to change length of authorization on header from 30 days to 60 days. The Committee also recommended requiring a 10% change from baseline to the BMI renewal criteria and to refer requests for patients with the R117H mutation to the Medical Director for manual review.

#### Pediatric SSRI High Dose PA Criteria

The Committee recommended implementing the updated PA criteria as presented, to address children less than five years of age and require the prescription be written by, or in consultation with a child psychiatrist.

#### Rifaximin PA Criteria

The Committee recommended adopting the updated PA criteria as presented, but amended the length of approval from lifetime to one year.

### Codeine PA Criteria

The Committee recommended approving the PA criteria as presented for children less than 18 years old, but amended the proposed criteria to switch question #2 with #3 and instead ask if the medication is being prescribed for an OHP-funded condition. The Committee directed staff to perform a RetroDUR for age and to perform prescriber education.

### Leuprolide Hormone Therapy PA Criteria

The Committee rejected the proposal to change the PA criteria and recommended continuing to approve only when prescribed by a pediatric endocrinologist. The Committee asked staff to solicit input from a pediatric endocrinologist on this request. The Committee also asked staff to evaluate cross-sex hormone therapies.

### Non-Preferred PDL PA Criteria

The Committee recommended adopting the updated PA criteria and require non-preferred PMPDP requests be prescribed for FDA approved indications. The Committee also recommended limiting the length of authorization to the lesser of six months, or until the anticipated review by P&T Committee.

### HIV Class Review / Drug Use Evaluation

The Committee recommended creating a voluntary Preferred Drug List (PDL) class for HIV antiretroviral drugs and combination products and to designate all drugs as preferred at this time. The Committee directed staff to work with established, high Medicaid volume HIV clinics to try to identify ARV regimens with broad tolerability and high viral response rates in most patients and that have favorable or equivalent comparative price (preferred) and try to identify ARV regimens with common tolerability problems or lower viral response rates in most patients and with an unfavorable comparative price (non-preferred).

### Antiplatelet Class Update / Policy Evaluation

The Committee recommended continuing the PA policy and approved updating the criteria to be consistent with treatment guidelines. The Committee recommended implementing a retrospective safety net program to identify patients that do not start antiplatelet therapy within 14 days of encountering a PA to provide additional transition assistance with a focus on insuring patients qualifying for DAPT are not discontinued prematurely. The Committee also recommended continuing to list aspirin and clopidogrel as preferred drugs due to high level evidence of benefit and

to evaluate comparative costs of other antiplatelet drugs in executive session for PDL changes.

### Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

#### Antiplatelet Class Update

After comparative cost consideration in executive session, the Committee recommended making cilostazol preferred and no other changes to PMPDP.

DRUG	CHANGE
cilostazol	Make preferred on the PMPDP

#### Secukinumab New Drug Evaluation

The Committee recommended modifying the PA criteria to move topical therapies from the systemic biologicals PA criteria and incorporate into the topical drugs in the proposed psoriasis PA criteria. The Committee also approved incorporating secukinumab into the PA criteria for Biologicals and to limit use to patients with moderate to severe psoriasis diagnosed by a dermatologist, after they have failed first-line therapies. After comparative cost consideration in executive session, the Committee recommended maintaining secukinumab as non-preferred and no changes to the PMPDP.

#### Idiopathic Pulmonary Fibrosis (IPF) New Drug Evaluations

The Committee recommended implementing the Idiopathic Pulmonary Fibrosis (IPF) Agents PA criteria to limit use to appropriate patients and to add the IPF Class to PMPDP. After comparative cost consideration in executive session, the Committee recommended making pirfenidone and nintedanib non-preferred.

DRUG	CHANGE
pirfenidone	Make non-preferred on the PMPDP
nintedanib	Make non-preferred on the PMPDP

#### Intranasal Allergy Inhalers Class Review

The Committee recommended creating a PMPDP class for “Intranasal Allergy Drugs” and to prefer at least one intranasal corticosteroid due to evidence of effectiveness for OHP-funded conditions. The Committee also approved the updated PA criteria as presented. After comparative cost consideration in executive session, the Committee recommended making legend fluticasone propionate preferred; designating non-steroid products non-preferred due to a lack of data; and to make all other steroid products non-preferred and to not grandfather.

DRUG	CHANGE
fluticasone propionate	Make preferred on the PMPDP
All other agents in Intranasal Allergy class	Make non-preferred on the PMPDP

### Antifungals Class Update

The Committee recommended updating the PA criteria as proposed to reflect changes to the OHP prioritized list. The Committee also recommended maintaining open access to fluconazole; maintaining the clinical PA requirement for griseofulvin, itraconazole and terbinafine; and to make ketoconazole non-preferred due to increased risk. The Committee also agreed with the proposal to allow hematology, oncology and infectious disease specialty prescribers approval for voriconazole to cover invasive aspergillosis. After comparative cost consideration in executive session, the Committee recommended making ketoconazole non-preferred and not grandfather and no other changes to the PMPDP.

DRUG	CHANGE
ketoconazole	Make non-preferred on the PMPDP

### Calcium Channel Blockers Class Update

The Committee recommended creating a “Combination Antihypertensive” PMPDP class to include fixed-dose combination products containing two antihypertensive drugs, as well as combinations containing an antihypertensive drug with a non-antihypertensive drug (e.g., statin) After comparative cost consideration in executive session, the Committee recommended making the following fixed dose combinations preferred:

- AMLODIPINE-OLMESARTAN
- ENALAPRIL-HYDROCHLOROTHIAZIDE
- LISINOPRIL-HYDROCHLOROTHIAZIDE
- LOSARTAN-HYDROCHLOROTHIAZIDE
- METOPROLOL SUCCINATE- HYDROCHLOROTHIAZIDE
- OLMESARTAN-AMLODIPINE- HYDROCHLOROTHIAZIDE
- OLMESARTAN-HYDROCHLOROTHIAZIDE
- PROPRANOLOL-HYDROCHLOROTHIAZIDE

The Committee recommended making all other products in Combination Antihypertensives class non-preferred and no other changes to the PMPDP.

The Committee has made these recommendations to the Oregon Health Authority for approval by the Director of the Oregon Health Authority.

**APPROVAL BY THE DIRECTOR OF THE OREGON HEALTH AUTHORITY**

The recommendations of the Drug Use Review / Pharmacy and Therapeutics Committee are approved. Recommendations with respect to the inclusion of a drug on the Practitioner-Managed Prescription Drug Plan will be put into place no earlier than 60 days from the date this notice is posted on the web site.



Lynne Saxton  
Director, Oregon Health Authority

8-27-15

Approval date

A request for reconsideration of this decision to adopt the recommendations of the Drug Use Review / Pharmacy and Therapeutics Committee must be filed with and received by the Director no later than 30 calendar days from the

---

<sup>i</sup>[http://pharmacy.oregonstate.edu/drug\\_policy/sites/default/files/pages/dur\\_board/meetings/meetingdocs/2013\\_07\\_25/finals/2013\\_07\\_25\\_PnT\\_Complete.pdf](http://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/meetings/meetingdocs/2013_07_25/finals/2013_07_25_PnT_Complete.pdf)

<sup>ii</sup>[http://pharmacy.oregonstate.edu/drug\\_policy/sites/default/files/pages/dur\\_board/meetings/meetingdocs/2013\\_07\\_25/finals/2013\\_07\\_25\\_WrittenTestimony.pdf](http://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/meetings/meetingdocs/2013_07_25/finals/2013_07_25_WrittenTestimony.pdf)



December 21, 2021

Submitted via: [1115.WaiverRenewal@dhsosha.state.or.us](mailto:1115.WaiverRenewal@dhsosha.state.or.us)

Mr. Patrick Allen  
Director  
Oregon Health Authority (OHA)  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

**Re: Oregon 2022-2027 Medicaid 1115 Demonstration Application (Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver)**

Dear Director Allen:

ViiV Healthcare Company (ViiV) appreciates the opportunity to submit comments to the Oregon Health Authority (OHA) regarding the proposed Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver, the “Oregon 2022-2027 Medicaid 1115 Demonstration Application.”<sup>1</sup>

ViiV is the only company 100 percent dedicated to combating, preventing, and ultimately curing HIV and AIDS. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment.

As an exclusive manufacturer of HIV medicines, ViiV is proud of the scientific advances in the treatment of this disease. These advances have transformed HIV from a terminal illness to a manageable chronic condition. Effective HIV treatment can help people with HIV to live longer, healthier lives and has been shown to reduce HIV-related morbidity and mortality at all stages of HIV infection.<sup>2,3</sup> Furthermore, effective HIV treatment can also prevent the transmission of the disease.<sup>4</sup>

---

<sup>1</sup> Oregon.gov, *Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver*, “Oregon 2022-2027 Medicaid 1115 Demonstration Application,” [https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf?utm\\_medium=email&utm\\_source=govdelivery](https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf?utm_medium=email&utm_source=govdelivery), (Accessed December 15, 2021)

<sup>2</sup> Severe P, Juste MA, Ambroise A, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. *N Engl J Med*. Jul 15 2010;363(3):257-265. Available at [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list\\_uids=20647201](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=20647201), (Accessed August 27, 2021)

<sup>3</sup> Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. *N Engl J Med*. Apr 30 2009;360(18):1815-1826. Available at [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list\\_uids=19339714](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=19339714), (Accessed August 27, 2021)

<sup>4</sup> Rodger et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *The Lancet* 2019; 393(10189):2428-2438. Available at: [https://doi.org/10.1016/S0140-6736\(19\)30418-0](https://doi.org/10.1016/S0140-6736(19)30418-0), (Accessed August 27, 2021)

## **The Medicaid Program Should Join Efforts to End the HIV Epidemic**

An estimated 1.2 million people in the United States are living with HIV and at least thirteen percent are unaware that they have the virus.<sup>5</sup> Despite groundbreaking treatments that have slowed the progression and burden of the disease, treatment of the disease is low – only half of diagnosed and undiagnosed people with HIV are retained in medical care, according to the Center for Disease Control and Prevention (CDC).<sup>6</sup>

Since the earliest days of the epidemic, Medicaid has played a critical role in HIV care. Nationally, Medicaid is the largest source of coverage for people with HIV.<sup>7</sup> In fact, more than 42 percent of people with HIV who are engaged in medical care have incomes at or below the federal poverty level.<sup>8</sup> The program is an essential source of access to medical care and antiretroviral therapy (ART) drug coverage for people with HIV. This medical care and drug treatment not only preserve the health and wellness of people with HIV and improves health outcomes, but it also prevents new HIV transmissions.

Medicaid is also a significant provider of HIV prevention, specifically pre-exposure prophylaxis (PrEP).<sup>9</sup> When taken properly, PrEP can reduce the risk of acquiring HIV from sex by 99 percent and reduces risk by 74 percent among those who inject drugs.<sup>10</sup> However, of the approximately 1.2 million people in the U.S. indicated for PrEP, only 18 percent are receiving it.<sup>11</sup> In Oregon the state's PrEP coverage ratio was only 17.2 percent in 2019 according to CDC.<sup>12</sup> Making PrEP available and accessible is an important step in reducing the number of new HIV diagnoses and ultimately ending the HIV epidemic.

In 2019, the U.S. Department of Health and Human Services (DHHS) released the "Ending the HIV Epidemic: A Plan for America (EHE)."<sup>13</sup> This plan proposes to use scientific advances in antiretroviral therapy to treat people with HIV and expand proven models of effective HIV care and prevention.<sup>14</sup> The plan coordinates efforts across government agencies to stop the HIV epidemic and focuses its efforts on local areas. The EHE Initiative is not only a landmark policy by all federal health agencies, it is also supported by the HIV community and the President's Advisory Council on HIV/AIDS (PACHA).<sup>15</sup>

As of 2019, there were 7,280 people living with HIV in Oregon, and 199 people were newly diagnosed with HIV in the state in 2019.<sup>16</sup> We applaud the Oregon Health Authority (OHA) for launching its own initiative to end HIV in the state, the "End HIV Oregon" strategy<sup>17</sup> following a two-year planning process with community members from across Oregon, facilitated by the Program Design & Evaluation Services (PDES) staff.<sup>18</sup> The End HIV Oregon strategy also centers around the three goals of access to HIV testing, accelerating prevention efforts including pre-exposure prophylaxis (PrEP), and promoting effective HIV treatment to promote viral suppression.

<sup>5</sup> Centers for Disease Control and Prevention. Volume 26 Number 2 | HIV Surveillance | Reports | Resource Library | HIV/AIDS | CDC <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-26-no-2/index.html> Published May 2021. (Accessed June 2, 2021)

<sup>6</sup> Centers for Disease Control and Prevention. Volume 26 Number 2 | HIV Surveillance | Reports | Resource Library | HIV/AIDS | CDC <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-26-no-2/index.html> Published May 2021. (Accessed June 2, 2021)

<sup>7</sup> Kaiser Family Foundation. Medicaid and HIV, <http://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/>

<sup>8</sup> Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017). HIV Surveillance Special Report 21. Revised edition. June 2019, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-21.pdf> (Accessed February 2021)

<sup>9</sup> Kaiser Family Foundation. Medicaid and HIV, <http://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/>. (Accessed August 8, 2021)

<sup>10</sup> "HIV Risk and Prevention: PrEP (Pre-Exposure Prophylaxis)," <https://www.cdc.gov/hiv/risk/prep/index.html>. (Accessed July 27, 2021)

<sup>11</sup> National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025, page 1, <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>, (Accessed August 27, 2021)

<sup>12</sup> CDC.gov, "Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2019", (Table 9b): <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf> (Accessed October 27, 2021)

<sup>13</sup> HIV.gov "Ending the HIV Epidemic" <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview> (Accessed: April 20, 2021)

<sup>14</sup> HIV.gov "Ending the HIV Epidemic" <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview> (Accessed: April 20, 2021)

<sup>15</sup> Presidential Advisory Council on AIDS (PACHA) Resolution in Support of "Ending the HIV Epidemic: A Plan for America" <https://files.hiv.gov/s3fs-public/PACHA-End-HIV-Elimination-Resolution-passed.pdf>, (Accessed August 27, 2021)

<sup>16</sup> AIDSvu, Oregon, <https://aidsvu.org/local-data/united-states/west/oregon/> (Accessed December 15, 2021)

<sup>17</sup> End HIV Oregon, <https://www.endhivoregon.org/#end-hiv-2> (Accessed December 15, 2021)

<sup>18</sup> Oregon.gov, "End HIV Oregon launches,"

<https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/PROGRAMDESIGNANDEVALUATIONSERVICES/Pages/Features-EndHIV.aspx> (Accessed December 15, 2021)

In order to promote the state and federal goal to end the HIV epidemic, it is imperative that state Medicaid programs participate in local and national efforts and promote policies that contribute to HIV public health goals.

Therefore, in providing our comments, ViiV wishes to comment on several of the proposals in the demonstration. We also want to call attention to the opportunity for this waiver proposal to align with the goals of the nation's public health effort to end the HIV epidemic in order to advance the care, treatment, and prevention needs of their enrollees with HIV and those vulnerable for acquiring HIV:

## 1. ViiV Healthcare Opposes a Closed Formulary for Medicaid

Medicaid plays an important role in the efforts to end the HIV epidemic because almost half of people with HIV who are engaged in medical care have incomes at or below the federal poverty level.<sup>19</sup> Medicaid is an essential source of access to medical care and antiretroviral therapy (ART) drug coverage for people living with HIV, which not only preserves the health and wellness of people with HIV, but also prevents new HIV transmissions.

The demonstration proposal<sup>20</sup> represents a substantial change to the coverage of drug therapies within Medicaid. Although we understand the state's fiscal goals in proposing a closed formulary, it would have a significant negative impact on people with HIV covered by Medicaid, and on Medicaid beneficiaries at risk for HIV who access prevention medications under the program. These changes work against the goal of ending HIV in the state by this department. We therefore offer the following comments on specific aspects of that proposal:



### a. ViiV Supports Open Access to HIV Antiretrovirals Within Medicaid for HIV Treatment



The proposed demonstration would create a closed formulary in the state, which would jeopardize access to necessary antiretrovirals for people with HIV, and directly work against efforts to end HIV in the state.

The End HIV Oregon website states that the state vision is "100% of Oregonians taking HIV medications achieve the health goal of being virally suppressed," and lists the noteworthy accomplishment of the state in achieving viral suppression among 82 percent of Oregonians with HIV.<sup>21</sup> The End HIV Oregon 2020 Progress Report,<sup>22</sup> explains more about the state's successful efforts in this area, stating:

Oregon's Early Intervention Services & Outreach (EISO) Program has improved treatment outcomes for people newly diagnosed with HIV: 79% of people newly diagnosed with HIV are now linked to HIV medical care in 30 days or less through EISO compared to only 66% before the program started. The median days to viral load suppression among EISO clients newly diagnosed with HIV was 57.5 days, a result that likely contributed to Oregon reaching its 5-year goal of having 55% of all newly diagnosed Oregonians achieve viral suppression within 90 days (see metrics). We have now increased the goal to 65%.

These accomplishments will be put in jeopardy if antiretrovirals and the other necessary medications utilized by people with HIV are subjected to a closed formulary.

<sup>19</sup> Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017). HIV Surveillance Special Report 21. Revised edition. June 2019, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-21.pdf> (Accessed February 2021)

<sup>20</sup> Oregon.gov, *Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver, "Oregon 2022-2027 Medicaid 1115 Demonstration Application,"* [https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf?utm\\_medium=email&utm\\_source=govdelivery](https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf?utm_medium=email&utm_source=govdelivery), (Accessed December 15, 2021)

<sup>21</sup> End HIV Oregon, <https://www.endhivoregon.org/#end-hiv-2> (Accessed December 15, 2021)

<sup>22</sup> Oregon.gov, End HIV Oregon, "End HIV Oregon 2020 Progress Report" [https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA\\_EndHIV\\_2020ProgressReport+FINAL.pdf](https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA_EndHIV_2020ProgressReport+FINAL.pdf) (Accessed December 15, 2021)

Open access to antiretroviral therapies is important for people with HIV to achieve viral suppression and maintain wellness. Effective treatment of HIV not only improves the health outcomes of people with HIV, but also can prevent transmission of HIV to others. When a person with HIV receives and maintains effective HIV treatment and receives quality medical care, they can reach viral suppression. Viral suppression means that the virus has been reduced to an undetectable level in the body with standard tests.<sup>23</sup> Viral suppression results in reduced mortality and morbidity and leads to fewer costly medical interventions.<sup>24</sup>

Viral suppression also helps to prevent new transmissions of the virus. When successful treatment with an antiretroviral regimen results in virologic suppression, secondary HIV transmission to others is effectively eliminated. The National Institute of Allergy and Infectious Diseases (NIAID) supported research that demonstrated when people with HIV achieve and maintain viral suppression, there is no risk scientifically of transmitting HIV to their HIV-negative sexual partner.<sup>25</sup> Multiple subsequent studies also showed that people with HIV on ART who had undetectable HIV levels in their blood, had essentially no risk of passing the virus on to their HIV-negative partners sexually.<sup>26, 27</sup> As a result, the CDC estimates viral suppression effectiveness in preventing HIV transmission at 100 percent.<sup>28</sup>

Reduced transmissions not only improve public health, but also saves money. Preventing new transmissions offers a substantial fiscal benefit to the state. It is estimated people with HIV who are not retained in medical care may transmit the virus to an average of 5.3 additional people per 100-person years.<sup>29</sup> A recent study of commercially insured people with HIV compared to individuals without HIV found that mean all-cause costs were almost seven times higher in those with HIV, culminating in an average discounted incremental cost of \$850,557 in cumulative costs from ages 25-69.<sup>30</sup> Successful treatment with an antiretroviral regimen results in virologic suppression and virtually eliminates secondary HIV transmission to others. As a result, it is possible to extrapolate that successful HIV treatment and medical care of each infected patient may save the system up to \$4.5 million by preventing further transmission to others. These savings can only occur if people with HIV have access to medical care, receive treatment, and remain adherent to their prescribed therapy.

Subjecting antiretrovirals to a closed formulary is not consistent with clinical guidelines for HIV treatment. We encourage the state of Oregon to cover all antiretrovirals in alignment with the DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV (DHHS Guidelines), as some innovations in time release, active ingredient, or dosage forms may provide benefit to patients in staying adherent to treatment regimens.

For people with HIV, adherence to antiretroviral medication is paramount in maintaining health, avoiding viral resistance, and preventing medical complications and co-morbidities.<sup>31,32</sup> Nonadherence – or

---

<sup>23</sup> National Institutes of Health (NIH) "Ten things to Know about HIV Suppression" <https://www.niaid.nih.gov/diseases-conditions/10-things-know-about-hiv-suppression>, (Accessed August 27, 2021)

<sup>24</sup> "Retention in Care and Adherence to ART are Critical Elements of HIV Care Interventions," Stricker, et al, AIDS and Behavior, October 2014, Volume 18, Supplement 5, pp 465–47.; <https://link.springer.com/article/10.1007/s10461-013-0598-6>

<sup>25</sup> [HIV Undetectable=Untransmittable \(U=U\), or Treatment as Prevention | NIH: National Institute of Allergy and Infectious Diseases](https://www.niaid.nih.gov/diseases-conditions/hiv-undetectable-untransmittable-u-u-or-treatment-as-prevention) (Accessed June 21, 2021)

<sup>26</sup> Bavinton, et al. The Opposites Attract Study of viral load, HIV treatment and HIV transmission in serodiscordant homosexual male couples: design and methods. BMC Public Health. 2014; 14: 917. doi: [10.1186/1471-2458-14-917](https://doi.org/10.1186/1471-2458-14-917).

<sup>27</sup> Cohen, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. September 1, 2016. N Engl J Med 2016; 375:830-839. <https://www.nejm.org/doi/10.1056/NEJMoa1600693> (Accessed August 27, 2021)

<sup>28</sup> Centers for Disease Control and Prevention (CDC) "Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV" <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html> Accessed September 20, 2019.

<sup>29</sup> Skarbinski, et al. Human immunodeficiency virus transmission at each step of the care continuum in the United States. *JAMA Intern Med.* 2015;175(4):588-596, (Accessed August 27, 2021)

<sup>30</sup> Cohen JP, et al. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. *PharmacoEconomics - Open* (2020) 4:687–696. <https://doi.org/10.1007/s41669-020-00209-8>, (Accessed August 27, 2021)

<sup>31</sup> Chesney MA. The elusive gold standard. Future perspectives for HIV adherence assessment and intervention. *J Acquir Immune Defic Syndr.* 2006;43 Suppl 1:S149-155, <http://www.ncbi.nlm.nih.gov/pubmed/17133199>.

<sup>32</sup> HRSA, Guide for HIV/AIDS Clinical Care (April 2014), <https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf>. Accessed October 13, 2017.

skipping HIV medicines – may lead to drug-resistance, and reduce or eliminate the effectiveness of treatment with some HIV medicines.<sup>33</sup> Due to the individualized nature of HIV treatment, it is important that treatment decisions not be subject to management processes which run the risk of disrupting established treatment regimens. A review of 29 studies evaluating the impact of non-medical switching (the practice of switching to a chemically distinct but similar medicine for reasons other than lack of clinical efficacy/response) found that among patients with stable, well-controlled disease switching led to poor side effects or nonadherence and was associated with mostly negative outcomes.<sup>34</sup> In one study, people with HIV who faced drug benefit design changes were found to be nearly six times more likely to face treatment interruptions than those with more stable coverage, which can increase virologic rebound, drug resistance, and increased morbidity and mortality.<sup>35</sup>

Health care providers work closely with patients to select HIV treatment options with great specificity for each patient. People with HIV often face a variety of medical challenges that impede access to, retention in, and adherence to HIV care and treatment. PLWH rely on open formularies because the effective treatment of HIV is highly individualized and accounts for a patient's size, gender, treatment history, viral resistance, coexisting illnesses, drug interactions, immune status, and side effects. In fact, the DHHS Guidelines<sup>36</sup> state that, “[r]egimens should be tailored for the individual patient to enhance adherence and support long-term treatment success.”<sup>37</sup> The guidelines also recognize that “[s]election of a regimen should be individualized based on virologic efficacy, potential adverse effects, childbearing potential and use of effective contraception, pill burden, dosing frequency, drug-drug interaction potential, comorbid conditions, cost, access, and resistance test results.”<sup>38</sup> Patients often respond differently to the same drug. Even drugs in the same class can have different side-effect profiles, with some patients best suited to one particular drug.

For these reasons, ViiV encourages the state to protect antiretrovirals from a closed formulary under this demonstration proposal as doing so would directly work against the state's own End HIV Oregon efforts, and against national efforts to end the HIV epidemic.

**b. ViiV Supports the Protection of Access to Antiretrovirals for HIV Prevention (PrEP) Within Medicaid**



ViiV supports coverage of pre-exposure prophylaxis (PrEP) to all at-risk populations. We urge the state to advance goals related to the EHE Initiative through working with the state to also provide counseling and education related to HIV prevention, specifically HIV PrEP.

According to DHHS, of the approximately 1.2 million people in the U.S. indicated for PrEP, only 18 percent are receiving it.<sup>39</sup> Again, in Oregon the state's PrEP coverage ratio was only 17.2 percent in

---

<sup>33</sup> AIDS Info, HIV Treatment Fact Sheet (March 2, 2017), <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/56/drug-resistance>. Accessed October 13, 2017.

<sup>34</sup> Nguyen E, Weeda E, Sobieraj D, et al. Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review. *Current Medical Research and Opinion*. 2016;32(7):1281-1290. Accessible at <https://www.ncbi.nlm.nih.gov/pubmed/27033747>.

<sup>35</sup> Das-Douglas, Moupali, et al. "Implementation of the Medicare Part D prescription drug benefit is associated with antiretroviral therapy interruptions." *AIDS and Behavior* 13.1 (2009): 1-9

<sup>36</sup> DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines> (Accessed December 17, 2021).

<sup>37</sup> Id.

<sup>38</sup> Id.

<sup>39</sup> National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025, page 1, <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>, (Accessed August 27, 2021)

2019 according to CDC.<sup>40</sup> Making PrEP available and accessible is an important step in reducing the number of new HIV diagnoses and ultimately ending the HIV epidemic.

Making PrEP available and accessible is also a key part of health equity initiatives. The HIV epidemic continues to have a disproportional impact on some communities. PrEP has the potential to address HIV specific disparities and, possibly, other disparities in health care. For instance, studies have shown a correlation between increased PrEP uptake and decreases in new HIV diagnoses in the U.S., and PrEP use is also associated with increased engagement in ongoing health care.<sup>41</sup> However, disparities in PrEP usage persist. Research from the Infectious Diseases Society of America has shown that despite equal levels of willingness to use PrEP between Black and White men who have sex with men (MSM), PrEP use was significantly higher among White MSM.<sup>42</sup> Inequities in access to PrEP across populations at high-risk have led to increasing disparities in HIV incidence, transmission, and viral suppression. Therefore, it is crucial to address disparities in PrEP uptake in order to address greater disparities present within the HIV epidemic.

The End HIV Oregon website states that the state vision is “100% of Oregonians most in need of PrEP, a daily pill to prevent HIV, have access to it.”<sup>43</sup> The End HIV Oregon 2020 Progress Report<sup>44</sup> shows significant success by the state on PrEP access, noting people living in all 36 Oregon counties have access to PrEP navigation services. Navigators can link new PrEP users to more than 350 Oregon medical providers listed on the PrEP directory, including 30 new providers in rural and frontier communities.<sup>45</sup>

These accomplishments will be put in jeopardy if antiretrovirals and the other necessary medications utilized by people with HIV are subjected to a closed formulary. The demonstration proposal therefore works against the state’s own End HIV Oregon efforts, and against national efforts to end the HIV epidemic.

### c. Precedent of Antiretroviral protection

We urge the state to further protect access to antiretrovirals for both HIV treatment and prevention within any policy initiative, including this demonstration. The state has previously cited a policy that is utilized to protect access to antiretrovirals (ARV) within Medicaid, (Attachment A: “Recommendations Of Drug Use Review / Pharmacy And Therapeutics Committee August 2015,<sup>46</sup>) which states:

#### HIV Class Review / Drug Use Evaluation

The Committee recommended creating a voluntary Preferred Drug List (PDL) class for HIV antiretroviral drugs and combination products and to designate all drugs as preferred at this time. The Committee directed staff to work with established, high Medicaid volume HIV clinics to



<sup>40</sup> CDC.gov, “Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2019”, (Table 9b): <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf> (Accessed October 27, 2021)

<sup>41</sup> National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025, page 19-20, <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>, (Accessed August 27, 2021)

<sup>42</sup> Avalere Health, “PACHA Highlights Need to Address HIV PrEP Coverage Disparities,” <https://avalere.com/insights/pacha-highlights-need-to-address-hiv-prep-coverage-disparities>, (Accessed August 27, 2021)

<sup>43</sup> End HIV Oregon, <https://www.endhivoregon.org/#end-hiv-2> (Accessed December 15, 2021)

<sup>44</sup> Oregon.gov, End HIV Oregon, “End HIV Oregon 2020 Progress Report”

[https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA\\_EndHIV\\_2020ProgressReport+FINAL.pdf](https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA_EndHIV_2020ProgressReport+FINAL.pdf) (Accessed December 15, 2021)

<sup>45</sup> Oregon.gov, End HIV Oregon, “End HIV Oregon 2020 Progress Report”

[https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA\\_EndHIV\\_2020ProgressReport+FINAL.pdf](https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA_EndHIV_2020ProgressReport+FINAL.pdf) (Accessed December 15, 2021)

<sup>46</sup> Oregon Health Authority, Office of the Director, Official Website Notice, [www.health.oregon.gov](http://www.health.oregon.gov) “RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE,” Posting Date: August 27, 2015

try to identify ARV regimens with broad tolerability and high viral response rates in most patients and that have favorable or equivalent comparative price (preferred) and try to identify ARV regimens with common tolerability problems or lower viral response rates in most patients and with an unfavorable comparative price (non-preferred).<sup>47</sup>

Although we applaud this provision, we do not believe it would be sufficient to protect access to ART under the closed formulary proposed in this demonstration. We do not support a closed formulary within Medicaid; however, if the state intends to move forward with pursuit of a closed formulary and this demonstration, we urge the state to encapsulate this protection as a clearly stated provision within this demonstration – a carve out of HIV antiretrovirals from the closed formulary.

Although we are categorically opposed to closed formularies in Medicaid, we wish to draw the state's attention to a recent policy precedent set by another state pursuing more control over its Medicaid formulary. Recently the state of Tennessee proposed a closed formulary within its "TennCare III" demonstration. The demonstration created a closed formulary in the state but contained a provision which requires coverage of "substantially all" antiretroviral drugs in accordance with Medicare Part D coverage rules. It also further extended Part D coverage protection to also include required coverage of antiretroviral drugs when used for PrEP.<sup>48</sup> It stated:

The formulary must comply with: ... 2) the "substantially all" Part D coverage rules for antidepressants, anticonvulsants, antipsychotics, immunosuppressants, antineoplastics, and antiretroviral drugs (including PrEP).<sup>49</sup>

Although ViiV opposed the creation of closed formulary within the Tennessee Medicaid program, and provided public comments in opposition of the demonstration to both the state and to CMS, ViiV highly supports policy efforts to bring Medicare Part D-like protections into Medicaid.

Within the Medicare Part D program, antiretrovirals are a protected drug class. Therefore, substantially all antiretroviral drugs must be included in formularies. Furthermore, within the Medicare Part D program, antiretrovirals are not subject to utilization management. The Medicare Prescription Drug Benefit Manual states:

"For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models."<sup>50</sup>

CMS set a policy precedent at the federal level for efforts to create Part D-like protections for antiretrovirals in Medicaid, in their guidance around the Healthy Adult Opportunity waiver. In 2020, CMS declared support for applying the Medicare Part D protected classes protection for HIV treatment to the Medicaid program in guidance, stating:<sup>51</sup>

In addition, to ensure that this demonstration supports CMS's objectives related to the treatment of HIV... CMS expects states to provide coverage of...

---

<sup>47</sup> Oregon Health Authority, Office of the Director, Official Website Notice, [www.health.oregon.gov](http://www.health.oregon.gov) "RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE," Posting Date: August 27, 2015

<sup>48</sup> Tennessee, approved TennCare III demonstration, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tn-cms-aprvl.pdf> (Accessed September 1, 2021)

<sup>49</sup> Tennessee, approved TennCare III demonstration, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tn-cms-aprvl.pdf> (Accessed September 1, 2021)

<sup>50</sup> CMS.gov "Prescription Drug Benefit Manual," Chapter 6, "Part D Drugs and Formulary Requirements," Section 30.2.5, "Protected Classes," <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals>. (Accessed Dec 20, 2021)

<sup>51</sup> Medicaid.gov, SMD# 20-001, Re: Healthy Adult Opportunity SMD, January 30, 2020: <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>. Accessed July 8, 2020.

substantially all antiretroviral drugs (including PrEP) consistent with Medicare Part D coverage...<sup>52</sup>

We urge the state to consider supporting policies to protect open access to antiretroviral drugs in Medicaid, similar to the protections found in Medicare Part D, and to also support extension of this protection to antiretroviral drugs utilized for PrEP.

**d. A Closed Formulary May Also Have Negative Impact on People with HIV's Ability to Manage Comorbidities**

In general, proposals related to closed formularies or to therapeutic drug class limitations are specifically problematic for people with HIV. Medical challenges for people with HIV include an increased risk for, and prevalence of, comorbidities that require additional drug treatment such as depression and substance use disorders, as well as cardiovascular disease, hepatic and renal disease, osteoporosis, metabolic disorders, and several non-AIDS-defining cancers.<sup>53,54,55,56</sup> The most common non-infectious co-morbidities of HIV are hypertension, hyperlipidemia, and endocrine disease.<sup>57</sup> Thus, people with HIV must have access to a robust formulary that provides physicians with the ability to prescribe the right treatments at the right time for their patients.

Aging people with HIV often experience non-HIV related comorbidities<sup>58</sup> that require polypharmacy which can increase risk for drug-drug interactions. In 2018, over half (51 percent) of people in the U.S. living with diagnosed HIV were aged 50 and older.<sup>59</sup> Polypharmacy is common in older patients with HIV; therefore, there is a greater risk of drug-drug interactions between antiretroviral drugs and concomitant medications. Clinically significant drug interactions have been reported in 27 to 40 percent of HIV patients taking antiretroviral therapy requiring regimen changes or dose modifications.<sup>60,61</sup> Potential for drug-drug interactions should be assessed regularly, especially when starting or switching antiretroviral therapy and concomitant medications.<sup>62</sup>

Therefore, we urge the state to discard its pursuit of a closed formulary, as it may have a negative impact on the health and wellness of people with HIV.

**e. We Oppose the Violation of OBRA 90**



<sup>52</sup> Medicaid.gov, SMD# 20-001, Re: Healthy Adult Opportunity SMD, January 30, 2020 (Page 9):

<https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>, Accessed July 8, 2020

<sup>53</sup> CDC. Behavioral and Clinical Characteristics of Persons Receiving Medical Care for HIV Infection. Medical Monitoring Project United States, 2013 Cycle (June 2013–May 2014). HIV Surveillance Report 16. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-hssr-mmp-2013.pdf>

<sup>54</sup> Joel Gallant, Priscilla Y Hsue, Sanatan Shrey, Nicole Meyer; Comorbidities Among US Patients With Prevalent HIV Infection—A Trend Analysis, *The Journal of Infectious Diseases*, Volume 216, Issue 12, 19 December 2017, Pages 1525–1533,

<https://doi.org/10.1093/infdis/jix518>

<sup>55</sup> Rodriguez-Penney, Alan T. et al. "Co-Morbidities in Persons Infected with HIV: Increased Burden with Older Age and Negative Effects on Health-Related Quality of Life." *AIDS Patient Care and STDs* 27.1 (2013): 5–16. PMC. Web. 21 June 2018.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3545369/>

<sup>56</sup> Joint HHS, CMCS, HRSA, and CDC Informational Bulletin, Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries, p. 9 (December 1, 2016), <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf> (Accessed September 8, 2021).

<sup>57</sup> Joel Gallant, Priscilla Y Hsue, Sanatan Shrey, Nicole Meyer; Comorbidities Among US Patients With Prevalent HIV Infection—A Trend Analysis, *The Journal of Infectious Diseases*, Volume 216, Issue 12, 19 December 2017, Pages 1525–1533,

<https://doi.org/10.1093/infdis/jix518>

<sup>58</sup> Schouten J, et al. Cross-sectional comparison of the prevalence of age-associated comorbidities and their risk factors between HIV-infected and uninfected individuals: the AGEHIV cohort study. *Clin Infect Dis*. 2014 Dec 15;59(12):1787-97.

<sup>59</sup> "HIV and Older Americans," CDC, <https://www.cdc.gov/hiv/group/age/olderamericans/index.html>

<sup>60</sup> Evans-Jones JG et al. Recognition of risk for clinically significant drug interactions among HIV-infected patients receiving antiretroviral therapy. *Clin Infect Dis* 2010;50:1419–1421

<sup>61</sup> Marzolini C et al. Prevalence of comedications and effect of potential drug-drug interactions in the Swiss HIV Cohort Study. *Antivir Ther* 2010;15:413–423.

<sup>62</sup> DHHS guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. August 16, 2021.. Accessible at <https://aidsinfo.nih.gov/guidelines> (Accessed September 8, 2021)

Under the Medicaid Drug Rebate Program (MDRP), drug manufacturers pay rebates on Medicaid utilization of their products in return for state Medicaid programs covering their products, subject only to certain “permissible restrictions” listed in the statute.<sup>63,64</sup> The proposed demonstration violates these coverage requirements by establishing a closed formulary that may include only one drug in each therapeutic class. This does not comply with the rebate statute’s more patient-protective formulary standards. The case *PhRMA v. Thompson* held that the statute (SSA § 1115) does not authorize waivers of the Medicaid Drug Rebate Program laws.<sup>65</sup>

Even if a waiver of the rebate statute were permitted, waiving its coverage requirements alone (without waiving the requirements for manufactures to pay rebates) would violate the legislative bargain reflected in the rebate statute. As CMS has explained: [The Medicaid rebate statute] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.<sup>66</sup>

The rebate statute’s legislative history<sup>67</sup> also emphasizes that the statute links manufacturer rebate obligations and Medicaid coverage obligations. Congress required states to cover all products of a manufacturer with a Medicaid rebate agreement (with specified exceptions), to ensure beneficiary access to the full range of drugs that are available to private patients. The statute purposely coupled the rebate requirements on manufacturers with the coverage requirements on states; it was described by Congressman Henry Waxman, a key sponsor, as a “government-industry compact.”<sup>68</sup>

Thus, the state of Oregon cannot retain the mandatory rebate for some classes and have a closed formulary for others. For further indications of this, we refer the state of Oregon to review the decisions previously made by CMS in response to a similar proposal from Massachusetts in 2018.<sup>69</sup>

## Conclusion

Thank you for your consideration of these comments. We hope that the state will continue it work to end the HIV epidemic in Oregon, and support national efforts to do the same.

Sincerely,



Kristen Tjaden  
Government Relations  
ViiV Healthcare

---

<sup>63</sup> SSA § 1927(d)(1)(B))

<sup>64</sup> Medicaid rebates for covered outpatient drugs, codified at 42 U.S.C. § 1396r-8

<sup>65</sup> *PhRMA v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001)

<sup>66</sup> 78 Fed. Reg. 4594, 4631 (Jan. 22, 2013)

<sup>67</sup> H. Rpt. 101-881, 101st Congress, 2d Session (Oct. 16, 1990)

<sup>68</sup> Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce, H. Hrg. 103-61, 103rd Cong. 453 (1993) (statement of Rep. Waxman).

<sup>69</sup> CMS letter to Daniel Tsai, Assistant Secretary, MassHealth, June 27, 2018

**From:** [Wendy Chan](#)  
**To:** [1115 Waiver Renewal](#)  
**Subject:** Letter of Support  
**Date:** Wednesday, January 5, 2022 8:15:08 AM

---

You don't often get email from wendykchan03@gmail.com. [Learn why this is important](#)

**Think twice** before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Health Policy and Analytics Medicaid Waiver Renewal Team Attn: Michelle Hatfield

Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Oregon Health Plan 1115 Demonstration Waiver Application for Renewal

Dear Ms. Hatfield:

Thank you for this opportunity to provide comments as the Oregon Health Plan (OHP) applies to the Centers for Medicare & Medicaid Services (CMS) for a new five-year Medicaid waiver, known as the 1115 Demonstration.

My 14 year old son Blake is autistic. This year, Blake grew 10 inches and 70 lbs and became adult sized. Blake can be aggressive. This fall we had to call 911 multiple times, Blake has lived in the ER for two 1 week periods, he has had two 2 month stays in psych wards in UCLA and now at Unity where they wanted to discharge Blake last week even though he attacked staff where they were left bleeding (and Blake was bleeding), multiple times in the 48 hours prior to discharge. When I refused to pick up Blake, they called DHA.

Multiple agencies are involved now and trying to help but the bottom line is that Oregon has no place for Blake – neither from a medical treatment facility nor a residential or therapeutic facility. I am left desperately searching for a placement where Blake can be safe and those are out of state.

Blake needs inpatient ABA and there is no place he can receive this in Oregon. This urgent and required care should be covered by his Medicaid insurance. We are trying our best to take care of our son and other siblings, but Oregon as a state has failed in supporting Blake. We have no where to turn and need to go out of state for his continued care. Blake spent 2 months at UCLA Resnick Psychiatric Hospital this summer.

Blake does not want to do any of these harmful behaviors. He is completely remorseful and feels terrible whenever he is in a rage. He pleads with me to ask me when this behavior will stop. It's heartbreaking. But he feels a compulsion to do it, or he cannot control his rage when some small random thing does not go as he expected.

Also, medical companies have refused to transport Blake because of a new Oregon law that comes into effect today - SB 710. So even if Blake gets into these out of state facilities, I don't know how I will transport him there.

To this end, I recommend as follows:

**1. Full Compliance with EPSDT**

**The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.**

**2. Prohibit the Use of Discriminatory QALY Measures**

**The waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, such as this:**

**“Prohibition on Reliance on Discriminatory Measures. The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per- quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”**

**3. Non-discrimination in Suicide Prevention Services**

**The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for lethal drugs under Oregon’s “Death with Dignity Act,” will be provided with the same harm and suicide prevention services<sup>7</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to die by**

**suicide because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.**

Sincerely,  
Wendy K Chan



BOARD OF COUNTY COMMISSIONERS

511 Washington St, Ste. 101 • The Dalles, OR 97058  
p: [541] 506-2520 • f: [541] 506-2551 • www.co.wasco.or.us

*Pioneering pathways to prosperity.*

To: Health Policy and Analytics Medicaid Renewal Team  
Attention: Michelle Hatfield

Re: 2022-2027 Medicaid 1115 Demonstration Application

Wasco County appreciates the opportunity to provide written testimony during the public comment period for the 2022-2027 Medicaid 1115 Waiver. Wasco County has been involved with the Columbia Gorge Health Council as a founding member of the regional Coordinated Care Organization. Many of the strategies focused in the current application reflect our local priorities of improving the wellness of OHP members across their continuum of coverage.

Specifically, Wasco County has been active in working with local public safety system to ensure that both adults and youth have access to services during time of incarceration in the local jail and detention facilities. We support the focus throughout the application on equity and ensuring the most vulnerable populations are able to access the full continuum of care.

We strongly support **Section 3.2 Improving Health Outcomes by Streamlining Life and Coverage Transitions**. Through collaboration with our Local Public Safety Coordinating Council and the Columbia Gorge Health Council a study was completed that identified the overlap of the high levels of Emergency Department usage and reoccurring instances for short incarceration stints. One of the key findings was the disruption in coverage and lack of access to both medication and primary care.

Recommendation for inclusion the term "local juvenile detention facility" in this section under "a) Retain benefits and/or extend full OHP Plus Medicaid benefits to all youth otherwise eligible for Medicaid upon entering the juvenile correction system throughout the duration of their involvement in juvenile corrections". This simple change in language mirrors the reference to jails and local correction facilities.

The section recommendation would be to add the reference in the section "d) Members (adults and youth) transitioning out (within/out) of the criminal justice system and juvenile justice system".

Respectfully,  
Wasco County Board of Commissioners

  
Kathleen B. Schwartz, Chair

  
Steven D. Kramer, Vice-Chair

  
Scott C. Hege, County Commissioner

January 7, 2022

Patrick Allen, Director  
Oregon Health Authority  
500 Summer Street, NE, E-20  
Salem, OR 97301

Subject: Response to Oregon's 1115 CMS Waiver Request

Dear Director Allen,

We write to you on behalf of the Willamette Health Council, the governing body to PacificSource Marion-Polk CCO. Our Community Advisory Council (CAC), which is comprised of local Medicaid members, representatives from local Community Based Organizations, County Health and Human Services Agencies, and local clinical organizations, offers the following feedback on Oregon's 1115 CMS Waiver proposal taking effect in 2022.

First and foremost, we would like to acknowledge and commend the Oregon Health Authority's goals regarding the topics of health equity and social determinants of health in your 1115 waiver proposal. The Willamette Health Council, including the Community Advisory Council, feel strongly that public policy and public resources must target these topics in order to create a healthcare and social care systems that meets the unique needs of *all* Oregonians. It is clear to us that OHA understands the importance of creating a system that is designed to address these priorities. We also believe it is important to recognize and respect the unique structures of local healthcare and social care delivery systems. The concept of focused equity investments would provide transformative financial support for the most marginalized community members across the Marion-Polk region, and the rest of the state; however, our CAC raised concern that the creation of Community Investment Collaboratives (CICs) may be redundant to the Willamette Health Council's existing role in which the CAC distributes funding for local initiatives. To have all three committee structures (Community Advisory Councils, Regional Health Equity Coalitions, and Community Investment Collaboratives), as one community member candidly expressed, would be "too many chefs in the kitchen" and ultimately lead to confusion as to how to get funding into the hands of those who truly need it.

For the past two years, the Willamette Health Council's CAC has worked diligently to invest Community Benefit Initiative resources into projects that align with the priorities identified in our Community Health Assessment and Community Health Improvement Plan. In addition to our CAC, the Willamette Health Council administers a Clinical Advisory Panel comprised of local healthcare professionals dedicated to improving the quality of healthcare services in the Marion/Polk community. The Willamette Health Council also administers a Community Impact Committee that addresses health and social care barriers by making investments in both clinical and community-based organizations. Equity has been a core value for each of these committees whenever investments are considered. *Will our unique community infrastructure be expected to build duplicative models in order to meet OHA's prescribed policy, or must we dismantle our current successful model and replace it with something new?*

Additionally, we would like to express concern with the heightened participatory expectations of Medicaid consumer members in the focused equity investment process. While their involvement is paramount to equitable and inclusive decision-making, we risk taking their input for granted without appropriate compensation for additional time commitment. For example, the Willamette Health

Council's CAC consumer members spend many hours throughout the year reviewing local funding proposals and are offered compensation at the allowable \$25.00 hourly stipend. These stipends, however, may ultimately impact their OHP eligibility according to income threshold. This presents a catch-22 with no safety net: consumer members can deny stipends and essentially volunteer their time with the CAC without incentive, or, they can risk their personal and family's health by accepting stipends and possibly losing their health insurance coverage entirely. Furthermore, the OHA Transformation Center has declined to offer financial literacy education to consumer members about how stipends could impact their OHP status. CAC consumer members should be reimbursed for their time without jeopardizing their eligibility for benefits, especially when OHA increasingly mandates their participation on local CCO committees. By expecting CAC members to dedicate more of their time and energy to reviewing focused equity investments, we undermine the trust of local community members who rely on us to keep them safe and healthy.

We look forward to hearing from OHA on how these concerns will be addressed during the 2022-2027 Waiver implementation period. Thank you for your time and for considering our feedback.

Sincerely,

**Lisa Lilloco (she/her)**, Community Advisory Council Co-Chair and OHP Consumer Member

**Rachel Lakey (they/she)**, Community Advisory Council Program Manager, Willamette Health Council

**Justin Hopkins (he/him)**, Executive Director, Willamette Health Council



January 4, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Ms. Hatfield:

Re: Comments in Support of Medicaid 1115 Demonstration Application

Willamette Partnership supports the Medicaid 1115 Demonstration Application because it advances equitable health investments and community-driven health values. In particular, the [Focused Equity Investments](#) are an opportunity for Oregon to champion community-led investments that address social determinants of health. We know that zip code impacts health outcomes, and increasing access to green space, job opportunities, education, housing, etc. in addition to quality health care coverage is a critical step towards equitable health for all communities. Due to a long history of racialized policies, [race continues to be the strongest predictor of someone being exposed to environmental health hazards](#), and focusing on priority communities begins to repair past discrimination and exclusion from health investment decisions.

Past investments in health and social infrastructure have often been deeply inequitable in their benefits, costs, and negative impacts. For the communities that live with these inequities - Black, Indigenous, and people of color (BIPOC), low-income, and rural communities, as well as older people and people with disabilities - historical social infrastructure disinvestment has led to critical failures, undermining public health, community resiliency, and economic development. The new Medicaid waiver allows for community agency and flexibility, giving impacted communities the room and power to identify and determine where investments need to be made to improve community health.

We believe in moving healthcare money into community hands, where investing in natural spaces is an option. This is particularly important in a changing climate, where natural infrastructure needs to be incorporated into built infrastructure so that our communities are climate-ready and more resilient to fires, flooding, and water quality and quantity issues. The 1115 Demonstration Application will move money to community wellness programs and communities can choose to invest in green spaces and natural infrastructure as one option among many. We are hopeful that this opens up more pathways for natural infrastructure, green spaces, and outdoor recreation to treat mental health and substance use, as it is currently not accessible to all.

Willamette Partnership is looking to make real impacts in communities that improve health and environmental outcomes, especially for communities that have experienced inequities. The new approach to Medicaid can help strengthen new and existing community projects, create and strengthen cross-sectoral partnerships, increase capacity and technical assistance to community partners, and offer collaborative facilitation in projects at the intersection of health and the environment. For a stronger, healthier, and just future for Oregon, leaders should adopt the thoughtful Medicaid Waiver Renewal.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sara O'Brien', written in a cursive style.

Sara O'Brien  
Executive Director  
Willamette Partnership  
[obrien@willamettepartnership.org](mailto:obrien@willamettepartnership.org)

January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team

Attn: Michelle Hatfield

500 Summer St. NE, E65

Salem, OR 97301

Submitted via email: [1115Waiver.Renewal@dhsosha.state.or.us](mailto:1115Waiver.Renewal@dhsosha.state.or.us)

**RE: Oregon Section 1115 Waiver**

Dear Ms. Hatfield:

Kaiser Permanente appreciates the opportunity to submit comments on Oregon's Section 1115 Demonstration Waiver. Kaiser Permanente (KP) is the largest private integrated healthcare delivery system in the U.S., delivering health care to 12.4 million members in eight states and the District of Columbia.<sup>1</sup> To provide care and coverage to Oregon Health Plan (OHP) members, KP serves nearly 65,000 Oregonians as a delegated subcontractor to Health Share of Oregon in the Portland metro area and PacificSource in Marion and Polk counties, on a capitated basis. Kaiser Permanente also participates as a primary care provider under PacificSource in Lane County. Additionally, Kaiser Permanente is a delegated Dental Care Organization within the Health Share of Oregon network serving members in the Portland metropolitan area. Kaiser Permanente supports programs and policies that ensure all individuals have access to affordable, high-quality health care, and applauds OHA for its efforts to prioritize the impacts of health disparities, inequities, and social determinants of health (SDOH) for OHP beneficiaries. We support the creation of a more equitable health care system, and throughout this comment letter, we indicate our support of policies that eliminate or reduce health disparities.

Collaboration across Coordinated Care Organizations (CCOs), community organizations, and with state and county agencies will be critical to meeting Oregon's 2022-2027 waiver goals, including:

- Creating a more equitable, culturally- and linguistically- responsive health care system,
- Helping contain costs by providing quality health care,
- Investing in equitable and culturally appropriate health care, and
- Ensuring everyone can get the coverage they need.

As individuals and as organizations, our communities now more than ever during the global pandemic are being stretched to do more with their existing resources. Collectively we have a shared responsibility to improve community health, and a critical component of this goal is improving engagement across our communities. While we are supportive of most of the components of the OHA proposal, there are elements of the proposal that are of concern or require additional detail. Kaiser Permanente offers the following comments on the 1115 waiver proposal:

**Continuous Coverage:** Consistent with our support of universal coverage and our support of Cover All People, we applaud OHA's efforts to initiate continuous enrollment for children up to the age of 6 and transitioning youth. We also support OHA's proposal to implement two-year continuous eligibility for all OHP members. Continuous eligibility will keep people covered, mitigate churn, and allow members to access their providers for care without disruption. Kaiser Permanente has long supported access to coverage, including by providing subsidized coverage to thousands of Oregonians through our Charitable Health Coverage Programs, and working to bridge care when families move between payers and coverage

types. We will continue to support access to coverage and look forward to working with the state to fill gaps between Cover All People and those ineligible for subsidies on exchange.

**Global Budget and Rate Alignment:** Kaiser Permanente understands that OHA plans for CCO rates to be in alignment with their global budget for capitation increases. We respectfully request that CCOs be included in the rate setting process, and that federal actuarial soundness requirements continue to be a part of this alignment effort. This is particularly important in rating periods when plan rates increase more rapidly than the global budget. We could see such changes in upcoming rating periods as the long-term impacts of COVID and delays in treatment increase in prevalence.

**Expedited enrollment for SNAP enrollees:** We applaud OHA's proposal to allow for expedited enrollment in OHP because of existing SNAP enrollment. Kaiser Permanente supports efforts to connect SNAP members to Medicaid and other services/resources in the community. As part of Kaiser Permanente's enterprise-wide SNAP Enrollment Project, KP launched an intervention in Oregon to assess how we can optimally target, engage, and connect potential enrollees with application assistance provided by partner organizations. More than 20,000 KP members in Oregon and SW Washington received application support for this critical food security program. KP has a national Food for Life strategy that involves screening and deploying multiple interventions to address food insecurity among our members, including SNAP enrollment support, medically tailored meals, and partnerships with food distribution partners. We look forward to working with the CCO community and OHA to design this initiative.

**Quality:** The current draft of the OHP 1115 waiver notes that the quality strategy is forthcoming. As the state works through the structure of a future quality strategy, Kaiser Permanente offers the following comments about this effort:

Kaiser Permanente supports quality programs that bring transparency, encourage high quality care, timely access, and patient satisfaction developed for Medicaid, including public reporting on clinical outcomes and patient satisfaction. In all cases, we encourage OHA to use tested, national quality and access standards to support alignment with the broader health care community in the state. Further, we support efforts to ensure quality and access through equity-driven performance metrics. Key principles we encourage OHP to consider as the quality strategy is developed include:

1. **Limiting Complexity:** Using nationally endorsed measures (e.g., National Quality Forum, National Committee for Quality Assurance, Dental Quality Alliance) will limit complexity in tracking and reporting.
  - a. OHA should continue to adopt the specifications for nationally endorsed measures as they are and refrain from making state-specific revisions.
2. **Use Multipayer Measures:** We believe there should be alignment of measures across states and programs (e.g. Medicare, Medicaid, and Marketplace).
3. **Outcomes Over Process:** Measuring the outcomes and consumer satisfaction (CAHPS) with health plans and their delivery systems, and publicly reporting the results of those measurements is a strong incentive for plans and providers to improve the quality of the services they provide.
4. **Phased Implementation:** Changes to the existing quality measurement effort for OHP should be implemented thoughtfully, in phases:
  - a. Phase 1: Initial measurement and testing period
  - b. Phase 2: Public disclosure of performance
  - c. Phase 3: Implementation of quality incentive programs

5. **Focus on Disparities and Equity:** Particularly for Medicaid, quality measurement should focus on addressing disparities and prioritize health equity
  - a. The plan and provider community should be engaged to identify measures that will support reduction in disparities and improve health
  - b. For measures where OHA wants to incentivize CCOs and providers to address disparities in outcomes/quality within populations that have historically been marginalized, we recommend that OHA craft a thoughtful stakeholder engagement strategy with meaningful participation of members from these groups in advance to mitigate the risk of adverse consequences to these communities.
  - c. In cases where it is difficult to ascertain numerically whether interventions have been successful in impacting inequities in outcomes across specific populations (e.g. denominator is too small, interventions may take >1 year or more to demonstrate impact, etc.), we recommend that OHA seek qualitative data from CCOs to better understand the work CCOs have already undertaken to address the systems/processes/policies driving these inequities.
  - d. We support efforts to use nationally recognized dental measures for OHP members.
6. **Measures Should be Tested for Validity for the Medicaid Population:**
  - a. Measures that are new and impact a smaller number of members or for sub populations should be assessed at the CCO or plan level first, and then later used for community reporting and incentives.
7. **Plan Engagement and Transparency is Critical in the Development of the Measure Set:**
  - a. CCOs should be engaged in measure selection, the development of benchmarking, measurement period, weighting of measures.
  - b. As OHA has proposed that the measures for the incentive metrics program should be drawn from CMS's Core set of Medicaid measures, we advocate that OHA engage with CCOs and providers to develop and provide public comment to CMS well in advance of the selection of these measures for each program year.
  - c. In cases where OHA is incentivizing CCOs to address outcomes within populations where the denominator may be exceedingly small (e.g., specific race and ethnic groups, members with a disability, etc.), we encourage OHA to develop criteria that establishes the minimum denominator required for the CCO to be held accountable to meeting a target for the measure. If no minimum denominator is established for CCOs, we encourage OHA to provide guidance to CCOs regarding the establishment of value-based contracts for sub populations, given that the number of members attributed to health care agencies or similar systems for these populations may be extremely small.

**Advancing Equity, Social Needs, SDOH:** Kaiser Permanente is addressing social needs in a variety of ways. KP was instrumental in launching the largest Community Information Exchange (CIE) to date in Oregon. Connect Oregon (also known as Thrive Local within KP) brings partners across the region and state together in an online, searchable social services resource directory and community network that allows healthcare and social service providers to connect with each other and make closed-loop referrals. Connect Oregon already includes partners in 19 of 36 counties in Oregon and will be live in 35 of 36 Oregon counties in 2022. Connect Oregon allows KP and hundreds of other partners throughout the state to connect people to the programs that improve health outcomes.

Kaiser Permanente has also developed a variety of social health interventions over the past several years; examples include:

- Resource Access Centers- a dedicated partnership with Impact NW, a Portland-based social service organization. Impact NW Resource Access Specialists are co-located at KP medical clinics across the region to provide information and referrals to patients with social needs.
- Housing for Health- a variety of strategies and projects including Metro300, an investment of over \$5 million to address senior homelessness in the Portland metro area.
- Medical-Legal Partnerships- a new partnership with Legal Aid Society of Oregon will launch in early 2022 to provide dedicated services to KP patients facing housing-related legal issues.

Kaiser Permanente appreciates OHA's long history of and commitment to innovation in care delivery to better support OHP members through innovative models of care. As the state works through the waiver proposal, we note that over the period of the demonstration, the delivery of many of the social needs related programs will move from a fee for service model of care to a capitated design. Given this change, funding and operations will be critical to meeting the goals of the waiver as noted earlier. Many services proposed in this waiver request (e.g., climate supports, the coordination of transportation for evacuation) are not areas of current CCO competency, and will require the development of new partnerships, assessments, and community engagement. Further, defining eligibility for new services will be critical, including the development of rates and infrastructure to support these services as they are delivered. As we drive toward delivering equitable health outcomes, Kaiser Permanente is committed to incorporating race and ethnicity segmentation into all quality performance reporting. We support the use of social factors that impact health in this effort and look forward to working with the state to reduce variation in experience of care based on race and ethnicity. To accomplish this, we encourage OHA to use national standards and guidance for capturing, documenting, and using Social Determinants of Health (SDOH) and social needs data. We encourage the state to work with national partners to develop and fund open-source solutions to promote the secure exchange of SDOH data information among health and social service providers.

**Supporting Members During Life Transitions:** OHA proposes to develop and fund a defined set of SDOH transition services to support members in need during life transitions. These include a variety of transitions including people experiencing houselessness, people vulnerable to extreme weather events; people transitioning out of justice systems and behavioral health institutions, Youth with Special Health Care Needs (YSHCN) to the age of 26 and youth who are child welfare-involved and transitioning in and out of foster care homes.

Kaiser Permanente agrees that providing health care services and coordinated care during a serious life transition (corrections involvement) and critical life stage (youth, and often youth of color being over-represented), could improve lifelong health and save long-term costs across multiple systems. We however note that the implementation of this benefit set will take time for CCOs to build and manage these services. The CCOs should be included in the development of these benefits and rate structure. It is particularly critical that OHA and the CCOs have a common understanding of these services, the universe of providers available to offer them, as well as the methodology by which these will be factored into capitation and risk adjustment.

In sum, Kaiser Permanente supports efforts to expand and integrate services that are deeply rooted in evidence and support a broad scope of social needs including housing and food assistance, employment

supports and health-related transportation, but request that the state work with CCOs to determine the eligibility, provider type and enrollment processes, network adequacy, rates, and other administrative processes to deliver these services to this group of members. CCOs and community organizations will need time to implement this effort. We encourage OHA to work with CCOs and community providers to develop realistic timelines for these services to be integrated into the CCO model.

**Coverage for Evidence-Based Prescription Drugs, Single Closed Pharmacy Formulary:** OHA proposes to adopt a commercial-style closed formulary approach for adult members, including at least a single drug per therapeutic class. In addition, the waiver application seeks to waive the federal Medicaid requirement for states to cover all drugs approved by the Food and Drug Administration (FDA).

We support efforts to prioritize patient access to clinically proven, effective drugs, and believe that plans and providers are best positioned to exercise discretion about which drugs should be covered, particularly in cases when there is limited or inadequate clinical efficacy. We support reforms that address the root causes of the high cost of prescription drugs and endorse efforts allowing insurers to use their power as part of the health care system to drive investment toward therapies that provide the greatest benefit for patients. We welcome the opportunity to work with OHA and the CCO community to allow the plans/providers to design programs that support their members best and offer flexibility to cover drugs that best meet the needs of the members, including the use of generic drugs.

Kaiser Permanente strongly opposes the use of a single closed formulary, and requests that OHA make the use of the statewide formulary optional for entities like KP that already have in place a robust, clinically driven, cost-effective formulary.

The Kaiser Permanente integrated model of care allows for an innovative approach to prescription drug coverage and purchasing for our members. At KP, we begin with teams of expert physicians and clinical pharmacists who collaborate to evaluate each medication's clinical value and safety. To conduct evaluations, we look to evidence both from published clinical trials as well as from our own electronic health record system where we can determine how well different medications perform among our members. Conducting these evaluations is the first step in developing cutting-edge, evidence-based formularies in-house, in a process led by clinicians who understand our patients' needs. Beginning with this rigorous approach ensures physicians and other clinicians can prescribe medications that work best for our patients.

Once we have conducted the initial evaluations, Kaiser Permanente's pharmacist contracting team works directly with drug manufacturers to negotiate drug prices. Our contracting efforts are focused on assuring that our purchases are receiving the best possible value for their dollar, especially when competing medications that perform similarly are available. Our pharmacy contracting team actively seeks to negotiate contracts prior to generic drug availability to ensure optimal access for our members to new generic drugs.

Our clinicians consistently prescribe according to our formulary guidelines with these factors in mind:

- **Trust in our evidence-driven, clinician-led approach:** Our prescribers trust our formularies because they know they are grounded in clinical evidence and built-in partnership with their expert colleagues. The evaluation of drugs for any disease or condition is led by both pharmacists and specialists in our medical groups who focus on treating that disease or condition. Drugs are placed on the KP formulary based on their efficacy and safety. Not only is this good medicine but choosing the most efficacious

drug the first time reduces downstream costs by ensuring positive outcomes, minimizing extra visits to the doctor or hospital, and eliminating prescription change costs.

- **Single integrated system:** Our integrated model allows us to be more efficient in making purchasing and prescribing decisions. Our providers are members of a single community and we use a common clinical infrastructure and electronic health record system, which makes it easier to share reliable information and evidence about drugs across our system.
- **Systemwide contracts:** We manage many traditional pharmacy benefit manager functions internally, including formulary maintenance and negotiation of contracted drug prices. KP's incentive is to purchase drugs at the lowest possible cost, and the different components of our integrated system are free of conflicts of interest since they are all part of the same broader organization.
- **Generic drug purchasing:** To achieve discounts on drugs, we leverage our purchasing power and unique ability to move market share among competing therapies that results from the confidence our clinicians have in our evidence-based formularies. Kaiser Permanente has long been an industry leader in generic utilization. More than 91 percent of drugs prescribed in our system are generic, which exceeds market averages of 89 percent.<sup>2</sup> Our evidence-based approach to designing pharmacy benefits helps facilitate competition between drugs, often leading to preference for high-quality generic drugs. Our pharmacists and the Permanente Medical Group physicians collaborate closely to develop our formularies, analyzing available evidence for each drug and making recommendations. When generics perform just as well or better than a more expensive brand drug, they prevail within Kaiser Permanente. Every 0.1 percent increase in generic utilization saves our system \$28 million. These savings help us invest in care delivery and quality initiatives that benefit our members.
- **Detailing restrictions:** Kaiser Permanente's medical groups have chosen to significantly restrict direct-to-clinician marketing by pharmaceutical sales representatives. Instead, pharmacist drug education coordinators actively provide our prescribers with unbiased, up-to-date information on medications. Additionally, prescribers can reach out to our pharmacists to ask specific questions about a medication.
- **Pharmacy excellence:** Pharmacists have access to the full patient electronic health record system as well as to the prescriber if questions or concerns arise, improving the safety of our medication use processes. Our pharmacists actively track medication adherence for patients with chronic conditions and regularly communicate with them on how to take their medications most effectively.
- **Mandating A Single Formulary Increases Costs for Medicaid and the Entire Health Care System:** Mandating CCOs and their partners to use a single formulary for our OHP members will dramatically increase costs due to several factors. First, it will disrupt the efficiencies and quality benefits inherent to our integrated system. Second, we would expect new reluctance by manufacturers to provide KP with price concessions on drug utilization attributed to OHP patients. Third, moving utilization from products on the KP formulary that have been contracted at favorable acquisition costs to products on the OHP formulary would increase the unit cost KP would experience. Lastly, KP's generic penetration rate is considerably higher than the U.S. average. Any decrease in this rate in favor of more expensive brand-name drugs on the OHP formulary would create a significant increase in KP's drug spend. There would also be increased operational and administrative costs to administer a separate formulary.

Because this proposal would change our cost structure, we anticipate that OHP rates would need to be adjusted upward to recognize the increase in costs, both from a service standpoint as well as from administration. This should certainly be factored into any savings estimate.

Finally, at this time, when the federal and state governments are planning for the redetermination of Medicaid members post-pandemic, such disruption in prescription drug coverage would be unwise. Once redeterminations are reinstated, many Medicaid members will be transitioning between coverage types (exchange, commercial), and moving from one formulary to another within the same integrated care/coverage model would be disruptive, costly, and clinically unnecessary. It is for these reasons that we reiterate that OHA make the use of the statewide formulary optional for entities like KP that already have in place a robust, clinically driven, cost-effective formulary.

\*\*\*\*

In sum, Kaiser Permanente stands ready to work with OHA and our partner CCOs on the implementation of the Oregon Section 1115 waiver. Thank you for considering our comments. If you have questions, please contact me, Jeff Collins ([Jeffrey.A.Collins@kp.org](mailto:Jeffrey.A.Collins@kp.org)) or Shannon McMahon ([Shannon.Mcmahon@kp.org](mailto:Shannon.Mcmahon@kp.org)).

Sincerely,

*jeffrey a collins*

jeffrey a collins (Jan 7, 2022 14:45 PST)

Jeff Collins

Regional President, Kaiser Foundation Health Plan of the Northwest

Shannon McMahon

Executive Director, Medicaid Policy



Date: December 7, 2021

To: Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield

From: Molly Rogers, MJM,   
Wasco County Youth Services Director & Northern Oregon Regional Juvenile  
Detention Facility

On behalf of Wasco County Youth Services and the Northern Oregon Regional Juvenile Detention facility (NORCOR Juvenile Detention), I am pleased to provide written comments for the 1115 Medicaid Demonstration Renewal. In my role I have had the opportunity to work locally with the Implementation of the Coordinated Care Organization (CCO) to move the health care system to a more data driven model. It has also been my pleasure to develop strategies to improve wellness for youth in Oregon with the outcome of reducing high-cost services later.

In the current application I would offer the following recommendations for changes:

**Section, 3.2 “Improving Health Outcomes by Streamlining Life and Coverage Transitions”, Strategy 1:** Explicitly state local juvenile detention facilities as a point in the juvenile justice system, similar to the reference to jails and local correction facilities for the adult population.

**Section 3.2. “Improving Health Outcomes by Streamlining Life and Coverage Transitions, Strategy 3: bullet point d) Members (adults and youth) transitioning out of the criminal justice system.”** Add “within and out”, of the criminal justice system and juvenile justice system.

Your consideration of the changes is appreciated. The application’s focus on equity and access is very exciting for youth in Oregon who find themselves within large institutional systems.



January 7, 2020

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer Street NE, E65  
Salem, OR 97301

**RE: DRO's Public Comment Urging OHA to End a Failed Medicaid Demonstration Waiver & Halt All Use of QALYS or Discriminatory Health Assessment Tools**

Dear Health Policy and Analytics Medicaid Waiver Renewal Team:

Disability Rights Oregon (DRO) submits this testimony to both request an end to the twenty-year-old failed Medicaid demonstration waiver and a rejection quality-adjusted-life-years (QALYs) to determine care. For more than 40 years, DRO has served as Oregon's federally authorized and funded Protection & Advocacy System. DRO is committed to ensuring the civil rights of all people are protected and enforced, including in healthcare settings.

#### Ending a Failed Demonstration Waiver

As you know, 1115 Medicaid demonstration waivers offer states an avenue to test new approaches in Medicaid that differ from what is required by federal statute. These waivers can provide states additional flexibility in how they operate their programs, beyond the considerable flexibility but foundational requirements available under federal law. Oregon's twenty-year old waiver has demonstrated that it does not work and should end.

In 1992, Oregon's initial waiver application was rejected by the U.S. Department of Health and Human Services. The next year, 1993, Oregon's waiver request was approved based on the state's promise that it would not discriminate against people with disabilities or violate the Americans with Disabilities Act (ADA). Oregon is the only state to be granted a waiver from the requirements to cover "all medically necessary treatments" for children aged 1-21. DRO believes granting this waiver was mistake and is not in compliance with Medicaid law.

The Medicaid legislative intent is clear: Congress directed states to cover medically necessary screening, testing and services to children even if that state did not cover them for adults. Federal Medicaid law makes clear that early intervention and treatment maximizes a child's success as an adult. It's time that Oregon prioritizes its children and complies with this law. Twenty years is long enough to try to prove whether the state's approach works. There is no

511 SW 10th Avenue, Suite 200 / Portland, OR 97205  
Voice: 503-243-2081 or 1-800-452-1694 / Fax: 503-243-1732 / [www.droregon.org](http://www.droregon.org)  
Disability Rights Oregon is the Protection and Advocacy System for Oregon

longer a compelling argument for why Oregon needs a waiver from EPSDT. The children of Oregon deserve access to medically necessary treatment like the rest of the nation.

### Rejecting QALYs

DRO also represents a diverse community of people with disabilities who strenuously oppose the use of quality-adjusted-life-years (QALYs) to determine care. QALYs attempt to measure the value of health outcome to help a health care provider determine the cost-effectiveness of any treatment. In the guise of cutting healthcare costs, QALY scores are inherently discriminatory, placing an arbitrary value on the lives of people with disabilities, patients, older adults and people of color because of existing disparities in healthcare. The measure of “quality of life” used as a multiplier in the QALY is not based in science but rather complete based on the bias perceptions of medical professionals. QALY scores have no place in deciding what conditions will be covered or not covered in Oregon’s Medicaid Program.

The National Council on Disability, an independent federal agency charged with making recommendations to the President and U.S. Congress, [found QALYs](#) place a lower value on the lives of people with chronic illnesses and disabilities. This approach leads to a devaluation of the lives of Americans and perpetuates unequal access to healthcare.

The Oregon Health Authority (OHA) now says they stopped rely on QALY scores in 2017 and only uses QALY scores for background information. Yet, OHA would not provide DRO with the scoring formula they are now using. OHA would also not commit to prohibiting the use of QALY in Health Evidence Review Committee (HERC) scoring conversations. Due to the lack of transparency regarding such a critical topic, we are left to assume that Oregon still relies on a discriminatory scoring process to determine who gets healthcare.

DRO opposes any policies that use QALYs or other discriminatory health assessment tools. People with disabilities, older adults and people of color already face discrimination in their lives, we don’t need healthcare policies implemented in a global pandemic to systemically deprioritize resources from protected classes. Such policies would move our state backwards rather than forward and exacerbate existing disparities.

While the disability community has been told our lives don't have as much value as other Oregonians, we refuse to accept this discrimination. What we need from policymakers is to make clear the lives of all Oregonians are equally valued and that discrimination against any protected class will not be tolerated. We need affordable, equitable, and safe medical treatments and technology. For this reason, we urge you to reject any discriminatory framework that values the lives of some people over others.

Sincerely,

511 SW 10th Avenue, Suite 200 / Portland, OR 97205  
Voice: 503-243-2081 or 1-800-452-1694 / Fax: 503-243-1732 / [www.droregon.org](http://www.droregon.org)  
Disability Rights Oregon is the Protection and Advocacy System for Oregon

Megan Moyer  
Public Policy Director



Disability  
Rights  
Oregon



Dear Policymaker,

We represent a diverse community of people with disabilities who strenuously oppose the use of quality-adjusted-life-years (QALYs) to determine care. QALYs attempt to measure the value of health outcomes to help a health care provider determine the cost-effectiveness of any treatment. In the guise of cutting healthcare costs, QALYs are discriminatory, placing an arbitrary value on the lives of people with disabilities, patients, older adults and people of color because of existing disparities in healthcare.

We can all agree that healthcare costs are too high and require an equitable, efficient review. However, QALYs will disproportionately harm Oregonians who need help most. Oregon went down this ill-advised road in the 1990s when the Oregon Health Services Commission ranked the value of healthcare treatments for various conditions in its Medicaid program, prompting the U.S. Department of Health and Human Services to reject the state's Medicaid waiver because the practice violated the Americans with Disabilities Act.

The phrase "quality of life" is often a euphemism for stereotypes and prejudice about the lives of people with disabilities and chronic health conditions. These biased equations often oversimplify the value a treatment would have on a person's life and have no place in the United States where, for over thirty years, we have outlawed discrimination against people with disabilities, patients, older adults and people of color that often result in healthcare disparities.

The National Council on Disability, an independent federal agency charged with making recommendations to the President and U.S. Congress, found QALYs place a lower value on the

511 SW 10th Avenue, Suite 200 / Portland, OR 97205

Voice: 503-243-2081 or 1-800-452-1694 / Fax: 503-243-1732 / [www.droregon.org](http://www.droregon.org)

Disability Rights Oregon is the Protection and Advocacy System for Oregon

lives of people with chronic illnesses and disabilities. This approach leads to a devaluation of the lives of Americans and perpetuates unequal access to healthcare.

We oppose any policies that use QALYs or other discriminatory health assessment tools and will oppose them. People with disabilities, older adults and people of color already face discrimination in their lives, we don't need healthcare policies implemented in a global pandemic to systemically deprioritize resources from protected classes. Such policies would move our state backwards rather than forward and exacerbate existing disparities.

While the disability and chronic disease community has been told our lives don't have as much value as other Oregonians, we refuse to accept this discrimination. What we need from policymakers is to make clear the lives of all Oregonians are equally valued and that discrimination against any protected class will not be tolerated. We need affordable, equitable, and safe medical treatments and technology. For this reason, we urge you to reject any discriminatory framework that includes QALYs and values the lives of some people over others.

Sincerely,  
Disability Rights Oregon  
Caring Ambassadors  
Epilepsy Foundation  
ICAN, International Cancer Advocacy Network  
Kaleidoscope Fighting Lupus  
Lupus Foundation of America  
NAMI Oregon  
The ALS Association Oregon & SW Washington Chapter

511 SW 10th Avenue, Suite 200 / Portland, OR 97205  
Voice: 503-243-2081 or 1-800-452-1694 / Fax: 503-243-1732 / [www.droregon.org](http://www.droregon.org)  
Disability Rights Oregon is the Protection and Advocacy System for Oregon

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
RE: 1115 Medicaid Demonstration Renewal Comments

Dear Oregon Health Authority:

Thank you for the opportunity to comment on the 1115 Medicaid Demonstration Renewal. Our names are Sadiya Muqueeth and Kristin Kovalik. We are writing in our capacities as Director of Community Health and Oregon Program Director at the Trust for Public Land (TPL). TPL has a long-standing commitment in Oregon, working for 40+ years to create parks and protect land for people. Our work extends from parks in Greater Portland and Bend, to large landscapes including the Columbia River Gorge and Steens Mountain. In addition, we are launching a three year Oregon Rural Schoolyard Program due to our success working with the Klamath Tribes on our Chiloquin Schoolyard project. We do this work with the recognition that our greenspaces have an impact on health, climate resilience, equity, and communities.

**Thus, we commend Oregon Health Authority's (OHA) inclusion of investment in social determinants of health,** with 1% of the global budget carved out to community investment collaboratives on health equity with citations to housing, climate, and other upstream factors. Retaining this investment will increase health equity across Oregon. In support of OHA's leadership in this work, we recommend:

1. OHA retain the requirement that CCOs invest at least 33% of the 3% of their global budgets with community investment collaboratives with flexible authority to invest in health equity. Community investments such as those in community led efforts significantly impact health and well-being.
2. OHA retain authority for expenditures on population health as healthcare investment in social determinants will have wide-ranging effects on myriad health outcomes.
3. OHA enhance opportunities for climate resilience through prevention not solely through response to disaster.

**Investment in Community Collaboration:** CCOs investments of their global budgets into community collaborative will generate distant and clear opportunities to improve health through community-led initiatives. Communities are experts in their contextual needs and priorities. Such decision making opportunities and cooperation mechanisms will strengthen the neighborhoods and social connectedness, a critical need in the context of an ever-evolving pandemic. Our work in Klamath County with the Klamath Tribes and numerous community partners including Oregon Health and Outdoors Initiative and Healthy Klamath Initiative serves as a principal example of this. For the past two years' students and community members in Chiloquin Oregon worked together to design a safe, multi-generational outdoor gathering space at Chiloquin Elementary School. The final design is reflective of the diverse culture and local priorities and needs. Private and public investments including funding from the Cascade Comprehensive Care (CCC)/Cascade Health Alliance (CHA), is supporting the creation of this green schoolyard which will also serve as a much needed public gathering space.

**Healthcare must invest in social determinants of health equity:** High healthcare costs and health inequities will continue to rise without intentional investment in social determinants of health such as education and climate change. We, therefore, recommend that OHA retain authority for expenditures on population health equity in the communities that need it most. Such investments in community-based efforts have wide-reaching intersectional ramifications. For example, in a study of 1,772 schools in Massachusetts, when controlling for race and household income, the increased level of greenness surrounding the schools was linked to reduction in chronic absenteeism. According to the study, an increase of 0.15 in the greenness index was associated with 25,837 fewer students

chronically absent every year (or a 2.6 percent reduction) (MacNaughton, 2017). Chronic absenteeism is associated with health outcomes across the lifespan.

These efforts may have significant implications for health care costs. Review studies find urban green space exposure consistently related to decreased mortality, reduced heart rate and violence, improved attention and mood, and increased or higher likelihood of physical activity (M. Kondo et al., 2018; Wolf et al., 2020). Systematic reviews find inverse relationships between greenness, measured through a normalized difference vegetation index (NDVI), and all-cause mortality (M. Kondo et al., 2018; Rojas-Rueda et al., 2019). Muller et al. (2019) studied 30 years of available data for all US counties and found that a \$100 increase in per capita investment in parks and recreation was associated with 3.4 fewer deaths per 100,000 people, suggesting that increased funding for parks could be considered a broader public health intervention (Mueller et al., 2019).

Analysis of data from Los Angeles projected that more than 164,000 years of life expectancy could be gained by addressing park needs in that city, with the majority of gains occurring among Black and Latinx residents (Yañez et al., 2020). Greenspace studies have also found protective associations with two leading risk factors for infant mortality, low birthweight and small for gestational age, with heightened effects among mothers in lower socio-economic positions (Ebisu et al., 2016). Kondo, et al. (2020)'s health impact assessment in The Lancet projected that 403 (95% interval 298–618) premature deaths could be prevented city-wide by attaining a 30% tree canopy cover by 2025, with the majority (244) of the deaths prevented in lower socio-economic census tracts (M. C. Kondo et al., 2020). If tree canopy increased by 5 percentage points in areas with non-tree vegetation alone, researchers projected an annual reduction of 302 deaths city-wide, with a monetary value of \$2.9 billion.

**Create opportunities for climate resilience through prevention not only disaster response:** The Waiver Renewal includes clear language on the health risks created by climate change as well as climate-related fires and extreme heat. However, the Waiver application frames climate support as a 'response to climate disasters'. This does not include specific authority to invest in climate resilience. With prevention serving as a central tenet of public health and healthcare, we recommend adding a bullet to the list of Climate Supports on p68 such as, "Increasing access to natural areas with shade."

In conclusion, we know that place-based inequities drive preventable health outcomes. The practice of community health is to address inequities through prevention and collaboration. This investment from OHA into communities will advance the health and well-being of communities, ensure they are more resilient to climate change, and place Oregon on a path to innovation and leadership against adaptive challenges that lie ahead. Thank you for your consideration of our comments.

Sincerely,

<b>Sadiya Muqueeth, DrPH, MPH</b> <b>Director of Community Health</b> The Trust for Public Land 100 M Street, Suite 7 Washington, D.C. 22202 <a href="mailto:Sadiya.Muqueeth@tpl.org">Sadiya.Muqueeth@tpl.org</a> 443.415.2029	<b>Kristin Kovalik</b> <b>Oregon Program Director</b> The Trust for Public Land 15 SW Colorado Ave., Suite 100 Bend, OR 97702 <a href="mailto:kristin.kovalik@tpl.org">kristin.kovalik@tpl.org</a> (541) 668-4390
--	---

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield

RE: 1115 Medicaid Demonstration Renewal Comments

Dear Oregon Health Authority:

Thank you for the opportunity to comment on the 1115 Medicaid Demonstration Renewal. My name is Aaron Clark and I am a biologist and green infrastructure professional. We are excited to see Oregon's waiver application embrace the science, community voices, and experiences that show how community-led investment leads to health equity. In particular:

We support the requirement that CCOs invest at least 33% of the 3% of their global budgets with community investment collaboratives with flexible authority to invest in health equity

My work focuses on improving quality of life in communities through environmental improvement through empowerment, and education in the Pacific Northwest. I have been astounded by the abundant research and personal observations that demonstrate the value of nature as medicine. The health and mental health of our communities is profoundly impacted by nearby nature and environmental quality.

Retain the authority for expenditures on population health and climate supports

Oregon's Waiver Renewal is explicit about the health risks posed by climate change and events such as fire and extreme heat. The science and community wisdom support those linkages. The Waiver's flexibility allows Oregon's Medicaid program to direct other investments more directly toward health and health equity in the communities that need it most (e.g., FEMA post-disaster mitigation funds, US Forest Service recreation funds, and HUD housing supports).

Broaden authority to improve climate resilience, not just respond to disaster

The focused equity investment final policy concept paper refers to "Increasing green space and other improvements to the built environment, such as climate resilient housing, can ameliorate the impact of climate change. Further, the evidence linking time outdoors with better mental health and social cohesion is substantial." (p15). Yet the Waiver application itself frames climate supports as a 'response to climate disasters.' There is no explicit request for expenditure authority of federal or OHP funds that would actually build climate equity and resilience. For example, emergency transportation and ability to stay housed is critical during a disaster. But if a community knows that neighborhood greenways and cooling centers in libraries can prevent catastrophic fire or heat stroke, then investment in those actions should be explicitly authorized as part of the focused equity investments. This framing of "climate supports" runs through the application (from strategy 3 on p 23, to the climate supports on p68). Please add a bullet to the list of Climate Supports on p68 such as, "Increasing access to natural areas with shade."

This flexible "glue" will help braid services, preventative investments, and disaster response into a more cohesive, effective, and efficient approach to building health so that everyone has the opportunity to thrive—no exceptions.

Thank you again for the opportunity to comment!

Sincerely,

Aaron D. Clark Ph.D.  
Director of Strategic Partnerships  
Stewardship Partners

## Public comment

### Draft Application of Oregon Health Plan 1115 Demonstration Waiver

January 3, 2022

Submitted by: Joshua K. Graves, MBA, QMHA,  
Catholic Community Services, CEO

Please accept the following as a public comment to the Oregon Health Plan 1115 Demonstration Waiver:

The world health organization created the social determinants of health framework in 2003. Social determinants apply more broadly than within the scope of healthcare. Social factors are critical for all community enterprises, including education, business, and government. Everyone needs stable and productive social systems. The Application needs to be more specific about creating reproducible and sustainable improvement in social determinants.

Healthcare cannot solve the social determinants issue because social systems are too big, different, and outside the scope of healthcare's already formidable and vital mission. But it can catalyze real change, as noted in the Application's Health Equity Plan. Its best hope is to support effective **local** systems development.

Getting this right will be difficult for healthcare because the social fundamentals lie outside its core experience and expertise. Community Advisory Councils (CAC) provide input and support for health plan decisions, but operational management of human services is appropriately outside any previous or proposed scope of operation.

The people working in human services are top-notch, and the people they serve have needs that those who are not directly providing social services cannot understand. Additionally, the current system's approach and tools do not match the nature of the growing problem. A radical local human service transformation is needed. CCO investment and support of systemic change will create more long-term value than picking a single issue to support or distributing smaller amounts across the community. A fresh perspective and innovative ideas will help everyone move forward.

Growing more effective **local** human service systems will deliver more value for healthcare by recruiting other stakeholders such as housing, education, and business. This growth will also be a catalyst for increased governmental coordination resulting in more efficient and effective service delivery.

Another catalyst of change for Oregon would be supporting a private, nonprofit, organization **Medicaid Match** as part of the 1115 waiver. Currently, states receiving Medicaid funds must provide a certain amount of matching funds. State policy should allow nationally accredited and

state-licensed private social service agencies to use charitable donations as Medicaid matching funds. This match would increase the available federal money and enable providers to enhance mental health services for the children, youth, and families. The current 1115 draft waiver references similar opportunities in Items 3,4,5. Innovative concepts such as this are reportedly included in waivers in other states, so the preliminary concept work should be easy to replicate. Policy recommendations should allow charitable donations as a source for Medicaid matching funds.

In looking at solutions, this is an opportunity to shift the paradigm. We can put new knowledge to work, restoring the core of society. Each community would have its solution and contract with healthcare and other stakeholders to deliver incremental improvement in social determinants. This value-based contracting would include measures based on new social determinant codes and billing sets from HL7<sup>i</sup>.

A better human service system would be local and connected to each person, family, or neighborhood through a local Traditional Health Worker (CHW or Peer Support Specialist). These THW's need community-level coordination support. A core component would be the integrating infrastructure designed for the dynamic reality of human services.

In the ideal scenario, a better human service system would be coordination-based like healthcare but implemented as an adaptive network that includes the client. In the same way, social media tracks behavior and network topology, we can learn and improve our solutions through understanding **local** complex system dynamics. This additional information is an avenue for data science to teach us more about our communities.

An improved human service system would have a **local** mutual benefit organization to support shared goals and performance. This organization is not a financially driven IPA but an outcome-driven platform of mutual support. This structure would enable concerted action on behalf of providers and those they serve.

Change is needed. Today, we seek to improve complex adaptive problems with complicated rigid solutions. We are trying to understand issues emerging from the dynamics of human behavior using static population-based data. We need to move away from the older top-down systems approach and embrace today's systems theory when dealing with complex and adaptive environments. The current path cannot take us where we need to go.

This Application is hopeful because it opens the door to improving the foundational systems supporting society.

---

<sup>i</sup> <https://vsac.nlm.nih.gov/> Value sets can support value-based reimbursement by tracking client state



**To: Oregon Health Authority**

**From: Colleen Reuland, Director of the Oregon Pediatric Improvement Partnership.**

**Re: Oregon 1115 Demonstration for 2022-2027**

Our organization works across sectors on **population-based improvement efforts**, with the common purpose of improving the **health of the children and youth of Oregon**. A key component of our mission to ensure that all efforts are informed by parents, youth and young adults.

As an organization and person deeply committed to and experienced with systemic change, we have found developing reliable and meaningful measures has always been a critical tool to drive and inform valid improvement efforts that impact the health of children. **What is measured, and HOW it is measured, is WHAT will be focused on.**

Given that nearly 40% of Oregon's Medicaid-insured are children (the majority age demographic of enrollees) and because Medicaid provides insurance for the majority of children of color in our state ([60% of Black children, 65% of Latino children, and 57% of AI/AN children](#)), we are extremely supportive of the elements of the waiver that **focus on children and focus on addressing structural racism**. Both areas of focus are root sources of where the drivers of inequity begin and are sustained.

Within OHA's and OHPB health equity definition and aims, a key component we see for children in Medicaid/CHIP is the **intentional inclusion of "disability"**.

- For **children with special health care needs** in Oregon, OHP **IS the safety net** for addressing and covering their **medical, behavioral, oral and care coordination** needs.
- To highlight? underscore? the magnitude of children (and their families) that count on Medicaid/CHIP to provide access, quality and coordinated care - according to the [2021 Child Health Complexity data](#), there are **145,000 children** enrolled in Medicaid/CHIP, which is **more than 1 in four children**, have some level of medical complexity, with 50,000 having a complex, chronic condition.

We have **significant concerns with the Waiver proposal related to *Incentivizing Equitable Care***. We appreciate and **overall support the intent and purpose of the upstream and downstream metrics**. However, the current proposal will result in no metric that will ensure equitable access to, or receipt of, high-quality care for children with special health care needs - in the very program meant to ensure these children's needs are met.

The upstream measures proposed, although critical in addressing some of the historical inequities and social challenges faced, do not contain metrics focused on children and youth with disabilities. The etiology of children with disabilities is different than adults, in that a

majority are not caused by lifestyle or life circumstances that could be addressed by upstream efforts.

The current proposal calls for “downstream metrics” that would ensure quality, access and outcomes of the health care system to ONLY be chosen from the CMS Medicaid Adult and Child Core Sets and potential MCO Quality Rating System.

- I personally know the [metric set](#) and identification of which metrics go into that set well as I am one of the only measure stewards that is not NCQA. I do not believe that narrowing our measures to this CMS Core Set - which need to be applicable to all 50 states, will allow Oregon to reach their goal of eliminating health inequities by 2030.
- There are **NO metrics for the population of children and youth with special health care needs**. While there is one metric focused on children who experience asthma, this is just one condition of the hundred chronic conditions that children experience. The result – we will have no quality metrics and levers to ensure **quality** for a population that this program is meant to serve.
- There are **NO metrics focused on the essential and critical function of care coordination and care integration that are essential for CYSHCN and central to the CCO model**. When this function is not measured and assured in a high-quality way, the responsibility inevitably falls on the family and the child, which can result in poor health outcomes, school absenteeism, and child risk for out of home placement.
- The metrics included in the Core Set focused on behavioral health that could be considered for inclusion in the downstream set, do not measure or focus on the innovative models of behavioral health that Oregon has been known to support including IBH and dyadic behavioral health. In Oregon, nearly [two in five \(38%\)](#) children have three or more social complexity factors, majority of which are aligned with adverse childhood events, for which behavioral health is an essential service for which equitable access and quality care is needed. In the current proposal, there would be no metrics to ensure this quality and innovation would continue.

We have seen the transformative and integral power that the metrics and, in particular, metrics tied to incentives to galvanizing improvements in quality.

As an organization that works with and hears from parents, youth and young adults every day, we hear **consistently** and **persistently** how their access and care coordination needs continue to be unmet.

It is imperative that the metrics program is designed in a way such that metrics of quality can be considered is an essential component to ensuring equitable access and high-quality care for this population, and therefore we strongly recommend reconsideration of the waiver language related to the downstream metrics.

We are ready and willing to partner on solutions that could address these concerns should there be an opportunity.



Thursday, December 9<sup>th</sup>, 2021

To: Oregon Health Policy Board  
Attention: David Bangsberg MSc, MD, MPH  
C/O: Tara Chetock, Oregon Health Authority  
[tara.a.chetock@dhsosha.state.or.us](mailto:tara.a.chetock@dhsosha.state.or.us)

From: Josh Balloch  
AllCare Health  
1701 NE 7<sup>th</sup> St  
Grants Pass, OR 97526  
[josh.balloch@allcarehealth.com](mailto:josh.balloch@allcarehealth.com)

Written public comment to the Oregon Health Policy Board for the December 7<sup>th</sup> 2021 meeting --  
RE: Draft Application for the 1115 Medicaid Waiver

Chair Bangsberg and members of the Oregon Health Policy Board,

AllCare Health is currently reviewing the 157-page publically available waiver application, and will be submitting formal comments soon. However, before those comments are completed, I wish to raise concern about this draft waiver's failure to comply with legislative direction, as outlined in HB 3353.

In 2020, when Oregon faced a massive budget shortfall because of the COVID pandemic, likely resulting in hundreds of millions of dollars taken from the Medicaid delivery system, many of us realized the impending negative impact on Oregon Health Plan members and providers. To minimize this impact, a strategy was created to use the 1115 Oregon Medicaid Waiver to leverage more federal dollars being directed into the Oregon Medicaid System. By allowing Coordinated Care Organizations to spend 3% of their funding on health equity improvements and upstream Social Determinants of Health investments, we could then provide significant health improvements for OHP members and the community as a whole. This strategy required that those funds count as "medical expenditures", ensuring the sustainability of those investments.

In late 2020, a coalition comprised of local equity groups, providers, Community Advisory Councils, and legislators, established a consensus that created House Bill 3353 (*Reference: <https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB3353>*). HB 3353 outlines a blue print for the 1115 Oregon Medicaid Wavier request in 2022, giving the Oregon Medicaid System more flexibility on spending Medicaid dollars. More importantly, it created local accountability for CCOs investing in the delivery system, in a way that meaningfully serves members and the communities as a whole.

During the 2021 session, the collation was focused on attaining comprehensive bi-partisan and bi-cameral support for HB 3353. The bill had four chief sponsors (Two Democrats and Two Republicans) and 22 regular sponsors (12 House Democrats; 6 House Republicans; 3 Senate Democrats and 1 Senate Republican). The broad legislative support resulted in the bill passing overwhelmingly (57-0 in the House; 19-10 in the Senate). This is the similar to the broad support enjoyed by the legislation that created the CCOs in 2011/2012.



This bi-partisan legislative support gives added credibility to Oregon's waiver request and demonstrates that funding and flexibility for Medicaid is a non-partisan core issue in Oregon. This is significant when Oregon is again seeking to be a national trailblazer for Medicaid.

Unfortunately, the Oregon Health Authority's Draft Waiver Proposal fails to match the language or the intent of HB 3353. The bill explicitly says CCOs are to "spend" their global budgets on specific investments. (*Reference: Section 2(1)(a) of HB 3353*). Instead, the OHA's draft application, in direct contravention of legislative intent, tells CCOs to give money to a newly formed third party that would "grant out" funds without CCO accountability.

The OHA's draft waiver request seemingly ignores the legislative directive to cause CCOs, at the local level, to be responsible for engaging the whole community in making health investments. (*Reference Section 2(3)(a) & (b) of HB 3353*). The waiver request also rejects the legislators' bi-partisan intent for accountability, by allowing a siloed, third party equity entity to make funding decisions. HB 3353 clearly states that expenditures "be approved by the coordinated care organization's community advisory council."

Another concerning aspect of the draft waiver is the misunderstanding of HB 3353's general operation. The bill specifically and intentionally outlines that unless the OHA can insure CMS will include the 3% expenditures as medical expenses **AND** is fully funded by the increased federal reimbursement, then the CCOs can "spend up to" 3%. Legislators made clear it is not a "shall spend", unless specific requirements are met (*Reference: Section 4 of HB 3353*).

Many of the accountability measures that were included in HB 3353, aimed at ensuring that community voices were present during the creation of spending strategies in an effort to hold both CCOs and the OHA accountable, were not included in the 1115 Draft Waiver. The bill states that in order for these dollars to be counted as this 3%, they have to be part of "a plan developed in collaboration with, or directed by, members of organizations or organizations that serve local priority populations that are underserved in communities served by the coordinated care organization." In short, the plan the CCOs use for investments (i.e. Community Health Improvement Plan or Health Equity Plan) must include voices from priority and underserved populations within the service region, in the development of that plan. (*Reference: Section 2(3)(a) of HB 3353*). Within HB 3353, there is clear direction that these investments must demonstrate "practice-based or community-based evidence", giving CCOs the flexibility they need in order to find innovative solutions in partnership with new community organizations, likely to serve smaller populations among the underserved communities. These requirements were included in the Bill as part of the discussion with RHECs and should apply to the full 3%, but the Draft Waiver only applies this to the third party equity silos. (*Reference: Section 2(3)(b) of HB 3353*).

There are many other conflicts between the current draft waiver proposal and HB 3353. This letter is only intended to highlight the most urgent concerns about the draft 1115 proposal, which I and other members of the coalition wish to bring to your attention.

The Oregon Health Policy Board must be informed of these concerns, as failure to follow both the language and intent of HB 3353 will create significant issues and unnecessary confusion. The lack of



alignment between the waiver and HB 3353, which is referenced many times in the waiver, will generate uncertainty when the Centers for Medicare and Medicaid (CMS) review Oregon's request. Confusion at CMS will make it difficult to obtain the flexible and sustainable funding Oregon needs to address health inequities by 2030. Failure to follow the language and intent of HB 3353 also disenfranchises partners, such as regional health equity commissions and community advisor councils, which supported and helped pass the bill. Importantly, creating a third party equity silo, will very likely fail to win the endorsement from many of HB 3353's bi-partisan supporters. Divisions in the federal Oregon Congressional delegation could create a reason for CMS to label the waiver as "partisan" and to reject it.

Many community members in our region are thoroughly disappointed about the current direction of this waiver. Concerns about third party equity silo concepts have been shared with the OHA many times, yet meaningful changes have not been made.

To be clear, AllCare is extremely supportive of incorporating more diverse voices and having community accountability to ensure that health needs of all people are being met. Our concern is that these third party equity silos create bifurcated efforts that are unsustainable in a "grant-based" system.

Based on our experience, the number one issue with a CCO's ability to support sustainable equity investments within the community, is the lack of a true global budget; not an absence of desire by our Community Advisory Councils, our CCO Board of Governors, or any of the locally-based organizations with whom we partner.

Our request to you, the Oregon Health Policy Board, is that you ask the OHA to make meaningful changes to Oregon's 1115 Waiver Request, in the following areas:

- 1.) Removal of the third party equity silos, replaced with bi-partisan concepts laid out in HB 3353, as written and supported by over 80% of the legislature.
- 2.) Make clearer the request that the identified 3% of investments in health equity and SDOH be recognized as Medical expenditures. This is key to making these investments sustainable.
- 3.) Make clearer a request for full federal funding of these important upstream investments.

HB 3353 was a significant bi-partisan accomplishment during a contentious legislative session. It is important that the negotiated cooperation of the stakeholders and legislators and their significant achievement is not squandered in this application to the Federal Government. Thank you for you considering this sincere request for the changes necessary for the waiver application to appropriately reflect House Bill 3353 and the will of the People of Oregon.

If you would like to discuss this further please feel free to call me anytime (503-508-5868).

Sincerely,

Josh Balloch  
AllCare Health  
Vice-President of Health Policy



January 7, 2022

Health Policy and Analytics Waiver Renewal Team  
Atten: Michelle Hatfield  
500 Summer St., NE, 5<sup>th</sup> Floor, E65  
Salem, OR 97301  
**Email:** [1115Waiver.Renewal@dhsoha.state.or.us](mailto:1115Waiver.Renewal@dhsoha.state.or.us)

*Re: Health Share Public Comment on 1115 Waiver*

To Whom It May Concern:

Thank you for the opportunity to offer public comment on Oregon's 1115 Waiver application. As Oregon's largest CCO, Health Share serves 400,000 Oregon Health Plan (OHP) members throughout Clackamas, Multnomah and Washington Counties. We have a demonstrated track record of responsibly and sustainably integrating Social Determinants of Health (SDOH) into health care. Health Share has set an example for our industry by cultivating a guaranteed supportive housing benefit that includes wrap-around services for members confronting major life transitions. Our CCO is committed to connecting the OHP members we serve to the care and resources they need. We believe the vision outlined in the draft 1115 Waiver Application represents a positive step towards building upon the integrated framework first started with CCOs in a manner that recognizes the reality of our members' lives. Nevertheless, Health Share is seeking additional information on the financing, timelines and operational planning mechanisms needed to ensure that these proposals achieve their goals.

**More information is needed on the financing of newly proposed benefits to understand whether they are sustainable.** The Waiver application outlines newly proposed benefits consisting of housing, food, transportation and employment assistance to 374,800 individuals who are at risk of becoming homeless. Similarly, the proposal also shapes broad benefits for 129,549 individuals vulnerable to extreme climate events as well as 48,000 youth who are involved or at risk of involvement with the child welfare system. Health Share seeks further clarification on the funding mechanisms that would be used to pay for these new benefits in a sustainable manner. We seek a clearer understanding of the resources that would be used to fund new benefits in years 1-3 as well as information on the extent of risk that a CCO should expect to absorb in their global budget during years 4-5 and beyond. Throughout Health Share's work developing a guaranteed supportive housing benefit for our members, we have tried to strike the right balance between introducing new benefits while also sustaining existing physical, behavioral health and oral care services. Since predictability is key to the successful administration of the OHP benefit, it is critical that we be able to ensure the financial viability of all current services alongside any new services that become available.

**CCOs and other stakeholders require more detailed information and meaningful engagement on the recommended timeline and process to operationalize new benefits.** The administration of the new SDOH transition benefits will require a monumental operational lift for CCOs, delivery systems and organizations providing social services to OHP members. This is especially true given the scale and breadth of these new programs. A timeline that allows for proper planning is critical to ensure that we build new benefits correctly and avoid any unintended harm or waste. Similarly, it will be important to have a process in place that allows CCOs, providers, Community-Based organizations, and other community stakeholders to work together in understanding each other's work. New benefits can only be administered successfully through a network of providers that are willing to take referrals and carry out the work. Health Share is currently in the process of developing a network of housing providers through relationships and contracts with housing service providers, community-based organizations, and traditional health workers for the purpose of operationalizing our supportive housing benefit. Simply put, the work takes time and patience and there are new lessons learned every day about how we can change or improve things. Therefore, any clarification on how Oregon plans to work with all stakeholders within a reasonable time frame to stand up the newly proposed benefits would be welcomed.

**The relationship between Community Investment Collaboratives (CICs) and CCOs must be structured in a manner that ensures deep and ongoing connection between institutions as our work unfolds.** Health Share recommends that there be both alignment and an explicit connection between the work of CCOs and the creation of CICs. Health Share supports investments in the community to address the needs of OHP members from a grassroots lens. We also, however, believe that it is critical for CCOs and CICs to work together towards a defined common goal and share information as to how we can collectively address health equity disparities in a complementary manner. To improve the population health of marginalized communities, it is essential that all stakeholders work on defining problems and posing solutions in a collaborative and connected manner. The work of CCOs and CICs will be interconnected because we serve many of the same individuals and cannot afford to ignore each other's efforts. As such, we recommend a more formal association be developed between CCOs and CICs to ensure we can carry out our work together.

**Oregon must take advantage of any opportunities in the 1115 Waiver, and other policy-making spheres, to bolster the Behavioral Workforce and broaden the ability of OHP to capture federal match funds to pay for expanded Traditional Health Worker (THW) services.** We acknowledge that much of the work needed to improve the Behavioral Health system is not limited to the renewal of the 1115 Waiver. Nevertheless, we encourage Oregon to make sure that we are doing everything possible through the 1115 waiver to bolster the state of our fragile Behavioral Health system. This includes, but is not limited to, expanding the role and scope of services that can be offered by traditional health workers and reimbursed through Medicaid. In addition, we believe it is critical to call attention to all arenas of public policy throughout the state and do everything possible to support Behavioral Health providers. The sad reality is that many existing residential service providers have significantly reduced capacity and others have closed entirely. Access to culturally and linguistically appropriate behavioral health services is critical to achieving CCO and OHA equity goals. Health Share recommends that we do everything possible to appropriately fund and staff existing bed capacity in our residential system to pre-covid levels. The failure to address the

behavioral health crisis in a strategic manner by enhancing access to care will only lead to greater costs down the line and will continue to shift the burden to other parts of the system.

**Health Share is concerned about the use of a single closed pharmacy formulary, and respectfully requests that the state allow the CCOs and their partners be able to continue to use their existing formularies to best manage care for patients.** We support reforms that address the root causes of the high cost of prescription drugs and endorse efforts allowing insurers to use their power as part of the health care system to drive investment toward therapies that provide the greatest benefit for patients. Mandating CCOs and their partners to use a single formulary will dramatically increase costs by disrupting efficiencies inherent to integrated systems. We anticipate that OHP rates would need to be adjusted upward to recognize the increase in service and administrative costs. Health Share is also concerned that once the redetermination process resumes, individuals transitioning off OHP to other forms of coverage will be forced to move from one formulary to another within the same integrated care model.

Thank you for the opportunity to provide comment. If you have any further questions, please contact Yoni Kahn-Jochowitz, Director of Public Policy, at [kahn-jochowitz@healthshareoregon.org](mailto:kahn-jochowitz@healthshareoregon.org).

Sincerely,

James Schroeder  
CEO, Health Share of Oregon



January 7, 2022

**To: OHA 1115 Waiver Renewal Team**

**Re: 1115 Waiver Renewal Comments**

**From: Association of Oregon Community Mental Health Programs**

---

These comments are submitted on behalf of the Association of Oregon Community Mental Health Programs (AOCMHP), representing all 32 CMHPs across the state, who have responsibilities for local behavioral health system management and services, from community-wide prevention to acute, forensic and crisis services delivery and coordination.

First, we agree with maximizing OHP Coverage in all categories listed in the draft 1115 waiver renewal.

Second, we agree on key benefit changes for populations who are transitioning from institutional care and incarceration, and from houselessness to residential treatment or supported housing. We also support key investments in social determinants of health to help people recover and thrive in their own communities.

In addition to Housing Supports, Food Assistance, Education Supports, Employment Supports, Health Related Transportation, and Climate Supports, we would like outreach and engagement, or pre-treatment services, to be included in the allowable service array. Outreach and engagement are essential to build trust and rapport with marginalized individuals who may not be willing to engage in other services for some time. Outreach and engagement serve as a bridge to the initial SDOH services, which hopefully lead to mental health and substance use treatment down the road. As mentioned in the draft waiver renewal, outreach and engagement could be paid through the flexible use of health-related services funds and meet the criteria for improving care delivery and overall health and well-being.

We highly value the focus on peer support services for various transitional services and support the wide expansion of peer support reimbursement. We would also add qualified mental health associates (QMHA) as a provider type to assist people during transitions, including outreach and engagement.

Our third comment is to express enthusiastic support for allowing people in custody to access or retain Medicaid benefits, including youth in the juvenile corrections system for the duration

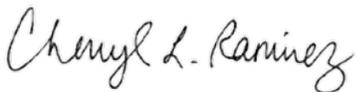
of their involvement, adults in prison or jail up to 90 days pre-release, and adults within 90 days of discharge from the Oregon State Hospital. These are all policies we have been advocating for at the federal level for years. Maybe it will take states, through waivers, to demonstrate to the federal government that allowing people to retain their Medicaid benefits to access the care they need immediately will result in better health outcomes and lower costs.

Our fourth comment is to emphasize the need for behavioral health investment and incentives to enable the public behavioral health system to retain and recruit its workforce. As mentioned in the waiver renewal draft, one of the CCO 2.0 priorities was to improve the behavioral health system. However, it was noted that the “distribution of spending within Oregon’s health care system (e.g., the amounts split between physical, behavioral, and oral health) remains largely the same, indicating spending is following historical habits and market power, rather than a true shift in focus to population health.”

The public behavioral health system has always served many of the most marginalized people, who have been disproportionately impacted by the COVID-19 pandemic and climate disasters. The public behavioral health system, together with social service agencies, provides upstream services and are first responders to help community members in distress and to stay safe. We know upstream care prevents poor health outcomes and high cost care later. Therefore, we would like to see flexibility in moving funding from medical to behavioral health and social services, without impacting the 3.4% cost growth threshold. If the public behavioral health system were able to receive more Medicaid investments, coupled with state general funds and other funds, we will be able to retain and recruit a more sustainable and diverse workforce with living wages.

On behalf of our AOCMHP membership, I want to express our appreciation for OHA’s Medicaid program innovation and dedication to improving health outcomes and striving for health equity. Thank you for this opportunity to provide comments on the 1115 waiver renewal draft and we look forward to working with you as system partners to implement the 2022-2027 waiver.

Sincerely,

A handwritten signature in black ink that reads "Cheryl L. Ramirez". The signature is written in a cursive, flowing style.

Cherryl L Ramirez  
Executive Director, AOCMHP



## In response to the Oregon Health Authority's draft application for the next §1115 Medicaid Demonstration Waiver

The §1115 Medicaid Demonstration Waiver offers an opportunity to innovate, improve, and strengthen the care members of the Oregon Health Plan (OHP) receive across the delivery system and coordinated care model. For these reasons, we focused our collective efforts on the principles below throughout the waiver application development process over the past year.

### CCO OREGON FRAMING FOR THE §1115 MEDICAID DEMONSTRATION WAIVER RENEWAL

1. Continue progress towards a true global budget that is flexible and allows for community-defined infrastructure development with improved health and social outcomes while maintaining a 3.4% rate of growth for CCOs.
2. Diminish regulatory barriers to delivery and payment innovation and maximize health system cost savings and federal investments in health and social services.
3. Further Oregon's health transformation goals, including new payment models, expanded coverage access, eliminating health disparities, and the quadruple aim.
4. Increase local accountability ensuring program goals and implementation are community-based, optimize existing systems, and center the elimination of health disparities.
5. Strengthen the coordinated care model, support the goals of CCO 2.0, and set a stage for growth towards CCO 3.0.

These principles were included in our [May 2021 public comment](#) to the Oregon Health Policy Board (OHPB). This comment also recommended additions to the Oregon Health Authority's (OHA's) initial ideas for the §1115 Medicaid Demonstration Waiver renewal. We offered further [public comment in July 2021](#) to the OHPB after OHA posted the first draft of the waiver renewal concept papers. In review of the OHA's revised concept papers released in early November 2021 and the draft waiver renewal application posted on December 1, 2021, we appreciate the incorporation of many of our earlier suggestions; these include developing care coordination or targeted coverage for those OHP members that are justice-involved including the pre-adjudication phase or placed at the Oregon State Hospital or Oregon Youth Authority as well as improved access to peer support with less barriers, such as the federal treatment plan requirements.

Moreover, we appreciate the overall direction of the draft application and proposed waiver concepts. We agree that maintaining and/or expanding coverage or care coordination for targeted populations and specifically those facing transitions where they may currently lose their continuity of care, supports, or coverage should be a priority. For these concepts to succeed, there are system challenges outside of the §1115 Medicaid Demonstration Waiver

that must be considered, such as a plan to fund the state's portion of the expansions and new programs in the short and long terms. Looking to the Triple Aim, we must ensure sustained funding and thereby program continuity to improve member experience and overall population health while maintaining a reasonable rate of cost growth.

The concepts in the §1115 Medicaid Demonstration Waiver renewal and other proposed expansions in coverage and care will impact our workforce at a time when we are already experiencing devastating burnout, retention, and recruitment challenges across the delivery system. We call upon the state to launch a coordinated effort with stakeholder input from all regions of Oregon to address the workforce crisis across all provider types and settings. We realize this may not be in the actual waiver application but request a statewide, streamlined public forum to begin now so Oregon may prepare for the implementation of the waiver concepts and other programs that will increase or expand access to care and coverage.

Similarly, expansions in care and coverage will be most successful with improved infrastructure elements, such as Health and Community Information Exchanges. Connect Oregon and similar platforms, which CCOs and community-based organizations have been developing in partnership for years, are critical in urban and rural communities as we continue to transform the delivery of care to ensure referrals, warm handoffs, a quality member experience, and making the best use of the already stretched health and social service workforce. We believe this work is critical to guarantee that the proposed coverage expansions lead to the delivery of successful and sustainable whole person quality care and will engage with the Health Information Technology Oversight Committee's work over the next year(s) to scale this work across Oregon.

As our previous comments from [May 2021](#) and [July 2021](#) reflect, we support the intentions behind the proposed health equity investment strategies and have questions about how they will be operationalized, align with existing processes and contract expectations, and include accountability for outcomes and optimized spending. CCOs and coordinated care partners are committed to working with historically underserved populations to better identify systemic health disparities and leverage the coordinated care model to amplify the community role in financial decision-making. We acknowledge that the voices of those with lived experience are essential to guiding our work. We understand that we must center the perspectives of those impacted by institutionalized racism, colonialism, sexism, ableism, and heteronormativity to ensure we eradicate all remnants of such perspectives in our health delivery system from frontline workers to system partners and from the state agency to our federal partners. We know these conversations may be challenging and that they are necessary.

Our goal is to better integrate our work with local communities as opposed to work apart from it. Regional networks and partnerships developed across the coordinated care model leverage

the role of the CCO as the hub or convener with a focus on local decision making and accountability. With CCOs as the hub, provider, community-based partners, and OHP member voices are engaged in identifying and choosing regionally developed strategies to improve overall health and address disparities through the CCO Community Advisory Councils (CACs), Boards, and the development of systems and strategies, such as the Community Health Improvement Plans (CHPs), Health Equity Plans (HEPs), and Comprehensive Behavioral Health Plans (CBHPs).

OHA's draft §1115 Medicaid Demonstration Waiver application identifies two primary sources of funding for the health equity investment strategy; these investments include 1% from CCO budgets. Questions remain about which entities(y) will be accountable for the outcomes of these funds, including how they may be reflected in various CCO deliverables and metrics and how the 1% would be calculated. Further, many details are yet to be defined to ensure the proposed health equity investment strategy is integrated with the existing coordinated care model and contracting expectations (i.e., the CHP, HEP, and CBHP) to avoid duplication at the patient, provider, and payer level and prevent the creation of new funding or programmatic silos. We also need to understand how the voice and work of the CACs and other existing community-based committees will be integrated. Moreover, it is important that OHA partner with other state agencies, such as those administering housing, education, and criminal justice, to maximize all opportunities for funding and the elimination of barriers to care, services, and supports.

Lastly, we appreciate the inclusion of strategies to address the impact of pharmacy costs on Medicaid spending in Oregon. Below are suggested adjustments (in blue) to the pharmacy strategies as presented on pages 76 and 77 of OHA's [draft application](#). Our goal is to support the FDA's accelerated pathway for innovative drugs and ensure these drugs move to full evidence-based FDA approval on the expected timeline.

### **Changes to Prescription Drug Benefits**

#### *Ability to define a preferred drug list for pharmacy benefits*

Oregon seeks the ability to more closely manage pharmacy costs in its Medicaid program, through a two-part strategy:

##### *A. Adopt a commercial-style **evidence-based** formulary approach*

Taking an **evidence-based, limited** formulary approach for adult members, including at least a single drug **with standard FDA approval** per therapeutic class, would enable OHA and CCOs to negotiate more favorable rebate agreements with **pharmaceutical** manufacturer **partners**. Oregon would keep an open formulary for children. For each therapeutic class, manufacturers could be

offered an essentially guaranteed volume in exchange for a larger rebate. Currently, OHA and CCOs have limited ability to explore and enact such agreements with manufacturers, given the requirement to cover all drugs in the Medicaid rebate program. OHA would create a collaborative process that includes CCOs to select drugs for the evidence-based formulary.

In recent years, the majority of commercial pharmacy benefit managers (PBMs) have adopted such limited formularies, which allow them to customize their drug offerings based on clinical efficacy and cost considerations. As an example, for 2021 CVS Health excluded from its formulary 57 additional products—some because a less expensive, medically equivalent drug had become available and some because the drugs were hyperinflationary, having dramatically increased in price without clear justification. Medicare Part D commercial plans are also permitted to employ such evidence-based, limited formularies (as authorized under 42 CFR 423.120) with at least two drugs per therapeutic class. Medicare Part D plans may also include just a single drug per class if only one drug is available, or if only two drugs are available, but one drug is clinically superior. Given that Medicare and other commercial plans are permitted to adopt evidence-based, limited formularies, we believe Oregon should have the same flexibility for Medicaid. As such, we request a formulary that is driven by clinical evidence and lowest net cost to best serve Oregon Health Plan members.

*B. Allow exclusion of drugs with limited or inadequate evidence of clinical efficacy*

Many drugs coming to market through the FDA's accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints. Oregon seeks the ability to use its own rigorous review process to determine coverage for drugs previously granted accelerated approval, but that have not confirmed benefit with conversion to full FDA approval in the expected time interval. Through this process, the state could incentivize drug sponsors to complete their regulatory obligations to demonstrate clinical benefit as laid out by the FDA upon approval. This will allow Oregon to avoid exorbitant spending on high-cost drugs marketed to treat conditions that have yet to demonstrate a clinical benefit despite ample time to do so. Many stakeholders agree that national policy changes are necessary to ensure proper oversight after approval of accelerated pathway drugs based on surrogate endpoints. Current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be covered without being fully clinically proven and despite drug manufacturers not meeting obligations set forth as a condition of accelerated approval.

To that end, Oregon proposes to limit the coverage of drugs approved through the accelerated pathway without traditional approval. Under this proposal,

Oregon would utilize the timelines set out in the FDA approval letter and review confirmation of benefit data in peer reviewed literature or clinicaltrials.gov. Applying the FDA developed guidance and timetables ensures a universal standard, clinically feasibility, and drug sponsor agreement.

New drugs approved under the FDA’s accelerated approval pathway **tend to be specialty medications that represent a significant portion of pharmacy expenditures. As such, it is our responsibility to ensure we are following through with the promise of expedited approval pathways.** In addition, re-formulations of older, existing drugs that provide no incremental clinical benefit might be labeled non-formulary as well. While commercial payers can exercise discretion to exclude drugs from their formularies in **certain** situations, OHA and CCOs currently do not have this ability.

In closing, the sustained success of many of the proposed concepts in the draft §1115 Medicaid Demonstration Waiver application will rest in implementation and operational specifics. We know many of these elements are yet to be determined and understand that the submission of the application is the start of the process. We look forward to partnering with the OHA, regional and system partners, providers, and advocates on next steps and those details that will ensure success. We expect organizations represented here may also submit individual comments presenting similar and additional ideas, concerns, or questions. We appreciate your consideration of our comments and look forward to next steps. Thank you for your work.





Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team

**Re: Comment on 1115 Medicaid Demonstration Waiver Renewal Application**

January 7, 2022

The Oregon Primary Care Association, on behalf of its 34 members, whom collectively serve **one in six OHP patients** and make up a critical portion of the provider networks within CCOs, would like to express its gratitude for your work on the 1115 Medicaid Demonstration Waiver renewal and amendment application. We understand the opportunity this provides to further innovation as well as improve and strengthen the care members on the Oregon Health Plan (OHP) receive across the delivery system and coordinated care model.

The Oregon Primary Care Association is the non-profit membership association of Oregon's 34 community health centers, also known as Federally Qualified Health Centers (FQHCs), and FQHC Look-Alikes. Community health centers deliver exceptional primary care, including behavioral health and oral health care, to over **450,000 Oregonians living in urban, rural and frontier communities** who may otherwise not have access to care.

As one of the state's larger Medicaid provider networks, FQHCs are largely supportive of the strategies proposed in the policy concepts and application as a whole and we appreciate the inclusion of our association in early waiver discussions. We would like to offer our recommendations on a few select strategies, articulated below, for your consideration.

**Advancing Health Equity**

OPCA's member health centers have over 270 sites statewide and are in all but 2 counties in Oregon, and for those who are designated as rural or frontier sites, concern was expressed about the lack of rural or "locality" in OHA's definition of health equity as well as the lack of reference throughout the application. To be clear, we understand the health equity definition was done separately from this application, as part of the Oregon Health Policy Board, and we would be remiss in representing our member voices if we didn't articulate that lack of inclusion or application felt by our rural and frontier providers. For those who are on the frontlines serving rural or frontier patient populations, their locality and rurality is intrinsically understood as an inequity in their care, and the lack of this inclusion in the definition makes it difficult for providers and their patients to understand their role in helping the state reduce health inequities.

**Recommendation** (in **blue**):

Oregon will have established a health system that creates health equity when all people can reach their full potential and well-being and are not disadvantaged by their race, ethnicity, language, disability, age, gender identity, sexual orientation, **locality**, social class, intersections among these communities or identities, or other socially determined circumstances.

*And/or,*

Achieving health equity requires the ongoing collaboration of all regions and **localities** of the state, including tribal governments to address: ...

### 3.2 Improving Health Outcomes by Streamlining Life and Coverage Transitions

#### *Strategy 4: Covering more providers outside the medical model*

In the context of today's racial/ethnic disparities in both COVID-19 cases and vaccination rates, the role of the CHW has become increasingly important, but often does not fit within the classical medical model for lack of mentorship, appropriate supervision, and financial incentive to enter the field. Many CHWs are left isolated, underutilized, or cannot stay employed due to lack of a living wage, at the same time that we watch disparities widen.

**Recommendation:** Ensure the roles articulated in the concept paper – Traditional Health Workers, Community Health Workers, navigators – are covered at a livable wage rate to promote the quality and quantity of these positions in our state. Expanding infrastructure so CHWs can provide services directly to OHP members and support for capacity building cannot be overstated. Engaging folks from rural communities and people of color should be a top priority moving forward as community members feel safe when they see health care workers that look like them.

**Recommendation:** If payors are required to focus on equity (and supporting THWs specifically), indicating where these funds come from is imperative. Building infrastructure, sustainable payments to these types of roles, and credentialing is a necessary step in implementation that is currently missing. It should be clear that this work is resourced as part of a CCOs global budget and/or separate funding needs to be earmarked for these services.

#### *Strategy 5: Invest in CBOs/health equity spending*

We understand the 1115 Waiver renewal is an integral part of a statewide strategy designed to center equity. However, we are concerned that multiple layers of additional administration are potentially being built “to support infrastructure for health equity investments.” There is a vast network of CBOs, Regional Health Equity Alliances, and CCO Community Advisory Councils in existence currently. CBOs have been a leading voice in the fight for health equity and equal access to health care. CBOs also have substantial trust in the community and are best positioned to provide culturally- and linguistically- appropriate outreach to communities, particularly those who are not currently engaged in the healthcare system.

**Recommendation:** We encourage the use of existing forums/channels, such as CCO Community Advisory Councils (CACs) and/or Regional Health Equity Coalitions, to drive community-level investment to avoid creating additional administrative overhead, and to ensure the largest investment can reach those who need it: the clients served by the CBOs and their community health centers.

**Recommendation:** Consider creating learning space for CBOs that have established themselves in the healthcare space to leverage connection and partnership with health systems in support of younger/newer CBOs.

### 3.4 Incentivizing Equitable Care

#### *a) Upstream metrics*

Community health centers are rooted in their communities – our model of care combines the resources of local communities with federal funds to establish “neighborhood” primary care homes in rural and urban areas. Integral to the communities they serve, FQHCs have also rooted their work in upstream health interventions, from job application assistance to transportation to the clinic. As social determinants of health have taken root and become shared language across the health systems and payors, FQHCs have often been at the forefront of piloting how to collect and utilize data that demonstrates a patients’ non-medical needs. OPCA and our members were instrumental in developing one of the first screening tools (Protocol for Responding to and Assessing Patients Assets, referred to as PRAPARE) and participated in the development of the Social Determinants of Health: Social Needs Screening and Referral metric referenced in the application. We recently completed a yearlong collaborative that partnered health centers with their CCO to assess not only screening methods but coding and referral processes. Incentivizing social needs is critical to reducing health inequities, and it must be done in tandem with both HIE and CIE initiatives across the state that link patients to community-based services and pay providers (Z-codes) for the inclusion of non-medical needs.

**Recommendation:** Screening tools (like PRAPARE) are generally administered by a clinician during a medical visit and the resulting information is contained in the medical record (as EMR allows). To better facilitate resources and ensure that social needs are addressed, screening tools could be administered at different entry points for Medicaid beneficiaries and the resulting data used to best meet their needs, rather than just held by the entity that screens.

### Changes to Prescription Drug Benefits

#### *Ability to define a preferred drug list for pharmacy benefits*

We appreciate the inclusion of strategies to address the impact of pharmacy costs on Medicaid spending in Oregon and, would like to express our deep concern about the impact the strategies, as included, could have in terms of significant impacts on already deep Medicaid rebates as well as limiting choice for OHP patients.

#### *A) Adopt a commercial style closed formulary approach*

In response to a similar recent effort by Massachusetts to implement its own drug formulary for its Medicaid program, Georgetown’s Center for Children and Families stated that pursuing the demo CMS is currently supportive of, “would harm access to drugs as its unlikely that state will get discounts as deep as the ones offered under the Medicaid drug rebate program”<sup>1</sup>. We understand that Oregon is electing to use CMS’ recommended pathway by including it in the demonstration, and want to ensure that the implementation of the proposed strategy does

---

<sup>1</sup> CMS Denies Massachusetts’ request to choose which drugs Medicaid covers. Modern Healthcare <<https://www.modernhealthcare.com/article/20180627/NEWS/180629925/cms-denies-massachusetts-request-to-choose-which-drugs-medicaid-covers>> accessed December 15, 2021.

account for disruptions to patients caused by changes (at any time) to formularies. Pharmacists at our FQHCs shared that “rebate managed formularies can cause a lot of disruption if rebate terms change and another drug becomes more favorable” and that one strategy to mitigate this impact, especially for patients who cannot change insurance plans to better fit their medical conditions, would be to build in strong grandfathering plans for drugs that are no longer covered under the new formulary. This must be done thoughtfully, and with intention, so that the goal of a closed formulary can be met without disruption or reducing access to drugs for a patient population that is already underserved and faces a number of inequities within our health care system. One of our member health centers shared the impact to their pharmacy program, which using the revenues it generates through programs like 340B and rebates, supports the following for their patients and the entire health center, including:

- *operating costs of 7 in-house, integrated pharmacies,*
- *access to medications for the uninsured and underinsured*
- *laboratory services*
- *7 FTE clinical pharmacists (who do diabetes and hypertension management, adherence support, transitions of care etc.)*
- *FTE support for an MA at our HIV clinic*
- *FTE support for drug assistance program enrollment*

While this is only one example, it is an example of how FQHCs do reinvest revenues and pharmacy savings (from the 340B program) back into patient care; that same health center fully understands the intention of tackling the drug spend in our state and believes that both strategies in this section would accomplish this. To ensure that this exercise in reducing prescription drug spend is done without the loss of “deep Medicaid rebates” or harming vulnerable patients by limiting/changing drugs, we recommend the following:

**Recommendation:** Any committee, workgroup or state commission charged with overseeing the development of a Medicaid formulary includes representation from entities who have clinical pharmacies that dispense to a large population of Medicaid beneficiaries, such as Federally Qualified Health Centers.

Thank you for your attention and consideration of our recommendations related to the 1115 Medicaid Demonstration Waiver. We look forward to continued partnership with the OHA in advancing the states equity goals and innovation within its Medicaid program. We are glad to provide clarification or additional information should it be needed.

Sincerely,



Danielle Sobel, MPH  
Sr. Director of Policy and Government Affairs



## **Patients Rising Now's Comments on Oregon's 1115 Waiver and Impact on Access**

The FDA's Accelerated Approval Program provides a path for earlier approval of drugs being developed to treat serious diseases and address unmet medical need. The process allows the use of a surrogate endpoint—an indirect marker of clinical benefit that allows the drug to be approved and in the hands of patients earlier, while the company continues to conduct post-marketing “confirmatory trials” to establish the drug’s benefits. It is important to understand that the FDA has processes in place to remove the drug from the market in case clinical benefit is not established with confirmatory trials.

### **Oregon's 1115 Waiver Will Block Much-Needed Access to These Drugs**

Oregon is asking to waive a key criterion that requires coverage for all FDA-approved drugs under the Medicaid Drug Rebate Program. If the waiver is approved, Oregon's Medicaid program would have a closed formulary for all adults, meaning there may only be one drug for each therapeutic class included in the formulary—a common restrictive strategy followed by commercial health plans. The decision for formulary inclusion would be based on the drug's price and the rebate being offered by the manufacturer. There are no exceptions or protected drug classes—unlike the closed formulary demonstration program that has been piloted by Tennessee Medicaid. Additionally, there is no mention of a process for enrollees to seek coverage for drugs not included in the formulary.

Oregon excludes coverage for children from its waiver request, undermining its stated justification of a waiver for a program for adults. The waiver gives Medicaid the power to decide which drugs have limited clinical benefit or “no incremental clinical benefit” compared to other drugs in the same class, even if they are approved by the FDA—this includes drugs that have received accelerated approval. This means that the Oregon Health Authority, may undermine and question the rigorous scientific and regulatory drug approval processes implemented by the FDA for the sake of cost savings.

Importantly, the proposed restrictive closed formulary will create access barriers for patients with chronic and debilitating conditions seeking prescription drugs and in turn have an adverse effect on their health outcomes. Patients Rising strongly opposes the implementation of such a restrictive program for Medicaid beneficiaries in Oregon—employing such policies will barricade patient access to innovative, life-altering treatment options.

Sincerely,

A handwritten signature in black ink that reads "Terry M. Wilcox". The signature is written in a cursive style with a horizontal line above the first name.

Terry Wilcox  
Co-Founder & Executive Director, Patients Rising Now

## Public comment

### Draft Application of Oregon Health Plan 1115 Demonstration Waiver

January 3, 2022

Authors: *Joshua K. Graves, MBA, QMHA*, Catholic Community Services, CEO, Fostering Hope Program, *Chris Barber MSN, ANP*, Director of Community Integration, Curandi Human Service Network, *Michael D. Rohwer MD*, Founder Curandi Human Service Network.

Please accept the following as a public comment to the Oregon Health Plan 1115 Demonstration Waiver:

The world health organization created the social determinants of health framework in 2003. Social determinants apply more broadly than within the scope of healthcare. Social factors are critical for all community enterprises, including education, business, and government. Everyone needs stable and productive social systems. The Application needs to be more specific about creating reproducible and sustainable improvement in social determinants.

Healthcare cannot solve the social determinants issue because social systems are too big, different, and outside the scope of healthcare's already formidable and vital mission. But it can catalyze real change, as noted in the Application's Health Equity Plan. Its best hope is to support effective **local** systems development.

Getting this right will be difficult for healthcare because the social fundamentals lie outside its core experience and expertise. Community Advisory Councils (CAC) provide input and support for health plan decisions, but operational management of human services is appropriately outside any previous or proposed scope of operation.

The people working in human services are top-notch, and the people they serve have needs that those who are not directly providing social services cannot understand. Additionally, the current system's approach and tools do not match the nature of the growing problem. A radical local human service transformation is needed. CCO investment and support of systemic change will create more long-term value than picking a single issue to support or distributing smaller amounts across the community. A fresh perspective and innovative ideas will help everyone move forward.

Growing more effective **local** human service systems will deliver more value for healthcare by recruiting other stakeholders such as housing, education, and business. This growth will also be a catalyst for increased governmental coordination resulting in more efficient and effective service delivery.

Another catalyst of change for Oregon would be supporting a private, nonprofit, organization **Medicaid Match** as part of the 1115 waiver. Currently, states receiving Medicaid funds must

provide a certain amount of matching funds. State policy should allow nationally accredited and state-licensed private social service agencies to use charitable donations as Medicaid matching funds. This match would increase the available federal money and enable providers to enhance mental health services for the children, youth, and families. The current 1115 draft waiver references similar opportunities in Items 3,4,5. Innovative concepts such as this are reportedly included in waivers in other states, so the preliminary concept work should be easy to replicate. Policy recommendations should allow charitable donations as a source for Medicaid matching funds.

In looking at solutions, this is an opportunity to shift the paradigm. We can put new knowledge to work, restoring the core of society. Each community would have its solution and contract with healthcare and other stakeholders to deliver incremental improvement in social determinants. This value-based contracting would include measures based on new social determinant codes and billing sets from HL7<sup>i</sup>.

A better human service system would be local and connected to each person, family, or neighborhood through a local Traditional Health Worker (CHW or Peer Support Specialist). These THW's need community-level coordination support. A core component would be the integrating infrastructure designed for the dynamic reality of human services.

In the ideal scenario, a better human service system would be coordination-based like healthcare but implemented as an adaptive network that includes the client. In the same way, social media tracks behavior and network topology, we can learn and improve our solutions through understanding **local** complex system dynamics. This additional information is an avenue for data science to teach us more about our communities.

An improved human service system would have a **local** mutual benefit organization to support shared goals and performance. This organization is not a financially driven IPA but an outcome-driven platform of mutual support. This structure would enable concerted action on behalf of providers and those they serve.

Change is needed. Today, we seek to improve complex adaptive problems with complicated rigid solutions. We are trying to understand issues emerging from the dynamics of human behavior using static population-based data. We need to move away from the older top-down systems approach and embrace today's systems theory when dealing with complex and adaptive environments. The current path cannot take us where we need to go.

This Application is hopeful because it opens the door to improving the foundational systems supporting society.

*This approach is supported by Catholic Community Services of the Mid-Willamette Valley and the Curandi Human Service Network.*

---

<sup>i</sup> <https://vsac.nlm.nih.gov/> Value sets can support value-based reimbursement by tracking client state



January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

**Re: Oregon Health Plan 1115 Demonstration Waiver**

Dear Deputy Director Hittle,

Thank you for the opportunity to comment on Oregon's Section 1115 Demonstration Waiver. On behalf of people with cystic fibrosis (CF) living in Oregon, we write to express our serious concerns with this waiver application. While we commend the state for its focus on health equity and inclusion of multi-year continuous eligibility in this application, we have serious concerns that several other proposals could create barriers to access care for people with cystic fibrosis (CF). Specifically, our comments below focus on the requests to adopt a commercial-style closed drug formulary, implement an internal review process to evaluate new drugs for clinical effectiveness, and eliminate retroactive coverage for nearly all beneficiaries.

Cystic fibrosis is a life-threatening genetic disease that affects more than 35,000 children and adults in the United States, including nearly 500 in Oregon. Roughly a third of adults and children living with CF in the state rely on Oregon Health Plan (OHP) for some or all of their health care coverage. Through careful, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. In addition to advances in care, recently approved genetically-targeted drugs that address the underlying cause of CF are available for patients with specific genetic profiles and have contributed to the increases in life expectancy. This milestone reflects over 50 years of hard work to improve CF treatments, develop evidence-based standards of care, and encourage adherence to a lifetime of chronic care. However, despite immense progress in recent decades, there is still critical work to be done to ensure that all those living with the disease have access to effective therapies and, ultimately, a cure.

Given the vital role Medicaid plays in helping this patient population access essential specialized care, we urge Oregon to consider the needs of people living with CF as the state seeks changes to OHP. Within Oregon's' 1115 demonstration request, we are particularly concerned with the following provisions:

**Adopt a commercial-style “closed formulary”**

Oregon seeks to waive the requirement that Medicaid provide at least some coverage for all FDA-approved drugs and instead implement a commercial-style closed formulary to include at least one drug available per therapeutic class. The CF Foundation recognizes the reality that growth in drug costs contributes to the increasing strain on state budgets. However, we are concerned that the adoption of a closed formulary could create barriers to accessing necessary, life-saving treatments.

Treatments for CF are finite and not interchangeable; more than one drug per class is necessary in some therapeutic areas such as CFTR modulators, inhaled antibiotics, and pancreatic enzymes. For example, inhaled antibiotics are an important part of the CF care regimen. Because the type of antibiotic, the dosage, and the length of time to take the drug all vary from person to person—and the fact that some people become resistant to antibiotics over time—it is critical that people with CF have access to all available inhaled antibiotics designed specifically for CF.

Similarly, access to all CFTR modulators, the only class of CF therapies to address the underlying cause of the disease, is necessary due to the highly individualized nature of cystic fibrosis. Ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), tezacaftor/ivacaftor (Symdeko®), and elexacaftor/ivacaftor/tezacaftor (Trikafta®) are FDA-approved therapies that improve the function of CFTR protein for individuals with specific mutations in the CFTR gene. Different CFTR mutations cause different defects in the protein; therefore, genetically targeted modulators are effective only in people with specific mutations, and multiple therapies are needed within the same class to ensure everyone has access. Individual treatment regimens for CF are best determined between a patient and their CF care team.

This application also states that there will be pharmacy protections so that the adoption of a commercial-style formulary does not negatively impact members' access to safe, effective drugs. However, we are alarmed that the waiver does not outline what these pharmacy protections will be, nor does it include an exception process or any other mechanism for patients to access medically necessary drugs that are not on the formulary. This proposal lacks clear detail and fails to specify exactly how this process will work or how the state would ensure patient access. Oregon should articulate a clearly defined exceptions process, including a timeline for decisions that protects patients from delays. The state should also ensure that this exceptions process does not create an undue burden for providers.

#### **Exclude drugs with limited or inadequate evidence of clinical efficacy from the formulary**

Oregon requests the authority to use its own review process, in partnership with the Coordinated Care Organizations (CCOs), to determine whether drugs are covered by OHP. The state maintains that many drugs coming to market through FDA's accelerated approval pathways have not yet demonstrated clinical benefit. However, this waiver could apply more broadly to any drug, with the state noting that it will prioritize any new drugs (not just accelerated approval drugs) as well as re-formulations of existing drugs.

Furthermore, the state's plan to adopt a closed formulary must include more specificity and transparency. This waiver application states that Oregon would use its "own rigorous review process" to develop the OHP formulary but does not provide any information about how coverage decisions would be made, how the state would ensure transparency around this process, or how it would result in timely access to therapies for members. Should the state receive approval for its commercial-style formulary, it must provide a clearly defined and transparent review process, with opportunities for public review and comment, including significant input from experts, such as CF clinicians.

#### **Remove retroactive eligibility**

We are also concerned with this waiver's request to extend the elimination of retroactive coverage for almost all beneficiaries. Retroactive eligibility helps adults living with CF in Oregon who rely on Medicaid avoid gaps in coverage and costly medical bills. Cystic fibrosis care and treatments are costly, even with coverage, and retroactive eligibility helps protect against additional out-of-pocket costs.

According to a survey conducted by George Washington University of 1,800 people living with CF and their families, over 70 percent indicated that paying for health care has caused financial problems such as being contacted by a collection agency, having to file for bankruptcy, experiencing difficulty paying for basics like rent and utilities, or having to take a second job to make ends meet. And while nearly 75 percent received some form of financial assistance in 2019 to pay for their care, almost half reported still having problems paying for at least one medication or service in that same year.<sup>1</sup> Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as cystic fibrosis, to begin treatment without being burdened by medical debt prior to their official eligibility determination.

\*\*\*\*\*

The Cystic Fibrosis Foundation appreciates the opportunity to provide input on these important policy changes. We look forward to working with the state of Oregon to ensure access to high-quality, specialized CF care and improve the lives of all with cystic fibrosis. Please contact Sage Rosenthal, State Policy Sr. Coordinator, at [srosenthal@cff.org](mailto:srosenthal@cff.org) or (301) 841-2631 with any questions or comments.

Sincerely,

**Mary B. Dwight**

Chief Policy & Advocacy Officer  
Senior Vice President, Policy & Advocacy  
Cystic Fibrosis Foundation

**Aaron Trimble, MD**

Director, Adult CF Care Center  
Oregon Health Sciences University  
Portland, OR 97239

**Mike Powers, MD**

Director, Pediatric CF Care Center  
Oregon Health Sciences University  
Portland, OR 97239

---

<sup>1</sup> Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Cost, coverage, and the underuse of medications among people with CF" (2020). Health Policy and Management Issue Briefs. Paper 57. [https://hsrc.himmelfarb.gwu.edu/sphhs\\_policy\\_briefs/57](https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/57)



Christian Moller-Andersen, Executive Director, A Smile for Kids  
Comments on OHA's Application for Renewal and Amendment of 1115 Waiver  
Submitted on 12/31/21 via the OHA public comment portal:  
[https://mslc.qualtrics.com/jfe/form/SV\\_7O1XVYN2bJqvd8G](https://mslc.qualtrics.com/jfe/form/SV_7O1XVYN2bJqvd8G)

**It is time to address the orthodontia inequity in Oregon's Medicaid program.** Oregon's current 1115 Medicaid waiver waives the federal requirements under the Early and Periodic Screening, Diagnostic and Testing (EPSDT) benefit for services listed below line 471 on the prioritized list of health services. Oregon's draft Application for Renewal and Amendment of the 1115 Waiver, dated 12-1-2021, proposes to continue to *"Restrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one."* (See pages 42, 147, and 156.)

As treatment of handicapping malocclusion is listed at line 618 of the current prioritized list, well below the line 471 cut off, the Oregon Health Plan (OHP) is proposing to continue to severely restrict children's access to medically necessary orthodontia services. Currently these services are covered by the OHP only when related to the treatment of cleft lip, cleft palate, or another craniofacial anomaly. Oregon is unique in the country in this respect. As required by EPSDT, all other state Medicaid programs cover children's orthodontia when necessary to correct or ameliorate medical conditions such as severe malocclusion. This coverage is required under federal law (unless waived) and enumerated in the Centers for Medicare & Medicaid Services' EPSDT Guidelines. It is time for Oregon to join every other state in offering this coverage.

**In this 1115 renewal, the Oregon Health Authority (OHA) should cease waiving EPSDT coverage for non-prioritized services.** As noted above, the waiver renewal application includes a request to continue the waiver of EPSDT requirements such that treatment needs identified during an EPSDT screening that are not consistent with the prioritized list of health services for children over age one would not be covered. We believe that continuing this waiver is unnecessary for OHA to meet its stated goals. Federal Medicaid law already provides all the tools a state needs to ensure that services are covered only when medically necessary. This gives states the necessary discretion to design an individualized benefit that also meets State fiscal goals. Forty-nine states and the District of Columbia have demonstrated that it is possible to craft coverage guidelines for children's orthodontia, along with individual medical necessity determination protocols, that ensure provision of the service only to children who need it. We stand ready to help Oregon do the same.

**Providing medically necessary orthodontia services to children covered through the Oregon Health Plan will advance health equity.** Severe malocclusion is a life-altering condition. It interferes with eating, speaking, sleeping, smiling, and normal social relating. It can affect both the physical and the social/emotional development of children. Its impacts can be felt over a lifetime in the loss of achievements in education, possibilities in employment, and a reduction in overall health and wellness, including mental health. The remedy for severe malocclusion – orthodontia – is well-established but only readily available to middle- and upper-income children. It is not currently available to low-income children in Oregon except through the very limited resources of A Smile for Kids (ASK), a charity that is able to serve fewer than 100 children each year. A failure to address severe malocclusion can combine with other social determinants of health to interfere with a child’s ability to access a healthy and successful life trajectory, leading to greater dependency and higher health care costs over a lifetime. Addressing this coverage gap is an essential part of Oregon’s aim, in this renewal package, to create more equity in health care and in health outcomes.

**Example:**

Oscar (name changed) entered the ASK orthodontic program when he was 13 years old in seventh grade. He suffered from a handicapping malocclusion, which led to teasing and bullying by peers. Oscar had a hard time with eating, speaking and drinking, and endured pain in his mouth due to the malocclusion. All of these challenges were exacerbated by the relentless teasing. He grew up in a family of eight with an annual household income of \$28,000. Both parents were undocumented immigrants, so work and income options were limited for them.

Under current OHP coverage and the limitations in the proposed renewal of the Medicaid Waiver, the State of Oregon is telling kids like Oliver that his need for braces is not important enough and that he’ll simply have to get used to it and somehow make it through despite this massive barrier. Before and after photos below:



Although the direct correlation is difficult to prove scientifically, Oscar went on to complete the orthodontic treatment funded by ASK, improved his grades in school, graduated high school and is now sophomore at private university in Oregon with a full four-year academic scholarship, majoring in political science. Oscar wants to be an attorney.

When asked to identify obstacles when growing up, Oscar provided the following answer: *"My teeth were definitely one of 2 obstacles. The other obstacle being limited financial resources. Having braces gave me the confidence to take my education and its opportunities to the next level. I don't think I would be where I am now if I had not had the braces."*

**To successfully meet its purpose, a new orthodontia benefit will need to be adequately funded and pay reasonable rates to providers.** Because orthodontia for children would be a new benefit in the OHP, when computing the base rate in the global budget OHA will need to go beyond the proposed 5-year look back at utilization and spending. OHA will need to estimate what amount it will pay for a course of orthodontic treatment and how many children will be approved for the service in the first year, and then incorporate those figures into the global budget computation. Further, when computing the projected future trend of the base rate, OHA would need to incorporate an assumption of gradually increasing utilization of the benefit. This approach will ensure that Coordinated Care Organizations (CCOs) are not caught short financially as the new orthodontia coverage eventually reaches more eligible children in Oregon.

**Lastly, OHA will need to design and implement a meaningful reporting and accountability structure to ensure that all affected children, including those in Tribal communities, can equitably access high quality orthodontic care in locations convenient to where they live.** This will help guard against inappropriate underutilization of the orthodontia benefit and outright denials of medically necessary care by CCOs. CCOs should, at the very least, be actively monitored to see that they are effectively implementing the new benefit. Ideally, they could be incentivized to ensure that affected children are being screened, referred, diagnosed, and served appropriately. Both member and provider satisfaction should regularly be assessed and reported. CCOs should be required to report data on utilization of, and satisfaction with, the orthodontic benefit, stratified by subpopulation so any gaps can be identified and addressed.

**Specific impacts and measures that are affected by orthodontic treatment** include an increase in middle- and high-school grades after orthodontic treatment, increased self-esteem as self-reported and as reported by third party professionals, higher community involvement, higher graduation rates, increased social interactions with peers, improved oral health/hygiene, and assignment of dental home for the child and rest of family.

**In conclusion, we urge OHA to include in its Application for Renewal and Amendment of the 1115 Waiver:**

- **An explicit withdrawal of the request to limit EPSDT treatment services to those on the prioritized list of health care services;**
- **A statement that OHA will begin to provide coverage for treatment for medically necessary orthodontia in children, i.e., fixed, and removable appliances and associated surgical procedures for handicapping malocclusion;**
- **An indication that OHA will incorporate in the global budget base rate, and in the projected future trending of the base rate, a reasonable provider rate and an expectation of a gradually increasing number of orthodontia cases over the five (5) year duration of the waiver; and**
- **An indication that the CCO accountability structure will include the necessary data collection and reporting requirements, stratified by subpopulation, to ensure that all affected children are being equitably served by the orthodontia benefit.**

Respectfully submitted,

Christian Moller-Andersen, Executive Director  
A Smile for Kids  
446 SW 7<sup>th</sup> Street  
Redmond OR 97756  
Phone: 541-280-4214  
Email: [cma@asmileforkids.org](mailto:cma@asmileforkids.org)



January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Deputy Director Hittle,

The Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, appreciates the opportunity to submit comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program. As the largest provider of social and emotional support services for people impacted by cancer, CSC has a unique understanding of the cancer patient experience. In addition to our direct services, our Research and Training Institute and Cancer Policy Institute are industry leaders in advancing the evidence base and promoting patient-centered public policies.

CSC is committed to ensuring that Oregon's Medicaid program provides quality and affordable healthcare coverage. We appreciate the focus that the Oregon Health Program has placed on equitable access to healthcare in the waiver. In addition, Oregon's request to provide continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver contains multiple proposals that undermine access to care for cancer patients and survivors. We are concerned with the proposed closed formulary for adult beneficiaries, which will make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries, as the proposal jeopardizes access to care for cancer patients and survivors.

We offer the following comments and suggested changes on the 1115 demonstration waiver for the Oregon Health Program.

#### *Continuous Eligibility*

We support the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage (Osorio & Alker, 2021). Research has also shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits (Sugar et al., 2021). Continuous eligibility will help reduce these negative health outcomes.

#### *Closed Formulary*

We are strongly concerned by the proposal to transition to a closed prescription drug formulary for adult beneficiaries. A closed formulary limits the ability of providers to make the best medical decisions for their patients, based on the patient's individual needs. A formulary that may only cover one or two drugs in a class could harm patients and potentially raise medical costs as patients do not react, or react poorly, to the limited medications that can be prescribed to them. This is particularly true for cancer patients who

often receive personalized or combination therapy. Rather, providers should be prescribing based on clinical guidelines and a shared decision-making process with the patient.

We are disappointed that Oregon's proposal does not even include an appeals process for patients to access non-formulary medications. However, even an appeals process or exemptions for certain classes of drugs would not eliminate the barriers to care that patients would face with a closed formulary. The closed formulary has the potential to create delays in appropriate care, cause patients to forgo care completely, increase patient distress, and ultimately even contribute to higher health care costs. In CSC's *Access to Care in Cancer 2016* study, we found that 25% of patients experience delays in accessing needed care (due to policy barriers such as prior authorization or step therapy), with Medicaid patients experiencing the greatest care delivery delays.

Additionally, Oregon's proposal to exclude prescription drugs that the state deems to have "limited or inadequate evidence of clinical efficacy," including those approved through the U.S. Food and Drug Administration's (FDA's) accelerated approval process, may also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new treatments have been approved through an accelerated approval process which makes therapeutically-important drugs available sooner without compromising the standards of safety and effectiveness of drugs for serious conditions like cancer. All patients enrolled in Oregon's Medicaid program should have the opportunity to access treatments that could extend or improve their quality of life.

We request that the Oregon Health Program remove these requests and provide a robust, open prescription drug formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

#### *Retroactive Coverage*

The demonstration waiver also continues to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind, and disabled. We have serious concerns with the continued limitations to retroactive coverage and encourage the state to expand retroactive coverage to include all Medicaid beneficiaries.

Medicaid's retroactive eligibility prevents gaps in health care coverage by covering individuals for up to 3 months prior to a beneficiary's application date, provided that the individual would have been eligible for Medicaid coverage during that period. Many people only become aware that they are eligible for Medicaid when they get diagnosed with a serious illness, such as cancer, or have a major health emergency and cannot complete the application process while undergoing treatment. Retroactive eligibility allows patients in these situations to begin treatment without being financially burdened prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility (CMS, 2016). Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy. Retroactive coverage is especially important during the COVID-19 pandemic, protecting patients and providers by ensuring that medical bills are paid even if a Medicaid application is not filed until the calendar month following a health crisis.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver (Dickson, 2016). Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the

COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs.

Thank you again for the opportunity to provide comments. Should you have any questions, please contact Phylicia L. Woods, Executive Director of the Cancer Policy Institute at the Cancer Support Community at [pwoods@cancersupportcommunity.org](mailto:pwoods@cancersupportcommunity.org).

Sincerely,



Phylicia L. Woods, JD, MSW  
Executive Director – Cancer Policy Institute  
Cancer Support Community Headquarters

## References

- Cancer Support Community. (2016). *Access to Care in Cancer 2016: Barriers and Challenges*. Retrieved from <https://www.cancersupportcommunity.org/sites/default/files/migrated/pdf/csc-access-to-care-barriers-challenges.pdf>.
- Centers for Medicare & Medicaid Services. (2016). *Healthy Indiana Plan 2.0 CMS Redetermination Letter*. Retrieved from <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>
- Dickson, V. (2016). Ohio Medicaid waiver could cost hospitals \$2.5 billion. *Modern Healthcare*. Retrieved from <http://www.modernhealthcare.com/article/20160422/NEWS/160429965>.
- Osorio, A., Alker, J. (2021). Gaps in Coverage: A Look at Child Health Insurance Trends. *Center for Children & Families of the Georgetown University Health Policy Institute*. Retrieved from <https://ccf.georgetown.edu/2021/11/22/gaps-in-coverage-a-look-at-child-health-insurance-trends/>.
- Sugar, S., Peters, C., De Lew, N., & Sommers, B.D. (2021). Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic. *Assistant Secretary for Planning and Evaluation Office of Health Policy*. Retrieved from <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>.



DEVELOPING THRIVING COMMUNITIES

Thursday, January 6th, 2022

To: Oregon Health Policy Board  
Attention: David Bangsberg MSc, MD, MPH  
C/O: Tara Chetock, Oregon Health Authority  
[tara.a.chetock@dhsosha.state.or.us](mailto:tara.a.chetock@dhsosha.state.or.us)

RE: Draft Application for the 1115 Medicaid Waiver

Chair Bangsberg and Oregon Health Policy Board Members:

DevNW is an affordable housing development and counseling agency serving six counties in Oregon. Our mission is serve low and moderate income Oregonians to increase their financial security, build assets and develop thriving communities. We administer the Linn Benton Health Equity Alliance, one of five Regional Health Equity Coalitions (RHEC) in Oregon.

We know that that systemic racism has led to disproportionately higher inequities for people of color within the health system. We also know that this can be undone, most notably when communities impacted are leading. When we give power and resources to communities they can direct them to the most important health-related issues their neighbors and families face. By shifting power and granting agency, we can make significant progress toward eliminating health disparities and achieving health equity in Oregon.

We are pleased to see focused equity investments in the final policy concepts that the Oregon Health Authority (OHA) has developed for Oregon's next 1115 Medicaid Waiver. The RHECs participated in co-writing HB 3353, and in an Oregon Health Authority (OHA) waiver workgroup related to the focused equity investments concept, and supported the creation of the Community Investment Collaborative (CIC) model specifically to address health inequities because *current efforts and investments are not working for our communities.*



DEVELOPING THRIVING COMMUNITIES

We stand behind the work of the RHECs and it is our hope that all waiver concepts will be aligned with these principles as reflected in HB 3353:

- Target investments and efforts to populations and communities who have been most impacted by historic and contemporary injustices and health inequities including but not limited to Tribal Nations, Tribal communities, Latino/a/x, Black/African American, Asian, Pacific Islander, and American Indian/Alaska Native populations, communities of color, people with disabilities, people with limited English proficiency, and immigrants and refugees.
- Shift power and decision-making authority so community voice related to needs ultimately leads to development of actions to mitigate ineffective approaches and unintended consequences.
- Create opportunities to build sustainable infrastructure that works to develop and maintain systems and programs that recognize, reconcile, and rectify historical and contemporary injustices.
- Support community leadership development.
- Build and rebuild trust between health systems and community.

We believe that this shift is fundamental to centering community voice and wisdom, allowing experts in their own lives to express where investments are most necessary. Thank you for all of your work on behalf of Oregonians and in considering this input as you move forward to finalize the waiver application and enter into negotiations with the Centers for Medicaid and Medicare Services.

Sincerely,

A handwritten signature in black ink, appearing to read "KSaxe".

Karen Saxe  
Chief Program Officer



January 7, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Oregon Health Plan 1115 Demonstration Waiver Application for Renewal

Dear Ms. Hatfield:

We appreciate this opportunity to provide comments as the Oregon Health Plan (OHP) applies to the Centers for Medicare & Medicaid Services (CMS) for a new five-year Medicaid waiver, known as the 1115 Demonstration. We hope that the state will incorporate the perspectives of people with disabilities that disproportionately are impacted by the state's prioritized list of services by barring the use of the discriminatory quality-adjusted life year (QALY) as a consideration; by ensuring that individuals with disabilities and significant health conditions do not face discrimination in accessing suicide prevention services; and by discontinuing the EPSDT waiver that too often fails to give children the care they need.

As you know, in 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage that was denied by the U.S. Department of Health and Human Services as "discriminatory and inconsistent with the Americans with Disabilities Act."<sup>1</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance. Despite ADA concerns, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Officially, Oregon excluded the survey-based QALY data that triggered denial of its initial waiver application in 1992. Yet, the voting members of Oregon's Health Policy Commission have authority to

---

<sup>1</sup> <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

override the results of non-QALY considerations, which they did in over 70% of the cases. The discriminatory outcome for how care is valued and prioritized is the same.<sup>2</sup>

Today, the Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, continues to use QALY-driven data and analysis in the formula for the prioritized list of services. As reconstructed in 2008, Oregon's revised prioritization framework emphasizes preventive services and chronic disease management in order to keep the "population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health." This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. Although Oregon removed a direct and explicit reference to QALYs from its cost-effectiveness framework in 2017, it continues to rely upon the QALY-driven prioritization scores for condition-treatment pairs that were already established at that time. In addition, HERC continues to consider QALY-based analysis in evaluating other factors in the formula.<sup>3</sup>

The HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by entities such as the Institute for Clinical and Economic Review (ICER) as they vote. After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list. A few excluded services for people with disabilities include treatment for hearing impairment, Bell's Palsy, Spastic Diplegia, and certain personality disorders.<sup>4</sup>

Oregon also chooses to provide coverage for some services that aren't on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of physician-assisted suicide, including counseling and lethal prescriptions. It has been reported that OHP patients who have been denied coverage of potentially life-extending health services that were "below the line" have been advised by OHP that physician assisted suicide is a covered alternative.<sup>5</sup> This outcome – preference for assisted suicide over treatment – is the direct result of the state's discriminatory policies and is clearly unethical and in violation of disability and civil rights protections.

The ethical challenges of Oregon's use of discriminatory metrics to ration services it will cover are exacerbated for children. Oregon is the only state with an EPSDT waiver. In every other state, under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called "Early and Periodic Screening, Diagnostic and Treatment" (EPSDT) to ensure that they receive "age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting." Critically, the EPSDT provision requires comprehensive coverage of health services for children – *regardless of whether or not such services are otherwise covered* under the state

---

<sup>2</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf>

<sup>3</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx>

<sup>4</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>

<sup>5</sup> <https://abcnews.go.com/Health/story?id=5517492&page=1>

Medicaid plan for adults ages 21 and older – to make certain that rationing is not imposed for this vulnerable population.<sup>6</sup> Even still, Oregon’s Section 1115 Medicaid waiver includes a provision authorizing it to withhold medically necessary care from children over the age of one if it is “below the line” on its “Prioritized List” of health services. A few examples include noncoverage of treatment for selective mutism, conduct disorder, recurrent ear infections, minor burns, and pica.

We believe it is time to end this failed experiment of relying on discrimination to ration care. Our specific recommendations are as follows:

**1. Full Compliance with EPSDT**

The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.

**2. Prohibit the Use of Discriminatory QALY Measures**

The waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, such as this:

“Prohibition on Reliance on Discriminatory Measures. The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per- quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”

**3. Non-discrimination in Suicide Prevention Services**

The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for lethal drugs under Oregon’s “Death with Dignity Act,” will be provided with the same harm and suicide prevention services<sup>7</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to die by suicide because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.

---

<sup>6</sup> <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>

<sup>7</sup> The term “harm and suicide prevention services” includes screening, diagnosis, psychiatric treatment, therapy, counseling, and other services whose purpose is the detection and treatment of suicidal ideation and tendencies and the causes thereof, including depression, mental disorders, and lack of access to rehabilitative and supportive care.

We appreciate the opportunity to comment.

Sincerely,

[Disability Policy Consortium](#)

[Disability Rights California](#)

[Disability Rights Education and Defense Fund](#)

[Not Dead Yet](#)

[Patients Rights Action Fund](#)

[Partnership to Improve Patient Care](#)

[The Coelho Center for Disability Law, Policy, and Innovation](#)



**Oregon Early Learning Council**

700 Summer Street NE, Suite 350

Salem, OR 97301

January 4, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team

Attn: Michelle Hatfield

500 Summer St. NE, E65

Salem, OR 97301

SUE MILLER  
*Chair, Early Learning  
Council*

PATRICK ALLEN  
*Director, Oregon Health  
Authority*

ANGELA BLACKWELL

KATY BROOKS

PETER BUCKLEY

COLT GILL  
*Deputy Superintendent,  
Oregon Department of  
Education*

ANNE KUBISCH

GEORGE MENDOZA

DR. MARGARET MILLER

MARGARET SALAZAR  
*Executive Director,  
Oregon Housing and  
Community Services*

KALI THORNE LADD

LIESL WENDT  
*Deputy Director,  
Oregon Department of  
Human Services*

ALYSSA CHATTERJEE  
*Early Learning  
System Director*

Dear Members of the Health Policy and Analytics Medicaid Waiver Renewal Team,

I write on behalf of the Early Learning Council in support of strategies aimed to bolster young children (0-5) and their families in Oregon's Medicaid 1115 Waiver. Thank you for prioritizing the youngest Oregonians by aligning several strategies of the Waiver with those of *Raise Up Oregon: A Statewide Early Learning System Plan*, specifically the goals to ensure that children and their families are healthy and supported to enter school. As noted in the Waiver, families with young children are at the poorest stage in their lifetimes, and families of color disproportionately make up young families in poverty.

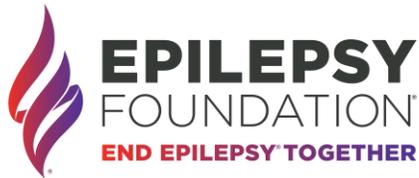
We commend you for the proposal of continuous enrollment for young children in Medicaid, which will facilitate access to routine care and needed specialized services, during the most critical growth and development period in their lives. We also support the proposed changes in the metrics and note the delineation of upstream and downstream metrics with the focus on equity and prevention. We note as well the focus on meeting the health care needs of children in the child welfare system, and appreciate this as so many of the children impacted by this system are in the birth to five age range. Finally, the proposed Community Investment Collaborative provide an important opportunity to give voice to community members.

As you seek to implement these, we encourage connection with the Early Learning Hubs and with families and providers who are part of the early care and education system and who are also participants in the Oregon Health Authority's Waiver programming.

Thank you again for your dedication to supporting the youngest Oregonians and their families through strengthening safety nets that keep young families thriving. You have our endorsement for the proposed Waiver.

Sincerely,

Sue Miller, Chair  
Early Learning Council



Oral Comments submitted to the Oregon Health Policy Board by Kevin Koppes, Executive Director, Epilepsy Foundation Oregon regarding the Oregon Health Plan 2022-2027 1115 waiver

January 4, 2022

Members of the Oregon Health Policy Board:

Thank you for hearing my comments today. I am here on behalf of Epilepsy Foundation Oregon and the 42,900 people with epilepsy in Oregon, including 5,400 children. There are aspects of this waiver proposal that we support, but there are also others with which we must raise grave concerns.

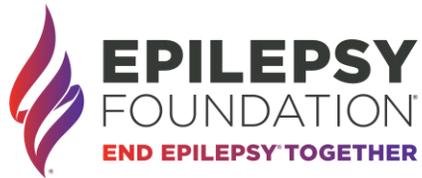
We support the proposal to maximize Oregon Health Plan coverage through continuous enrollment. People who are eligible for Medicaid often have fluctuating incomes and can “churn” on and off the program. Continuous enrollment reduces gaps in coverage that prevent people from accessing the care that they need during these fluctuations. Continuous access to care is especially important for people with epilepsy, where even one missed dose of medication can lead to significant complications.

However, we have significant concerns with a number of other proposals, including the requests to implement a new commercial-style closed formulary and the requests to continue waivers of retroactive coverage and the waiver of Early and Periodic Screening, Diagnostic, and Treatment services benefit for children.

The proposed closed formulary would cover as little as one medication per therapeutic class. This means that only one epilepsy medication could be covered for all adults in Medicaid. Epilepsy medications are not interchangeable and there is no one treatment that works best, or even works at all, for everyone with seizures. The response to medications, including effectiveness at controlling seizures and side effects, can be different for each person. Further, many people with epilepsy need to take more than one anti-seizure medication to gain seizure control. Physicians and patients work together to determine the appropriate regimen, based on the type of seizure, seizure frequency, age, gender, other health conditions, other medications, and side effects. Limiting coverage to one anti-seizure medication

Retroactive coverage is a critical part of Medicaid’s safety net. It is common for people to be unaware that they are eligible for Medicaid until a medical crisis. Retroactive eligibility allows people with epilepsy, who have either been newly diagnosed or need a new treatment regime, to begin treatment right away without the burden of medical debt while they work on eligibility paperwork and are approved. This is particularly important for some groups that experience health disparities, such as African Americans, who are more likely to be diagnosed with epilepsy in an emergency room.

Finally, the continuation of the waiver of EPSDT would continue to deprive children with epilepsy in Oregon of needed services. Children with epilepsy do not only need their anti-seizure medications. They frequently have related developmental disabilities or mental health needs, yet the current EPSDT waiver excludes treatment for disorders common in children with developmental disabilities, including selective



mutism, conduct and impulse disorders, deformities of the upper body and limbs, sleep disorders, and pica.

Thank you for hearing me today. We will be submitting more detailed written comments by the January 7 deadline.

Kevin Koppes  
Executive Director  
Epilepsy Foundation Oregon

January 7, 2022

Paul Terdal  
700 NW Macleay Blvd  
Portland, OR 97210

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301  
By email: [1115Waiver.Renewal@dhsola.state.or.us](mailto:1115Waiver.Renewal@dhsola.state.or.us)

Re: Public Comment on Oregon's Section 1115 Medicaid Demonstration Waiver Renewal Application

Dear Ms. Hatfield,

I am writing as a member of the public, and as the father of two Medicaid-eligible children with disabilities, to provide comment on Oregon's planned Section 1115 Medicaid Demonstration Waiver Renewal Application.

There are three critical fixes that should be included in Oregon's next waiver: removing the obsolete EPSDT waiver provision, renouncing the use of discriminatory Quality Adjusted Life Year (QALY) metrics in ranking services on the prioritized list, and ensuring that individuals with disabilities and significant health conditions do not face discrimination in accessing suicide prevention services.

**Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Waiver:**

Oregon is currently the only state in the country that reserves the right to withhold medically necessary care from children on Medicaid for the sole purpose of saving money, through the EPSDT waiver clause, which reads:

**3. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)  
Section 1902(a)(10)(A) and 1902(a)(43)(C)**

To allow the state to restrict coverage for treatment services identified during an EPSDT screening for individuals above age 1 to the extent that such services are not consistent with a prioritized list of conditions and treatments. (Applies to all Medicaid state plan populations, except population 23.)

This directly contradicts the U.S. Department of Health and Human Services explanation of EPSDT:<sup>1</sup>

“All medically necessary diagnostic and treatment services within the federal definition of Medicaid medical assistance must be covered, regardless of whether or not such services are otherwise covered under the state Medicaid plan for adults ages 21 and older.” (*emphasis added*)

---

<sup>1</sup> <http://mchb.hrsa.gov/epsdt/overview.html#1>

The Center for Medicaid and CHIP Services has further described EPSDT as follows<sup>2</sup>:

“In 1967, Congress introduced the Medicaid benefit for children and adolescents, known as Early and Periodic Screening, Diagnostic and Treatment (EPSDT). The goal of this benefit is to ensure that children under the age of 21 who are enrolled in Medicaid receive age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting. This broad scope supports a comprehensive, high-quality health benefit.”

The Oregon Department of Justice has published an opinion<sup>3</sup> asserting that this clause in the waiver permits Oregon to limit or exclude coverage of medically necessary care from children, even when those limits or exclusions specifically contradict CMS guidance, such as CMS guidance prohibiting “hard” limits on physical therapy visits for children.<sup>4</sup>

The State of Oregon has used this EPSDT clause to save money by withholding medically necessary care from needy children. Specifically, Oregon uses the prioritized list of health care services to determine which services are to be provided. Services that are “below the line” – or simply not recorded on the list at all – are withheld, regardless of individual determinations of medical necessity.

Over the past few months, I have met with a number of physicians and families on OHP who have struggled to access medically necessary care for their patients and children to learn about the human impact of Oregon’s EPSDT waiver.

Here are some findings and observations:

- Many of the condition / treatment pairs that are “below the line” are debilitating but treatable, and denying coverage can lead to significant harm. Some examples:
  - Selective mutism: untreated children cannot fully participate in school or community. HERC found that treatment was highly effective, but excluded coverage anyway because of an erroneous belief that the condition was insignificant to patients.
  - Chronic otitis media: physicians have advised us that they must wait until a child suffers actual hearing loss before they can get coverage of this condition.
  - Conduct disorder: low-income children on Medicaid who exhibit disruptive behavior are denied access to psychotherapy for this DSM-5 condition, resulting in a higher chance of incarceration.
  - Inpatient behavioral treatment for severe autism: while the prioritized list covers outpatient Applied Behavior Analysis (ABA) therapy as a treatment for autism, the list does NOT include any inpatient services. There are Oregon teens with severe autism

---

<sup>2</sup> <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html>

<sup>3</sup> Deanna Laidler, Sr. Assistant Attorney General, Oregon Department of Justice, to Darren Coffman, Director, Health Evidence Review Commission, “Mental Health Parity and Rehabilitative Therapies,” October 5, 2016

<sup>4</sup> CMS, EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents (“CMS EPSDT Guidance”), p.24, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html>

who require much more intensive, inpatient treatment to address self-injurious to aggressive behaviors – which are excluded from the list without regard to medical necessity. Some nationally ranked hospitals have begun refusing Medicaid patients from Oregon because of Oregon’s notorious refusal to pay for behavioral health treatment, and no Oregon hospitals have the necessary capabilities.

- Many physicians resort to “code games” to work around the prioritized list
  - For instance, coding “selective mutism” as “anxiety” or “depression”
  - This bypasses the list – defeating any intent at cost savings – while increasing bureaucratic burden
  - Obscures a patient’s true condition by disguising it as a coverable condition, making a patient’s medical history harder for future medical providers to follow and treat
  - Exposes physicians to risk of prosecution for fraud
- Oregon’s prioritized list places a high priority on coverage of common services for otherwise healthy people (routine dental exams) while deprioritizing rarer or more serious conditions for patients with disabilities.
  - Any “rare” condition that simply hasn’t been considered by HERC is automatically excluded (below the line) with no opportunity for a successful appeal
  - Palliative care (and even assisted suicide) are given a higher starting category weight (65 points) than life saving care (40 points)
- Priorities are set on the list without direct input from patients and families on values and preferences, resulting in strange or inappropriate decisions
  - Selective mutism and Pika were both scored below the line because HERC believed that the conditions had minimal impact on patients or that there was no need for treatment

Please refer to the attached issue briefs from Disability Rights Oregon on “How the Oregon Health Plan Discriminates” and “Oregon’s Unique EPSDT Waiver Allows OHP to Deny Medically Necessary Care to Children to Save Money” for more information.

Perhaps 30 years ago there was some policy justification for rationing care to low income children by withholding medically necessary care from them to save money – but not now. America has come a very long way since then in providing universal access to health care, especially for children, with a substantial expansion in Medicaid funding under the Affordable Care Act. It’s time for Oregon to catch up to the rest of the nation – and comply fully with EPSDT’s requirement to provide “all medically necessary diagnostic and treatment services ... regardless of whether or not such services are otherwise covered ... for adults ages 21 and older”.

**Recommendation:** The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.

## Quality Adjusted Life Year (QALY) Metrics:

Oregon has consistently used discriminatory “Quality Adjusted Life Year” (QALY) metrics as a factor in ranking services on the prioritized list. QALY is a tool that estimates the value of a treatment according to years of additional life – discounted by the level of disability. This approach places a lower value on years of life for those with disabilities – such as my children – than on years of life for people without disabilities – and is inherently discriminatory.

Over the past six months, I have studied the Oregon Health Plan’s use of QALY metrics in detail, and have met with senior OHA leadership for input. Here are my initial observations:

- Oregon Health Authority records show that when the US Department of Health and Human Services directed Oregon NOT to use the QALY metric in 1992, on grounds that it violated the Americans with Disabilities Act, the HRC simply worked around this by voting to adopt essentially the same discriminatory results derived from the QALY-based formula.<sup>5</sup>
- Despite Federal guidance to the contrary, Oregon continued to use the QALY as an explicit input in the “cost effectiveness” factor in the prioritization formula until 2017
  - Most of the condition-treatment pairs now on the list continue to be ranked using the old QALY-based factor
- HERC continues to rely upon QALY-based cost effectiveness reports from ICER, NICE, and other organizations. When staff prepare summaries of those reports for the commissioners, they frequently cite and call attention to the QALY scores, as is clearly documented in meeting materials
- Other factors in the formula, such as “Impact on Health Life” closely resemble the QALY concept. When HERC commissioners vote on these factors, they do so immediately after reviewing staff briefings and reports with QALY scores

When the Oregon Health Plan ranks services on the prioritized list, using QALYs in any way, it engages in discrimination against individuals in violation of the Americans with Disabilities Act and contrary to the mission of the Oregon Health Policy Board to promote health equity.

**Recommendation:** The Waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, with a provision such as this:

**“Prohibition on Reliance on Discriminatory Measures.** The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per-quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”

---

<sup>5</sup> Bob DiPrete and Darren Coffman, “A Brief History of Health Services Prioritization in Oregon,” Oregon Health Authority, March 2007. <https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf>

## Non-discrimination in Suicide Prevention Services

Oregon also chooses to provide coverage for some services that aren't on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of physician assisted suicide, including counseling and lethal prescriptions.<sup>6</sup> OHP patients who have been denied coverage of potentially life-saving health services that were "below the line" have been advised by OHP that physician assisted suicide is a covered alternative to life saving care.<sup>7</sup> This sends a message to patients with disabilities or serious illness that they are not worth treating – but Oregon will pay to expedite their death.

It is ethically essential to ensure that any patients with disabilities or serious illness continue to receive full suicide prevention services, especially if they have been confronted with a denial of life-saving care due to the prioritized list. Physicians and CCOs should NOT assume that a disabled patient who has been denied access to care is making a "rationale" or reasonable choice to hasten the end of their lives without first providing the same range of suicide prevention services that any other member of the general public would receive.

### Recommendation:

The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for lethal drugs under Oregon's "Death with Dignity Act," will be provided with the same harm and suicide prevention services<sup>8</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to die by suicide because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.

Sincerely,

/s

Paul Terdal

### Attachments:

- DRO Issue Brief: Oregon's Unique EPSDT Waiver Allows OHP to Deny Medically Necessary Care to Children to Save Money
- DRO Issue Brief: How the Oregon Health Plan Discriminates

---

<sup>6</sup> Oregon Health Authority, "Prioritized List of Health Services," 2/1/2021, P. SI-1, "STATEMENT OF INTENT 2: DEATH WITH DIGNITY ACT."

<sup>7</sup> Susan Donaldson James, "Death Drugs Cause Uproar in Oregon. Oregon woman denied drugs for lung cancer, but offered assisted-death drugs." ABC News, 8/6/2008. (<https://abcnews.go.com/Health/story?id=5517492>)

<sup>8</sup> The term "harm and suicide prevention services" includes screening, diagnosis, psychiatric treatment, therapy, counseling, and other services whose purpose is the detection and treatment of suicidal ideation and tendencies and the causes thereof, including depression, mental disorders, and lack of access to rehabilitative and supportive care.

## Oregon's Unique EPSDT Waiver Allows OHP to Deny Medically Necessary Care to Children to Save Money

Under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called “Early and Periodic Screening, Diagnostic and Treatment” ([EPSDT](#)) to ensure that they receive “age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting.” Critically, the EPSDT provision requires comprehensive coverage of health services for children – *regardless of whether or not such services are otherwise covered* under the state Medicaid plan for adults ages 21 and older – to make certain that rationing is not imposed for this vulnerable population.

### Except in Oregon.

Oregon's Section 1115 Medicaid waiver includes a provision authorizing it to withhold medically necessary care from children over the age of 1 if it is “below the line” on its “Prioritized List” of health services:

*3. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Section 1902(a)(10)(A) and 1902(a)(43)(C) To allow the state to restrict coverage for treatment services identified during an EPSDT screening for individuals above age 1 to the extent that such services are not consistent with a prioritized list of conditions and treatments. (Applies to all Medicaid state plan populations, except population 23.) [Centers For Medicare & Medicaid Services Amended Waiver List and Expenditure Authority; Number: 21-W-00013/10 and 11-W-00160/10 Title: Oregon Health Plan \(OHP\)](#)*

Effective January 1, 2020, Oregon Health Plan covers [Prioritized List](#) lines 1 through 471. Any service that is “below the line” – numbered higher than 471 – is automatically excluded from coverage regardless of need, as is any service that isn't included anywhere on the list at all.

The Oregon Department of Justice has published an opinion asserting that this clause in the waiver permits Oregon to limit or exclude coverage of medically necessary care from children, even when those limits or exclusions specifically contradict CMS guidance, such as [CMS guidance](#) prohibiting “hard” limits on physical therapy visits for children. [Meeting Packet, April, 2016](#)

The purpose of the waiver – and of this EPSDT clause – is to save money by withholding medically necessary care from needy children. Some services for children that have been excluded because they fall below the line include: Selective Mutism – Medical / Psychotherapy (line 473), Conduct Disorder, Age 18 or Under (Line 479), Chronic Otitis Media (line 475).

Selective Mutism fell below the line and is excluded even though it scored high on effectiveness (4 out of 5), and even though Oregon's Health Evidence Review Commission (HERC) concluded that 80% of affected individuals would need care – because the category weight in [HERC's methodology](#) was low (Non Fatal condition = 20), and because HERC staff concluded that the “impact on healthy life” for a child unable to speak was very low (1 out of 10); that the impact on suffering was low (1 out of 5); and there was no impact to the general population for a child who is unable to communicate.

Conduct Disorder fell below the line and is excluded because the category weight is low (Non Fatal condition = 20) and because HERC staff rated effectiveness low (1 on a 0 to 5 scale). As a result, children and adolescents in Oregon with a conduct disorder who might have a chance of benefiting from professional counseling or psychotherapy are denied care and placed at much higher risk of incarceration in the juvenile justice system.

Chronic Otitis Media (recurrent ear infection) fell below the line and is excluded even though it scored medium on effectiveness (3 out of 5), and even though Oregon’s Health Evidence Review Commission (HERC) concluded that 80% of affected individuals would need care – because the category weight was low (Non Fatal condition = 20), and because HERC staff concluded that “impact on healthy life” for a child with chronic otitis media was low (2 out of 10), even though it can result in [severe complications](#) if left untreated, including permanent hearing loss and problems with speech and language development.

Prioritization of Selective Mutism, Conduct Disorder, and Chronic Otitis Media with [HERC Methodology](#):

Factor:	Selective Mutism (line 473)	Conduct Disorder (line 479)	Chronic Otitis Media (line 475)	Range:
Category Weight	20*	20*	20*	1 to 100
Impact on Healthy Life:	1	5	2	0 to 10
Impact on Suffering:	1	3	1	0 to 5
Population Effects:	0	2	0	0 to 5
Vulnerable Population:	0	2	0	0 to 5
Tertiary Prevention:	1	1	1	0 to 5
Effectiveness:	4	1	3	0 to 5
% Need for Service:	80%	70%	80%	0% to 100%
Total Score:	192	182	192	

\* Nonfatal Conditions, Where Treatment is Aimed at Disease Modification or Cure

For children whose families can afford commercial insurance plans, coverage of all three conditions is required under Oregon and Federal law as an “Essential Health Benefit” – insurers would face severe civil penalties for refusing to provide coverage.

**Oregon’s vulnerable youth deserve better. It is time to end this failed experiment relying on discrimination to ration care.**

Disability Rights Oregon (DRO)

For more than 40 years, DRO has served as Oregon’s federally authorized and funded Protection & Advocacy System. DRO is committed to ensuring the civil rights of all people are protected and enforced, including youth in correctional settings.

## Issue Brief: How the Oregon Health Plan Discriminates

The Oregon Health Plan (OHP) delivers Medicaid and EPSDT under a Section 1115 demonstration waiver ranking health care services in a prioritized list from most to least important. Only services over a certain line are funded regardless of individual determinations of medical necessity.

In 1992, Oregon submitted a waiver application relying on the quality-adjusted life year (QALY) to prioritize services for coverage that was denied by the U.S. Department of Health and Human Services as violating the Americans with Disabilities Act (ADA):

*“Our principal concern is that Oregon’s plan in substantial part values the life of a person with a disability less than the life of a person without a disability. This premise is discriminatory and inconsistent with the Americans with Disabilities Act.”* [New York Times, HHS Secretary Louis W. Sullivan, M.D.](#)

The waiver was later approved in 1993, after committing to changes for ADA compliance. Despite ADA concerns, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the quality-adjusted life year (QALY). Officially, Oregon excluded the survey-based QALY data that triggered denial of its initial waiver application in 1992. Yet, the voting members of Oregon’s Health Policy Commission have authority to override the results of non-QALY considerations, which they did in over 70% of the cases. The outcome for how care is valued and prioritized is the same:

*“Because most objective measures representing health outcomes were not allowed, the subjective collective judgment of the Commissioners became more of a factor. As a result, many of the public values on health that had been expressed through the community meetings, the telephone survey, and in public testimony were reflected through the application of Commissioner judgment in the final prioritization process.”* [Bob DiPrete and Darren Coffman, A Brief History Of Health Services Prioritization In Oregon.](#)

Today, the Health Evidence Review Commission (HERC) website explicitly describes the use of QALYs in its cost effectiveness framework, and it is embedded in the prioritization formula.

As reconstructed in 2008, Oregon’s [revised prioritization framework](#) emphasizes preventive services and chronic disease management in order to keep the “population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health.” This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. The process uses QALYs both explicitly – as a direct part of the formula – and implicitly, through QALY-based analyses of factors within the formula:

$$Score = \left( \begin{matrix} \text{Category} \\ \text{Weight} \end{matrix} \right) \times \left[ \begin{matrix} \text{Impact on Healthy Life} \\ + \text{Impact on Suffering} \\ + \text{Population Effects} \\ + \text{Vulnerability of Population} \\ + \text{Tertiary Prevention} \end{matrix} \right] \times Effectiveness \times \left( \begin{matrix} \% \text{ Need for} \\ \text{Medical} \\ \text{Services} \end{matrix} \right)$$

Under this category weighting scheme, preventative services start with a category weighting multiplier of 95 – more than double that of care to cure a fatal illness, with a weight of just 40, and nearly 5 times the weight of services for nonfatal conditions. As an example, a routine dental exam is considered preventative, so it has a weight of 95 – while an appendectomy to treat appendicitis, or surgery to remove a treatable cancer would have a weight of just 40.

After the category weight, five population and individual impact measures are summed together - Impact on Healthy Life (sometimes referred to as Impact on Health Life Years and reflecting QALY inputs); Impact on Suffering Population Effects; Vulnerability of Population Affected; and Tertiary Prevention. The scores for these five factors are proposed by the HERC Medical Director and confirmed or amended by a vote of HERC's Value-based Benefits Subcommittee. HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by the Institute for Clinical and Economic Review (ICER) as they vote.

The final two factors in the formula – effectiveness and need for medical services – are multiplied together into an “effectiveness” score. The “effectiveness” score is proposed by the HERC Medical Director based on a review of medical evidence and factoring in QALY-based cost effectiveness analyses and confirmed or amended by the HERC Evidence-based Guidelines Subcommittee with this QALY-based framework:

*“The cost of a technology will be considered according to the grading scale below, with “A” representing compelling evidence for adoption, “B” representing strong evidence for adoption, “C” representing moderate evidence for adoption, “D” representing weak evidence for adoption and “E” being compelling evidence for rejection:*

- *A = more effective and cheaper than existing technology*
- *B = more effective and costs < \$25,000/LYS or QALY > existing technology*
- *C = more effective and costs \$25,000 to \$125,000/LYS or QALY > existing technology*
- *D = more effective and costs > \$125,000/LYS or QALY > existing technology*
- *E = less or equally as effective and more costly than existing technology”*

[Prioritization of Health Services: A Report to the Governor, 2013](#), p. 24. (**Emphasis** added)

After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list.

Oregon also chooses to provide coverage for some services that aren't on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of physician assisted suicide, including counseling and lethal prescriptions. OHP patients who have been denied coverage of potentially life-extending health services that were “below the line” have been advised by OHP that physician assisted suicide is a covered alternative. (See for instance “[Death Drugs Cause Uproar in Oregon. Oregon woman denied drugs for lung cancer, but offered assisted-death drugs,](#)” ABC News, 2008)

**Below the line – examples of excluded services for disabilities:**

- Selective Mutism (psychotherapy recommended)
- Otosclerosis (hearing aid, cochlear implant or surgery options)
- Bell's Palsy (facial palsy, medication and physical therapy often recommended)
- Spastic Diplegia (form of cerebral palsy, physical therapy recommended)
- Personality Disorders Excluding Borderline and Schizotypal (psychotherapy recommended)

[Prioritized List of Health Services](#), Oregon Health Authority website.

**Oregonians deserve better. It is time to end this failed, discriminatory experiment.**

### **Disability Rights Oregon (DRO)**

**For more than 40 years, DRO has served as Oregon's federally authorized and funded Protection & Advocacy System. DRO is committed to ensuring the civil rights of all people are protected and enforced, including youth in correctional settings.**



January 7, 2022

**BOARD OF DIRECTORS**

**Mark Dant, Chair**

Executive Director  
Ryan Foundation

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Frank Sasinowski, MPH, JD, Vice Chair**

Director, Hyman, Phelps &  
McNamara, P.C.

**RE: Application for Renewal and Amendment Oregon Health Plan, Section 1115 Demonstration Waiver**

**Vicki Seyfert-Margolis, PhD,**

**Treasurer**  
Founder and CEO, MyOwnMed

On behalf of the EveryLife Foundation for Rare Diseases, which is dedicated to empowering the rare disease patient community to advance laws and policies to improve lives of all people and families impacted by rare diseases and disorders, we are pleased to provide comments to inform the Oregon Health Authority's (OHA) Section 1115 Waiver Application for the period of 2022-2027.

**Julia Jenkins, Secretary**

Executive Director  
EveryLife Foundation

EveryLife's policy priorities are informed by the needs of our community and our shared mission of advancing the equitable development of, and access to, lifesaving diagnoses, treatments, and cures. To inform our policy work, we convene the Community Congress, a forum for collaboration across stakeholders, representing over 200 individual rare disease patient advocacy organizations in addition to over 90 other healthcare and biotechnology organizations.

**Emil D. Kakkis, MD, PhD**

Founder  
President/CEO, Ultragenyx

The EveryLife Foundation appreciates the many worthy goals laid out by OHA in the Waiver planning process, however we are concerned that the policies proposed under Strategy 3: *Increase predictability of costs and ensure value for spending through closer management of pharmacy costs by adopting commercial-style closed formularies and by excluding drugs with limited or inadequate evidence of clinical efficacy* will have serious adverse consequences for rare disease patients and families. These proposed policies stand in direct conflict with the overall goals that the Waiver request is premised on.

**Ritu Baral**

Managing Director  
Senior Biotechnology Analyst  
Cowen and Company

**Jennifer Bernstein**

Executive Vice President, Horizon  
Government Affairs

**Richard S. Finkel, MD**

Director, Center of Experimental  
Neurotherapeutics  
St. Jude Children's Research  
Hospital

Over 30 million Americans live with one or more rare diseases, 95% of which have no approved treatment<sup>1</sup>. Rare disease patients and families navigate how to manage expenses from multiple inpatient and outpatient encounters, costs for prescription therapies and medical devices, and the support services that are critical for managing their health and wellbeing. For millions of these patients and families, Medicaid is their lifeline. It is imperative that policies support timely access to all care and treatments recommended by clinical providers, including innovative therapies that address the significant unmet need, without restrictive formularies that do not reflect the individualized nature of rare disease care.

**Stephen C. Groft, PharmD**

Special Volunteer, NCATS, NIH

**Amrit Ray MD, MBA**

Senior Advisor, Bain Capital Life  
Sciences

Patients and families need relief from the high costs associated with managing a rare disease. But such relief must take into account the total cost of patient care, not just the cost of pharmaceutical therapies. [EveryLife Foundation's National Economic Burden of Rare Disease Study in the U.S.<sup>2</sup>](#) included 379 rare diseases affecting 15.5 million people and found the overall economic impact in 2019 exceeded \$966 billion. Non –medical and In-direct costs, costs absorbed directly by affected families, accounted for nearly 60 percent of overall costs. Relief is needed. But such relief must not come at the expense of access to life changing therapies or the next generation of innovation that 95% of rare diseases are still awaiting.

To reflect the realities of the need to lower costs across stakeholders, the EveryLife Foundation engaged with Community Congress members to create the Rare Disease Community Statement on Drug Pricing Policy Priorities. Principles from this statement are reflected throughout our comments and the full statement can be found at <https://everylifefoundation.org/drug-pricing/>.

*Policy solutions should recognize FDA's statutory authority in determining a medical product's safety and effectiveness and promote timely access to approved therapies.*

OHA's proposal to "allow exclusion of drugs with limited or inadequate evidence of clinical efficacy" and to establish their own review procedure to make this determination undermines the FDA's statutory authority, their expertise and understanding of the complexities involved in bringing therapies to the market for complex rare diseases, and the high level of rigor in the FDA regulatory review process.

In 1992, in response to the HIV/AIDS crisis, the U.S. Food and Drug Administration (FDA) instituted the Accelerated Approval pathway to improve the time to approve drugs that treat serious conditions that fill an unmet medical need based on substantial evidence of safety and efficacy and a surrogate endpoint that is reasonably likely to predict outcomes like irreversible mortality or morbidity. In the years since establishing the accelerated approval pathway, it has also facilitated the transformation of oncology care and enabled rare disease treatments to reach patients who otherwise had limited or no options.

*OHA's proposal is predicated on several misperceptions about the use of the accelerated approval pathway in rare diseases and will serve to undermine the purpose and future use of the pathway.*

During the EveryLife Foundation's Annual [Scientific Workshop in December 2021](#), rare disease scientific, clinical, patient and regulatory experts examined the use of the Accelerated Approval Pathway in rare disease to identify common challenges and opportunities for optimizing the pathway to transform rare disease care in the way that is has been transformational for HIV/AIDS and oncology.

A summary of the Workshop's proceedings is pending release, however several key themes emerged that address the concerning misperceptions of accelerated approval that underly OHA's decision to pursue exclusionary policies based on the use of this pathway.

- ❖ Therapies approved via the accelerated approval pathway are not the main driver of costs to state Medicaid programs. A 2021 study showed that spending on drugs approved through AAP accounted for less than one percent of annual Medicaid spending between 2007 and 2018<sup>3</sup>.
- ❖ Surrogate biomarkers are often superior to traditional clinical endpoints. In many cases, because surrogate biomarkers are intermediate markers of disease progression or improvement, they offer a way to more accurately capture patient data in real-time and be more accurate due to the complex and variable nature of rare diseases as compared to traditional clinical endpoints.
- ❖ The FDA has rigorous requirements for biomarker qualification that result in only a small fraction of biomarker based rare disease therapy approvals. In fact, less than 20 rare disease therapies have been approved using accelerated approval.<sup>4</sup>
- ❖ The safety of rare disease treatments approved via the accelerated approval pathway is evaluated in the same rigorous manner as in traditional drug approvals.

We urge OHA to reconsider their problematic proposals related to the accelerated approval pathway and to instead consider engaging in efforts prioritized by the Scientific Workshop participants as essential to ensuring the optimization of accelerated approval to transform rare disease outcomes and to consider the actions suggested within the Rare Disease Community Statement on Drug Pricing Policy Priorities. These actions include;

- ❖ The need for payer entities such as Medicaid programs to engage early and often with patient, scientific, clinical and regulatory stakeholders to develop the knowledge and evidence available for rare disease biomarkers. As payers engage early in the process, the understanding of the biomarkers being used and the rationale for their use will produce outcomes that payers can meaningfully incorporate into their decision-making process.
- ❖ Reject policies that treat all AAP medications as experimental, thus exacerbating health inequality among communities eligible for life-saving medications.
- ❖ Support the robust collection of real-world outcomes to enhance the evidence for AAP therapies in the post-market setting.
- ❖ Seek new and alternative payment models, including outcomes-based contracting, that allow rare disease patients to have access to novel therapies and ensure reimbursement policies encourage development of future curative therapies
- ❖ Exclude rare disease therapies from policy experiments or demonstrations (such as those proposed under Strategy 3) until or unless it is proven that the changes do not threaten patient access and medical innovation.

Oregon's proposal to implement a closed formulary, including the exclusion of therapies approved via the accelerated approval pathway, will have serious adverse consequences for rare disease patients and families. These proposed policies stand in direct conflict with the overall goals the Waiver request is premised on. Further, the proposed policies will create further disparities in care between adults and children and will result in increasing burdensome utilization management barriers which lead to delays

accessing life sustaining and life-saving therapies, while also not addressing the biggest cost drivers in rare disease care for state Medicaid programs.

Meaningful policy solutions must focus on the total cost of patient care. Policy reforms that focus on only one aspect of healthcare costs and that threaten access to the few treatment options available to those with rare diseases will result in negative repercussions for patient health and have detrimental economic outcomes for families and society overall. We urge OHA to consider the extensive unmet needs and scientific challenges inherent in the rare disease community and ensure policy solutions reflect these complexities by removing Strategy 3 from the 1115 Waiver Extension and investing in long-term actions that will support future policy innovation to ensure the sustainable delivery of life-saving treatments to those most vulnerable Oregonians.

Thank you for the opportunity to provide comments on Oregon's 1115 Waiver Extension application. Please contact Jamie Sullivan, Director of Policy at [jsullivan@everylifefoundation.org](mailto:jsullivan@everylifefoundation.org) if we can provide any additional information to inform your process.

Sincerely,



Julia Jenkins  
Executive Director  
EveryLife Foundation for Rare Diseases



Annie Kennedy  
Chief of Policy, Advocacy, & Patient Engagement  
EveryLife Foundation for Rare Diseases

<sup>1</sup> <https://www.fda.gov/patients/rare-diseases-fda>

<sup>2</sup> [https://everylifefoundation.org/wp-content/uploads/2021/02/The\\_National\\_Economic\\_Burden\\_of\\_Rare\\_Disease\\_Study\\_Summary\\_Report\\_February\\_2021.pdf](https://everylifefoundation.org/wp-content/uploads/2021/02/The_National_Economic_Burden_of_Rare_Disease_Study_Summary_Report_February_2021.pdf)

<sup>3</sup> <https://www.fightchronicdisease.org/sites/default/files/FINAL%20Quantifying%20Impact%20-%20White%20Paper%20v6.pdf>

<sup>4</sup> <https://www.fda.gov/media/151146/download>



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Oregon Health Plan 1115 Demonstration Waiver Application for Renewal

Dear Ms. Hatfield:

We appreciate this opportunity to provide comments as the Oregon Health Plan (OHP) applies to the Centers for Medicare & Medicaid Services (CMS) for a new five-year Medicaid waiver, known as the 1115 Demonstration. We hope that the state will incorporate the perspectives of people with disabilities that disproportionately are impacted by the state's prioritized list of services by barring the use of the discriminatory quality-adjusted life year (QALY) as a consideration; by ensuring that individuals with disabilities and significant health conditions do not face discrimination in accessing suicide prevention services; and by discontinuing the EPSDT waiver that too often fails to give children the care they need.

As you know, in 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage that was denied by the U.S. Department of Health and Human Services as "discriminatory and inconsistent with the Americans with Disabilities Act."<sup>1</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance. Despite ADA concerns, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Officially, Oregon excluded the survey-based QALY data that triggered denial of its initial waiver application in 1992. Yet, the voting members of Oregon's Health Policy Commission have authority to override the results of non-QALY considerations, which they did in over 70% of the cases. The discriminatory outcome for how care is valued and prioritized is the same.<sup>2</sup>

Today, the Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, continues to use QALY-driven data and analysis in the formula for the prioritized list of

<sup>1</sup> <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html> <sup>2</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf>

services. As reconstructed in 2008, Oregon’s revised prioritization framework emphasizes preventive services and chronic disease management in order to keep the “population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health.” This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. Although Oregon removed a direct and explicit reference to QALYs from its cost-effectiveness framework in 2017, it continues to rely upon the QALY-driven prioritization scores for condition treatment pairs that were already established at that time. In addition, HERC continues to consider QALY-based analysis in evaluating other factors in the formula.<sup>3</sup>

The HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by entities such as the Institute for Clinical and Economic Review (ICER) as they vote. After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list. A few excluded services for people with disabilities include treatment for hearing impairment, Bell’s Palsy, Spastic Diplegia, and certain personality disorders.<sup>4</sup>

Oregon also chooses to provide coverage for some services that aren’t on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of medical aid in dying. It has been reported that OHP patients who have been denied coverage of potentially life-extending health services that were “below the line” have been advised by OHP that medical aid in dying is a covered alternative.<sup>5</sup> This outcome – intentional or not – implies some patients lives are not worth living.

The ethical challenges of Oregon’s use of discriminatory metrics to ration services it will cover are exacerbated for children. Oregon is the only state with an EPSDT waiver. In every other state, under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called “Early and Periodic Screening, Diagnostic and Treatment” (EPSDT) to ensure that they receive “age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting.” Critically, the EPSDT provision requires comprehensive coverage of health services for children – *regardless of whether or not such services are otherwise covered* under the state Medicaid plan for adults ages 21 and older – to make certain that rationing is not imposed for this vulnerable population.<sup>6</sup> Even still, Oregon’s Section 1115 Medicaid waiver includes a provision authorizing it to withhold medically necessary care from children over the age of one if it is “below the line” on its “Prioritized List” of health services. A few examples include noncoverage of treatment for selective mutism, conduct disorder, recurrent ear infections, minor burns, and pica.

<sup>3</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx>

<sup>4</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>

<sup>5</sup> <https://abcnews.go.com/Health/story?id=5517492&page=1>

<sup>6</sup> <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>

We believe it is time to end this failed experiment of relying on discrimination to ration care. Our specific recommendations are as follows:

### **1. Full Compliance with EPSDT**

The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.

### **2. Prohibit the Use of Discriminatory QALY Measures**

The waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, such as this:

“Prohibition on Reliance on Discriminatory Measures. The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per- quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”

### **3. Non-discrimination in Suicide Prevention Services**

The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for Oregon’s “Death with Dignity Act,” will be provided with the same harm and suicide prevention services<sup>7</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to utilize medical aid in dying because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.

<sup>7</sup> The term “harm and suicide prevention services” includes screening, diagnosis, psychiatric treatment, therapy, counseling, and other services whose purpose is the detection and treatment of suicidal ideation and tendencies and the causes thereof, including depression, mental disorders, and lack of access to rehabilitative and supportive care.

Sincerely,

Disability Rights Oregon

Allergy & Asthma Network

Alliance for Aging Research

American Association of Kidney Patients (AAKP)

American Speech-Language-Hearing Association

Association of University Centers on Disabilities

Autism Business Association

Autism Insurance for Oregon

Autism Society of Oregon

Autism Speaks

Autistic Self Advocacy Network

Behavioral Health Center of Excellence

CancerCare

Care About Fibroids

Caring Ambassadors Program

Center for Autism and Related Disorders

Cockayne Syndrome Network - Share & Care

Colorado Cross-Disability Coalition

Council of Autism Service Providers

Cystic Fibrosis Research Institute

Disability Policy Consortium

Epilepsy Foundation

Epilepsy Foundation Oregon

FACT Oregon

Familia Unida Living with MS

Genetic Alliance and PXE International

GO2 Foundation for Lung Cancer

HCMA - Hypertrophic Cardiomyopathy Association

Health Hats

ICAN, International Cancer Advocacy Network

Independent Health Care Policy Consultant

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

M-CM Network  
Men's Health Network  
Mental Health and Autism Insurance Project  
MLD Foundation  
National Coalition for Access to Autism Services (NCAAS)  
National Council on Severe Autism  
National Disability Rights Network (NDRN)  
NBIA Disorders Association  
New York State Sickle Cell Advocacy Network, Inc,  
Northwest PANDAS/PANS Network  
One Rare  
Oregon Family Support Network, Inc.  
Oregon Speech-Language Hearing Association  
Organic Acidemia Association  
Partnership to Fight Chronic Disease  
Partnership to Improve Patient Care  
Pulmonary Hypertension Association  
Rare New England  
SYNGAP1 Foundation  
The Bonnell Foundation: Living with Cystic Fibrosis  
The Migraine Diva, LLC  
TSC Alliance  
Whistleblowers of America



January 4, 2022

TO: Oregon Health Policy Board and Oregon Health Authority  
FROM: Children's Institute  
RE: Investing in Children and Families to Improve Health Equity in Oregon's Next 1115 Medicaid Waiver

Dear Oregon Health Policy Board and Oregon Health Authority,

Children's Institute is a statewide research, policy, and advocacy organization working to ensure all young children in Oregon have the opportunity to thrive. We work in partnership with families, schools, and community organizations to improve health and learning outcomes for children.

We are excited to see a strong focus on children and families in the final policy concepts that the Oregon Health Authority (OHA) has developed for Oregon's next 1115 Medicaid Waiver. We believe that investing in young children, starting prenatally, is a crucial strategy for impacting the upstream determinants of health. By improving health care coverage, access, and service quality for children and their families, and through addressing the needs and barriers faced by communities furthest from opportunity, we can make significant progress toward eliminating health disparities and achieving health equity in Oregon.

We offer the below input, informed by our work in early childhood systems, early learning programs, and policy advocacy and reflective of feedback from many early childhood partners across the state committed to ensuring every Oregon family has the resources and supports needed to help children thrive from the start.

1. We strongly support ensuring continuous eligibility for children from birth through age 5 and two-year continuous enrollment for all Oregon Health Plan members ages 6 and up. Reducing barriers to coverage and reducing the burden of annual reenrollment will help families stay healthy and ensure children have consistent access to coverage during this important developmental period.
2. We are disappointed to see that Oregon proposes to continue waiving three-month retroactive coverage for pregnant women and children, along with other Medicaid beneficiaries. Retroactive coverage provides a critical protection to families against the financial burden of medical debt. If Oregon continues to waive retroactive coverage families will remain at risk of the added and unnecessary financial burden of costs incurred from needed medical services provided in the three months prior to enrolling in Medicaid.
3. We believe the time is overdue for Oregon to stop waiving Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. [EPSDT](#) is Medicaid's comprehensive and guaranteed pediatric benefit, ensuring all children from birth to age 21 receive all preventive, dental, mental health and specialty services that their doctor or other medical professional deems necessary. Oregon has previously been allowed to waive its provision of the EPSDT benefit, the full impacts of which are unknown since there is no mechanism to track and resolve issues with children's access to medically necessary services. Moving forward Oregon must reinstate the EPSDT benefit and establish



accountability mechanisms so that children have equitable access to timely prevention and treatment services for their healthy development.

4. We agree that supporting families' health and social needs through important life transitions is important. Research shows that community health workers (CHWs), doulas, home visitors, and peer navigators are highly effective at supporting families during the perinatal period and throughout early childhood, including for families experiencing developmental disabilities or special health care needs and navigating the foster care system. These interventions, particularly if they are culturally specific and representative, often achieve better health outcomes for families than the health care system can achieve on its own. We encourage OHA and CCOs to intentionally invest in this workforce so that more families get the trusted and responsive health care and navigation support they need.

This focus area presents an opportunity to align with the federal Build Back Better investment package, which includes proposed funding to support women and children throughout the perinatal period. Build Back Better would require all states provide 12 months of Medicaid coverage for postpartum women, offer states additional Medicaid funds to create "maternal health homes" as team-based care hubs for women and children, and provide new funding to grow and diversify the perinatal workforce, including expanding doula training programs. Oregon's early investments in these strategies could lay a strong foundation for future federal support, so we encourage OHA to double down on prioritizing and resourcing this work.

5. While behavioral health is named as a priority, we believe Oregon's next waiver needs to have a deeper focus on the behavioral health needs of children. The American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association have [declared a national emergency in child and adolescent mental health](#). Of the recommendations included in the declaration, several are ripe for advancement through Oregon's waiver:
  - Accelerate adoption of effective and financially sustainable models of integrated mental health care in primary care pediatrics, including clinical strategies and models for payment.
  - Fully fund comprehensive, community-based and community-developed systems of care that connect families in need of behavioral health services and supports for their child with culturally relevant evidence-based interventions in their home, community, or school.
  - Promote and pay for trauma-informed care services including those that are culturally specific and community-based to support relational health and family resilience.
  - Accelerate strategies to address longstanding workforce challenges in child mental health, including innovative training programs, grow-your-own initiatives, loan repayment, and intensified efforts to recruit underrepresented populations into mental health professions.

Young children face unique and persistent challenges accessing services that promote social-emotional health and treat behavioral health challenges. Oregon will continue to lack workforce and service capacity and families will continue to suffer unless we intentionally name, resource, and prioritize these services for young children and their families.



6. We are encouraged to see how this waiver lifts up community and consumer engagement, particularly in the redesign of the CCO metrics program and in the formation and implementation of community investment collaboratives. Through our multi-year effort to recommend and develop CCO incentive metrics for the health aspects of kindergarten readiness, as well as our work engaging with community partners and families in early childhood advocacy, we have learned that engagement is most effective when it is 1) built on a foundation of community trust, 2) adequately resourced (e.g., paying parents as consultants, dedicating sufficient staff support for engagement), 3) multimodal to offer a variety of engagement opportunities at multiple stages, and 4) flexible to allow for continuous improvement as feedback is gathered about what is working and what is not.

In order to advance Oregon's vision for healthy children, families, and communities, we also encourage OHA to consider ways to align CCO contracts, policy guidance, and resources with the spending priorities outlined in this waiver application.

Thank you for considering this input as you move forward to finalize the waiver application and enter into negotiations with the Centers for Medicaid and Medicare Services. We would be happy to connect if you have questions, reactions, or would like further details.

Sincerely,

Elena Rivera, MPH *on behalf of Children's Institute*  
Senior Health Policy and Program Advisor  
[elena@childinst.org](mailto:elena@childinst.org)



January 6, 2022

**VIA ELECTRONIC SUBMISSION**

Michelle Hatfield  
Health Policy and Analytics Medicaid Waiver Renewal Team  
500 Summer St. NE, E65  
Salem, OR 97301

RE: Oregon Health Plan 1115 Demonstration Waiver Renewal and Amendment

To Whom It May Concern:

Thank you for the opportunity to comment on the draft renewal application for the “Oregon Health Plan” 1115 demonstration waiver. The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005. As part of the McCourt School of Public Policy, Georgetown CCF conducts research, develops strategies, and offer solutions to improve the health of America’s children and families, especially those with low and moderate incomes.

As explained below, we strongly support the proposal to provide multiple years of continuous eligibility for children and adults. We commend Oregon for leading the country with this request. We also applaud the state’s focus on and investments in health equity, which would work to address racial and health disparities in the state.

However, we strongly oppose the request to waive the Early and Periodic Screening, Diagnostic Treatment (EPSDT) benefit for children over age one, which is critical to ensure children receive all services necessary for their growth and development. Waiving this benefit serves no demonstration purpose and is potentially harmful to children’s health and development. We also strongly oppose the request to waive the three-month retroactive coverage period for almost all Medicaid beneficiaries as well as the proposed closed formulary and exclusions of certain prescription drugs. These provisions reduce coverage and services for children and their families and do not promote the objectives of Medicaid. The flexibilities requested related to managed care raise serious concerns, especially for the potential effects on beneficiaries, and some are not allowable under a section 1115 demonstration. Finally, Oregon does not enumerate the specific waiver and expenditure authorities needed for its renewal request and therefore fails to comply with federal regulations for an extension application.

## **Multi-year continuous eligibility would reduce gaps in coverage and improve continuity of care.**

Oregon already provides 12-month continuous eligibility to children in its Medicaid program and Children’s Health Insurance Program (CHIP) at state option. In its proposal, the state would test extending the length of the continuous eligibility period by providing continuous coverage for children until the age of six and two years of continuous eligibility for all beneficiaries age six and up with the goal of maximizing access to coverage. *We strongly support Oregon’s proposals on continuous eligibility.* Oregon is the first state to make such a request – and we commend you for the state’s bold vision. Such a proposal is exactly the kind of request that section 1115 demonstrations are well-suited for, and we will strongly encourage CMS to approve it.

Continuous eligibility is a significant tool to reduce gaps in coverage and enhance continuity of care. Covering children from birth to six can help form the backbone of a new nationwide commitment to children’s health.<sup>1</sup> The policy improves health status and well-being, promotes health equity, allows for better measurement of quality of care, and reduces administrative burdens.<sup>2</sup> Extending continuous eligibility for longer periods for children would promote consistent access to health care to address any concerns that may affect school readiness, especially for young children who are at the most critical development period.<sup>3</sup> The benefits of continuous eligibility are also afforded to adults. As CMS noted in its 2013 guidance, providing continuous eligibility to parents and other adults results in greater stability of coverage for the whole family.<sup>4</sup>

The proposal would also help reduce “churn” for both child and adult beneficiaries. Individuals with Medicaid are at risk of moving on and off coverage due to temporary changes in income that affect eligibility; continuous eligibility can help mitigate the effects of this income volatility that result in churn. Individuals that experience churn or other coverage disruptions are more likely to delay care and have periods of uninsurance.<sup>5</sup> According to recent data from MACPAC, even in states with 12-month continuous eligibility, almost three percent of children in Medicaid and over seven percent of children

---

<sup>1</sup> Kelly Whitener and Joan Alker, “Covering All Children,” Georgetown University Center for Children and Families, February 2020, <https://ccf.georgetown.edu/wp-content/uploads/2020/02/CoverAllKidsFinal.pdf>.

<sup>2</sup> Tricia Brooks and Allegra Gardner, “Continuous Coverage in Medicaid and CHIP,” Georgetown University Center for Children and Families, July 2021, <https://ccf.georgetown.edu/wp-content/uploads/2021/07/Continuous-Coverage-Medicaid-CHIP-final.pdf>.

<sup>3</sup> Elisabeth Wright Burak, “Promoting Young Children’s Healthy Development in Medicaid and the Children’s Health Insurance Program,” Georgetown University Center for Children and Families, October 2018, <https://ccf.georgetown.edu/wp-content/uploads/2018/10/Promoting-Healthy-Development-v5-1.pdf>.

<sup>4</sup> Center for Medicaid and CHIP Services, “SHO #13-003: Facilitating and CHIP Enrollment and Renewal in 2014,” May 2013 <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SHO-13-003.pdf>.

<sup>5</sup> Sarah Sugar, *et. al.*, “Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic,” HHS Assistant Secretary for Planning and Evaluation, April 12, 2021, [https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files//199881/medicaid-churning-ib.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//199881/medicaid-churning-ib.pdf).

in CHIP had less than a full year of coverage.<sup>6</sup> Research has shown that children have the highest rates of Medicaid enrollment churn compared to other eligibility groups.<sup>7</sup>

We encourage you to examine how providing multiple years of continuous eligibility affects administrative cost for the state and CCO's. In Montana, state officials reported administrative spending savings and fewer staff hours needed to process individuals moving on and off the program as a result of adopting continuous eligibility for adults.<sup>8</sup>

### **Significant investments in health equity would address racial disparities the state.**

We applaud the state's intent to center on health equity in its request. The proposal would include several significant changes to invest in community investment collaboratives and utilizing Traditional Health Workers to promote culturally responsive care. We are strongly supportive of the state's goals and efforts to reduce racial disparities.

The state seeks to engage communities as a key part of its health equity investments, specifically in the proposed community investment collaboratives (CICs). CICs would serve as a "community-led accountability structure" that would help oversee all spending on health equity and are intended to focus on populations that have been most harmed by health inequities including communities of color, people with disabilities, and immigrant communities, among others. Though progress has been made in reducing racial disparities, people of color still experience worse health outcomes and lower coverage rates than white individuals.<sup>9</sup> By engaging in a community-based approach to health equity, the state will ensure spending truly addresses the needs and barriers faced by populations that have been historically marginalized and can help improve persistent disparities.

Under the proposal, Traditional Health Workers would be utilized to improve access to services particularly among beneficiaries experiencing life transitions. Traditional Health Workers would include community health workers, peer wellness and support specialists, and doulas. These providers may be more trusted by beneficiaries and can assist them in receiving culturally competent care. For example, doulas have been found to be beneficial to women of color or with low incomes; expanding access to these providers can help reduce health disparities.<sup>10</sup>

---

<sup>6</sup> MACPAC, "An Updated Look at Rates of Churn and Continuous Coverage in Medicaid and CHIP," October 2021, <https://www.macpac.gov/wp-content/uploads/2021/10/An-Updated-Look-at-Rates-of-Churn-and-Continuous-Coverage-in-Medicaid-and-CHIP.pdf>.

<sup>7</sup> Bradley Corallo, *et al.*, "Medicaid Enrollment Churn and Implications for Continuous Coverage Policies," Kaiser Family Foundation, December 14, 2021, <https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-churn-and-implications-for-continuous-coverage-policies/>.

<sup>8</sup> Niranjana Kowlessar *et al.*, "Federal Evaluation of Montana Health and Economic Livelihood Partnership (HELP): Summative Evaluation Report," Social & Scientific Systems, November 30, 2020, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/summative-eval-rpt-montana-2020.pdf>.

<sup>9</sup> Nambi Ndugga and Samantha Artiga, "Disparities in Health and Health Care: 5 Key Questions and Answers," Kaiser Family Foundation, May 11, 2021, <https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/>.

<sup>10</sup> Tomas Guarnizo and Maggie Clark, "Lessons Learned from Early State Experiences Using Medicaid to Expand Accesses to Doula Care," Georgetown University Center for Children and Families, December 15, 2021,

## Waiving the EPSDT benefit risks children’s access to necessary services.

Oregon is requesting to continue waiving the Early and Periodic Screening, Diagnostic Treatment benefit, Medicaid’s comprehensive, child-focused benefit. As you know, children represent a substantial portion of Medicaid beneficiaries in the state, with 469,000 children under 19 currently covered.<sup>11</sup> In 2019, 36.8 percent of children in Oregon were covered by Medicaid.<sup>12</sup> EPSDT guarantees that children and young adults under age 21 receive the full scope of services necessary for their growth and healthy development. Oregon is the only state in the country to have a limit in place on these benefits for children under 19.

EPSDT ensures children with Medicaid coverage are screened regularly for health problems and developmental delays, *and* treatment must be provided as needed. Without this critical benefit, children are at risk of not receiving necessary services. This risk is especially true since the Oregon Health Plan’s covered services are determined by the state’s “prioritized list of health services,” which excludes services that fall below the designated funding line. On the state’s current prioritized list of 662 services, only the first 471 are covered.<sup>13</sup>

Medicaid’s EPSDT benefit is especially important for children with special health care needs or disabilities. These children may have more extensive health care needs or chronic conditions that require types or amounts of services that most children do not generally need.<sup>14</sup> EPSDT is also important for children of color who are more likely to have Medicaid coverage. In Oregon, approximately 60 percent of the child population who are American Indian/Alaskan Native, Black, or Latino are covered by Medicaid (57 percent of AIAN children; 60 percent of Black children; 65 percent of Latino children).<sup>15</sup> Limiting their benefits undermines the very core of what Oregon purports to do with its demonstration—advance health equity and maximize equitable access to coverage.

Oregon has been restricting EPSDT benefits since the inception of the OHP demonstration in 1994. The purpose of a section 1115 demonstration is to test new approaches that promote the objectives of Medicaid. While there was never a justification for stripping children of their entitlement to EPSDT, any potential experiment has long

---

<https://ccf.georgetown.edu/2021/12/15/lessons-learned-from-early-state-experiences-using-medicaid-to-expand-access-to-doula-care/>.

<sup>11</sup> Oregon Health Authority, “Monthly Medicaid Population Report, August 2021 (Preliminary),”

<https://www.oregon.gov/oha/HSD/OHP/DataReportsDocs/August%202021%20Physical%20Health%20Service%20Delivery%20by%20Age%20Group.pdf>.

<sup>12</sup> Kaiser Family Foundation, “Health Insurance Coverage of Children 0-18,” <https://www.kff.org/other/state-indicator/children-0->

[18/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22oregon%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D](https://www.kff.org/other/state-indicator/children-0-18/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22oregon%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

<sup>13</sup> Oregon Health Authority, “Prioritized List of Health Services,” <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>.

<sup>14</sup> Tricia Brooks and Kelly Whitener, “At Risk: Medicaid’s Child-Focused Benefit Structure Known as EPSDT,” Georgetown University Center for Children and Families, June 2017, <https://ccf.georgetown.edu/wp-content/uploads/2017/06/EPSDT-At-Risk-Final.pdf>.

<sup>15</sup> Tricia Brooks and Alexa Gardner, “Snapshot of Children with Medicaid by Race and Ethnicity, 2018,” Georgetown University Center for Children and Families, July 2020, <https://ccf.georgetown.edu/wp-content/uploads/2020/07/Snapshot-Medicaid-kids-race-ethnicity-v4.pdf>.

expired. Denying needed health care to children does not serve any valid experimental purpose and should not be continued.

Furthermore, in the application, there is no explanation of the services that would not be covered nor what protections the state has in place to ensure that restrictions on EPSDT services do not have a disparate impact on children of color. With the omission of these details, Oregon has not explained the potential impact the waiver has, and will continue to have, which does not allow for full public engagement on the proposal.

We urge you to remove this waiver as part of Oregon's extension request.

### **The proposed closed formulary and exclusion of certain prescription drugs from coverage undermines Medicaid.**

The state is seeking to adopt a closed prescription drug formulary for adult beneficiaries, with only a minimum of one drug per class. Cost, not just clinical efficacy, would be a key criteria. Separately, the proposal would also exclude drugs, including but not limited to those coming to the market through the Food and Drug Administration's accelerated approval pathway, that the state determines to have "limited or inadequate clinical efficacy" as well as drugs that are determined to have "no incremental clinical benefit" compared to others in its therapeutic class. Unlike the broader closed formulary authority the state is seeking, this proposal would apply to pediatric drugs as well.

These proposals are a drastic change to the current requirement under the Medicaid Drug Rebate Program that Medicaid programs must cover nearly all FDA-approved outpatient drugs. As a result, they will likely restrict beneficiary access to needed prescription drugs; this does not promote the objectives of Medicaid but rather undermines them.

The proposal fails to outline any appeals process to allow beneficiaries to obtain off-formulary drugs under either provision, let alone describe in detail how such a process would work and the criteria for determining whether off-formulary coverage would be approved. The proposed changes to the Medicaid prescription drug benefit would likely be most detrimental to beneficiaries with multiple or complicated health conditions including individuals with chronic conditions or with disabilities who require very high-cost specialty drugs.

The state also holds up Medicare Part D as an example of a program that is permitted to operate a closed formulary. Yet, the proposal is actually more restrictive than Medicare Part D as it does not include some key protections that are a requirement in Medicare Part D. First, Oregon's closed formulary would only cover at least one drug per therapeutic class compared to two in Medicare Part D. Also, the state does not include any exemptions for six "protected" classes of drugs—anti-depressants, anticonvulsants, antipsychotics, immunosuppressants, antineoplastics, and antiretroviral drugs—that Medicare Part D is required to cover.

While the first proposal would maintain an open formulary for children, the state does not define the age ranges that comprise the child population. Specifically, it is unclear whether 19-and-20-year-olds are considered children or if they are included in the adult eligibility category. This is particularly important because, with the waiver of EPSDT benefits (which normally apply to individuals under 21), 19-and-20-year-olds may have their access to prescription drugs restricted. And, as noted above, the second proposal would apply not just to adults but also to children.

The state claims it is pursuing the proposed prescription drug changes in order to obtain larger supplemental rebates from drug manufacturers. It is important to recognize that Medicaid already obtains the lowest prices, net of rebates and discounts, compared to other federal programs and agencies, including not just Medicare Part D but also the Department of Veterans Affairs.<sup>16</sup> This is driven by the mandatory rebates required under the highly successful Medicaid Drug Rebate Program, with supplemental rebates only a small share of total rebates.<sup>17</sup> It is not clear the proposal would actually result in significant new savings, as states already have levers such as preferred drug lists and prior authorization when negotiating with manufacturers today. The proposal would therefore likely only generate significant savings if the state used its two proposed new authorities to substantially restrict access to needed prescription drugs and thus reduce utilization and spending.

There is no research or experimental justification to reduce prescription drug coverage for beneficiaries and it is inconsistent with the purpose of Medicaid. In fact, federal courts have ruled that “[a] simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy” the section 1115 requirement for an experiment.<sup>18</sup>

### **Eliminating retroactive coverage does not promote the objectives of Medicaid.**

Under the proposal, almost all Medicaid beneficiaries including pregnant women, infants, and children, would not have protection from the financial burden of medical debt resulting from the costs of care they need during the three months prior to applying for Medicaid. With the continued waiver of three-month retroactive coverage, low-income children and their families are exposed to medical bills that may be financially devastating. The policy reduces coverage and therefore fails to promote the principal objective of Medicaid.

Furthermore, while we do not believe there was ever a legitimate purpose for eliminating retroactive coverage, the state’s continued waiving of coverage is well past the

---

<sup>16</sup> Edwin Park, “New CBO Study Compares Net Prices for Brand-Name Drugs Among Federal Programs, Finds Medicaid Gets Largest Discounts,” Georgetown University Center for Children and Families, February 22, 2021, <https://ccf.georgetown.edu/2021/02/22/new-cbo-study-compares-net-prices-for-brand-name-drugs-among-federal-programs-finds-medicaid-gets-largest-discounts/>.

<sup>17</sup> Edwin Park, “How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs,” Georgetown University Center for Children and Families, January 9, 2019, <https://ccf.georgetown.edu/2019/01/09/how-to-strengthen-the-medicaid-drug-rebate-program-to-address-rising-medicaid-prescription-drug-costs/>.

<sup>18</sup> *Beno v. Shalala*, 30 F. 3d 1057 (9<sup>th</sup> Cir. 1994)

point of being an experiment; the waiver has been in place for *over two decades*. The state does not provide a hypothesis for this policy nor does it include the policy in its proposed evaluation. The waiver of retroactive coverage does not meet the statutory requirement to be an experiment that is likely to assist in furnishing coverage. In fact, it does the opposite. There is no justification to continue waiving retroactive coverage, especially when the state identifies reducing gaps in coverage as one of its goals of the renewal request, and that the policy would disproportionately affect people of color, which is counter to the efforts to reduce health inequities.

**The requested managed care flexibilities are fundamentally flawed and several lack adequate details.**

The proposal contains multiple requests related to new or additional flexibilities in managed care. While we are supportive of the intent of Oregon's initiatives aiming to expand access to services addressing health-related social needs (HRSN), we have serious concerns regarding some of the waiver requests related to managed care.

Medicaid regulations at 42 C.F.R. § 438.5(d) require that managed care rate-setting trend factors "be reasonable and developed in accordance with generally accepted actuarial principles and practices" and "be developed primarily from actual experience of the Medicaid population or from a similar population." We do not believe the state's proposed trend rates (ranging from 3.0 to 3.4%) meet any of these standards. It is particularly important, legally and practically, that managed care rates be actuarially sound, as defined in the law at section 1903(m)(2)(A)(iii) of the Social Security Act, and based upon the actual costs of providing services to enrollees. While CMS has historically waived freedom of choice many times, there is no authority for CMS to waive managed care standards or section 1903 through section 1115. Approving rates that are not actuarially sound also does not promote the objectives of Medicaid.

More broadly, while we do not object in principle to the state considering HRSN-related services in the rate-setting and MLR processes, we do not support such proposals when the HRSN services replace needed state plan services. We are concerned that Oregon's proposal, which includes prioritized lists of services, would do that. We recommend the state make two adjustments to its proposal. First, we recommend the state drop the list of prioritized services. This provision is clearly no longer needed as the state projects its accrued historical savings will grow to more than \$11 billion over the life of the demonstration. Second, we recommend that the state develop rates based on all state plan services *and* supplement those rates by adding HRSN-services. There is no statutory barrier to such an approach, and effective investments will lead to state plan services reductions over time based on beneficiaries' reduced need, as opposed to artificial timelines and budgets.

We recommend the state retract several waiver provisions related to mandatory enrollment and prohibiting disenrollment that violate the statutory standards set out in sections 1903 and 1932 of the Social Security Act. These provisions are not waivable and

exist to protect at-risk populations, such as older adults, persons with disabilities, and individuals who are newly enrolled into managed care plans.

Finally, we are unable to comment on several of the proposed waiver authorities which are undefined but raise questions. The state suggests that it is considering options for “risk-sharing arrangements” and “brokering re-insurance or stop-loss insurance,” and lists several critical Medicaid requirements, including contract requirements, access standards, and solvency standards, which may need to be waived to pursue the policy. The state should not pursue such policies without offering the public a chance to comment on concrete and detailed policies and waiver requests, and even then, we again note that there are limits to what the state can waive through section 1115 (as described above). It is similarly unclear what the state’s request to “[i]mplement Value-based payment methodologies” by waiving 42 C.F.R. § 438.6 is intended to accomplish, as no waiver is generally needed to implement § 438.6 strategies. Thus, we are unable to comment on this proposal.

**The application does not meet federal requirements for the state public notice process.**

As part of a section 1115 extension application, under federal regulations Oregon is required to provide the “the specific waiver and expenditure authorities that [it] believes to be necessary to authorize the demonstration.”<sup>19</sup> The state’s application does include a section on waiver and expenditure authorities; however, *the section does not describe the specific authorities that would be needed to implement its new and existing proposals*. For example, the state says that for new provisions it is requesting, it will determine with CMS whether additional waiver authority is needed to authorize those provisions. The failure to explain the authorities necessary to implement its requests undercuts the ability of the public to understand the proposal and meaningfully comment on it. Oregon should revise its application to specify the authorities needed for its demonstration and reopen the state comment period.

Thank you for consideration of our comments. If you need any additional information, please contact me at [jca25@georgetown.edu](mailto:jca25@georgetown.edu).

Joan Alker  
Research Professor, McCourt School of Public Policy, Georgetown University  
Executive Director, Center for Children and Families

---

<sup>19</sup> 42 CFR § 431.408

January 7, 2022

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**BY ELECTRONIC DELIVERY**

**Re: Comments on the Oregon Health Plan (OHP) 1115(a) Draft Demonstration Waiver Renewal Application**

Dear Director Allen and Team:

Novartis Services, Inc. is submitting this letter on behalf of Novartis Pharmaceuticals Corporation, Advanced Accelerator Applications USA, Inc. (AAA), and Sandoz Inc., collectively referred herein as “Novartis.”

Novartis appreciates the opportunity to comment on the Oregon Health Authority’s (OHA) Oregon Health Plan (OHP) 1115(a) Demonstration Waiver Renewal Application (proposed waiver),<sup>1</sup> which is intended for submission to the Centers for Medicare & Medicaid Services (CMS). Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our broad portfolio of medicines includes treatments in the areas of: ophthalmics; neuroscience; immunology, hepatology and dermatology; respiratory and allergy; cardiovascular, renal and metabolism; oncology, including targeted therapies, immuno-oncology, chimeric antigen receptor T cells (CAR-T) and radioligand therapy; and gene therapies. We are also a global leader in generic and biosimilar medicines, committed to playing a leading role in driving access to medicine worldwide.

At Novartis, we are united by a single purpose to reimagine medicine to improve and extend people’s lives. Through innovative science and technology, we address some of society’s most challenging healthcare issues. Every day we work to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Our vision is to be a trusted leader in changing the practice of medicine.

Novartis applauds Oregon for addressing the significant unmet need of patients through health equity initiatives. Novartis believes an important way we can achieve greater health equity is to address persistent disparities in the way healthcare is approached, accessed, and delivered. However, the proposed waiver presents several fundamental legal and policy-based concerns that may harm Medicaid beneficiaries. Specifically, the proposed waiver:

- Undermines the bargain that Congress struck in enacting the Medicaid Drug Rebate Program (MDRP) and contradicts the basic terms of the Medicaid rebate agreement (MDRA), which have contributed to the MDRP’s success over the past

---

<sup>1</sup> OHA, Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver 30–32 (as revised Dec. 7, 2021).

- three decades;
- Excludes safeguards that Congress has affirmed as essential in the provision of services within state Medicaid programs;
- Seeks to limit drug coverage in a manner inconsistent with federal law and that would fundamentally harm Medicaid beneficiaries;
- Fails to satisfy the statutory requirements for a Section 1115 demonstration program; and
- Restricts access to life-saving medications which leads to worse outcomes and runs counter to the OHA's mission of health equity.

We firmly believe that OHA should revise its approach, and not proceed with the proposed waiver as written on several grounds. The proposed waiver should instead pursue implementation of alternative payment methodologies and stay focused on health equity for all OHP beneficiaries.

### **I. The Proposed Waiver Violates the Bargain Underlying the Medicaid Drug Rebate Program Enshrined in the Medicaid Drug Rebate Agreement**

First, the proposed waiver violates the bargain struck by Congress in enacting the MDRP, Social Security Act (SSA) § 1927. SSA § 1927 codifies a carefully constructed compromise between manufacturers and states, which is memorialized in the MDRA that manufacturers enter into with the Secretary of Health and Human Services (HHS). Under the MDRA, manufacturers agree that, in exchange for federal approval of the payment by state Medicaid programs for all of their Food and Drug Administration (FDA) approved covered outpatient drugs, the manufacturers will make generous rebate payments to the states on such drugs “for as long as an agreement with the Secretary is in force and state utilization data reports that payment was made for that drug.”<sup>2</sup>

As a result of this agreement between states and manufacturers, over the past several decades SSA § 1927 has helped provide Medicaid beneficiaries with access to critical, innovative, life-saving therapies and has helped ensure that states receive substantial rebates on the cost of those therapies. The proposed waiver would introduce an unprecedented and inappropriate departure from this long-standing arrangement. In simple terms, OHA is proposing to waive only its obligations under SSA § 1927 — to provide coverage of all covered outpatient drugs of a manufacturer that has entered into a MDRA. The state, however, appears to anticipate that manufacturers continue paying rebates on the state Medicaid program's utilization of its drugs.

This proposal is fundamentally inconsistent with the Congressional intent underlying SSA § 1927 and with the rebate agreement memorializing the terms of the § 1927 bargain.

### **II. The Proposed Waiver Fails to Include Congressionally Designed and Mandated Safeguards**

Second, the proposed waiver fails to include essential safeguards that Congress incorporated into SSA § 1927 and has since affirmed. In the plain text of SSA § 1927, Congress narrowly (and exhaustively) outlines the ways in which states may limit access to covered outpatient drugs. For example, states may limit coverage of covered outpatient drugs by creating a formulary. However, Congress requires that the formulary have various safeguards for Medicaid beneficiaries, including: (i) a drug may only be excluded from a formulary on the basis of a clinical determination based on the drug's label, (ii) the state must provide a written explanation of its decision to exclude a drug in such a manner, and (iii) the state must still make such a drug available through a federally compliant prior

---

<sup>2</sup> OHA, Application for Renewal and Amendment, Oregon Health Plan 1115 Demonstration Waiver 30–32 (as revised Dec. 7, 2021). 12785 (Mar. 23, 2018).

authorization process.<sup>3</sup>

The proposed waiver would disregard the safeguards that Congress instituted under § 1927. OHA has proposed to introduce a “closed formulary” that is not, a formulary as that term is recognized under SSA § 1927(d)(4). The “closed formulary” would restrict coverage in a manner not permissible under federal law. For example, OHA’s proposal neither limits clinical determinations regarding a drug’s therapeutic advantage based on a review of the drug’s label, nor make available to the public a written explanation of the state’s decision to exclude a particular drug from the formulary. Instead, OHA’s proposal is to include as few as one drug per therapeutic class, irrespective of whether additional drugs qualify as “covered outpatient drugs” under § 1927 or would be medically appropriate - and superior, from a patient health standpoint - to the single available drug.

Novartis is also concerned with OHA’s proposal to exclude from coverage various therapies that have been approved by the FDA through the accelerated approval pathway. OHA would thereby substitute its judgment regarding whether products meet certain clinical efficacy criteria over the judgments of the key federal regulatory agency tasked with making such determinations – the FDA. Indeed, a decision by the FDA to approve a drug based on surrogate endpoints, or contingent on confirmatory trials, does not reflect a judgment by the agency that the drug has no “demonstrated actual clinical benefit”; it is improper for OHA to make such a judgment when the federal agency with the legal and regulatory authority and clinical expertise to make such determinations has not done so. The FDA has allowed for approval of a particular therapy based on a reported surrogate endpoint, rather than a clinical outcome, where it would be too challenging or inappropriate to measure a defined clinical outcome for that therapy. As an example, the surrogate endpoint of bone mineral density might be utilized, rather than the clinical outcome of hip fractures, because requiring the clinical outcome would require an unreasonably large and lengthy clinical trial given the relatively low incidence of hip fractures. In instances where the FDA has approved a drug based on trials utilizing surrogate endpoints, OHA should not exclude coverage of these therapies merely because only surrogate endpoints have been reported.

Also concerning is the attempt by OHA to subvert the FDA’s policy priority of accelerating patient access to innovative therapies. In this age of pharmaceutical innovation, FDA has created an accelerated approval pathway in order to expedite the process for the agency’s approval of safe and effective drugs for patients with serious and/or unmet medical needs. We submit that OHA’s proposed waiver will likely harm patients with serious and unmet medical needs by undermining this important policy objective.

Notably, CMS has affirmed that such therapies qualify as covered outpatient drugs that are subject to coverage under the MDRP. Indeed, on June 27, 2018, CMS sent a notice to the states regarding Medicaid coverage for FDA approved drugs under the accelerated approval pathway stating:

... this release clarifies that drugs that are granted “accelerated approval” are drugs approved by FDA under section 505(c) of the [Federal Food, Drug, and Cosmetic Act], and are able to satisfy the definition of covered outpatient drug, and if used for a medically-accepted indication, then the drug must be covered by state Medicaid programs if the manufacturer has an applicable signed Medicaid national drug rebate agreement for participation in the MDRP. States can use utilization management mechanisms such as prior authorization to assure appropriate use of these medications.<sup>4</sup>

---

<sup>3</sup> See SSA § 1927(d)(4).

<sup>4</sup> See CMS, Medicaid Drug Rebate Program Notice, Release No. 185, State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway (June 27, 2018).

Thus, consistent with § 1927, states must cover drugs approved under this pathway. While states may utilize prior authorization to assure appropriate use of such therapies, the wholesale denial of access to such potentially life-saving therapies would be detrimental to the health and well-being of Medicaid beneficiaries and a violation of the law.

### **III. The Proposed Waiver Would Potentially Harm Medicaid Beneficiaries**

The proposed waiver would deprive Medicaid beneficiaries in Oregon of medically appropriate therapies and therapeutic advances, including personalized medicines based on patients' unique medical needs and biological make-up, that would be available to non-Medicaid beneficiaries in Oregon and Medicaid beneficiaries in other states. Indeed, the proposed "closed formulary" threatens to prevent the state's most vulnerable residents from accessing such innovative therapies without regard to the appropriateness of the therapy and the possibility of better health outcomes and fewer side effects. Medicaid beneficiaries, unlike persons with greater financial means, are not afforded an opportunity to select an alternative coverage policy when a drug is not available through the Medicaid program. As such, the proposed waiver threatens to create a profoundly inequitable brand of second-class healthcare in Oregon.

We note that, should OHA wish to limit coverage of covered outpatient drugs, it can do so by establishing a "formulary" that comports with § 1927(d)(4) requirements. Under the proposed waiver, it does not appear that OHA will attempt to design appropriate coverage policies consistent with this federally permitted option. OHA should avail itself of the opportunities that already exist under federal law rather than deprive Medicaid beneficiaries of access to innovative therapies in contravention of § 1927.

We urge OHA to consider beneficiary access as a guiding principle for designing any waiver or model, especially with regard to the Medicaid population. Limitations on access to drugs could adversely affect beneficiary health and lead to increased overall costs for the Medicaid program, and thus, for taxpayers. Every waiver or other model that is approved for Medicaid should be designed in a way that protects beneficiary access to prescription drugs, incentivizes better health outcomes, and aligns payment with value. Additionally, we encourage the state to follow a collaborative approach in working with relevant stakeholders and focus on initiatives that drive value-based care while not restricting access to medicines.

### **IV. The Proposed Waiver Fails to Satisfy the Federal Criteria for a Section 1115 Waiver**

The proposed demonstration program fails to satisfy foundational requirements of demonstration projects under SSA § 1115. Under federal law, a demonstration program must be "likely to assist in promoting the objectives of [the Medicaid program]" – i.e., it must assist in providing support to low-income individuals who, in the absence of the Medicaid program, may lack coverage for health services. The State's proposed "closed formulary" manifestly fails to satisfy this requirement. It would not assist Medicaid beneficiaries in accessing health services. Rather, it would unquestionably lead to narrower drug coverage and, for many patients, could deprive them of appropriate therapies to which patients would have had access in the absence of the proposed waiver. As CMS has previously acknowledged, drug coverage restrictions "could result in recipients being treated with alternate therapies that may not be in their best interest. This could result in increased program costs if other medical services, such as inpatient hospital services, are necessary because a drug therapy is made less accessible under the State Medicaid program."<sup>5</sup>

The proposed waiver also fails to set forth a true "experimental, pilot, or demonstration

---

<sup>5</sup> 60 Fed. Reg. 48442, 48454 (Sept. 19, 1995).

project” – another federal requirement for Section 1115 waivers. At least one court has affirmed that, in reviewing a proposed demonstration project, HHS “must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money but has no research or experimental goal, would not satisfy this requirement.”<sup>6</sup> The proposed demonstration would institute such a “simple benefits cut,” without serving a research or experimental goal. Accordingly, it lacks an essential requirement of SSA § 1115.

## **V. CMS Rejected the Massachusetts 1115 Waiver Demonstration that Sought to Limit Medication Access**

On June 27, 2018, CMS sent a letter to Massachusetts, denying its request to create a closed formulary for the state Medicaid (MassHealth) population. CMS said that it would consider a similar demonstration project that included a closed formulary if Massachusetts (or another state) instead directly negotiated with pharmaceutical manufacturers and agreed to forgo rebates under the MDRP. According to CMS, “(t)he state could then be provided flexibility to exclude specific drugs from coverage based on cost effectiveness or other approved criteria, or to employ a closed formulary structure similar to Medicare Part D or commercial plan formularies. Under such an approach, the state would have to ensure that federal expenditures under the demonstration would not exceed federal expenditures incurred without the demonstration.”<sup>7</sup> As previously discussed, the proposed waiver seeks to exclude certain covered outpatient drugs from coverage while continuing to collect manufacturers rebates under § 1927. Accordingly, the OHA proposed waiver is impermissible under the standard set forth by CMS in rejecting the Massachusetts waiver.<sup>8</sup>

## **VI. The Proposed Waiver Should Consider Alternative Payment Models**

We appreciate that OHA has significant concerns regarding prescription drug spending. However, in fiscal year 2019, only 2.9 percent of the state Medicaid budget was spent on retail medications, inclusive of all rebates.<sup>9</sup> As an alternative to severe access restrictions, a number of states are experimenting with new methods of Medicaid prescription drug contracting through alternative payment models (APMs) for higher cost medications and/or for medications that meet an urgent public health need. APMs aim to promote value via savings on the total cost of care, total savings for a specific population, improved access, and/or better outcomes.

States that pursue market-based alternatives such as these can improve access to therapies, may lower overall spending, and/or improve health outcomes while incentivizing manufacturers to compete on attributes that include access, cost, quality, and value. Alabama, Arizona, Colorado, Louisiana, Massachusetts, Michigan, North Carolina, Oklahoma, and Texas have all been approved by CMS for Medicaid supplemental rebate agreements (SRAs) that allow for value-based agreements (VBAs) with pharmaceutical manufacturers for a variety of treatments. Louisiana and Washington have received CMS approval of SRA arrangements that allow for Hepatitis C “subscription agreements,” and at least 14 states use risk distribution models including high-risk pools, reinsurance, and risk corridors to help manage program costs. These states have developed approaches that address spending concerns while also maintaining, and

---

<sup>6</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

<sup>7</sup> See CMS, 11-W-00030/1 <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-ca.pdf>.

<sup>8</sup> Novartis recognizes that in early 2021, CMS approved a demonstration proposal from Tennessee to create a closed formulary under its Medicaid program. Since then, CMS has decided to reopen implementation of the demonstration proposal and has requested a new round of public comments. Novartis firmly believes that CMS does not have the legal authority to approve Tennessee’s proposal to implement a closed formulary. Oregon should therefore not base its decision to implement the proposed waiver on CMS’s initial approval of the Tennessee waiver, especially since CMS has reopened the approval determination by seeking a new comment period.

<sup>9</sup> PhRMA, “The Facts About Medicaid in Oregon”, [https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2020/OR-One-Page\\_20.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2020/OR-One-Page_20.pdf).

even improving, Medicaid beneficiary access to innovative medicines.

Novartis has, for instance, entered into VBAs with a number of these states for the spinal muscular atrophy (SMA) gene therapy, Zolgensma, whereby the state receives additional rebates if the desired clinical outcomes are not achieved in the first five years post-administration. Furthermore, a CMS final rule becomes effective in July of this year that will make developers' commercial VBAs more accessible to state Medicaid programs and generally reduce current burdens for states pursuing VBAs.<sup>10</sup> OHA should pursue these types of program reforms and explore new CMS VBA opportunities rather than changes that threaten Medicaid beneficiary access to potentially life-saving therapies.

## **VII. The Proposed Waiver Restricts Access to Life-Saving Medications, Leading to Poorer Outcomes, and Runs Counter to the OHA's Mission of Health Equity**

Novartis believes an important way we can achieve greater health equity is to address persistent disparities in the way healthcare is approached, accessed, and delivered. We are confronting these disparities in innovative ways, such as promoting greater diversity in biopharmaceutical clinical trials and supporting educational programs that raise awareness about diseases and treatments. Often, we work in partnership with patient and community organizations that share our commitment to health equity.

Novartis appreciates the state's focus on health equity. We commend its efforts to improve coverage for vulnerable populations, addressing social determinants of health, assessing health equity quality metrics, and focusing on improving health outcomes. The proposed waiver, however, may have the opposite effect as intended, as it is well documented that restricted access to medicines reduces adherence to prescribed medication regimens, worsens health outcomes, drives up long-run costs, and exacerbates healthcare disparities. A systematic literature review concluded that "formulary restrictions were most frequently negatively correlated" with desirable outcomes, including a consistent negative effect on medication adherence.<sup>11</sup>

A closed formulary ignores and detracts from real opportunities to improve health equity. Underserved communities, who are disproportionately burdened by chronic disease, often already face barriers to accessing medicines and are often treated later for many diseases, such as certain cancers.<sup>12, 13, 14</sup> Timely access to provider-recommended medicines is central to reversing that trend, improving health outcomes, decreasing avoidable healthcare utilization and costs, and reducing mortality.<sup>15,16,17</sup> Improving health equity must begin with addressing the obstacles to accessing care that are most significant to underserved communities.

A closed formulary involves "one size fits all" determinations about clinical efficacy, fails to accommodate the diverse needs of a heterogenous patient population like in Oregon. In fact, a

---

<sup>10</sup> 85 Fed Reg. 87000 (Dec. 31, 2020).

<sup>11</sup> Happe LE, Clark D, Holliday E, Young T. A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. *J Manag Care Spec Pharm.* 2014;20(7):677-84.

<sup>12</sup> Minority Population Profiles. Office of Minority Health. <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=26>.

<sup>13</sup> Gracia JN. COVID-19's Disproportionate Impact on Communities of Color Spotlights the Nation's Systemic Inequities. *Journal of Public Health Management and Practice* 2020; 26(6):518-521. doi: 10.1097/PHH.0000000000001212.

<sup>14</sup> Halpern MT, Holden DJ. Disparities in timeliness of care for US Medicare patients diagnosed with cancer. *Curr Oncol.* 2012;19(6):e404-e413. doi:10.3747/co.19.1073

<sup>15</sup> Lloyd JT, Maresh S, Powers CA, Shrank WH, Alley DE. How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program? *Med Care.* 2019 Mar;57(3):218-224. doi: 10.1097/MLR.0000000000001067. PMID: 30676355.

<sup>16</sup> Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care.* 2005 Jun;43(6):521-30. doi: 10.1097/01.mlr.0000163641.86870.af. PMID: 15908846.

<sup>17</sup> Khunti K, Seidu S, Kunutsor S, Davies M. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. *Diabetes Care.* 2017 Nov;40(11):1588-1596. doi: 10.2337/dc16-1925. Epub 2017 Aug 11. PMID: 28801474.

recent study found if the Medicaid program implemented rigid cost-effectiveness criteria for a set of chronic conditions treated with long-term drug regimens, a significant percentage of beneficiaries would be required to change their current prescriptions.<sup>18</sup> As a result of the OHA's proposal, patients with chronic conditions may lose access to their current treatments or experience interruptions in care. The state should take this opportunity to revise its harmful formulary policy proposal that, if implemented, would exacerbate existing healthcare inequalities for vulnerable patients in Oregon.

## Conclusion

In sum, the proposed waiver poses a significant risk to the health and well-being of Medicaid beneficiaries in Oregon. It would also mark a serious departure from the principles undergirding SSA § 1927, and from CMS' long-standing policy of "remain[ing] committed to Medicaid beneficiaries continuing to have access to needed prescribed medications."<sup>19</sup> It also fails to satisfy the essential criteria for a § 1115 demonstration program. As such, Novartis strongly objects to the prescription drug restrictions in the proposed waiver and encourages OHA to revise its OHP proposal to ensure appropriate access to prescription drugs and the inclusion of beneficiary protections.

Moving forward, Novartis would like to work with OHA to develop meaningful solutions to meet its budgetary and health equity goals while upholding the current Medicaid rebate statute. We stand ready to work with the state if there is interest in applying for a state plan amendment to implement VBAs and health equity strategies to ensure that OHP beneficiaries have access to life-saving and life-enhancing medications.

\* \* \* \* \*

We appreciate the opportunity to comment and would be happy to provide further information regarding our comments above. Please feel free to contact me at 862-778-3284 if we can provide further assistance.

Sincerely,

Leigh Anne Leas  
Vice President and Head, North America Public Policy  
Novartis Services, Inc.

---

<sup>18</sup> Xcenda, Impact Analysis of ICER Formulary Implementation in Medicaid, [https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/icer-medicaid-analysis\\_march-2019.pdf?la=en&hash=03590A12822FB95144692F0BF6FFF846E2E26F1A](https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/icer-medicaid-analysis_march-2019.pdf?la=en&hash=03590A12822FB95144692F0BF6FFF846E2E26F1A). The conditions studied were: multiple sclerosis (99% of prescriptions would need to be changed), rheumatoid arthritis (87%), non-small cell lung cancer (78%), psoriasis (77%), and multiple myeloma (42%).

<sup>19</sup> See CMS, Medicaid Drug Rebate Program Notice, Release No. 172, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015).



January 06, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer Street NE, E65  
Salem, OR 97301

Dear Ms. Hatfield,

Findhelp (formerly Aunt Bertha), would like to thank you for the opportunity to comment on Oregon's 1115 Draft Waiver Renewal Application for the Oregon Health Plan (OHP) and commend you on the person-centered, integrated, and holistic approach to meeting the medical, behavioral, emotional, functional, and social needs of all OHP members.

Founded in 2010, findhelp is a Public Benefit Corporation that runs the largest social care network in the United States and has served more than eight million Americans. Our interoperable social care network is used by over 250 health systems, health plans, community health centers, and health departments in the United States to manage social care referrals, as well as by tens of thousands of community organizations. Our mission is to connect people in need with the programs that serve them, with dignity and ease.

We commend OHA on your efforts to advance health equity through the OHP, including the emphasis in the Renewal Application on addressing the social determinants of health (SDOH), focus on streamlining transitions for individuals in state custody and youth in the juvenile justice and child welfare systems through defined SDOH benefits packages, and refined methodology to pay for population health. We also commend the state for seeking expenditure authority to invest in implementation capacity at the community level, including payments for provider and community-based organizations (CBO) infrastructure and capacity building. To address health-related social needs and advance health equity, it is critical that CBOs are adequately and sustainably funded. We applaud OHA for prioritizing funding and capacity building for CBOs.

Through the proposed Waiver Renewal, you have the opportunity to thoughtfully drive the way that Oregon strengthens connections between social care providers and health care providers to better address people's social care needs and advance health equity. A truly interoperable approach to social care navigation can support your vision by making it easier for individuals to navigate to available community resources, on their own, or with assistance from a health care provider or professional care coordinator. We believe that to advance health equity, we must adopt approaches that serve all people, including individuals who receive care through the OHP, as well as those who access services through other channels.

We also want to commend OHA on the recent charter of the Health Information Technology Oversight Council (HITOC) Community Information Exchange (CIE) Workgroup, and the diversity of voices OHA brought to the



table to shape the CIE approach. As you embark on the next phase of the Oregon Health Plan, the direction set by the CIE Workgroup's recommendations will be critical for shaping the way that the state builds capacity to support SDOH benefits for transition populations and progress toward meeting upstream metrics related to SDOH screening and referral. The CIE work will provide critical infrastructure for advancing the OHP's health equity goals.

As you further refine the Waiver Renewal, we would like to highlight three critical areas related to social care navigation and community information exchange that will require thought leadership from OHA and the HITOC CIE Workgroup: 1) supporting a truly interoperable approach, 2) fostering an open and focused network; and 3) protecting individual data privacy.

**Interoperability:** A truly interoperable approach is founded on agreed upon data standards and incentivizes vendors to support consistent data reporting. Approaches like the Accountable Health Communities Grant Model, which requires documentation, reporting, and standards consistency, provides a good model in which any vendor can be certified to support a state's reporting needs. As part of efforts to build CBO capacity, it is critical that we continue to develop integrations that allow systems to communicate with each other, and prioritize the ability of CBOs to continue to use their existing Systems of Record to manage screenings, needs assessments, appointment scheduling, and tracking of service delivery. OHP can play a role in this process by requiring integration and advancing interoperability standards. Healthcare systems, providers, and CBOs must be able to receive social care data from various sources within their own environment and Systems of Record.

**Open and Focused Network:** An open network ensures that members have access to a broad array of services, including services that are trusted in their community and culturally competent. An open network can also be focused and include preferred providers, meaning that health plans and providers have targeted, and sometimes contractual, relationships with specific CBOs to target specific member needs. To advance health equity requires an active open AND focused network of service providers, to meet the needs of all communities. In addition, members should be empowered and afforded the opportunity to seek services through self-navigation, without being required to have someone else do it for them.

**Protecting Individual Privacy:** Incorporating referrals to social care into our healthcare infrastructure relies on the collection, storing, and sharing of some of the most private and personal information. As you expand upon the current infrastructure for facilitating referrals from healthcare providers to CBOs, OHA must address critical questions of who will own the data, who will be able to view and analyze the data, and how the data will be protected from unauthorized access and cyber attacks. With the inclusion of more CBOs that are not HIPAA-covered entities, it will be imperative that the protection of privacy is at the center of this conversation, with individuals maintaining control over their personal information. We should not compromise privacy to build an interconnected social care network that allows referrals to services for those in need, produces high-quality data, measures outcomes, and builds upon best practices.



Other states are developing best practices that should be implemented to ensure that individual data and privacy is protected, which include:

- Requiring a per-referral consent model, in which individuals are asked to *opt-in* to share their information for each referral and network members' access to referral history is permission-based.
- Maintaining the individual's right to obtain help without conditioning referrals on consent to share personal information.
- Requiring that individuals seeking help maintain the right to opt-out of sharing their information at any time, and that revoking network access to personal information is simple for the individual.
- Establishing provisions governing the length of time non-health identifiable information will be maintained in a database, and;
- Prohibiting the sale of personal information without explicit individual consent.

Again, we commend you on the innovative and holistic approach you have outlined in the Waiver Renewal Application to meet the medical, behavioral, emotional, functional and social needs of all OHP members. We appreciate your leadership in this important area as we are at a pivotal moment that will set the course for how states construct coordinated systems of care, and welcome the opportunity for further discussion of these issues and how we might partner in this area.

*Submitted on behalf of findehelp, a Public Benefit Corporation*



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority (OHA)  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Prescription Drug Limitations in Proposed Oregon Medicaid Waiver

Dear Ms. Hatfield:

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. **We write to express our strong opposition to the proposed limits to the prescription drug formulary that have been included as part of Oregon's 1115 Medicaid Demonstration Waiver. The stated goal of the waiver is to promote greater equity; however, not only do we believe what Oregon is proposing is not legal, but it will have the opposite effect of promoting equity. We urge you to not include these proposals in your waiver submission.**

People with HIV, hepatitis, and others with serious and chronic conditions rely on an array of medications to remain healthy and alive. People with HIV and hepatitis B rely on drug regimens that they must take for the rest of their lives, while people with hepatitis C can be cured of their disease in as little as 8 to 12 weeks. For those who are at risk of HIV, there are daily oral medications and just recently, a long-acting injectable that can lead to better adherence. Having a full range of medications available will lead to better health outcomes and greater equity.

Not all medications are the same, and each person may react differently to a particular medication. Together, doctors and patients make careful treatment decisions about which therapies are most appropriate on a case-by-case basis. Some individuals may develop side effects to a particular drug, while another person may need a certain therapy to avoid a harmful interaction with a drug being taken for another health condition. Drug resistance can occur, and they must have the ability to switch to another drug without interruption.

While the focus of these comments is on HIV, since that is our area of expertise, the same reasoning can be made for many other classes of drugs to treat other health conditions as well.

**HIV + HEPATITIS** POLICY INSTITUTE

1602B Belmont Street NW | Washington DC 20009 | 202-462-3042  
HIVHep.org | Twitter: @HIVHep | Facebook: HIVHep

## **HIV and Disparities**

According to the Kaiser Family Foundation, Medicaid is the largest source of insurance coverage for people with HIV, estimated to cover 42 percent of the adult population, compared to just 13 percent of the adult population overall.<sup>1</sup> HIV disproportionately impacts Blacks/African-Americans and Hispanics/Latinos. According to the CDC, while Blacks/African-Americans represent just 13.4 percent of the overall population, they represent 40.3 percent of all people living with HIV. For Hispanics/Latinos, they represent 18.5 percent of the population but 24.7 percent of people living with HIV. Gay and bisexual men are the most disproportionately affected group. They account for about 66 percent of new HIV infections each year, even though they account for only 2 percent of the population, with the highest burden among Black and Latino gay and bisexual men and young men. In 2019, 26 percent of new HIV infections were among Black gay and bisexual men and 23 percent were among Latino gay and bisexual men.<sup>2</sup>

Black women are also disproportionately affected compared to women of other races/ethnicities. The rate of new HIV infections among Black women was 11 times that of White women and 4 times that of Latina women. Transgender people, particularly those who are Black/African-American, are also disproportionately impacted by HIV.<sup>3</sup>

These same disparities exist in Oregon. According to the Oregon Public Health Division, the rate of Blacks/African-Americans with HIV is 20.2 per 100,000, while it is at least 8 per 100,000 for American Indians/Alaska Natives, Native Hawaiians/Pacific Islanders, and Latinos; however, for Whites it is just 4.2 per 100,000.<sup>4</sup>

## **Ending HIV**

Due to the remarkable advancements in antiretroviral therapy, we believe we can end HIV, which is still an infectious disease of significant public health concern. If people with HIV have access and are adherent to the medications they are prescribed, they can live relatively healthy lives. In addition, the medications suppress the virus so well that they cannot sexually transmit the virus to other people. Therefore, HIV treatment is also HIV prevention. There are also drugs called pre-exposure prophylaxis, or PrEP, that people who are at risk of HIV can take that prevent infection of HIV. Due to these advancements, we can end HIV by reducing the level of virus in the population, if people have access to these medications. In fact, there is a concerted effort to end HIV by 2030 and the Biden administration recently released an updated *National HIV/AIDS Strategic Plan* to end HIV. The strategic plan recognizes the importance of Medicaid

---

<sup>1</sup> "Medicaid and HIV," Kaiser Family Foundation, updated October 1, 2019, accessed January 6, 2022, <https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/>.

<sup>2</sup> *National HIV/AIDS Strategy for the United States: 2022–2025*, White House, 2021, p. 15, <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>.

<sup>3</sup> *National HIV/AIDS Strategy for the United States: 2022–2025*, White House, 2021, p. 16.

<sup>4</sup> *End HIV Oregon*, Oregon Public Health Division—HIV, STD, & TB Section, updated January 6, 2022, accessed January 5, 2022,

<https://public.tableau.com/app/profile/oregon.health.authority.public.health.divison/viz/EndHIVOregon/EndHIVORHome>.

and the role of prescription drugs by stating, “Medicaid is the largest source of insurance coverage for people with HIV, covering a broad range of services from inpatient and outpatient care, **to prescription medications**, to preventive services” (emphasis added).<sup>5</sup>

Oregon has its own program to end HIV, the End HIV Oregon initiative run by the Oregon Health Authority (OHA) and its community partners (EndHIVOregon.org). It incorporates the same elements of increasing treatment for people living with HIV to lead to greater viral suppression and increasing access to PrEP for those who are at risk of HIV.

### **Oregon Proposals to Limit Prescription Drugs**

Oregon is proposing to drastically curtail the number of drugs that its Medicaid program must cover by creating a drug formulary that only includes one drug per class from its current open formulary that is required under federal law. Additionally, Oregon is proposing to exclude altogether certain FDA approved drugs.

**Proposal Violates Federal Medicaid Law.** Section 1927 of the Social Security Act requires states to cover all drugs of a pharmaceutical manufacturer that participates in the federal Medicaid rebate program, while allowing them to use “permissible restrictions.” In exchange for this requirement, states receive a minimum 23.1 percent rebate plus additional rebates when manufactures increase the price of their drug above inflation. States may receive supplemental rebates by using a preferred drug list. The closed formulary Oregon is proposing that would only include one drug per therapeutic class violates current federal law, cannot be waived, and should not be proposed by the state.

Oregon is also proposing to exclude certain FDA-approved drugs that gain their approval through its accelerated approval pathway. This also would circumvent current Medicaid law. Section 1927 does not allow states to pick and choose what types of medications that must be covered but requires coverage of all FDA-approved drugs of manufactures that participate in the rebate program. These drugs are FDA-approved. Secondly, these accelerated approval drugs still must meet FDA standards for approval and are on the accelerated approval process in order to meet the needs of patients who have rare or complicated diseases with few or no treatment options.

**Flawed Basis for Proposal.** In making this proposal, Oregon states incorrectly that by doing so it will match what is done by commercial payers and by Medicare. In both those instances, this is not correct.

Under the rules implementing the Affordable Care Act (ACA), plans must cover *at least the greater of*: (i) One drug in every United States Pharmacopeia (USP) category and class; or (ii) The same number of prescription drugs in each category and class as the Essential Health Benefit-benchmark plan. (See 45 CFR § 156.122) These essential health benefits benchmark plans are widely used commercial plans and include a wide array of drugs in each class. These same regulations also state that plans must have a pharmacy and therapeutic committee to

---

<sup>5</sup> *National HIV/AIDS Strategy for the United States: 2022–2025*, White House, 2021, p. 13.

help formulate drug formularies that are based on “scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.”

Recently, in the proposed *Notice of Benefits and Payment Parameters Rule for 2023*, CMS reminded plans “issuers should expect to cover and provide sufficient access to treatment recommendations that have the highest degree of clinical consensus based on available data, such as professional clinical practice guidelines.”<sup>6</sup>

The mention of at least one drug per class is to ensure that every plan has at least one drug to treat a certain condition. However, commercial plans are required to cover more than this and follow clinical guidelines.

For HIV, there are NIH treatment guidelines, which include a wide range of medications, and for PrEP, the CDC recently released the Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update—A Clinical Practice Guideline, which includes all current FDA-approved drugs for PrEP. Allowing Oregon to cover only one drug per class would not keep its Medicaid formulary current with scientific based clinical guidelines for the treatment and prevention of HIV.

Oregon states that Medicare Part D also employs a closed formulary and can limit a plan to just one drug per class. Again, Oregon has not fully or accurately described current Medicare Part D law and regulations. Medicare regulations, which have been codified by the Congress, including as part of the ACA, require Medicare plans to cover all or substantially all medications to treat some of the most serious health conditions. Part D requires plans to cover basically all drugs in the six classes: antidepressants, immunosuppressants, antipsychotics, anticonvulsants, and antiretrovirals. Drugs in these six “protected classes” (as defined in Section 1860D-4(b)(3)(G)(iv)) are used to treat the most vulnerable of patients for whom medicines are not interchangeable due to sensitivity or resistance to a drug, the unique biochemistry of the individual, or severe side effects.

Like many Medicare beneficiaries, Medicaid beneficiaries, including those with HIV or at risk of HIV, are among the most vulnerable in society and should have access to the full range of medications, not just one drug per class, to treat their health conditions. In order to promote greater equity and to end HIV, Oregon must maintain its statutorily required open formulary. While we do not like it, Oregon can utilize a preferred drug list in order to gain additional rebates from drug manufacturers.

Thank you for this opportunity to comment on this proposal. Should you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at [cschmid@hivhep.org](mailto:cschmid@hivhep.org).

---

<sup>6</sup> *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023*, Department of Health and Human Services, Federal Register, updated January 5, 2022, p. 235, <https://public-inspection.federalregister.gov/2021-28317.pdf>.

Sincerely,

A handwritten signature in blue ink, appearing to read "Carl E. Schmid II". The signature is fluid and cursive, with a prominent loop at the end.

Carl E. Schmid II  
Executive Director

January 4, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Ms. Hatfield:

Re: Comments in Support of Medicaid 1115 Demonstration Application

Willamette Partnership supports the Medicaid 1115 Demonstration Application because it advances equitable health investments and community-driven health values. In particular, the [Focused Equity Investments](#) are an opportunity for Oregon to champion community-led investments that address social determinants of health. We know that zip code impacts health outcomes, and increasing access to green space, job opportunities, education, housing, etc. in addition to quality health care coverage is a critical step towards equitable health for all communities. Due to a long history of racialized policies, [race continues to be the strongest predictor of someone being exposed to environmental health hazards](#), and focusing on priority communities begins to repair past discrimination and exclusion from health investment decisions.

Past investments in health and social infrastructure have often been deeply inequitable in their benefits, costs, and negative impacts. For the communities that live with these inequities - Black, Indigenous, and people of color (BIPOC), low-income, and rural communities, as well as older people and people with disabilities - historical social infrastructure disinvestment has led to critical failures, undermining public health, community resiliency, and economic development. The new Medicaid waiver allows for community agency and flexibility, giving impacted communities the room and power to identify and determine where investments need to be made to improve community health.

We believe in moving healthcare money into community hands, where investing in natural spaces is an option. This is particularly important in a changing climate, where natural infrastructure needs to be incorporated into built infrastructure so that our communities are climate-ready and more resilient to fires, flooding, and water quality and quantity issues. The 1115 Demonstration Application will move money to community wellness programs and communities can choose to invest in green spaces and natural infrastructure as one option among many. We are hopeful that this opens up more pathways for natural infrastructure, green spaces, and outdoor recreation to treat mental health and substance use, as it is currently not accessible to all.

Willamette Partnership is looking to make real impacts in communities that improve health and environmental outcomes, especially for communities that have experienced inequities. The new approach to Medicaid can help strengthen new and existing community projects, create and strengthen cross-sectoral partnerships, increase capacity and technical assistance to community partners, and offer collaborative facilitation in projects at the intersection of health and the environment. For a stronger, healthier, and just future for Oregon, leaders should adopt the thoughtful Medicaid Waiver Renewal.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sara O'Brien', with a stylized, cursive script.

Sara O'Brien  
Executive Director  
Willamette Partnership  
[obrien@willamettepartnership.org](mailto:obrien@willamettepartnership.org)



January 7, 2022

Mr. Patrick Allen  
Director, Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Re: Comments on Oregon’s Draft 2022-2027 Medicaid 1115 Demonstration Application**

Dear Director Allen:

Gilead Sciences, Inc. (Gilead) welcomes this opportunity to comment on Oregon’s Draft 2022-2027 Medicaid 1115 Demonstration Application (the “Draft Application”). Gilead is a US-based, global biopharmaceutical company that is committed to discovering, developing, and delivering innovative therapeutics for people with life-threatening diseases in areas of unmet medical need. Our marketed products include medicines for the prevention and treatment of HIV/AIDS and treatment of liver diseases including hepatitis B and C, cancer, and COVID-19, as well as certain cardiovascular and respiratory diseases.

Gilead has significant concerns with the Draft Application, specifically its provisions relating to the adoption of a closed-formulary in the Oregon Medicaid program outpatient prescription drug benefit. As a member of both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO), we join their critique of the Draft Application. We write separately to emphasize the following points for your consideration:

- The State cannot waive protections for access to the full range of FDA approved medications granted under SSA Section 1927.
- The requested waiver would fail to meet the essential criteria under SSA Section 1115, because it does not specify an experiment that supports the objectives of the Medicaid program.
- The state has existing authorities that it can leverage in order to manage formularies.
- The proposed waiver would undermine a crucial component of health equity.
- The proposed waiver would inhibit the coverage of drugs approved under accelerated approval pathways by substituting the state’s judgment for the FDA approval process.
- The proposed waiver would result in substandard coverage for Medicaid compared to Medicare or Exchanges.

Our comments on each of these points are below.

**1. The State cannot waive protections for access to the full range of FDA approved medications granted under SSA Section 1927.**

In the Draft Application, Oregon seeks to “increase predictability of costs and ensure value for spending” in its Medicaid program through implementation of a “commercial-style closed formulary” and “exclusion of drugs with limited or inadequate evidence of clinical efficacy.” Oregon seeks to accomplish this through a SSA Section 1115 waiver of SSA Section “1902(a)(54) insofar as it incorporates” SSA Section 1927(d)(1)(B) – the provision of the Medicaid Rebate Statute that limits the state’s ability to exclude certain drugs from coverage. Notably, Oregon’s request would leave the remainder of SSA Section 1927, including the rebate obligation for participating manufacturers under SSA Section 1927(b), intact. There are several reasons why Oregon’s request is legally impermissible.

As a threshold matter, by its express terms, SSA Section 1115 does not permit waiver of any requirements of SSA Section 1927. Pursuant to SSA Section 1115(a)(1), the Secretary may waive compliance “with any of the requirements of section 402, 454, 1402, 1602, or 1902....” Notably, SSA Section 1927 is not among the enumerated statutes subject to waiver. This interpretation is supported by the D.C. Circuit’s holding in *PhRMA v. Thompson*, which addressed whether Section 1115 permits waivers of the rebate statute requirements:

The Social Security Act, of which the Medicaid statute is a part, authorizes HHS to approve experimental “pilot” or “demonstration” projects that the Secretary determines are “likely to assist in promoting the objectives of [Medicaid].” [42 U.S.C.] § 1315(a). Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r-8’s [SSA Section 1927’s] rebate provision.<sup>1</sup>

Furthermore, an almost identical closed formulary proposal was rejected by CMS in 2018 in response to the Commonwealth of Massachusetts’ SSA Section 1115 Demonstration Amendment request. Massachusetts argued that waiving the open formulary requirements would “improve [its] ability to negotiate additional supplemental rebates.”<sup>2</sup> CMS determined, however, that it would be impermissible for the Commonwealth to exclude certain Medicaid covered outpatient drugs from coverage and continue to: (a) provide drug coverage pursuant to its state plan under SSA Section 1902 and (b) claim mandatory rebates from manufacturers under SSA Section 1927(b).<sup>3</sup> Oregon’s proposal is similarly flawed for the same reasons, among others.

Moreover, the state’s proposal to categorically deny coverage of covered outpatient drugs would undermine the congressionally-declared objective of SSA Section 1927 and its carefully designed bargain between manufacturers, the States, and the Federal government. Congress enacted SSA

---

<sup>1</sup> *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001).

<sup>2</sup> Office of Medicaid, Mass. Executive Office of Health & Human Services, MassHealth Section 1115 Demonstration Amendment Request at 8 (Sept. 8, 2017).

<sup>3</sup> Letter from Tim Hill, Acting Director, CMS, to Daniel Tsai, Assistant Secretary, MassHealth at 2 (June 27, 2018).

Section 1927 to guarantee that “[s]tates that elect to offer prescription drugs . . . cover all the products of any manufacturer that agrees to provide price rebates.”<sup>4</sup> As Congress made abundantly clear, “[s]tates that elect to offer prescription drug coverage under their Medicaid programs will be required to cover all of the drugs of any manufacturer entering into and complying with such an agreement, with the exception of drugs (e.g., cosmetic drugs) on a statutory list (which may be revised by the Secretary).”<sup>5</sup> As the Supreme Court has emphasized, “strict adherence to the language and structure of an act is particularly appropriate where . . . a statute is the result of a series of carefully crafted compromises.”<sup>6</sup>

But Oregon’s proposal, which would enable the state to escape its coverage obligations under SSA Section 1927, would unravel this carefully designed bargain. That is, Oregon would continue to provide prescription drug coverage under its Medicaid state plan, and thus continue to subject manufacturers to rebate obligations, all without complying with its corresponding obligation under the Medicaid Drug Rebate Program (MDRP) – coverage of all of a participating manufacturer’s covered outpatient drugs. This would contravene the terms of the compromise Congress carefully designed between manufacturers and the government; it would be fundamentally unfair to require manufacturers to uphold their side of the arrangement and could dissuade some manufacturers from participating in the MDRP, if states were permitted to avoid their set of reciprocal requirements.

## **2. The requested waiver would fail to meet the essential criteria under SSA Section 1115, because it does not specify an experiment that supports the objectives of the Medicaid program.**

Oregon’s draft proposal would fail to satisfy the plain language requirement of SSA Section 1115(a)(1), which only allows “Secretary [to] waive compliance with any of the requirements” of SSA Section 1902 “[i]n the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of” Medicaid. This is because the state failed to specify what would be tested by waiving the Medicaid coverage requirements, the waiver would conflict with the objectives of the Medicaid program, and the waiver proposal does not include essential beneficiary protections.

First, Oregon has failed to specify a research or experimental proposition that it seeks to test under its demonstration project as a result of the requested waiver. A waiver of compliance with SSA Section 1927 to enable a truly closed formulary would be tantamount to nothing more than a “simple benefits cut” , which, as the Ninth Circuit Court of Appeals has ruled, does not serve an experimental purpose.<sup>7</sup> In particular, the Ninth Circuit has held that the Secretary, in reviewing a proposed demonstration project, “must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement . . . . The statute was not enacted to enable

---

<sup>4</sup> H. R. NO. 101-881, at 98 (1990).

<sup>5</sup> STAFF OF H. COMM. ON WAYS AND MEANS, H. COMM. ON ENERGY AND COMMERCE, & S. COMM. ON FINANCE, 101ST CONG., SUMMARY OF MEDICARE AND MEDICAID PROVISIONS IN THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990 19 (Comm. Print. 1990).

<sup>6</sup> *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 748 n.14 (1989).

<sup>7</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).

states to save money or to evade federal requirements but to ‘test out new ideas and ways of dealing with the problems of public welfare recipients.’”<sup>8</sup> Oregon has failed to set forth any meaningful research proposition or purpose that would be tested as a result of the requested waiver.

Second, under SSA Section 1115(a), a demonstration project must, in the judgment of the Secretary, be “likely to assist in promoting the objectives of ... [the Medicaid statute].”<sup>9</sup> Medicaid was enacted by Congress in order to provide medical care to the needy and medically needy.<sup>10</sup> Indeed, recently the D.C. Circuit determined in striking down CMS’ approval of an Arkansas waiver that “[T]he intent of Congress is clear’ that Medicaid’s objective is to provide health care coverage and, as a result, [CMS] ‘must give effect to [that] unambiguously expressed intent of Congress.’”<sup>11</sup> Put another way, Medicaid beneficiaries cannot be “significantly burdened—that is, for example, their eligibility significantly restricted or benefits significantly cut—in the name of saving money.”<sup>12</sup> If a state were allowed to deny access to otherwise-covered and potentially life-saving therapies, as Oregon contemplates here, a demonstration project would do precisely that – it would substantially limit Medicaid beneficiaries’ access to medically-necessary therapies, many of which have life-saving potential. This would undermine, as opposed to promote, the attainment of Congress’ fundamental objective in enacting the Medicaid program.

Finally, through SSA Section 1927, Congress also intended to provide Medicaid beneficiaries with key safeguards to protect their access to medically necessary therapies. In enacting SSA Section 1927, “Congress made it clear that Medicaid recipients should be assured access to all medically necessary covered outpatient drugs.”<sup>13</sup> This guarantee has endured over the ensuing decades as SSA Section 1927 has been amended by Congress over time.<sup>14</sup> A waiver of a state’s obligation to comply with SSA Section 1927’s coverage obligations would undercut, rather than further, Congress’ key goal of ensuring access to covered outpatient drugs.

---

<sup>8</sup> *Id.*; cf. *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011) (finding, in examining the research value of a state’s proposal to impose cost-sharing requirements on Medicaid beneficiaries, that “[p]laintiffs’ public health expert stated that ‘[o]ver the last 35 years, a number of studies have looked at the effects of cost sharing on the poor. Of all forms of cost sharing, copayments are the most heavily studied.’ The administrative record contains no finding from the Secretary that Arizona’s demonstration project will actually demonstrate something different than the last 35-years’ worth of health policy research.”).

<sup>9</sup> SSA § 1115(a).

<sup>10</sup> See STAFF OF H. COMM. ON WAYS AND MEANS, 89TH CONG., SUMMARY OF MAJOR PROVISIONS OF H.R. No. 6675, THE “SOCIAL SECURITY AMENDMENTS OF 1965” 1 (Comm. Print 1965); see also S.R. No. 89-404, pt. 1, at 73-74 (1965) (“[the Medicaid statute] is designed to liberalize the Federal law under which States operate their medical assistance programs so as to make medical services for the needy more generally available”).

<sup>11</sup> *Gresham v. Azar*, 950 F.3d 93, (D.C. Cir. 2019).

<sup>12</sup> *Stewart v. Azar*, 366 F. Supp. 3d 125, 152 (D.D.C. 2019).

<sup>13</sup> See 60 Fed. Reg. 48,442, at 48,454 (citing H.R. Rep. No. 881, 101st Cong., 2d Sess. 96-98 (1990)).

<sup>14</sup> Even when Congress added SSA Section 1927(d)(4), thereby enabling states to establish formularies that meet specific requirements, it remained the case that “section 1927(d)(4)(D) provides that the State plan must permit coverage of a drug excluded from the formulary (other than any drug excluded or restricted under section 1927(d)(2)) pursuant to a prior authorization program.” 60 Fed. Reg. at 48,454.

### **3. The state has existing authorities that it can leverage in order to manage formularies.**

In its draft application, Oregon notes that “taking a closed formulary approach” would enable its Medicaid program “to negotiate more favorable agreements with manufacturers.” However, Oregon does not need a waiver of compliance with SSA Section 1927 in order to achieve its apparent objective. Under SSA Section 1927(d)(5), states have the authority to impose prior authorization requirements for drugs based upon valid criteria through a preferred drug list (PDL) program. Under such a program, the state can negotiate supplemental rebates in a manner that encourages the use of preferred drugs over non-preferred drugs. Preferred drugs, for which the state receives supplemental rebates from the manufacturer, can be covered without prior authorization. Non-preferred drugs, for which the state does not receive supplemental rebates, are in turn subject to prior authorization.

These existing authorities have provided states ample opportunities to negotiate significant additional rebates from manufacturers. Specifically, Gilead reviewed publicly available CMS-64 reports for states with similar Medicaid enrollments as Oregon and found that Oregon received supplemental rebates that were significantly lower than the other states.<sup>15</sup> This further suggests that the state may be able utilize existing authority to seek additional supplemental rebates as part of its preferred drug list.

### **4. The proposed waiver would undermine a crucial component of health equity.**

We are concerned the closed formulary component of the Draft Application would further exacerbate health inequities, conflicting with one of the objectives laid out by the state.<sup>16</sup> The adults served by Oregon’s Medicaid program are not only low-income, but also disproportionately people of color and people with disabilities.<sup>17</sup> In June 2020, Governor Kate Brown released a new diversity, equity, and inclusion framework of the state of Oregon, which states “[O]ur state government must take proactive and anti-racist measures to build a more equitable Oregon.<sup>18</sup> To redress longstanding health inequities, Oregon must ensure that Medicaid beneficiaries are able to access the medications they need, as determined by their healthcare provider.

If Oregon were permitted to limit therapies (potentially to as few as a single drug per therapeutic class), the results would be highly detrimental to Medicaid beneficiaries. Medicaid patients often have one or more chronic health conditions and require multiple, specific prescription drugs in

---

<sup>15</sup> Gilead analysis of CMS-65 reports from FY2016-2020.

<sup>16</sup> See Draft Application page 3. “Focusing our waiver application on meaningful progress toward health equity... will allow us to improve health outcomes in communities most harmed by social injustices.”

<sup>17</sup> Black and Hispanic Oregonians are substantially more likely than White Oregonians to be enrolled in the Medicaid program. *Compare QuickFacts: Oregon*, U.S. Census Bureau (last updated July 1, 2019), <https://www.census.gov/quickfacts/OR> with *Medicaid Coverage Rates for the Nonelderly by Race/Ethnicity: Oregon*, Kaiser Family Foundation (2019), <https://www.kff.org/medicaid/state-indicator/nonelderly-medicaid-rate-by-raceethnicity/?currentTimeframe>. Nationwide, “nearly a quarter of nonelderly adults with Medicaid report having a disability.” M. Musumeci & K. Orgera, *People with Disabilities Are At Risk of Losing Medicaid Coverage Without the ACA Expansion*, Kaiser Family Foundation (Nov. 2, 2020), <https://www.kff.org/medicaid/issue-brief/people-with-disabilities-are-at-risk-of-losing-medicaid-coverage-without-the-aca-expansion/>.

<sup>18</sup> <https://www.myoregon.gov/2020/06/11/oregons-equity-guidelines/> (last visited Dec. 29, 2021).

order to adequately manage those conditions.<sup>19</sup> Such a narrow coverage policy would deprive Medicaid beneficiaries of medically necessary therapies on which they have long relied to address their conditions and co-morbidities.

Sadly, these health disparities are particularly stark with respect to HIV. The incidence rates of new HIV infection in Oregon between 2009-2018 are nearly five times higher among Black and African Americans than among Whites, and Black and African Americans are less likely to be virally suppressed than Whites.<sup>20</sup> Limiting access to HIV drugs for Medicaid beneficiaries could delay treatment initiation or interrupt therapy and exacerbate these distressing health disparities, undermining President Biden's commitment to end the HIV/AIDS epidemic by 2030.<sup>21</sup> Given that Black people are both more likely to be diagnosed with a new HIV infection, more likely to not be virally suppressed, and more likely to be enrolled in Oregon's Medicaid program than other racial groups, policies and programs are needed to support vulnerable communities in achieving fair outcomes in care.<sup>22</sup> Strong coverage and access protections are necessary to protect against potential discrimination—intentional or inadvertent—in the design and implementation of healthcare benefits, as demonstrated by the long history of complaints against health plans for discrimination against those living with HIV.<sup>23</sup> As discussed further below, this is why antivirals are one of Medicare's protected classes.

Similarly, despite the development of policies to support breast cancer patients, recognition of the specific effects of health disparities and inequities on Triple Negative Breast Cancer (TNBC) patients and actions to mitigate them are limited. TNBC is an aggressive form of breast cancer, is often diagnosed at later stages, and presents a higher chance at becoming metastatic than other types of cancers.<sup>24</sup> Black women are two times more likely to be diagnosed with TNBC than white women in the US.<sup>25</sup> Studies have shown that TNBC disease-specific mortality rates are often

---

<sup>19</sup> See, e.g., *The Role of Medicaid for Adults with Chronic Illnesses*, Kaiser Family Foundation (Nov. 2012), available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8383.pdf>.

<sup>20</sup> Oregon Health Authority, HIV Infection in Oregon as of Dec. 31, 2018, <https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le9985.pdf>.

<sup>21</sup> The White House. Fact Sheet: The Biden-Harris Administration Marks World AIDS Day 2021 With Renewed Commitments to Ending the HIV/AIDS Epidemic by 2030. December 1, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/01/fact-sheet-the-biden-%E2%81%A0harris-administration-marks-world-aids-day-2021-with-renewed-commitments-to-ending-the-hiv-aids-epidemic-by-2030/>

<sup>22</sup> See *Id.* at 15.

<sup>23</sup> See, e.g., Nat'l Health Law Program, *Florida Insurance Commissioner fines Humana \$500,000* (Feb. 18, 2016) (describing litigation that resulted in a consent order in which “Humana agreed to ‘maintain procedures to ensure that it does not by effect or design treat people living with HIV/AIDS less favorably than any other condition.’”), <https://healthlaw.org/news/florida-insurance-commissioner-fines-humana-500000/>; Ctr. for Health Law & Policy Innovation (CHLPI), *CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States*, Harvard Law School (Sept. 6, 2016), <https://www.chlpi.org/chlpi-launches-groundbreaking-campaign-enforce-health-care-rights-people-living-hiv-seven-states/>.

<sup>24</sup> American Cancer Society, Triple-Negative Breast Cancer, 2019. <https://www.cancer.org/cancer/breast-cancer/understanding-abreast-cancer-diagnosis/types-of-breast-cancer/triple-negative.html>

<sup>25</sup> American Cancer Society. *Breast Cancer Facts and Figures 2019-2020*. Atlanta, GA: American Cancer Society Inc; 2021

higher if patients have Medicaid or Medicare or are lower socio-economic status;<sup>26</sup> and compared with non-Hispanic white women, Black women are 48% less likely to receive guideline adherent care and have an approximate 2-fold higher mortality incidence, resulting in a disproportionately higher risk of death from TNBC.<sup>27,28</sup> Recent innovation in targeted therapies has led to advances in treatment for TNBC, yet barriers in care and treatment remain significant for minority women disproportionately impacted. Targeted policy strategies are needed to comprehensively address these barriers to ensure early TNBC diagnosis and effective treatment initiation. We are concerned however, that a closed formulary approach could create difficulty in obtaining needed therapies for some of the most vulnerable women impacted by TNBC in the state.

The two examples above illustrate the potential of the Medicaid program to remedy health inequities, but only if Medicaid beneficiaries are allowed broad and timely access to medically necessary medications and other care.

##### **5. The waiver would inhibit the coverage of drugs approved under accelerated approval pathways by substituting the state’s judgement for the FDA approval process.**

Oregon’s Draft Application seeks to “allow exclusion of drugs with limited or inadequate evidence of clinical efficacy.” Specifically, Oregon seeks authority to deny access to “drugs coming to market through the FDA’s accelerated approval pathway” on the grounds that they “have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints.” Gilead strongly objects to this characterization of the accelerated approval pathway and to the exclusion of such drugs, given that the FDA instituted the accelerated approval pathway “to allow for earlier approval of drugs...that fill an unmet medical need based on a surrogate endpoint.”<sup>29</sup> Exclusion of such drugs would represent a significant departure from current law, which protects access to cutting edge therapies for Medicaid beneficiaries. Oregon’s Medicaid beneficiaries should not be restricted from accessing therapies approved under FDA’s accelerated approval pathway as soon as they are available.

First, by attempting to limit Medicaid beneficiaries’ access to these therapies, Oregon would deprive patients suffering from serious or life-threatening diseases of medicines that FDA has determined are safe and effective for their condition after a full review of available data. This barrier may negatively impact health outcomes for Medicaid beneficiaries, who are already some

---

<sup>26</sup> Ubbaonu C, Chang J, Ziogas A, et al. Disparities in the receipt of National Comprehensive Cancer Network (NCCN) guideline adherent care in triple-negative breast cancer (TNBC) by race/ethnicity, socioeconomic status, and insurance type. Presented at: ASCO20 Virtual; May 29-31, 2020. Accessed June 15, 2020.

<https://meetinglibrary.asco.org/record/185233/abstract>; Cho B, Han Y, Lian M, et al. Evaluation of Racial/Ethnic Differences in Treatment and Mortality Among Women With Triple-Negative Breast Cancer. *JAMA Oncol.* 2021;7(7):1016–1023. doi:10.1001/jamaoncol.2021.1254

<sup>27</sup> Lu Chen and Christopher I. Li, Racial Disparities in Breast Cancer Diagnosis and Treatment by Hormone Receptor and HER2 Status, *Cancer Epidemiol Biomarkers Prev* November 1 2015 (24) (11) 1666-1672; DOI: 10.1158/1055-9965.EPI-15-0293

<sup>28</sup> Cho B, Han Y, Lian M, et al. Evaluation of Racial/Ethnic Differences in Treatment and Mortality Among Women With Triple-Negative Breast Cancer. *JAMA Oncol.* 2021;7(7):1016–1023. doi:10.1001/jamaoncol.2021.1254

<sup>29</sup> FDA, Accelerated Approval Program. Available at: <https://www.fda.gov/drugs/information-health-care-professionals-drugs/accelerated-approval-program>

of the sickest and most vulnerable residents of the state. Moreover, accelerated approval drugs, are often the latest cures and advances in medical science. Medicaid beneficiaries would, thus, have inferior healthcare as compared to other Oregonians and Medicaid beneficiaries in other states jeopardizing health outcomes. This contravenes CMS' long-standing "commit[ment] to Medicaid beneficiaries continuing to have access to needed prescribed medications."<sup>30</sup>

Second, we are also deeply concerned that Oregon's proposal to "use its own rigorous review process" to define coverage of new drugs and determine which drugs are "clinically proven, effective drugs" improperly supplants the FDA's clearly established role in the determination of safety and effectiveness of a particular drug. Drug manufacturers rely on this defined process in bringing new therapies to market. Given that Congress has granted the FDA authority to determine a particular product's efficacy, we believe they are best suited to conduct this rigorous analysis rather than the State. As one state court recently noted, "it is the FDA's job, not that of the [state] Medicaid agency, to evaluate the clinical data to determine whether a drug meets efficacy and safety standards. So long as FDA has approved the drug and the manufacturer has signed a Medicaid Drug Rebate Agreement ... the Social Security Act mandates that a state Medicaid agency cannot rely on new or different clinical data to determine whether it deems a drug worthy of coverage."<sup>31</sup>

Third, we also object to Oregon's unfounded assertion that accelerated approval drugs may have "limited or inadequate clinical efficacy." Both Congress and the FDA have made clear that nothing about accelerated approval dilutes the FDA's approval standards. In 2016, the 21<sup>st</sup> Century Cures Act incorporated FDA's existing regulatory program for accelerated approval<sup>32</sup> into statute, expressly providing, "Nothing in this section shall be construed to alter the standards of evidence" for approval.<sup>33</sup> Like all other drugs approved under New Drug Applications, drugs approved through the accelerated approval pathway are subject to a demanding standard of review — demonstration of "substantial evidence" of effectiveness.<sup>34</sup> Instead of altering the approval standard, the program is intended to encourage FDA "to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs."<sup>35</sup> It should also be noted that surrogate endpoints commonly used as the basis for granting accelerated approval are thoroughly evaluated and must be reasonably likely to predict clinical benefit in patients who are very ill and without good options.<sup>36</sup> By denying Medicaid patients access to therapies that rely on surrogate endpoints, the state could effectively discriminate against individuals with rare diseases or few treatment options and compromise the health of Oregon Medicaid members.

In response to a question about whether the accelerated approval pathway provides for a less rigorous standard, the FDA confirmed that it does not:

---

<sup>30</sup> See CMS, Medicaid Drug Rebate Program Notice, Release No. 172, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015).

<sup>31</sup> *Ark. Dep't of Human Servs. v. Sarepta Therapeutics, Inc.*, 2021 Ark. App. 330, 2021 Ark. App. LEXIS 356.

<sup>32</sup> See 57 Fed. Reg. 58697 (Dec. 11, 1992) (FDA's final regulations establishing the accelerated approval program).

<sup>33</sup> 21 U.S.C. § 356(e)(2).

<sup>34</sup> 21 U.S.C. § 355(d)(5).

<sup>35</sup> 21 U.S.C. § 356(e)(1).

<sup>36</sup> FDA. Accelerated Approval. Available at: <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>

Approval under this rule requires ... that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. ***This judgment does not represent either a "lower standard" or one inconsistent with section 505(d) of the act,*** but rather an assessment about whether different types of data show that the same statutory standard has been met.<sup>37</sup>

Senior Biden Administration FDA officials also recently reiterated that all drugs, regardless of the pathway, are held to the same approval standards.<sup>38</sup>

Congress has clearly outlined the circumstances under which the FDA can consider a drug for accelerated review. Specifically, the FDA must determine “that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit ... taking into account the severity, rarity, or prevalence of the condition and availability or lack of alternative treatments.”<sup>39</sup>

Fourth, Gilead is further concerned about the Draft Application because the accelerated approval pathway has been vital for patients suffering from a wide range of serious diseases where alternative therapies do not exist, including cancer and HIV. According to Dr. Richard Pazdur, director of the FDA’s Oncology Center of Excellence (OCE), “[t]he FDA has successfully applied accelerated approval in oncology over the past three decades, making innovative therapies available to patients years earlier than they would otherwise have been available.”<sup>40</sup> Further, studies have found that drugs approved through the accelerated approval process have provided larger health gains compared to drugs approved through the traditional approval process.<sup>41</sup>

Beyond cancer, the accelerated approval pathways can help patients with rare disease with no approved treatment to date, such as a Hepatitis D virus (HDV) and Hepatitis B virus (HBV) co-infection. The HDV-HBV co-infection is the most severe form of chronic viral hepatitis due to its more rapid progression towards hepatocellular carcinoma and liver related death.<sup>42</sup> Patients with HDV have a mortality rate of 20 percent, the highest mortality rate of any viral hepatitis.<sup>43</sup> Further, the risk of developing cirrhosis is three times higher in HDV infected patients compared to those

---

<sup>37</sup> 57 Fed. Reg. at 58944 (emphasis added).

<sup>38</sup> B. Wang, *Woodcock, Marks: Expedited Approval Paths Do Not Lower FDA Standards*, Inside Health Policy (Aug. 28, 2019), <https://insidehealthpolicy.com/daily-news/woodcock-marks-expedited-approval-paths-do-not-lower-fda-standards>.

<sup>39</sup> 21 U.S.C. § 356(e)(2), (c)(1)(A).

<sup>40</sup> J. A. Beaver & R. Pazdur, “Dangling” Accelerated Approvals in Oncology, *N Engl J Med* 384:18 (May 6, 2021), <https://www.nejm.org/doi/pdf/10.1056/NEJMp2104846?articleTools=true>.

<sup>41</sup> J. D. Chambers et al., *Drugs Cleared Through The FDA’s Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process*, *HEALTH AFFAIRS* 36, NO. 8 (2017): 1408–1415, <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2016.1541>.

<sup>42</sup> World Health Organization. (2021, January 28). *Hepatitis D*. Retrieved from <https://www.who.int/news-room/fact-sheets/detail/hepatitis-d>

<sup>43</sup> Romeo R, Petruzzello A, Pecheur EI, et al. Hepatitis delta virus and hepatocellular carcinoma: an update. *Epidemiol Infect.* 2018;146(13):1612-1618. doi:10.1017/S0950268818001942.

with HBV alone.<sup>44,45</sup> Given that there are no approved therapies for this unmet, rare disease, Oregon should not restrict access to future medicines based on a product's regulatory pathway for approval.

Additionally, Gilead believes that by excluding accelerated approval drugs from coverage, the Oregon Health Authority effectively removes clinical decision-making from practitioners and from patients. Given the complex nature of cancer treatment, no single drug is medically appropriate to treat all cancers, as tumors respond differently depending on the cancer type, stage of diagnosis, and other factors. By attempting to interfere with Medicaid beneficiaries' current access to these therapies based on a long-standing and well-established regulatory pathway for accelerating approval of therapies to treat the most serious and unmet illness, Oregon would deny patients access to treatments their medical practitioner determines are the most appropriate, safe, and effective.

Lastly, if Oregon or other states restrict access to drugs approved through the accelerated approval pathway, this could discourage the development of innovative therapies, and ultimately deprive Medicaid beneficiaries (and others) of access to potentially life-savings drugs.

## **6. The proposed waiver would result in substandard coverage for Medicaid compared to Medicare or Exchanges.**

In the Draft Application, Oregon states "Given that Medicare and other commercial plans are permitted to adopt closed formularies, we believe Oregon should have the same flexibility for Medicaid."<sup>46</sup> However, this ignores important differences between Medicaid and Medicare and commercial plans. For example, Medicare Part D beneficiaries currently have a broad choice, among multiple coverage options, with transparency into the drugs included on any individual formulary and protections against mid-year formulary changes. As a result, Medicare Part D beneficiaries can choose, on an annual basis, the formulary that best suits their medical needs. Medicaid patients have no comparable choices and will often face limited provider networks. Given that Medicaid is traditionally the "payer of last resort" any restrictions on coverage must be carefully weighed against the risk they could lead to a loss of access to medically necessary care.

Furthermore, as the Draft Application notes, Medicare Part D formularies are generally required to cover two drugs per class, while the State seeks flexibility to limit coverage to just one drug per class. In Medicare Part D, plans are only permitted to include one drug in a class when there is actually only one drug available (or only two drugs are available but one drug is clinically superior to the other for a particular category or class).<sup>47</sup> The significance of this difference in coverage levels cannot be overstated.

---

<sup>44</sup> Farci P, Niro GA. Clinical features of hepatitis D. *Semin Liver Dis.* 2012;32(3):228-236. doi:10.1055/s-0032-1323628.

<sup>45</sup> Fattovich G, Giustina G, Christensen E, et al. Influence of hepatitis delta virus infection on morbidity and mortality in compensated cirrhosis type B. The European Concerted Action on Viral Hepatitis (Eurohep). *Gut.* 2000;46(3):420-426. doi:10.1136/gut.46.3.420.

<sup>46</sup> Draft Application. Page 31.

<sup>47</sup> Medicare Prescription Drug Benefit Manual, ch. 6 § 30.2.1.

In addition, the Part D program has an exceptions and reconsideration process that provides access to off-formulary therapies as well as the six protected classes of drugs, for which Part D plans must include all, or substantially all, drugs in the class on-formulary. These classes include anti-convulsants, anti-depressants, anti-psychotics, anti-neoplastics (oncology), immunosuppressants, and anti-retrovirals (which are used to treat HIV and AIDS). The Oregon Health Authority has not suggested that it would provide such protections in its Draft Application.

The requirement to cover all protected class drugs in Medicare Part D was established by Congress and the importance of open access to antiretrovirals has been reaffirmed by CMS. When Congress enacted Part D, it recognized that ensuring comprehensive access to drug treatments for patients, and ensuring prescriber choice of the full range of treatment options (including antiretrovirals) is critical. Moreover, the legislative history of the Medicare Part D program further illustrates this point. For example, a colloquy in the United States Senate among Senators Dianne Feinstein (D-CA), Max Baucus (D-MT), and Chuck Grassley (R-IA) during discussions of the Medicare Modernization Act of 2003 emphasized that one purpose of Medicare Part D is to ensure broad medication coverage for patients, especially those “who need exactly the right medicine for them.”<sup>48</sup> The protected classes were later codified in statute as part of the 2008 Medicare Improvements for Patients and Providers Act (MIPPA) and strengthened by the Affordable Care Act. CMS has repeatedly reaffirmed the importance of sustained access to protected class drugs, including in its final rule on modernizing Medicare Part D.<sup>49</sup>

CMS has provided further protection for antiretroviral medications in Part D by prohibiting prior authorization and step therapy for that class.<sup>50</sup> This safeguard is critical because a provider’s careful selection of an effective treatment regimen for the patient, and a patient’s ability to access and start on that regimen as soon as possible after diagnosis, helps people living with HIV stay healthy and have a better chance of living nearly as long as someone without HIV.<sup>51</sup> In contrast, delays in initiating therapy – which could occur under a closed formulary – may lead people to stop or delay engaging in care and lengthen the time for them to reach viral suppression. Immediate treatment upon diagnosis has been associated with improved virologic suppression even five years later.<sup>52</sup> In fact, the Department of Health and Human Services guidelines (DHHS guidelines) recommend “initiating [antiretroviral therapy or ART] immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to

---

<sup>48</sup> 149 Cong. Rec. S15887 (Nov. 25, 2003).

<sup>49</sup> 42 C.F.R. § 423.120(b)(2)(vi)(C).

<sup>50</sup> Id.

<sup>51</sup> Marcus JL, Leyden WA, Alexeeff SE, et al., “Comparison of Overall and Comorbidity-Free Life Expectancy Between Insured Adults With and Without HIV Infection, 2000-2016,” JAMA Netw Open, June 2020, 2020;3(6):e207954, <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2767138>.

<sup>52</sup> See S. Lodi et al., *Comparative effectiveness of immediate antiretroviral therapy versus CD4- based initiation in HIV-positive individuals in high-income countries: observational cohort study*, 2 LANCET HIV E335 (2015) (demonstrating that “rapid start”, or immediate initiation of HIV therapy upon diagnosis, has been shown to suppress the virus faster, and to improve retention in care); Liz Highleyman, *RAPID Program Leads to Faster HIV Suppression*, AIDSmag, <https://www.aidsmap.com/news/jul-2015/same-day-start-antiretroviral-treatment-leads-faster-hiv-suppression-san-francisco> (2015) (stating that participants in San Francisco General Hospital’s “Rapid- start” ART program achieved an undetectable viral load within 56 days of diagnosis, compared with 119 days for those on a standard treatment schedule).

viral suppression for patients, and improve the rate of virologic suppression among persons with HIV.”<sup>53</sup>

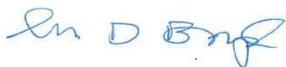
Like Medicare Part D beneficiaries, patients who obtain coverage through the health insurance exchanges can choose plans with a formulary that is best suited to their individual needs and can also change their plan during the annual open enrollment period. In addition, these patients would have access to an exceptions process to obtain their medically necessary medications.<sup>54</sup> Thus, for prescription drugs, the Draft Application would result in a system in which Medicaid beneficiaries receive a demonstrably lower level of access than similarly situated Oregonians who receive coverage through Medicare Part D or the health insurance exchanges under the Affordable Care Act.

\*\*\*

Gilead has been serving and supporting people enrolled in Medicaid for years, including those in Oregon. We are dedicated to ensuring that the state’s policy decisions support health and wellbeing for these individuals, and for all vulnerable populations in Oregon. We, therefore, encourage the Oregon Health Authority to carefully reconsider its demonstration proposal, specifically by continuing to cover all medicines subject to a National Drug Rebate Agreement through the Medicaid program. This is especially critical for infectious diseases and for cancer in which many innovative life-saving therapies have been approved by the FDA via an accelerated pathway. A closed formulary clearly exceeds CMS’s authority and fails to promote the recognized objectives of the Medicaid program. Accordingly, we ask that Oregon ensure that Medicaid beneficiaries have continued access to quality, medically necessary care.

Thank you for the opportunity to provide comments on Oregon’s Draft 2022-2027 Medicaid 1115 Demonstration Application. If you have any questions about our comments, please contact Ryan Faden at [ryan.faden@gilead.com](mailto:ryan.faden@gilead.com).

Yours sincerely,



Michael D. Boyd  
Senior Vice President,  
Government Affairs and Policy

---

<sup>53</sup> Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed [September 8, 2021] [Page E-1]

<sup>54</sup> Know Your Rights in the Health Insurance Marketplace. Available at: <https://marketplace.cms.gov/outreach-and-education/know-your-rights.pdf>.

January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

*Submitted electronically via Oregon.gov/1115WaiverRenewal*

**RE: Oregon Section 1115 Oregon Health Plan (OHP) Draft Waiver Application for Renewal and Amendment**

Dear Director Allen and Director Vandehey,

As the statewide advocacy and political voice for Planned Parenthood's two Oregon affiliates (Planned Parenthood Columbia Willamette and Planned Parenthood of Southwestern Oregon), Planned Parenthood Advocates of Oregon (PPAO) submits these comments regarding Oregon Health Authority's (OHA) draft waiver extension and amendment application for the Oregon Health Plan (OHP) demonstration program. In its draft application, Oregon is seeking to implement several changes to the program, with the main overarching goal of advancing health equity. These changes include implementing 24-months continuous eligibility for OHP enrollees age 6 and older, providing transitional social determinants of health (SDOH) services to vulnerable populations, and implementing a closed prescription drug formulary and excluding certain drugs, among others. As a trusted sexual and reproductive health (SRH) care provider, educator and advocate, we appreciate the opportunity to provide input on this draft application.

Planned Parenthood is a safety net provider for the populations in Oregon most in need of health services. Planned Parenthood operates 11 health centers across the state of Oregon and serves as a leading health care provider, educator and advocate of high-quality, affordable health care for women, men, non-binary individuals, and young people. Our health centers range in size and location from small rural clinic practices to larger metropolitan clinics. Every year, our health centers provide affordable birth control, lifesaving cancer screenings, testing and treatment for STIs, abortion, and other essential care to more than 60,000 patients annually. Approximately 50% of Planned Parenthood's patients use Medicaid coverage or other state-funded programs to access affordable, preventive care and are therefore likely to be affected by Oregon's draft application.

Medicaid is a vital part of the health care system and plays a major role in ensuring access to essential primary and preventive care services. Medicaid is critical to improving the health and well-being of individuals and families with low incomes across Oregon and the rest of the nation. In particular, Medicaid is a crucial program for people of reproductive age, enabling them to access necessary SRH and maternal health services. Approximately 1 in 5 women of reproductive age use Medicaid,<sup>1</sup> and

---

<sup>1</sup> Adam Sonfield, "Why Protecting Medicaid Means Protecting Sexual and Reproductive Health," Guttmacher Institute (Mar. 9, 2017), available at <https://www.guttmacher.org/gpr/2017/03/why-protecting-medicaid-means-protecting-sexual-and-reproductive-health#>.

roughly two-thirds of adult women enrolled in Medicaid are in their reproductive years.<sup>2</sup> For nearly half of women giving birth, Medicaid is the source of coverage for essential care, including prenatal and delivery care; recent data found that in 25 states 40 percent or more of births are covered by Medicaid.<sup>3</sup> Finally, the program is the largest payer of reproductive health care coverage in the country,<sup>4</sup> paying for 75 percent of publicly-funded family planning services.<sup>5</sup>

Because women make up the majority of Medicaid enrollees, they will be disproportionately affected by Oregon's draft application. In particular, Medicaid coverage of family planning services and supplies helps individual's health, lives, educational success, and economic empowerment. Moreover, due to racism and other systemic barriers that have contributed to income inequality, women of color disproportionately comprise the Medicaid population and will be further impacted by the draft application; 31 percent of Black women and 27 percent of Hispanic women are enrolled in Medicaid, compared to only 16 percent of white women.<sup>6</sup>

Due to Medicaid's outsized role for people of color, Medicaid is essential in narrowing health disparities and improving access to care for their communities. Indeed, research shows that Medicaid expansion has contributed to such reductions in racial disparities in health coverage, in particular for Black and Hispanic individuals.<sup>7</sup> In addition, Medicaid expansion is associated with decreased disparities in some health outcomes for communities of color, including in infant and maternal health.<sup>8</sup>

As the political and advocacy voice for Oregon's two Planned Parenthood affiliates and for SRH, PPAO takes every opportunity to comment on Medicaid program features that increase or decrease access to care and impact people with Medicaid. Accordingly, our comments will address the following proposals:

- 24-months continuous eligibility for enrollees ages 6+;
- investing in social determinants of health (SDOH) transition services for vulnerable populations;
- the continued waiver of retroactive coverage; and
- implementing a closed formulary for adult OHP enrollees and excluding drugs with limited or inadequate evidence of clinical efficacy.

---

<sup>2</sup> "Medicaid's Role for Women," Kaiser Family Foundation (Mar. 28, 2019), available at <https://www.kff.org/medicaid/fact-sheet/medicaids-role-for-women/>.

<sup>3</sup> In Oregon, Medicaid covers 43 percent of births, see Births Financed by Medicaid, Kaiser Family Foundation, available at <https://www.kff.org/medicaid/state-indicator/births-financed-by-medicaid/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>.

<sup>4</sup> Usha Ranji, "Medicaid and Family Planning: Background and Implications of the ACA," Kaiser Family Foundation (Feb. 3, 2016), available at <https://www.kff.org/womens-health-policy/issue-brief/medicaid-and-family-planning-background-and-implications-of-the-aca/>.

<sup>5</sup> Adam Sonfield et al., "Public Funding for Family Planning, Sterilization and Abortion Services, FY 1980-2006," Occasional Report, New York: Guttmacher Institute, No. 38. (Jan. 2008), available at <https://www.guttmacher.org/sites/default/files/pdfs/pubs/2008/01/28/or38.pdf>.

<sup>6</sup> *Supra* note 1, "Why Protecting Medicaid Means Protecting Sexual and Reproductive Health."

<sup>7</sup> Madeline Guth, et al., "Effects of the ACA Medicaid Expansion on Racial Disparities in Health and Health Care," Kaiser Family Foundation (Sep. 30, 2020), available at <https://www.kff.org/report-section/effects-of-the-aca-medicaid-expansion-on-racial-disparities-in-health-and-health-care-issue-brief/>.

<sup>8</sup> *Id.*

PPAO applauds OHA's commitment to advancing health equity through many of the requested changes in the draft waiver application. However, the policies around retroactive coverage and prescription drugs do not achieve the draft waiver's goal of advancing health equity. Therefore, PPAO urges OHA to remove these program features and proceed forward with the draft waiver application without them.

**I. Twenty-four months continuous eligibility is an important program feature that increases access to care and can improve health outcomes for people with Medicaid, and OHA should proceed forward with this program feature.**

Continuous eligibility is vital to ensuring that Medicaid coverage, such as OHP coverage, is stable, continuous, and accessible for eligible individuals. Continuous eligibility keeps people enrolled in Medicaid for at least 12 months regardless of changes in their income. This policy has been shown time and again to reduce the likelihood that Medicaid enrollees will lose their affordable health insurance coverage due to small fluctuations in income or burdensome administrative requirements.<sup>9</sup> For example, a variety of Montana stakeholders, including health care providers and the state's Medicaid agency, have noted the benefits of this feature, which include: (1) stabilizing coverage, especially for seasonal workers; (2) improving continuity of care, particularly for preventive care services; and (3) saving on Medicaid administrative costs.<sup>10</sup>

Continuous eligibility is particularly important in ensuring access to essential SRH services for at least 12 months. Crucially, time is of the essence when accessing critical SRH services. Being unable to access SRH care can result in not only missed appointments, but also unintended pregnancies, undiagnosed STIs, and life-threatening cancers. People who utilize birth control and regular STI testing, including parents, cannot afford to be without Medicaid temporarily even for a few days time, let alone being without it for a month or longer; such a disruption in coverage could have enormous consequences on an individual's present and future health and lives, including educational and work commitments.

Moreover, continuous eligibility ensures that individuals who may experience income fluctuations or are unable to keep up with burdensome paperwork requirements, are also able to stay current on their medications and other health needs. A study by the Government Accountability Office (GAO) reinforces this positive effect, finding that enrollees covered by Medicaid for a full year reported fewer difficulties in obtaining necessary medical care and prescription medicine compared to those who were covered between one and eleven months.<sup>11</sup>

In addition to comprehensive SRH services, PPAO underscores that the continuous eligibility feature is particularly important for people who currently qualify for OHA's pregnancy eligibility group and have recently given birth. As Oregon has not adopted the American Rescue Plan's state option to extend Medicaid postpartum coverage to a full year after delivery, continuous eligibility ensures continuity of

---

<sup>9</sup> Jennifer Wagner and Judith Solomon, "Continuous Eligibility Keeps People Insured and Reduces Costs," Center on Budget and Policy Priorities (May 4, 2021), available at <https://www.cbpp.org/research/health/continuous-eligibility-keeps-people-insured-and-reduces-costs>.

<sup>10</sup> "Federal Evaluation of Montana Health and Economic Livelihood Partnership (HELP): Draft Interim Evaluation Report," Social & Scientific Systems: Prepared for CMS (Jul. 22, 2019), available at <https://www.medicaid.gov/medicaid/downloads/mt-fed-eval-draft-interim-eval-rpt.pdf>.

<sup>11</sup> "Medicaid: States Made Multiple Program Changes, and Beneficiaries Generally Reported Access Comparable to Private Insurance," Government Accountability Office (Nov. 2012), available at <https://www.gao.gov/assets/gao-13-55.pdf>.

care during the critical postpartum period for OHA women and birthing people. Based on Centers for Disease Control and Prevention (CDC) data, up to 33 percent of pregnancy-related deaths occur between one week to one full year after childbirth.<sup>12</sup> Indeed, the Oregon Maternal Mortality and Morbidity Review Committee (OMMMRC) found several factors contributing to maternal deaths in the state, including: (1) inadequate access and missed opportunities to health care and medical services; (2) inadequate access to wrap-around services; (3) inadequate resources and missed screening opportunities for mental health and substance use disorder (SUD); (4) possible implicit biases toward homelessness, tobacco/drug abuse, mental illness, low income, alcohol abuse, etc.; (5) histories of intimate partner violence (IPV); and (6) untreated childhood physical and emotional trauma.<sup>13</sup>

Given the ongoing maternal health crisis, it is necessary that comprehensive Medicaid coverage enable individuals to seek diagnosis, treatment, and monitoring for chronic health conditions, especially in the postpartum period, when individuals are at elevated risk for experiencing pregnancy-related complications that could lead to death.<sup>14</sup> Providing 24 months of continuous eligibility for these individuals means they would be able to continue accessing care from the same health care professionals that have served them throughout their pregnancies and who have the best sense of their health needs and risks. This would have the biggest positive impact on populations most impacted by maternal death in Oregon, including Black and Hispanic women.<sup>15</sup>

Finally, PPAO agrees with OHA that the continuous eligibility feature will be especially important after the public health emergency (PHE) ends in the United States. Nationally, enrollment in the Medicaid program increased by 16.2% from February 2020 to May 2021, and this increase is reflected in every state.<sup>16</sup> As OHA notes in the draft application, implementing continuous eligibility is an effective method to preserve the coverage continuity gains that were achieved during the pandemic through the continuous coverage requirement in the Families First Coronavirus Response Act (FFCRA).<sup>17</sup> Maintaining this continuity of coverage is crucial to prevent eligible OHP enrollees from losing coverage after the PHE ends.

Given the importance of 24 months of continuous eligibility in increasing access to timely SRH and maternal health services, in particular for people of reproductive age and women of color, PPAO supports this program change and urges OHA to proceed forward with it in their application to CMS.

---

<sup>12</sup> “Vital Signs: Pregnancy-related deaths,” CDC (May 7, 2019), available at <https://www.cdc.gov/vitalsigns/maternal-deaths/index.html>.

<sup>13</sup> “Oregon Maternal Mortality and Morbidity Review Committee Biennial Report,” OHA (Jan. 1, 2021), available at [https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/DATAREPORTS/SiteAssets/Pages/Maternal-Mortality-Morbidity-Review-Committee/2020\\_MMRC%20First%20Biennial%20Report%20FINAL%204.1.21.pdf](https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/DATAREPORTS/SiteAssets/Pages/Maternal-Mortality-Morbidity-Review-Committee/2020_MMRC%20First%20Biennial%20Report%20FINAL%204.1.21.pdf).

<sup>14</sup> “Extend Postpartum Medicaid Coverage,” The American College of Obstetricians and Gynecologists, available at <https://www.acog.org/advocacy/policy-priorities/extend-postpartum-medicaid-coverage>.

<sup>15</sup> *Supra* note 11, “Oregon Maternal Mortality and Morbidity Review Committee Biennial Report.”

<sup>16</sup> Bradley Corallo and Avirut Mehta, “Analysis of Recent National Trends in Medicaid and CHIP Enrollment,” Kaiser Family Foundation (Oct. 29, 2021), available at <https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/>.

<sup>17</sup> FFCRA, § 6008(b)(3).

## II. Investing in SDOH transition services for vulnerable populations will improve health outcomes, and OHA should proceed forward with these program features.

The social determinants of health, defined by the World Health Organization (WHO) as the “conditions in which people are born, grow, live, work, and age, and the wider set of forces and systems shaping the conditions of daily life” have become a frequently discussed concept in the areas of health and social services.<sup>18</sup> Accounting for up to 90 percent of a person’s health status, SDOH are far-reaching, and include factors such as safe and affordable housing, access to education, public safety, the availability of healthy foods, local emergency/health services, and environments free of harmful toxins.<sup>19</sup> PPAO emphasizes that while sometimes SDOH are discussed, researched, and pursued independently from racism, discrimination, and inequality, they are, in fact, intertwined. Indeed, SDOH are mostly responsible for health inequities and they are “shaped by the distribution of money, power and resources at global, national and local levels.”<sup>20</sup>

PPAO supports OHA’s initiative to provide housing, health-related transportation, and food assistance, among other SDOH transition services, to vulnerable populations and urges OHA to proceed forward with these program features.

- A. *Housing access is vital to improving health outcomes, in particular for women of reproductive age and people of color and therefore, OHA should proceed forward with providing transitional housing services, including rental assistance or temporary housing.*

Among SDOH, significant research and data show that homelessness and housing instability (frequently moving, falling behind on rent, facing eviction) are detrimental to one’s health. The health impacts of homelessness and housing instability are myriad:

- People who are chronically homeless face substantially higher morbidity in both physical and mental health,<sup>21</sup> as well as increased mortality.<sup>22</sup>
- Unstable housing situations can cause individuals to experience increased hospital visits, lead to loss of employment and employer-provided health insurance benefits, dramatically increase the risk of an acute episode of a behavioral health condition, including relapse of addiction in adults, and are associated with increased likelihood of mental health problems in children.<sup>23</sup>

---

<sup>18</sup> “Social determinants of health,” World Health Organization, available at [https://www.who.int/health-topics/social-determinants-of-health#tab=tab\\_1](https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1).

<sup>19</sup> “Social Determinants of Health,” Healthy People 2030, Office of Disease Prevention and Health Promotion, Department of Health and Human Services, available at <https://health.gov/healthypeople/objectives-and-data/social-determinants-health>.

<sup>20</sup> *Id.* at “Social Determinants of Health,” World Health Organization.

<sup>21</sup> David L. Maness and Muneza Khan, “Care of the Homeless: An Overview,” *Am Fam Physician* (Apr. 2014), available at <https://www.aafp.org/afp/2014/0415/p634.html>.

<sup>22</sup> Colette L Auerswald, et al., “Six-year mortality in a street-recruited cohort of homeless youth in San Francisco, California,” *PeerJ* (Apr. 14, 2016), available at <https://peerj.com/articles/1909/>.

<sup>23</sup> See Will Fischer, “Research Shows Housing Vouchers Reduce Hardship and Provide Platform for Long-Term Gains Among Children,” Center on Budget and Policy Priorities (Oct. 7, 2015), available at <https://www.cbpp.org/research/research-shows-housing-vouchers-reduce-hardship-and-provide-platform-for-longterm-gains>; see also Linda Giannarelli et al., “Reducing Child Poverty in the US: Costs and Impacts of Policies Proposed by the Children’s Defense Fund,” Urban Institute (Jan. 2015), available at <https://www.urban.org/sites/default/files/publication/39141/2000086-Reducing-Child-Poverty-in-the-US.pdf>.

- When systemic barriers force people with low incomes to spend too much of their income on their rent, they cannot afford to pay for health care. In fact, many renters delay needed medical care because they are unable to afford it.<sup>24</sup>
- People who are evicted from their homes, or even threatened with eviction, are more likely to experience health problems such as depression, anxiety, and high blood pressure than people with stable housing.<sup>25</sup> This exacerbates the heightened risk women, particularly women of color, have for experiencing depression,<sup>26</sup> anxiety,<sup>27</sup> and high blood pressure.<sup>28</sup>

Crucially, stable housing has consistently been shown to lead to improved health outcomes, particularly among individuals who have past experiences with housing insecurity. These improved health outcomes include reduced psychological distress, intimate partner violence (IPV), behavior issues, and sleep problems.<sup>29</sup>

It is also important to note that access to stable housing is vital for women and the LGBTQ+ communities. That is because women and the LGBTQ+ community are more likely to face economic insecurity at all stages of their lives, due to ongoing employment discrimination, overrepresentation in low-wage jobs, difficulty accessing affordable and comprehensive health care, and greater responsibilities for unpaid caregiving. As a result, housing assistance is vital for these individuals and their families.

Indeed, data show how critical housing is for people of reproductive age in obtaining needed SRH services. The Kaiser Family Foundation conducted a study evaluating access to reproductive health care

---

<sup>24</sup> “Renters Report Housing Costs Significantly Impact Their Health Care,” Enterprise (Apr. 3, 2019), available at [https://www.enterprisecommunity.org/news-and-events/news-releases/2019-04\\_renters-report-housing-costs-significantly-impact-their-health-care](https://www.enterprisecommunity.org/news-and-events/news-releases/2019-04_renters-report-housing-costs-significantly-impact-their-health-care); see also Munira Z. Gunja et al., “How the Affordable Care Act Has Helped Women Gain Insurance and Improved Their Ability to Get Health Care.” Commonwealth Fund (Aug. 10, 2017), available at <https://www.commonwealthfund.org/publications/issue-briefs/2017/aug/how-affordable-care-act-has-helped-women-gain-insurance-and> (noting that even though health insurance coverage gains through the Affordable Care Act have reduced the share of women skipping or delaying care because of costs, in 2016, 38 percent of women age 19 through 64 still reported not getting the health care they needed because of costs).

<sup>25</sup> Alison Bovell & Megan Sandel, “The Hidden Health Crisis of Eviction,” Children’s Health Watch Blog (Oct. 5, 2018), available at <http://childrenshealthwatch.org/the-hidden-health-crisis-of-eviction/>.

<sup>26</sup> Paul R. Albert, “Why is depression more prevalent in women?,” 40 J. Psychiatry Neurosci. 219-221 (Jul. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4478054/> (noting the higher prevalence of major depression in women than in men); National Institutes of Health, Office of Research on Women’s Health, “Women of Color Health Data Book” p. 147 (Oct. 2014), available at <https://orwh.od.nih.gov/sites/orwh/files/docs/WoC-Databook-FINAL.pdf> (more women seek treatment for depression than men, though white, non-Hispanic women are more likely to receive treatment for depression than Latinx and Black women).

<sup>27</sup> “Anxiety Disorders,” Office on Women’s Health (last updated Jan. 30, 2019), available at <https://www.womenshealth.gov/mental-health/mental-health-conditions/anxiety-disorders> (reporting that women are twice as likely as men to get an anxiety disorder in their lifetime and noting that more American Indian/Alaskan Native women have generalized anxiety disorder than women of other races and ethnicities).

<sup>28</sup> *Id.* at “Women of Color Health Data Book” p. 121 (noting that Black women experience high blood pressure at a higher rate than Latinx or white, non-Hispanic women).

<sup>29</sup> “Follow-Up Family Options Study: Long-Term Housing Subsidies are Most Effective Intervention for Homeless Families,” National Low-Income Housing Coalition (Oct. 31, 2016), available at <http://nlihc.org/resource/follow-family-options-study-long-term-housing-subsidies-are-most-effective-intervention> (finding long-term subsidies had a range of positive impacts on adult and child well-being).

for women with low incomes in five communities across the United States and found that in each of the communities, a shortage of affordable housing (among other SDOH) resulted in women prioritizing food and shelter above preventive health care and family planning.<sup>30</sup> Planned Parenthood also conducted a survey assessing the SDOH-related needs of women of reproductive age and found the following:

- Women living at or below 300 percent of the federal poverty level (FPL) have high and varying SDOH-related needs, including access to stable housing.<sup>31</sup> In fact, more than two-thirds of women say it is very or somewhat hard to pay for basics, such as housing.<sup>32</sup>
- While the types of social needs varied, housing/having a steady place to live and support with utilities (such as heating and electricity) were among the most commonly reported.<sup>33</sup>
- Black, Asian/Pacific Islander, and Hispanic women of reproductive age are more likely to report needing SDOH-related support, with Black women reporting the highest need for support in almost all areas.<sup>34</sup>

Finally, as evidenced by the data from Planned Parenthood’s study, people of color are disproportionately affected by homelessness and housing insecurity, and addressing this SDOH is critical for these groups. In Multnomah County alone, Black people face a greater risk of homelessness, making up 16.1% of the homeless population—more than double their share of the general population in the county, which is 7.2%.<sup>35</sup>

Given the importance of housing as an SDOH that is integral to one’s health and wellbeing, PPAO urges OHA to move forward with providing transitional housing services, including rental assistance or temporary housing.

- B. Transportation is necessary to enable individuals to get to and from their appointments and will increase access to SRH care, and therefore, OHA should proceed forward with providing health-related transportation for eligible OHP enrollees.*

Transportation, including non-emergency medical transportation (NEMT), is essential for many individuals enrolled in the Medicaid program and increases access to care. In FY2018 alone, there were over 60 million NEMT ride-days (days in which a Medicaid enrollee had at least one NEMT ride).<sup>36</sup>

---

<sup>30</sup> Usha Ranji, et al., “Beyond the Numbers: Access to Reproductive Health Care for Low-Income Women in Five Communities,” Kaiser Family Foundation (Nov. 14, 2019), available at <https://www.kff.org/report-section/beyond-the-numbers-access-to-reproductive-health-care-for-low-income-women-in-five-communities-executive-summary/>.

<sup>31</sup> “What about Her? — Assessing Social Determinants of Health Among Women of Reproductive Age,” Planned Parenthood Federation of America (2020), available at [https://www.plannedparenthood.org/uploads/filer\\_public/33/97/33976d5a-f402-4b14-ab68-671aa58a0f00/210115-hcip-sdoh-what-about-her-update-v2.pdf](https://www.plannedparenthood.org/uploads/filer_public/33/97/33976d5a-f402-4b14-ab68-671aa58a0f00/210115-hcip-sdoh-what-about-her-update-v2.pdf).

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* (finding that Black women of reproductive age report the highest need for SDOH support in all surveyed areas except for intimate partner violence, where non-Hispanic white women report the highest rate of need for support).

<sup>35</sup> Latisha Jensen, “Black Residents of Multnomah County Face a Greater Risk of Homelessness,” Willamette Week (Jan. 6, 2021), available at <https://www.wweek.com/news/2021/01/06/black-residents-of-multnomah-county-face-a-greater-risk-of-homelessness/>.

<sup>36</sup> “Mandated Report on Non-Emergency Medical Transportation,” MACPAC (Jun. 2021), available at <https://www.macpac.gov/wp-content/uploads/2021/06/Chapter-5-Mandated-Report-on-Non-Emergency-Medical-Transportation.pdf>.

It is vital to note that many families with low incomes have lower vehicle ownership rates and less access to reliable transportation.<sup>37</sup> In addition, transportation barriers are often cited as barriers to accessing care, leading to rescheduled or missed appointments, delayed care, and missed or delayed medication use.<sup>38</sup> Notably, data from Iowa indicates that women, people of color, and younger people are significantly more likely to report a transportation barrier.<sup>39</sup>

In particular, transportation barriers can affect people's access to health care services. These barriers may result in missed or delayed health care appointments, increased health expenditures and overall poorer health outcomes. Many individuals with low incomes do not have access to affordable transportation to get to and from medical appointments. For them, transportation issues can be a major barrier to needed health care, including receiving necessary postpartum contraception, pregnancy tests, Pap smears, and tests for sexually transmitted infections.

As transportation access has outsized importance in increasing access to timely SRH care, PPAO urges OHA to move forward with providing health-related transportation services in addition to the already provided NEMT services.

- C. Access to healthy and nutritious foods is another important SDOH to improve health outcomes and therefore, OHA should proceed forward with providing food assistance services, including links to the Supplemental Nutrition Assistance Program (SNAP).*

Importantly, extensive research has found that food insecurity is associated with poorer health outcomes.<sup>40</sup> Adults who experience food insecurity are also more likely to report lower health status overall than those with high food security.<sup>41</sup> This includes: (1) women of color, who already have less access to healthy food,<sup>42</sup> safe housing, and basic health care due to the intersections of structural

---

<sup>37</sup> Mobility Challenges for Households in Poverty, FHWA (2014), available at <https://nhts.ornl.gov/briefs/PovertyBrief.pdf>; Wolfe, M.K., McDonald, N.C., and Holmes, G.M., "Transportation Barriers to Health Care in the United States: Findings from the National Health Interview Survey, 1997-2017," Am. J. Public Health (Jun. 2020), available at <https://pubmed.ncbi.nlm.nih.gov/32298170/> (finding that Hispanic people, those living below the poverty threshold, Medicaid recipients, and people with a functional limitation had greater odds of reporting a transportation barrier after controlling for other sociodemographic and health characteristics).

<sup>38</sup> Samina T. Syed, et al., Traveling Towards Disease: Transportation Barriers to Health Care Access, J Community Health (Dec. 13, 2014), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265215/pdf/nihms646723.pdf>.

<sup>39</sup> Suzanne Bentler et al., "Non-Emergency Medical Transportation and the Iowa Health and Wellness Plan," University of Iowa Public Policy Center (Mar. 1, 2016), available at [https://ppc.uiowa.edu/sites/default/files/nemt\\_report.pdf](https://ppc.uiowa.edu/sites/default/files/nemt_report.pdf).

<sup>40</sup> Craig Gundersen and James P. Ziliak, "Food Insecurity and Health Outcomes," Health Affairs (Nov. 2015), available at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0645>.

<sup>41</sup> Christian A. Gregory and Alisha Coleman-Jenson, "Food Insecurity, Chronic Disease, and Health Among Working-Age Adults," United States Department of Agriculture (July 2017), <https://www.ers.usda.gov/webdocs/publications/84467/err-235.pdf?v=4606.4>.

<sup>42</sup> Treuhaft, Sarah & Karpyn, Allison, "The Grocery Gap: Who Has Access to Healthy Food and Why It Matters," PolicyLink & The Food Trust (2010), available at [http://thefoodtrust.org/uploads/media\\_items/grocerygap.original.pdf](http://thefoodtrust.org/uploads/media_items/grocerygap.original.pdf).

racism, inequality, sexism, classism, xenophobia, and other systemic barriers; and (2) LGBT people, who are more likely than non-LGBT people to experience food insecurity.<sup>43</sup>

Research shows that SNAP reduces poverty and food insecurity, and that over the long-term, these impacts lead to improved health and economic outcomes, especially for those who receive SNAP as children.<sup>44</sup> SNAP plays a critical role in addressing hunger and food insecurity in the communities of people of color<sup>45</sup> and the LGBTQ+ community.<sup>46</sup>

Access to healthy and nutritious food is an essential SDOH and as such, PPAO urges OHA to move forward with its initiative to provide food assistance services, including linkages to SNAP, to vulnerable populations in need.

### **III. Retroactive coverage increases access to timely SRH care, and PPAO urges OHA to reinstate this program feature for all OHP enrollees.**

As OHA is aware, federal law and policy requires states to pay for covered services provided to individuals during the three month period prior to the date of applying for Medicaid coverage, provided that the individual would have been eligible during that period.<sup>47</sup> This provision helps safeguard enrollees' continuous access to care when there are delays in determining eligibility. PPAO underscores that retroactive coverage has been a requirement of the Medicaid program since 1972; waivers of retroactive coverage are a departure from this long-standing requirement.

Retroactive coverage is critical to reducing individuals' medical debt, as well as financial strain on the health care system that stems from uncompensated care. When individuals have coverage, they are more likely to be able to receive the care they need in a timely manner, which enables the health care system to treat conditions before they become more serious and more costly. PPAO also underscores the importance of retroactive coverage during the COVID-19 pandemic, which has seen enormous increases in Medicaid enrollment<sup>48</sup> due to the ongoing employment and income fluctuations many individuals are experiencing.<sup>49</sup> Ensuring access to timely care for all Medicaid enrollees is more important than it has ever been.

---

<sup>43</sup> Brown, Taylor N.T., et al., "Food Insecurity and SNAP Participation in the LGBT Community," The Williams Institute (Jul. 2016), available at <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Food-Insecurity-and-SNAP-Participation-in-the-LGBT-Community.pdf>.

<sup>44</sup> "Chart Book: SNAP Helps Struggling Families Put Food on the Table," Center on Budget and Policy Priorities (Nov. 7, 2019), <https://www.cbpp.org/research/food-assistance/chart-book-snap-helps-struggling-families-put-food-on-the-table>.

<sup>45</sup> "SNAP Helps Millions of African Americans," Center on Budget and Policy Priorities (Feb. 26, 2018), available at <https://www.cbpp.org/research/food-assistance/snap-helps-millions-of-african-americans>; "SNAP Helps Millions of Latinos," Center on Budget and Policy Priorities (Feb. 26, 2018), available at <https://www.cbpp.org/research/food-assistance/snap-helps-millions-of-latinos>.

<sup>46</sup> Rooney, Caitlin, et al., "Protecting Basic Living Standards for LGBTQ People," Center for American Progress (Aug. 2018), available at <https://cdn.americanprogress.org/content/uploads/2018/08/10095627/LGBT-BenefitCuts-report.pdf>.

<sup>47</sup> 42 U.S.C. § 1396a(a)(34); 42 C.F.R. § 435.914.

<sup>48</sup> *Supra* note 16, "Analysis of Recent National Trends in Medicaid and CHIP Enrollment."

<sup>49</sup> Paul Shafer, et al., "Medicaid Retroactive Eligibility Waivers Will Leave Thousands Responsible for Coronavirus Treatment Costs," Health Affairs (May 8, 2020), available at <https://www.healthaffairs.org/doi/10.1377/hblog20200506.111318/full/>.

Timely access to care is particularly relevant in the context of family planning care, as only a few days without contraception can result in an unintended pregnancy. Moreover, STIs that go untested and untreated can spread throughout communities and cause lifelong problems, including infertility and pelvic inflammatory disease.<sup>50</sup> Urinary tract infections are one of the most common infections women experience and are easily treatable, but without treatment, can result in emergency room care, which can cost a state nearly \$1,500 per patient.<sup>51</sup>

In addition, data shows that retroactive coverage has positively impacted individuals in states that have kept this feature in their Medicaid programs. In New Hampshire, in one 16-month period, 4,567 Medicaid expansion individuals benefited from the policy, which paid more than \$5 million for their medical expenses.<sup>52</sup> Conversely, data show that the absence of retroactive coverage has increased financial burdens for people with low incomes, as well as safety net providers that serve those individuals. In Indiana, nearly 14 percent of the parent and caretaker relatives eligibility group needed retroactive coverage, and individuals in this group incurred medical costs averaging \$1,561 per person.<sup>53</sup> These costs would have been paid for by Medicaid if retroactive coverage was in place.<sup>54</sup> Finally, sixteen percent of providers in Indiana experienced increases in the provision of uncompensated care after retroactive coverage was waived.<sup>55</sup>

Retroactive coverage also bolsters critical provider participation in the Medicaid program as providers know in advance that they will be adequately compensated, which means that patients are better able to meaningfully access care. Medicaid programs are already faced with provider shortages, with more than two-thirds of states reporting difficulty in ensuring provider participation in Medicaid.<sup>56</sup> Provider shortages are particularly acute for people who can get pregnant, as states are especially challenged in recruiting OB/GYNs. A report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that Medicaid managed care plans had extreme provider shortages, with only 42 percent of in-network OB/GYN providers able to offer appointments.<sup>57</sup>

---

<sup>50</sup> Chlamydia: Fact Sheet, Centers for Disease Control and Prevention (Jan. 23, 2014), available at <https://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm>.

<sup>51</sup> Nolan Caldwell, et al., “How Much Will I Get Charged for This?” Patient Charges Top Ten Diagnoses in the Emergency Department,” Plos One Journal (Feb. 27, 2013), available at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0055491>.

<sup>52</sup> Conditionally Approved Waiver of Retroactive Coverage, NHDHHS (Dec. 21, 2015), available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/health-protection-program/nh-health-protection-program-premium-assistance-retro-cov-waiver-submission-12212015.pdf>.

<sup>53</sup> Letter to Director McGuffee, CMS (Jul. 29, 2016), available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>.

<sup>54</sup> *Id.*

<sup>55</sup> Harris Meyer, “New Medicaid Barrier: Waivers ending retrospective eligibility shift costs to providers, patients,” Modern Healthcare (Feb. 9, 2019), available at <https://www.modernhealthcare.com/article/20190209/NEWS/190209936/new-medicaid-barrier-waivers-ending-retrospective-eligibility-shift-costs-to-providers-patients>.

<sup>56</sup> “States Made Multiple Program Changes, and Beneficiaries Generally Access Comparable to Private Insurance,” Government Accountability Office (Nov. 2012), available at <http://www.gao.gov/assets/650/649788.pdf>; “Access to Care: Provider Availability in Medicaid Managed Care,” Department of Health and Human Services, Office of the Inspector General (Dec. 2014), available at <http://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

<sup>57</sup> *Id.*

Yet, despite the shortages of OB/GYN providers, people who can get pregnant often rely on their OB/GYN providers as their main source of care.<sup>58</sup> Any policy, including the current lack of retroactive coverage, that reduces the availability of SRH providers in the Medicaid program can cause longer wait times for appointments and delays in accessing critical SRH. Due to the unique way women and people who can get pregnant experience the health care system, delays in access to OB/GYNs and other SRH providers can also impact their access to the broader health care system and result in them lacking access to other essential primary and preventive care. Sufficient provider participation is essential to ensure Oregon's success in improving health care delivery systems. Indeed, health care coverage is meaningless if patients are unable to receive care from quality providers in a timely manner.

For all the reasons set forth above and retroactive coverage's importance to accessing timely SRH care, PPAO urges OHA to reinstate retroactive coverage for all OHP enrollees.

**IV. A closed prescription drug formulary for OHP adults and exclusion of certain drugs limits patient choice, including for contraceptives, and therefore, OHA should not proceed forward with these program features.**

In the draft application, OHA seeks to implement a closed prescription drug formulary for OHP adults, with only at least one drug per therapeutic class. In addition to the closed formulary, OHA seeks to use its own review process to determine coverage of new drugs for OHP enrollees. OHA states that through this process, Oregon could "avoid exorbitant spending on high-cost drugs that are not medically necessary."<sup>59</sup> PPAO strongly urges OHA to not proceed forward with these program features, as these changes are not waivable under Section 1115 and they dramatically narrow enrollee choice and access.

First, PPAO notes that Congress ensured that Medicaid enrollees have broad access to outpatient prescription drugs. Except for a very limited set of drug classes, state Medicaid programs cannot outright deny coverage of drugs produced by manufacturers participating in Medicaid's Drug Rebate Program. Section 1396r-8 of the Medicaid Act outlines these requirements for state Medicaid programs, including those that govern the development and use of a formulary.<sup>60</sup>

Second, modifications to prescription drug policy should be developed to benefit patients, with a focus on decreased costs and a commitment to robust access and choice. OHA's closed formulary and proposed drug exclusions fail to offer sufficient safeguards to ensure that enrollees, including people who can get pregnant who benefit from a wide array of birth control choices, will continue to have access to the prescriptions that work for them. These changes also set a harmful precedent wherein drug cost is weighed more heavily than health care needs, absent patient input.

Importantly, many patients require significant trial and error to find the therapeutics best suited to their needs. This is particularly true for contraceptive care. For these patients, a closed formulary could be

---

<sup>58</sup> *Id.*

<sup>59</sup> Application for Renewal and Amendment: Oregon Health Plan 1115 Demonstration Waiver, OHA (Dec. 1, 2021), available at <https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf>.

<sup>60</sup> 42 U.S. Code § 1396r-8.

particularly disruptive, given that access to the drug or device that works for them would not be guaranteed.

Finally, not only is it vital to safeguard enrollee access; ensuring that people have access to the contraceptive that works best for them reaps many benefits. A majority of women who access care through publicly funded family planning providers said birth control has allowed them to take better care of themselves or their families (63 percent), complete their education (51 percent), support themselves financially (56 percent), or keep or get a job (50 percent).<sup>61</sup> Furthermore, greater access to all approved Food and Drug Administration (FDA) contraceptive methods<sup>62</sup> would help improve health outcomes for pregnancy-related illness, injury, and death, especially for people who have medical conditions that may be exacerbated by pregnancy.<sup>63</sup> Implementing a closed formulary and restricting access to FDA-approved contraception will likely lead to worse health outcomes for all enrollees who need access to contraception of their choice.

Further, PPAO also strongly urges OHA to not adopt a closed formulary for HIV treatment medications, for the following reasons:

HIV is a highly individual disease. Different people living with HIV have different treatment needs based on their specific medical history and the resistance(s) to medication that may have developed in their bodies. As a result, people living with HIV and their healthcare providers need maximum flexibility to select an HIV treatment regimen that is right for them.

HIV disproportionately impacts people who are also experiencing challenges such as homelessness, mental illness, and/or substance-use disorder. Members of this population may need simpler, more manageable HIV treatment regimens (e.g., single-tablet regimens) to remain adherent to their medications, but closed formularies can restrict access to those regimens by not factoring social determinants of health into decision-making on coverage.

Utilization-management techniques used in a closed-formulary approach, such as prior-authorization requirements, can cause abandonment of treatment, especially for those already at risk of falling out of care. For people living with HIV, in particular, the consequences can be disastrous: Medication non-adherence can lead not only to poor health outcomes, but also to permanent resistance to a drug or entire class of drugs.

People who are living with HIV and in successful treatment cannot transmit the virus through sex. However, if people fall out of care, as utilization management can cause them to do, they can spread HIV to their sexual partners. Adherence is, therefore, a public-health issue as well as an individual one.

---

<sup>61</sup> Jennifer J. Frost and Laura Duberstein Lindberg, "Reasons for using contraception: Perspectives of US women seeking care at specialized family planning clinics," *Contraception*, Vol. 87, Issue 4 (Apr. 2013), available at <https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/j.contraception.2012.08.012.pdf>.

<sup>62</sup> Birth Control Guide, Food and Drug Administration, available at <https://www.fda.gov/media/99605/download>.

<sup>63</sup> Megan L. Kavanaugh and Ragnar Anderson, "Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers," New York: Guttmacher Institute (Jul. 2013), available at <http://www.guttmacher.org/pubs/health-benefits.pdf>.

For all these reasons, it is considered best practice to ensure access to HIV treatment medications, even within a closed-formulary approach. This is why antiretrovirals are designated as a drug class “of clinical concern” within Medicare Part D, requiring Part D plans to cover all drugs within that class (rather than only two or more drugs, as for most classes). It’s also why the federal agencies responsible for ending the HIV epidemic direct states to “design their prescription drug formularies to minimize potential barriers presented by utilization management techniques so that Medicaid...beneficiaries can readily access all [HIV] regimens.”<sup>64</sup> Several states, including California, Colorado, and Illinois, have gone so far as to codify in statute protections from utilization-management techniques for Medicaid members living with HIV.

Oregon currently includes all U.S. Food and Drug Administration-approved HIV drugs on its Preferred Drug List, and the above-average health outcomes of Oregonians living with HIV reflects such public policies. Ensuring access to HIV treatment medications bolsters not just Oregon’s efforts to end the HIV epidemic, but the state’s commitment to eliminating health inequities as well, because Black, Latinx, and Indigenous Oregonians are more likely to be living with HIV, and more likely to experience poor HIV health outcomes (e.g., viral non-suppression). We hope that Oregon will remain aligned with best practice and the state’s own strategic goals by committing in its 1115 waiver application to maintain open access to HIV treatment medications.

For all the reasons set forth in this section, we strongly urge OHA to not proceed forward with the closed formulary and exclusion of certain drugs through OHA’s review process.

**V. PPAO urges OHA to consider how open access to safety net providers and other community providers will create meaningful change for patient access and provider burden.**

An important aspect of increasing access to and utilization of quality preventative and SRH care is patients being able to go to a trusted provider of their choice and where it is convenient for them. Planned Parenthood affiliates are contracted with the majority of coordinated care organizations (CCOs) in Oregon, but not all. When patients arrive at Planned Parenthood health centers needing urgent reproductive health care, they are often unable to serve them if they are not contracted with their CCO plan. Or, Planned Parenthood provides necessary care without reimbursement. In the past six months, Planned Parenthood Columbia Willamette served close to 400 patients who were covered by a CCO plan not contracted with them.

Ensuring there is ‘no wrong door’ for patient care is vital for patients to receive timely care, especially if they have traveled outside their community and cannot easily access alternate providers in a timely manner. Similar barriers occur when a patient’s plan changes to one which is not contracted with Planned Parenthood. Health center staff are often informing patients of a change in coverage and, if the new CCO is not contracted, their limited ability to offer patient care. This is wasteful for staff and stressful for patients.

Open access to safety net providers and other community providers would create meaningful change for patient access and provider burden. These services are often low cost yet carry high cost implications if

---

<sup>64</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf>

not addressed in a timely manner. Claims data from these visits would inform CCOs of where patients are accessing care, and which providers they are choosing for specific services. This open access could even encourage new contracts with diverse providers.

**VI. PPAO agrees with OHA that advancing health equity is paramount, and supports OHA in proceeding forward with several other equity-driven requests in the draft application and notes the importance of provider choice for OHP enrollees.**

Advancing health equity is paramount in transforming the OHP program to effectively serve people with low incomes, including people of color, in Oregon. As discussed in detail in this comment letter, due to longstanding systemic barriers to economic advancement, these populations are disproportionately enrolled in the Medicaid program and experience worse health outcomes on several measures. To meaningfully address access to care and improve health outcomes for people with low incomes, including women of color, a comprehensive equity-driven approach must be taken.

OHA has included several requests and changes in the draft application to advance health equity. In addition to the proposals discussed at length in this letter, PPAO notes its support for the following proposals that increase access to care and ensure continuity of coverage for critical populations:

- providing continuous eligibility for children until their 6th birthday;
- providing an expedited OHP enrollment path for people who apply for SNAP benefits;
- retaining benefits and/or extending full OHP Plus Medicaid benefits to justice-involved individuals;
- providing transitional employment support services for vulnerable populations and benefits for people impacted by climate disasters and at high-risk for extreme weather;
- expanding the infrastructure needed to support access to services using providers outside the medical model, including personal health navigators and doulas; and
- investing in provider and community-based organizations' (CBO) infrastructure and capacity building.

Taken together with the other program features discussed in detail in this letter, these features provide a strong foundation to meaningfully make progress on health equity for Oregonians. PPAO urges OHA to move forward with these program features and work with community-based reproductive health care providers when implementing these changes.

\*\*\*

Thank you for the opportunity to comment on the OHP draft waiver application. OHA has put forward a comprehensive approach in addressing health equity through several program features, which would have an outsized impact on women of color, in this draft application. Planned Parenthood urges OHA to move forward with seeking 24-months continuous eligibility for OHP enrollees ages 6 and over and investing in SDOH transition services for vulnerable populations, along with several other features. However, Planned Parenthood strongly urges OHA to reinstate retroactive coverage for all OHP enrollees and not proceed forward with the prescription drug policy changes proposed in the draft application. The continued waiver of retroactive coverage and prescription drug policy proposals undermine OHA's goal of advancing health equity by decreasing access to care and limiting patient choice.



Planned Parenthood Advocates of Oregon

If you have any questions about the issues raised in this letter, please do not hesitate to contact An Do, Executive Director, at [an.do@ppaoregon.org](mailto:an.do@ppaoregon.org).

Respectfully submitted,

An Do  
Executive Director  
Planned Parenthood Advocates of Oregon



January 7, 2022

Dana Hittle  
Interim Deputy State Medicaid Director  
500 Summer St. NE, E65  
Salem, OR 97301

RE: Comments on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

Dear Deputy Director Hittle:

At The Leukemia & Lymphoma Society (LLS), our mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and to improve the quality of life of patients and their families. We support that mission by advocating that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. On behalf of the thousands of Oregonians whose lives have been changed forever by blood cancer, we appreciate this opportunity to comment on the Oregon 1115 Demonstration Waiver for the Oregon Health Program.

LLS supports the focus that the Oregon Health Program has placed on equitable access to healthcare in the 1115 Demonstration Waiver and thanks the department for its innovative thinking and leadership to eliminate inequities in access to care. In addition, Oregon's request to provide multi-year continuous enrollment for children under six and continuous eligibility for all beneficiaries ages six and over will help to eliminate gaps in coverage.

Unfortunately, this waiver contains multiple proposals that undermine access to care for patients with blood cancer. LLS is concerned the proposed closed formulary for adult beneficiaries will make it harder for patients to access the medications they need to stay healthy. We also oppose Oregon's proposals to limit retroactive coverage for nearly all Medicaid beneficiaries and to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for beneficiaries over the age of one, as both proposals will significantly jeopardize access to care for patients we represent.

LLS offers the following comments and suggested changes on the 1115 Demonstration Waiver for the Oregon Health Program.

***Continuous Eligibility***

LLS supports the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility reduces gaps in coverage that prevent patients from accessing the care that they need. Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.<sup>i</sup> Research has also shown that individuals with disruptions in coverage during a year are

more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.<sup>ii</sup> People in the midst of cancer treatment, for example, rely on regular visits with healthcare providers, and many of those patients must adhere to frequent, if not daily, medication regimens. The loss of coverage or a gap in coverage is a grave prospect for anyone living with blood cancer. Continuous eligibility will help reduce these negative health outcomes.

### ***Closed Formulary***

LLS is concerned that the proposal to adopt a commercial-style closed formulary and to exclude from that formulary drugs with “limited or inadequate evidence of clinical efficacy” will reduce access for certain cancer patients to the only appropriate treatment available. This proposal may negatively impact access to care for patients living with a range of serious diseases and conditions. But for patients living with cancer, this proposal is especially grave, as there is very little interchangeability among the drug therapies used to treat most cancers, including most blood cancers. Typically, treating cancer is a profoundly complex undertaking. Indeed, even among patients with the same diagnosis, the same treatment may be insufficient or altogether inappropriate.

In particular, LLS is alarmed by the language on page 31 of the Application for Renewal and Amendment stating that “[m]any drugs coming to market through the FDA’s accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints” and by Oregon seeking “the ability to use its own rigorous review process to determine coverage of new drugs and to prioritize patient access to clinically proven, effective drugs.”

In our own analysis of drugs with an FDA-approved blood cancer indication approved prior to July 2021, more than 40 were approved through accelerated pathways, including 31 just in the past decade. Furthermore, the State’s claim that this will induce programmatic savings is diminished by the intent to “use its own rigorous review process” to determine a drug’s efficacy. LLS is alarmed by the prospect of a secondary state-level review process that claims rigor without any transparency around the methods or standards the state intends to put in place to achieve it. Indeed, the application provides no detail on how Oregon will establish such a review process. Given the rigorous standards the FDA and manufacturers follow before a drug reaches the market through even an accelerated pathway, such a program is likely to be expensive: to Oregon’s Medicaid budget, to those beneficiaries who may be denied access to a treatment or therapy while the State decides whether they think it merits coverage, and potentially even to the broader healthcare system if such a secondary review process results in health spending that would have been obviated by timely adherence to the FDA-approved medication. If adopted in multiple states, this could result in dramatic variation in access to new cancer therapies across the country.

In its application, the State suggests that they seek the same “discretion” regarding formulary design as that available to commercial payers. Enrollees in commercial plans, however, have access to appeals and exception processes that can provide access when necessary to excluded drugs, whereas the Oregon application includes no indication of intent to provide that same due process to Medicaid beneficiaries impacted by a formulary limitation. To make adequate comparisons between Medicaid

and commercial payer formularies, it is also important to note that commercial payers do not receive the same mandatory rebates that Medicaid programs, including Oregon's, receive for all drugs covered under the program. Moreover, patients covered by commercial plans can choose alternative coverage, while Oregonians on Medicaid have no similar alternative.

Given the small population of cancer patients relying on these new medications and the importance of timely adherence to treatment regimens, LLS believes the creation of a closed formulary, without a clear and robust exception process, would be harmful to blood cancer patients.

While LLS certainly appreciates the need for state resources to be spent on benefits and services of high value, adopting this as a blanket approach will no doubt prevent or delay some cancer patients from accessing medically appropriate and potentially life-saving therapies simply because they are Medicaid beneficiaries. LLS requests that the Oregon Health Program remove these requests and provide a robust, open formulary for all beneficiaries that will allow patients to access the medications that their providers believe are best for them.

### ***Retroactive Coverage***

LLS is concerned by the proposal to continue to eliminate retroactive coverage for nearly all beneficiaries, excluding the aged, blind and disabled. Retroactive eligibility in Medicaid prevents gaps in coverage by covering individuals for a set amount of time prior to the month of application, assuming the individual is eligible for Medicaid coverage during that time frame. It is common that individuals are unaware they are eligible for Medicaid until a medical event or diagnosis occurs. Eligible applicants may also delay necessary healthcare until the Medicaid enrollment process is complete, which can increase their health risks and exacerbate any health conditions that they may have.

Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as blood cancer, to begin treatment without being burdened by medical debt prior to their official eligibility determination. In Indiana, Medicaid recipients were responsible for an average of \$1,561 in medical costs with the elimination of retroactive eligibility.<sup>iii</sup> Without retroactive eligibility, Medicaid enrollees could then face substantial costs at their doctor's office or pharmacy.

Patients with underlying health conditions who are unable to access regular care are often forced to go to emergency rooms and hospitals if their conditions worsen, leading health systems to provide more uncompensated care. For example, when Ohio was considering a similar provision in 2016, a consulting firm advised the state that hospitals could accrue as much as \$2.5 billion more in uncompensated care as a result of the waiver.<sup>iv</sup> Increased uncompensated care costs are especially concerning as safety net hospitals and other providers continue to deal with limited resources and capacity during the COVID-19 pandemic. Limiting retroactive coverage increases the financial hardships to rural hospitals that absorb uncompensated care costs. LLS opposes the continued limitations to retroactive coverage and encourages the state to expand retroactive coverage to include all Medicaid beneficiaries.

### ***EPSDT Benefit***

LLS is opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnosis and Treatment (EPSDT). The purpose of the EPSDT benefit is to ensure that children receive appropriate healthcare, however, the limiting of that care to a prioritized list of services leaves families vulnerable to the cost of care for non-prioritized services or simply unable to access those needed services. Many of the services that have not been prioritized are for serious and concerning conditions, such as the special health care needs of children with cancer. In fact, blood cancers are among the most common pediatric cancers, with leukemia and lymphoma accounting for more than 1 in 3 cancer diagnoses among patients under the age of 20.<sup>v</sup> These limitations to services can place low-income families under financial strain to cover the cost of necessary services that fall outside of the prioritized list.

While the state has demonstrated other efforts to increase equitable access to healthcare, the continued restriction of the EPSDT benefit is a step in the opposite direction. For example, children of color are enrolled in Medicaid at disproportionately higher rates<sup>vi</sup> and as mentioned before, are also more likely to be affected by gaps in coverage.<sup>vii</sup> These children are likely to be disproportionately affected by the limitations to the EPSDT benefit. LLS supports the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit.

### ***Conclusion***

LLS believes that healthcare coverage should be affordable, accessible and adequate for children and adults with cancer. Questions or requests for further information on LLS and our position can be addressed to [sara.kofman@lls.org](mailto:sara.kofman@lls.org).

Thank you for the opportunity to provide comments.

Sincerely,

Sara Kofman  
Regional Director, Government Affairs  
Leukemia & Lymphoma Society

---

<sup>i</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)

<sup>ii</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>

<sup>iii</sup> Healthy Indiana Plan 2.0 CMS Redetermination Letter. July 29, 2016. Available at: <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-lockouts-redetermination-07292016.pdf>

---

<sup>iv</sup> Virgil Dickson, "Ohio Medicaid waiver could cost hospitals \$2.5 billion", Modern Healthcare, April 22, 2016.

(<http://www.modernhealthcare.com/article/20160422/NEWS/160429965>)

<sup>v</sup> "Childhood and Adolescent Blood Cancer Facts and Statistics," The Leukemia & Lymphoma Society. Available at:

<https://www.lls.org/facts-and-statistics/childhood-and-adolescent-blood-cancer-facts-and-statistics>

<sup>vi</sup> Brooks, Tricia. Whitener, Kelly. "At Risk: Medicaid's Child-Focused Benefit Structure Known as EPSDT," Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, June 2017. EPSDT-At-Risk-Final.pdf (georgetown.edu)

<sup>vii</sup> Osorio, Aubrianna. Alker, Joan, "Gaps in Coverage: A Look at Child Health Insurance Trends", Center for Children & Families (CCF) of the Georgetown University Health Policy Institute, November 21, 2021. [Gaps in Coverage: A Look at Child Health Insurance Trends – Center For Children and Families \(georgetown.edu\)](#)



January 7, 2022

VIA ELECTRONIC FILING

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Lilly USA, LLC**

Lilly Corporate Center  
Indianapolis, Indiana 46285  
U.S.A.  
+1.317.276.2000  
[www.lilly.com](http://www.lilly.com)

**RE: Application for Renewal and Amendment Oregon Health Plan, Section 1115  
Demonstration Waiver**

Dear Director Allen:

Lilly USA, LLC (Lilly) appreciates the opportunity to submit comments on the proposed application by Oregon Health Authority for renewal and amendment of the Oregon Health Plan (OHP) 1115(a) Demonstration Waiver. Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies, as well as through the analysis and distribution of health information. Ultimately, our goal is to develop products that save and improve patients' lives.

Lilly supports Medicaid beneficiaries' access to high quality health care and medicines and is concerned that the Oregon Health Authority's Section 1115 waiver, which proposes to impose a closed formulary and exclude important innovative drugs approved through the FDA instituted Accelerated Approval Program which would seriously limit patient access to medicines and is not permissible by law. Our primary arguments are as follows:

- The closed formulary may harm patients, reduce medication adherence, and will not result in a reduction in health care costs;
- Denied access of the FDA's accelerated approved drugs will significantly restrict patient access to innovative and complex medicines;
- CMS has rejected a nearly identical proposal by Massachusetts due to the violation of the existing Social Security Act law. Provisions of the Medicaid Drug Rebate Statute cannot be waived under Section 1115 of the Social Security Act;
- The closed formulary and medication coverage restrictions are not permitted under Section 1115 of the Social Security Act as they sever the compact in the Medicaid Drug Rebate Statute; and,
- Cost containment options and tools are available to help control drug expenditures and mitigate risk.

Lilly also supports the comments provided to the Centers for Medicare & Medicaid Services (CMS) by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO).

## **I. Oregon Health Plan Closed Formulary Could Harm Patients, Reduce Medication Adherence, and Will Not Result in a Reduction in Health Care Costs**

The Oregon Health Plan, Section 1115 waiver, proposes to restrict access to one drug per class with intent to exclude drugs approved through the FDA's accelerated approval process. Implementation of both policies would hinder patients' access to a diverse range of innovative treatment options that could best serve their needs, including the individual plaintiffs in the case of *McCutchen v. Becerra* (pending, D.D.C). This is particularly troubling given the vulnerability of the Medicaid population. Non-elderly Medicaid beneficiaries are more likely to be in poor health than those with private insurance.<sup>1</sup> Children covered by Medicaid are also more likely to be in fair or poor health as well as have a higher prevalence of certain behavioral health conditions than those with private coverage.<sup>2</sup> Unlike patients with commercial or Medicare insurance, Medicaid patients do not have the ability to choose amongst various plans for coverage that better fits their individual health challenges, so the application of a commercial-like benefit design is wholly inappropriate in this context.

Moreover, research has shown that formulary restrictions can harm medication adherence<sup>3</sup>. In addition, they may have unintended consequences and result in increased costs. For example, a study found that formulary restrictions for Arizona Medicaid beneficiaries living with arthritis had unintended consequences including increasing hospitalizations and costing an additional \$900 annually per beneficiary. For these reasons, CMS should be highly skeptical of any proposal to limit Medicaid beneficiary access to necessary medications.

## **II. Restricting Access to Drugs Approved under FDA's Accelerated Approval Pathway Will Harm Patients Facing Greatest Unmet Need**

For nearly 30 years, the Accelerated Approval pathway has facilitated approval of medicines that treat serious and life-threatening diseases and conditions for patients who have no adequate treatment options. Nearly 270 medicines have received accelerated approval,<sup>4</sup> extending – even saving – patients' lives by providing earlier access to novel therapies than would have been possible using the traditional approval pathway.

Oregon's proposal to exclude drugs approved through the accelerated approval (AA) process is wholly inappropriate and reflects a substantial misunderstanding of FDA's drug approval process and evidentiary standards.<sup>5</sup> Oregon suggests this proposal is part of an effort to "prioritize patient

---

<sup>1</sup> MACPAC, "MACStats: Medicaid and CHIP Data Book," December 2016, Available at: [https://www.macpac.gov/wp-content/uploads/2016/12/MACStats\\_DataBook\\_Dec2016.pdf](https://www.macpac.gov/wp-content/uploads/2016/12/MACStats_DataBook_Dec2016.pdf), cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 58.

<sup>2</sup> MACPAC, "Chapter 4: Behavioral Health in the Medicaid Program—People, Use, and Expenditures," June 2015, Available at: <https://www.macpac.gov/wp-content/uploads/2015/06/Behavioral-Health-in-the-Medicaid-Program%E2%80%94People-Use-and-Expenditures.pdf>, cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 59.

<sup>3</sup> Happe LE, Clark D, Holliday E, Young T, "A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and HealthCare Resource Utilization," *J Manage. Care Spec. Pharm.* 2014; 20(7):677-84, cited in PhRMA letter to Secretary Sudders, August 15, 2017, footnote 72.

<sup>4</sup> U.S. Food & Drug Admin., CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint as of June 30, 2021, <https://www.fda.gov/media/151146/download>.

<sup>5</sup> Separately, Oregon also mischaracterizes the 21<sup>st</sup> Century Cures Act, suggesting it was "intended to expedite the drug approval process by reducing the level of evidence required for drugs to reach the market and allowing

access to clinically proven, effective drugs.” Yet, drugs that have received accelerated approval must meet the same standards of safety and efficacy as a therapy that is approved under the traditional pathway. The difference between the two pathways is the type of endpoints that may be utilized in the clinical trials supporting approval. CMS itself recognized this in 2018 guidance when it stated, unambiguously, that accelerated approval drugs must be covered by Medicaid, like all other drugs:

Therefore, as with any other drug, if the drug is labeled by a manufacturer that has signed a Medicaid National Drug Rebate Agreement, and the drug meets the definition of covered outpatient drug, then the drug is covered by the Medicaid Drug Rebate Program (MDRP) and is to be covered by state Medicaid programs.<sup>6</sup>

Imposing policies that make it harder for patients suffering from serious or life-threatening conditions to access approved medicines would undermine the important policy goal behind accelerated approval – facilitating earlier patient access to approved therapies. Furthermore, there is no data to suggest that drugs that go through the AA pathway are driving spending for Medicaid. In fact, a recent analysis of Medicaid spending found that accelerated approval drugs consistently accounted for less than 1% of spending. Since passage of the Food and Drug Safety and Innovation Act which encouraged accelerated approval use for serious and life-threatening conditions in addition to oncology and HIV/AIDS, Medicaid spending on accelerated approval drugs remained steady at 0.6% to 0.8% a year.<sup>7</sup>

Denying Medicaid patients access to medicines approved under the Accelerated Approval pathway deprive some of the sickest patients, who are most in need of treatment, access to innovative, life-saving drugs.

### **III. CMS has rejected a nearly identical proposal by Massachusetts due to the violation of the existing Social Security Act law. Provisions of the Medicaid Drug Rebate Statute cannot be waived under Section 1115 of the Social Security Act.**

In 2017, Massachusetts, MassHealth Section 1115 Demonstration Amendment suggested a similar proposal that failed to meet the intended goal of ensuring robust access to medically necessary drugs and ultimately excluded a vast number of FDA-approved drugs for vulnerable populations. The proposed demonstration amendment mischaracterized the FDA Approval Process, failed to consider the importance of individualized patient-centered care, and disregarded research that revealed the negative effects of closed formularies. Furthermore, CMS responded to the Massachusetts waiver amendment by issuing “Release No. 185” stating that a drug approved by the FDA under the accelerated approval pathway must be covered by state Medicaid programs, if the drug meets the definition of “covered outpatient drug” as found in Section 1927 of the Social Security Act and has signed a Medicaid National Drug Rebate Agreement.<sup>8</sup>

---

doctors, patients, and payers to decide whether to purchase them.” This is simply false. Nothing in the Cures Act altered FDA’s strict approval standards. The legislative history also reflects an ongoing commitment to maintain these high standards. *See e.g.*, House E&C Subcommittee on Health Ranking Member Frank Pallone (Nov. 30, 2017) (“At FDA, the Cures Act aims to bolster the medical product review process in order to get treatments to patients faster while also maintaining FDA’s gold standard for safety and effectiveness.”).

<sup>6</sup> CMS, MDRP Notice for State Technical Contacts, Release No.185, at 1 (June 27, 2018), [state-rel-185.pdf](#).

<sup>7</sup> Thorpe, K. E., PhD, & Holtz-Eakin, D., PhD. (2021). Limiting Medicaid Access to Accelerated Approval Drugs: Costs and Consequences. *American Journal of Managed Care*.

<sup>8</sup> CMS State Release No. 185, June 27, 2018.

Social Security Act § 1115(a)(1) provides that, “[i]n the case of any experimental, pilot, or demonstration program which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid or certain other programs], in a state or states— (a) the Secretary may waive compliance with any of the requirements of section 402, 454, 1402, 1602, or 1902 . . . to the extent and for the period he finds necessary to enable such state or states to carry out such project.” SSA § 1927 (the Medicaid rebate statute, codified at 42 U.S.C. § 1396r-8 [SSA 1927’s] is not on the list of waivable provisions. Accordingly, the D.C. Circuit held in *PhRMA v. Thompson*, CMS had no authority to waive requirements of the rebate statute under § 1115. *PhRMA v. Thompson* is the only case that has addressed whether SSA § 1115 permits waivers of rebate statute requirements. The D.C. Circuit’s ruling has never been overturned or questioned by later cases<sup>9</sup>.

No later cases have overturned this decision. Other courts have agreed that benefit cuts are not valid “demonstrations” under federal law. For example, in the context of a work requirement to qualify for food stamps, the federal court of appeals for the Ninth Circuit emphasized that “[a] simple benefits cut, which might save money but has no research or experimental goal, would not satisfy th[e] criteria [of] ha[ving] a research or demonstration value.” That logic is applicable here, as all the Oregon Health Plan “demonstration” seeks to test is whether cutting benefits by limiting the drugs that are covered by the state, results in “savings.” This is not a good-faith demonstration exercise but is simply an effort for the state of Oregon to shirk its obligations under the Medicaid Drug Rebate program.

Any 1115 demonstration project must be “likely to assist in promoting the objectives of [Medicaid].” Based on the language of the Medicaid statute, courts generally describe Medicaid’s objectives as providing medical assistance to those whose income and resources are inadequate to meet the costs of such care. Allowing a waiver of the drug coverage requirements in the rebate statute would not promote those purposes. Instead of enabling states to assist people who cannot afford necessary medical care, such a waiver would reduce beneficiaries’ access to medicines and adversely affect their health in two ways: directly, by permitting the State to cut back on drug coverage; and indirectly, by eliminating or curtailing manufacturers’ incentive to participate in the Medicaid rebate program—a program that has successfully provided Medicaid beneficiaries “access to the same range of drugs that the private patients of their physicians enjoy” since its start in 1991. The rebate program could unravel quickly if one selective waiver of the rebate statute’s coverage requirements were granted, as other states would likely seek the same waiver once the precedent was established; this would be a serious setback for Medicaid objectives and for beneficiaries’ health and well-being.

#### **IV. The Medicaid Drug Rebate Statute (Section 1927) Represents a Two-Part Agreement That Cannot be Severed by Waiving the Coverage Requirements Alone**

Even if CMS could waive the Medicaid Drug Rebate Statute, it could not waive only the statute’s coverage requirements while leaving in place the obligation that manufacturers pay rebates on Medicaid utilization. The existing statute requires states to cover all products of manufacturers with Medicaid rebate agreements. This coupling of the rebate and coverage requirements was described by a key sponsor of the Medicaid Drug Rebate Statute, Congressman Henry Waxman, as a “government-industry compact.” CMS has also explained the connection between the coverage and rebate requirements as follows:

---

<sup>9</sup> *PhRMA v. Meadows*, 304 F. 3d 1197 (11th Cir. 2002); *PhRMA v. Thompson*, 362 F. 3d 817, 823-24 (D.C. Cir. 2004).

[The Medicaid Drug Rebate Statute] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.

As elucidated by CMS 2013 regulatory preamble regarding Medicaid coverage: “[D]rug manufacturers must pay statutorily-defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.” CMS’s respect for this statutory compact was evident when, in 2018, CMS rejected Massachusetts’ request to establish a closed formulary under the state plan. This policy “would have allowed the State to continue to collect manufacturer rebates under Section 1927, while enabling the State to exclude certain drugs from coverage,” thereby rupturing the statute’s careful balance. CMS expressed its willingness to “consider a demonstration” that would provide “coverage of outpatient drugs under the expenditure authority in section 1115(a)(2),” thereby giving the state the “ability to exclude certain Medicaid covered outpatient drugs from coverage.”

Hence, CMS has recognized and validated the link between the coverage and rebate requirements. It therefore follows that, were Oregon to fail to comply with the coverage requirements of the Medicaid Drug Rebate Statute through implementation of the closed formulary and other proposed coverage restrictions, it would not be in compliance with the statute. This would thereby remove manufacturers’ obligation to pay rebates under the Medicaid Drug Rebate Statute. Instead, manufacturers could negotiate price concessions directly with the state.

#### **V. Oregon Has Access To Cost Containment Options And Tools Are Available To Help Control Drug Expenditures And Mitigate Risk**

The benefits of the statutory Medicaid rebate program are significant. Of the many services Oregon provided for its Medicaid beneficiaries in FFY2019, only 2.9% of the total budget was spent on retail brand and generic drugs. Brand drugs alone were only 1.4% of the total Medicaid budget. Furthermore, manufacturers rebated \$403 million back to Oregon and the federal government, 57% of the total Medicaid spending on drugs.

The states’ tools to save money on prescription drugs provide it with meaningful chances to reduce prescription drug spending. For example, states may: 1) impose prior authorization requirements on any drug, subject to certain timing and supply requirements; 2) impose restrictions authorized by an agreement with a drug manufacturer; 3) create Medicaid formularies and exclude drugs from such formularies under certain specified conditions; 4) create Preferred Drug Lists (PDLs) and may demand supplemental rebates as the price for including a drug on the PDL, among other options; and 5) implement reinsurance mitigation risk programs to decrease the pharmacy expenditures for high-cost enrollees and stabilize premiums.

Furthermore, as noted above, the closed formulary proposal would disrupt the compact of the Medicaid Drug Rebate Statute. This could result in the State losing access to statutorily defined

rebates, which could lead to increased costs to the State for prescription drugs and ultimately result in access challenges for Medicaid beneficiaries.

\*\*\*

Thank you for the opportunity to submit comments in opposition to Oregon's 1115 Demonstration Waiver proposal. We respectfully request that CMS deny these portions of the request as they will pose a serious threat to patient access to health care and could result in higher health care costs. If you have any questions, please do not hesitate to contact me at [oneail\\_shawn@lilly.com](mailto:oneail_shawn@lilly.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'Shawn O'Neil', with a long horizontal stroke extending to the right.

Shawn O'Neil  
Vice President, Government Affairs



January 7, 2022

Director Patrick Allen  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

Re: **Oregon's Application for Renewal and Amendment of Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

On behalf of the 300 members of the Oregon Dermatology Society, we are writing to express our strong opposition to a proposal that would restructure the Oregon Health Plan ("OHP") pharmacy benefit to create a commercial-style closed formulary for adult patients, as outlined in Oregon's 1115 Medicaid Waiver Demonstration renewal. The proposal would authorize the state to exclude drugs that have limited evidence, but still have demonstrated clinical efficacy that can be very beneficial to subgroups of patients. The broad guidelines for such determinations will negatively impact the sickest and most vulnerable patients and will conflict with the overarching goal of the waiver renewal to advance health equity. The creation of a closed formulary will only exacerbate existing health inequities by limiting patient access to medically necessary prescription medications.

Our members are keenly aware of the nation's increased health care costs and their own responsibility to prescribe a treatment plan that wisely manages limited

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

health care resources; however, a closed formulary is an ineffective, draconian approach to reducing health care costs by creating a one-size-fits-all solution. If approved, more than 700,000 Oregonians will unnecessarily be at risk, as explained below. Therefore, we urge Oregon policymakers to explore alternative strategies to reduce health care costs. Patients should not be expected to bear this burden.

Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases and many genetic disorders. When developing a treatment plan for our patients, dermatologists base their recommendations and decisions on a thorough understanding of their patients' medical history and medical needs. This knowledge enables them to identify potential contraindications and life-threatening adverse reactions, which is particularly critical for patients covered by OHP, many of whom have multiple chronic conditions. Comorbidity often results in adverse health outcomes and complex clinical management. Requiring a patient to take a medication that the physician knows is not in the patient's best interest and in some instances, will jeopardize the patient's health, not only defies logic but violates the Hippocratic oath.

The American Academy of Dermatology's guiding position on access to effective and affordable drugs is set forth in its *Position Statement on Patient Access to Affordable Treatments*<sup>1</sup>:

*"Physicians should have the entire compendium of pharmaceutical therapies available to them and the freedom to work with their patients to determine the appropriate course of treatment based on each patient's unique circumstances.*

*"Each formulary must be developed based on scientifically valid evidence that the selected pharmaceuticals sufficiently provide the most effective therapies for any given condition and that options are available should patients not be able to utilize a given agent due to lack of response, side effects, allergy, etc."*

---

<sup>1</sup> <https://server.aad.org/Forms/Policies/Uploads/PS/PS-Patient%20Access%20to%20Affordable%20Treatments.pdf>

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

A closed formulary will significantly limit the physicians' ability to treat patients with complicated skin diseases, such as cutaneous autoimmune disorders. Forcing these patients to make consequential, potentially lengthy and disease-altering changes is a great challenge and hardship. Withdrawal of a medication for a patient, particularly abrupt withdrawal, can aggravate a quiescent disease and result in disease that is resistant to prior effective therapy or the development of aggressive disease. The consequences, which cannot be predicted for individual patients, include worsening life-threatening disease, severe flares including those requiring hospitalization, therapeutic failure, antibody development and risk for greater adverse effects than those associated with current therapy. For many patients, the disease burden extends beyond physical findings; there is lost work and wages and a significant psychological impact.

A specific example is pemphigus vulgaris, which is a rare, auto-immune disease that causes blistering of the skin and mucous membranes. Treatment typically involves the prolonged use of steroids and immunosuppressive/immunomodulating agents, many of which do not have specific "approved indications" to treat pemphigus. This condition requires a patient-centric customized approach because if it is left untreated, the complications can be fatal. Each patient who presents with this disease is a unique challenge due to the diversity in the disease. Comorbidities, which include diabetes, hypertension, malignancies, chronic infections, among others, affect the choice of the most appropriate treatment.

Additionally, the waiver request will profoundly impact patients with chronic conditions and who are stable on a drug that is no longer included in the closed formulary. Forcibly switching a patient to another drug poses significant risk to patients, possibly resulting in harmful outcomes like flaring of the disease, immunogenicity, adverse effects, and secondary nonresponse. It may also lead to the loss of effectiveness of the original medication, should the patient switch back in the future.

As physicians, our number one priority is the health and welfare of our patients. We appreciate the opportunity to provide written comments on this important issue. Retaining physicians' medical judgement in patients' treatment plans is a cost-effective way to prevent health care dollars from being used on medications that are not effective. We respectfully urge you to carefully consider the ramifications of moving to a closed formulary and reject such provisions of the waiver renewal. Please contact Patrick Sieng, Executive Director for the Oregon

Page 4 of 4

January 7, 2022

Comments re: 1115 Medicaid Waiver Demonstration Renewal

Dermatology Society at [patrick@oregondermatology.org](mailto:patrick@oregondermatology.org) or (503) 799-8280 if you require clarification on any of the points above or would like further information.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Bar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anna Bar, MD, FAAD, FACMS  
President  
Oregon Dermatology Society

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

**RE: Oregon's Draft Medicaid Demonstration 1115 Waiver Application**

Dear Ms. Hatfield,

The ALS Association of Oregon and Southwest Washington is concerned with the proposal by Oregon Health Authority to potentially restrict access for Medicaid patients to new ALS treatments. We request that you remove "Strategy 3" from the 1115 Medicaid Demonstration Waiver.

Our organization is the central source for services and education for people with Amyotrophic Lateral Sclerosis (ALS), their families, caregivers, and health care professionals in all of Oregon and the six counties of SW Washington. We provide a range of services: direct services to people with ALS including clinics, support groups, access to medical and speech equipment, funding cutting-edge research and generally connecting those whose lives have been impacted by ALS.

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. ALS robs people of their ability to walk, talk, eat and speak; it is always fatal disease with an average life expectancy for of 2-5 years from diagnosis. There is no current cure for ALS, and only a few drugs approved for treating various symptoms of ALS. The pipeline for ALS treatments depends on the FDA accelerated approval pathway, as ALS has a serious condition with unmet needs. Moreover, the short life expectancy of a person diagnosed with ALS makes every second count, whether in research, approval, access and treatment.

Stated plainly, there are very few reasons for people living with ALS and their families to be hopeful following diagnosis. The pipeline for new treatments is one thing they cling to, and the FDA accelerate approval process makes that hope real. Unfortunately, Oregon Health Authority's (OHA) draft 1115 Waiver application would create one more potential barrier for access if OHA determined that it would not cover a new, approved ALS drug. This would be crushing to a patient and family on Medicaid, already inundated with the challenges of coverage while facing a complex labyrinth of health care costs and administration in light of an impossible diagnosis.

While the ALS Association sympathizes with OHA's challenges in containing costs, focusing on the accelerate approval process as a mechanism for restricting access or reducing utilization is dangerously misplaced. The proposed language directly undermines the FDA's scientific approach for determining that a drug is safe and effective (and purports to replace it with a "rigorous state review process" which doesn't exist). Worse, the application specifically refers to accelerate approval drugs as drugs with "limited or inadequate evidence of clinical efficacy" which is plainly false and continues to undermine patients and the public's faith in scientific rigor. The purpose of the accelerated approval



**OUR VISION** Create a world without ALS.

**OUR MISSION** To discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

Main Office: 825 NE Multnomah St, Suite 940, Portland, Oregon 97232  
Phone 503.238.5559 • FAX 503.296.5590 • [www.alsa-or.org](http://www.alsa-or.org)

pathway is to benefit patients with conditions like ALS, where there are unmet medical needs and for those facing with rare diseases. It is NOT a shortcut for rigorous scientific review.

By law (21 U.S.C. § 356(e)(2)), FDA must find "substantial evidence of effectiveness" to approve any drug, including AA drugs. FDA and Congress have both made clear that neither FDASIA's accelerated approval provisions nor the 21<sup>st</sup> Century Cures Act diluted FDA's approval standards. There is no reason (nor evidence) that OHA current infrastructure, including Oregon's "Health Evidence Review Commission" or Pharmacy and Therapeutics Committee has the staff, expertise, resources to duplicate the FDA process. Any such review would be redundant, costing patients valuable time and options where treatments may be available.

Secondly, with rare disease, such as ALS, reducing access to drugs approved through the accelerated approval process won't provide meaningful savings for our state Medicaid program anyway (or at least OHA should demonstrate that it will). According to the American Journal of Managed Care, accelerated approval drugs have accounted for less than 1% of Medicaid spending consistently every year ([https://cdn.sanity.io/files/Ovv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC\\_06\\_2021\\_Thorpe\\_final.pdf](https://cdn.sanity.io/files/Ovv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC_06_2021_Thorpe_final.pdf)). Coupling the scientific rigor of the FDA process and the limited savings, there is no rational reason to seek authority to limit access to drugs for those with rare conditions or no other treatment options.

Further, the waiver application will create even more disparities in care and sends a message to Oregonians that those with high unmet need, rare conditions and needing access to new therapies are a lower priority for full Medicaid coverage. The disparity of care would only be magnified where people with ALS could access a new drug through a private insurance carrier, but low-income Oregonians seeking access through Medicaid may not (or worse, spend valuable time fighting a challenging prior authorization process while their condition continues to progress). While the value of accelerated approval drugs to our community is clear, has OHA provided evidence that excluding these drugs would result in savings to the state system? If not, this is a significant risk to patient access and their hopes and realization of better quality of life with no clearly established benefits flowing to the state.

On a broader scale, these types of proposals only further discourage innovation for diseases like ALS where the only viable pathway to bring a treatment to market is the accelerated approval pathway. With so many conditions where investment and research can provide a quicker (and already more certain) return on investment, OHA's application would only increase our community's challenges in finding researchers and companies who will focus on treatments for ALS.

On a final note, we are also concerned with the request for the state to create a closed formulary. Again, this change is counter to Oregon's purported goal of the 1115 waiver: "to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon." In addition to the few ALS treatment currently available, ALS patients rely on an array of drugs to deal with the myriad symptoms of a degenerative neurological condition. Medicaid patients should have access to the drugs their providers prescribe without OHA preliminarily determining which have more value.

OHA's Section 1115 demonstration amendment request to exclude new drugs approved under the FDA's accelerated approval pathway is misplaced and potentially significantly damaging for patients

with rare conditions and unmet needs. It could very likely lead to perverse disparities in care and limit options for ALS patients on state Medicaid.

We urge you to remove Strategy 3 from the waiver application.

Thank you,

A handwritten signature in black ink that reads "LANCE CHRISTIAN". The signature is written in a cursive, slightly slanted style.

Lance Christian  
Executive Director



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

DATE: January 7, 2022

TO: Oregon Health Authority

RE: Protecting Kids under Oregon's 1115 Medicaid Waiver for 2022-2027

The Oregon Pediatric Society (OPS)—the state chapter of the American Academy of Pediatrics (AAP)—is a nonprofit organization representing approximately 700 primary care, medical subspecialty, and surgical specialty pediatricians and child health providers from across the state who are dedicated to the health, safety, and well-being of all Oregon infants, children, adolescents, and young adults. Thank you for the opportunity to provide comments on the proposed Oregon Health Plan 1115 Demonstration Waiver Application for the 2022 – 2027 Renewal and Amendment (December 1, 2021).

First, we acknowledge and thank the Oregon Health Authority (OHA) for the significant thought and commitment to serving all enrollees that have gone into the crafting of this waiver application. Beginning with the original federal waiver from traditional Medicaid rules (granted in March 1993), Oregon remains a national, transformative leader in the delivery of health care due in considerable part to the efforts to build and, over time, revise the Oregon Health Plan (OHP). The goals of this waiver application will expand upon this broad foundation.

The Oregon Health Plan is uniquely indispensable for children, currently serving as a lifeline of coverage to two out of five kids and youth across the state. (According to the Kaiser Family Foundation, in 2019 36.8% of the state's children are on Medicaid/CHIP, as are 49% of Oregon's children with special health care needs). Therefore, any policy changes made to OHP will continue to have an outsized effect on children. With this in mind, OPS applauds numerous provisions of the waiver proposal that will advance health equity, expand access to care, address social determinants of health (SDOH), and do more to strengthen children's health care. At the same time, we call attention to the State's proposals to continue waiving Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit and three months of retroactive coverage, and look forward to working with the state toward a resolution where these critical protections are part of Oregon's Medicaid program. We also want to draw attention to the importance of continuing to expand the capacity of Medicaid oral health and mental health services for children and youth, domains where our State services and access must be improved.

Oregon's pediatricians enthusiastically support the following components of this waiver application:

- **Continuous enrollment for children until age six, and 2-year continuous enrollment for all older than six:** Continuous coverage is enormously beneficial for children and the



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

clinics that provide their care. Research demonstrates that disruptions in Medicaid coverage are common, and this leads to periods of uninsurance, delayed care, and less preventive care.<sup>1</sup> Moreover, children of color are more likely to experience "churning" on and off Medicaid coverage.<sup>2</sup> Moving to uninterrupted coverage during the first five years of life and for two years subsequent to that will have an enormous, positive effect on the ability of children to maintain coverage, courses of treatment, and relationships with their medical homes and specialty and subspecialty care. Moreover, it will help address health inequities caused by churn among families of color.

- **Expedited enrollment for those with SNAP benefits:** This will not only decrease the burden on families applying for different programs, but has the potential to reduce administrative costs to the State, making this a "win-win" policy for Oregon and children and families.<sup>3</sup>
- **Covering all individuals regardless of immigration status:** As pediatricians, we acutely understand the connection between a parent's health and well-being with that of their children. Healthy parents have healthier children, and healthier parents are better equipped to care for and meet the needs of their children. Conversely, parents in poor physical or mental health may not be able to meet their children's needs, and increased family stress caused by ill health or unpaid medical bills can directly affect children. Building on the success of "Cover All Kids," moving to "Cover All People" will help ensure that parents, other caregivers, and extended family are covered by OHP and can receive needed care. This is particularly important right now as many adult immigrants are uninsured and work in jobs where the current pandemic has exposed them to considerable health risk.<sup>4</sup>
- **Providing coverage during life transitions and climate events:** These important steps will ensure that OHP is there for children and families when it is needed most. Of note, extending OHP coverage to youth in the juvenile justice system will provide much-needed care for a population that is at high risk and faces many barriers to reaching full

---

<sup>1</sup> <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>

<sup>2</sup> <https://ccf.georgetown.edu/2021/10/08/macpac-research-shows-closing-the-continuous-coverage-gap-for-kids-is-within-reach/>

<sup>3</sup> <https://www.cbpp.org/sites/default/files/atoms/files/9-9-20health2.pdf>

<sup>4</sup> <https://www.shvs.org/wp-content/uploads/2021/10/State-Funded-Affordable-Coverage-Programs-for-Immigrants.pdf>



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

potential, including exposure to adverse childhood experiences (ACEs) as well as unmet physical and mental health needs.<sup>5</sup>

- **Extending OHP coverage at existing income levels to youth with special health care needs (YSCNH) to age 26:** As stated in the waiver amendment application, "[m]any of these [YSCNH] are from communities of color, LGBTQAI+, members of Tribes in Oregon and have experienced homelessness, Intellectual and Developmental Disability (IDD) or poverty." This coverage extension at 305% FPL to age 26 will help with YSCNH transition preparation and ensure continuity of care during this critical time.
- **Providing SDOH services to vulnerable populations in transition:** Focusing on individual and family needs such as housing, transportation, food assistance, and employment supports are a recognition that so much of health care happens outside the medical setting. Health starts in our homes, schools, workplaces, neighborhoods, and communities, and providing these supports will have a significant impact on outcomes for children and their families.
- **Investments in community-based organization (CBO) infrastructure and capacity building as well as statewide health equity initiatives.** Such initiatives will help the state build its capacity to address service needs in places where families live, and better address root causes of health inequities.
- **A "comprehensive accountability structure" to address health inequities, ensure member/provider satisfaction, and protect member access to and quality of care.** Through better monitoring and data collection, this will help OHP identify coverage gaps, address health equity needs, and improve outcomes and satisfaction with the program. Moreover, it is important to note that when examining network adequacy for children, their access to *pediatric* primary, medical subspecialty, and surgical specialty care is paramount. Children are a unique population, and the care they require is unique. Children and adults have significantly different patterns of illness, injury, and death, and children have distinct needs in regard to their anatomic, physiologic, developmental, and psychological characteristics. Access to an adult physician or specialist must not substitute for care by pediatricians or pediatric specialists when measuring network adequacy.

---

<sup>5</sup> <https://publications.aap.org/pediatrics/article/146/1/e20201755/37020/Advocacy-and-Collaborative-Health-Care-for-Justice>



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

However, OPS highlights two provisions of the waiver amendment application that should be resolved:

**Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit is a critical protection and its full inclusion in the OHP would safeguard Oregon children now and for years to come.** EPSDT is a cornerstone of federal Medicaid protection that guarantees all Medicaid-eligible children are screened to assess and identify problems early, and ensures the provision of medically necessary health services to correct or ameliorate those identified health problems.<sup>6</sup> EPSDT is designed to address a broad range of child health needs, including preventive care; physical and mental health; oral, hearing and vision care; habilitative care; and social and emotional development. EPSDT ensures health issues for children are not only identified early *but also appropriately treated*. This protection is critically important for children and youth with special health care needs as well as children in low-income families, who have higher rates of a number of health conditions (such as asthma, heart conditions, hearing problems, digestive disorders, and elevated blood lead levels).<sup>7</sup>

While EPSDT has been historically waived under Oregon's Medicaid program, many children may indeed have had all their health needs met. However, it is not known how many Oregon children have not received timely medically necessary treatment because their needed care was not included in the OHP Prioritized List of Health Services. Returning the protection of EPSDT to Oregon's Medicaid program—in place for Medicaid-eligible children in every other U.S. state—would give Oregon the accountability and responsiveness to ensure that needed care for children occurs, both now and into the future. EPSDT will comprehensively safeguard children's health care in Oregon and protect future children enrolled in OHP. We encourage the state to reexamine this waiver amendment provision with the goal of including all EPSDT services in the OHP program.

We also acknowledge the national health and economic research opportunity that Oregon's unique decades-old EPSDT waiver has created in comparing measurable health outcomes for kids in Oregon with A) those in other states rigorously following EPSDT requirements; and/or B) services delivered in Oregon both under the current system and with EPSDT. If EPSDT is formally reinstated to Oregon's Medicaid

---

<sup>6</sup> <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>

<sup>7</sup> Woolf, S, Laudan A, et al. *How are Income and Wealth Linked to Health and Longevity?* Urban Institute, April 2015. Available at: <https://www.urban.org/sites/default/files/publication/49116/2000178-How-are-Income-and-Wealth-Linked-to-Health-and-Longevity.pdf>



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

program, there would be statewide comparison information available before and after its adoption that might determine system and pediatric population impact. Analyzing historical data with future comprehensive Medicaid EPSDT coverage would help the State and CCOs better understand what pediatric services are now more widely covered and used, benefits and challenges, as well as noting changes to clinical operations.

- **Three months of retroactive Medicaid coverage is essential and must also not be waived.** This longstanding protection—one not offered in the private market but explicitly included in Medicaid—ensures that health care expenses for three months prior to the Medicaid application date are also covered, provided the enrollee would have been eligible for Medicaid. This is particularly important for families who may lose coverage from an employer or face a sudden illness or injury. Eliminating retroactive eligibility could deter beneficiaries from seeking needed care for fear they would be responsible for medical bills they cannot afford. This can result in higher medical costs in the long-term as Medicaid beneficiaries delay seeking care. It could also result in increased rates of uncompensated care as physicians, hospitals, and pharmacies—many of whom may have agreed to provide acutely-needed services even before ensuring Medicaid coverage was secure—are not reimbursed for (some of the) services they have already provided.
- **The proposed drug exclusion raises questions about children's prescription drug coverage:** While we understand the state's concerns over increased costs associated with prescription drugs and appreciate that children will be exempted from the proposed closed formulary, we first question this approach for adults. It is not clear what process would be in place for adults to obtain needed medication should the single drug in a closed formulary not work for that patient. Moreover, we support the medically informed use of prescription drugs with limited or inadequate evidence of clinical effectiveness from coverage. For children, two federal laws, the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) have resulted in enormous strides in our understanding of the safe and effective use of medicine in children, with a significant increase in drug labeling for the pediatric population. However, off-label use of medication in children remains an unfortunate, but necessary component of pediatric practice, as roughly one-half of drugs still have no FDA-approved labeling for their use in children. For special child populations, such as preterm and full-term neonates, infants and children



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

younger than two years, and children with chronic or rare diseases, off-label use of drugs is significant and beneficial.<sup>8</sup>

Finally, we call attention to two specific areas that the waiver application and subsequent OHP services should prioritize for children: oral health and mental/behavioral health treatment, beyond screening.

- **Oral health:** CCOs are responsible for providing oral health services, however children in Oregon continue to suffer in obtaining needed oral health care. A recent study published by Oregon Health and Sciences University found that 40% of Medicaid-enrolled children in our state did not receive any dental services in 2018. Moreover, only 45% of Black Medicaid-enrolled children received dental services that year.<sup>9</sup> Pediatric services like topical fluoride varnish are included in Medicaid benefits, but access is very difficult through dental and primary care offices. OPS hopes to work with OHA and community partners to improve primary care oral health screenings and rates of preventive services.
- **Mental/behavioral health:** As was also commented upon by our partners at the Children's Institute in their 12/16/21 Waiver letter, the American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association recently declared a national emergency in child and adolescent mental health. Exacerbated by the pandemic and the ongoing struggle for racial justice, pediatricians are caring for children suffering from soaring rates of depression, anxiety, trauma, loneliness, and suicidality. While the waiver amendment application includes an increased focus on mental/behavioral health, we believe this or future waiver amendments can go further to advance children's health in this domain.

OPS especially highlights the importance of addressing solutions to aiding growth of child mental health professional services through supporting workforce training, financial incentives, and recruitment in underrepresented cultural populations; , integrated pediatric mental health services in primary care; and comprehensive systems of behavioral health care.

---

<sup>8</sup> <https://publications.aap.org/pediatrics/article/133/3/563/32274/Off-Label-Use-of-Drugs-in-Children>

<sup>9</sup> [https://static1.squarespace.com/static/5d97a4561a002c5b8061d827/t/5e334de678d5f55da08d8733/1580420589070/ocf\\_dental\\_brief\\_200122\\_FINAL.pdf](https://static1.squarespace.com/static/5d97a4561a002c5b8061d827/t/5e334de678d5f55da08d8733/1580420589070/ocf_dental_brief_200122_FINAL.pdf)



# Oregon Pediatric Society

A Chapter of the American Academy of Pediatrics. Incorporated in Oregon

Thank you for the opportunity to provide comments on this Medicaid waiver amendment; we hope the thoughts of Oregon's pediatricians will be considered as amendments to this proposal. If you have questions for our organization or concerns, please contact me at [julie.scholz@oraap.org](mailto:julie.scholz@oraap.org).

Sincerely,

A handwritten signature in black ink that reads "Julie Scholz". The signature is written in a cursive, flowing style.

Julie Scholz, MBA - Executive Director  
On behalf of the Oregon Pediatric Society



**Joyce Rogers**  
Vice President  
US Policy and Public Affairs  
Pfizer Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017  
Email: [joyce.rogers@pfizer.com](mailto:joyce.rogers@pfizer.com)

January 6, 2022

**VIA ELECTRONIC DELIVERY**

Mr. Patrick Allen  
Director, Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**Re: Comments of Pfizer Inc. Regarding Draft Application for Renewal and Amendment Oregon Health Plan, Section 1115 Demonstration Waiver**

Dear Director Allen,

Pfizer, Inc. (“Pfizer”) appreciates the opportunity to comment on the Oregon Health Authority’s (OHA) proposed renewal and amendment of its Section 1115 waiver (“proposed 1115 waiver”). Pfizer is committed to saving and improving lives through the development of medicines and vaccines, applying the latest science and technology to meet the most demanding healthcare challenges of today. Pfizer believes that the proposed 1115 waiver would jeopardize the ability of Medicaid beneficiaries—among the neediest of patients—to access life-saving therapies, among other troubling outcomes.

Pfizer is particularly concerned by the OHA’s proposal to implement a closed formulary and exclude drugs approved via FDA’s accelerated approval pathway—which the proposal calls “drugs with limited or inadequate evidence of clinical efficacy.”<sup>1</sup> Pfizer agrees with other commenters, including the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and the Biotechnology Innovation Organization (“BIO”), that these proposals fail to meet certain basic requirements for Medicaid waivers under Social Security Act (“SSA”) section 1115,<sup>2</sup> and thwart the Congressional intent underlying the Medicaid rebate statute,<sup>3</sup> which reflects a pact

---

<sup>1</sup> Oregon Health Authority, Oregon Health Plan, Section 1115 Demonstration Amendment Draft Application for Public Comment (Dec. 1, 2021), <https://www.oregon.gov/oha/hsd/medicaid-policy/pages/waiver-renewal.aspx> (“Waiver Request”).

<sup>2</sup> Codified at 42 U.S.C. § 1315.

<sup>3</sup> Codified at 42 U.S.C. § 1396r-8.

between government and industry to provide deep rebates in exchange for patient access. Further, the proposed formulary exclusions (even if allowable) would block access to therapeutic advances for serious and life-threatening conditions approved as safe and effective by the FDA for the most vulnerable and neediest group of patients.

## **I. The Commonwealth’s Proposal Fails to Satisfy the Requirements for Section 1115 Waivers.**

Pfizer shares the objections raised by PhRMA, BIO, and other organizations that OHA’s proposal falls outside the scope of waivers allowed by section 1115 and upends key requirements of the Medicaid rebate statute. First, the proposal flies in the face of PhRMA v. Thompson, in which the D.C. Circuit held that SSA section 1115 does not authorize waivers of the Medicaid rebate statute.<sup>4</sup> Second, such a waiver would destroy an essential element of the legislative compromise codified by Congress in the Medicaid rebate statute. Under the rebate statute, manufacturers of innovator drugs pay deep rebates to Medicaid programs, in exchange for Medicaid beneficiaries receiving the drug coverage protections. For innovator drugs, the statute provides Medicaid programs with a price net of the rebate that is at least as low as the manufacturer’s best price to any commercial customer. In fact, the price to Medicaid is often lower than any commercial customer’s price, because the Medicaid rebate statute guarantees Medicaid at least a 23.1% discount on most innovator drugs and an additional rebate that pays dollar-for-dollar the amount by which the average manufacturer price of the drug increases faster than the inflation rate.<sup>5</sup> Many cases have held that when a statute reflects such a legislative compromise, the interpretation of the law should uphold the compromise—not tear it apart.<sup>6</sup> As other commenters have argued, OHA’s proposal would fall short of section 1115 waiver requirements in other significant ways. For example, the proposal is not, in fact, a demonstration, test, pilot, or study—it does not involve any investigation of the impacts on healthcare outcomes, access, delivery, or secondary healthcare costs—but instead represents a mere benefits cut, which is not a permissible subject for a section 1115 waiver.<sup>7</sup>

Other commenters have also addressed the concerns for patient access under the proposal as well as the need for OHA to use the many tools already at its disposal (rather than this problematic proposed 1115 waiver). These themes are explored in more depth in the remainder

---

<sup>4</sup> 251 F.3d 219, 222 (D.C. Cir. 2001) (“Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r–8’s [the Medicaid rebate statute’s] rebate provision or the requirement that Medicaid beneficiaries contribute no more than a ‘nominal’ amount to the cost of medical benefits they receive.”).

<sup>5</sup> Specifically, the Medicaid rebate for innovator drugs equals the higher of the drug’s average manufacturer price (AMP) minus the drug’s best price, or the mandated minimum percentage discount based on product type (23.1 percent for most innovator drugs, 17.1 percent for clotting factors and drugs approved only for pediatric indications, and 13 percent for non-innovator/generic drugs). An additional dollar-for-dollar rebate, referred to as the CPI Penalty, is also required for price increases greater than the inflation rate (and applies to both innovator and non-innovator drugs).

<sup>6</sup> See, e.g., *General Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992) (upholding statutory provisions necessary to “preserve[] the delicate legislative compromise that had been struck by [prior] laws”).

<sup>7</sup> *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994) (“[Section 1115] requires that the state project be an ‘experimental, demonstration or pilot’ project. The statute was not enacted to enable states to save money or to evade federal requirements but to ‘test out new ideas and ways of dealing with the problems of public welfare recipients.’”).

of this comment, in keeping with Pfizer’s support for policies that appropriately promote patient access to prescribed products. We also explain below how granting OHA’s request would be inconsistent with FDA’s authority to grant accelerated approvals.

## **II. OHA’s Proposal Would Jeopardize Access for the Neediest Patients and Block Coverage of Cutting-Edge Treatments for Life-Threatening Conditions.**

### **A. The Proposal Would Exclude Important Medicines That Have Met FDA Standards of Safety and Efficacy**

OHA proposes to “[a]dopt a commercial-style closed formulary with at least one drug available per therapeutic class” and to “[e]xclude from the formulary drugs with limited or inadequate evidence of clinical efficacy,”<sup>8</sup> under sections 3a and 3b of its waiver request, respectively.

Regarding closed formularies, studies suggest that allowing more choice of medications has positive results for patients, including lowering the chances of drug interactions and adverse events, and increasing the efficacy of treatment.<sup>9</sup> Years of research have also shown that limiting formularies correlates to poor medication adherence outcomes.<sup>10</sup> Studies featuring Medicaid recipients with severe health conditions indicate that in many instances, these restrictions can result in negative health outcomes and other outcomes without generating program savings or other intended benefits (and sometimes increasing overall state costs).<sup>11</sup>

Regarding drugs with “limited or inadequate clinical efficacy,” OHA defines this term “as when one or more of the following conditions exist”:

- “Primary endpoints in clinical trials have not been achieved;
- Only surrogate endpoints have been reported;

---

<sup>8</sup> Waiver Request at 30-31.

<sup>9</sup> See, e.g., DiMasi, “Competitiveness in follow-on drug R&D: a race or imitation?” 10 Nat. Rev. Discov. 23-27 (Jan. 2011); Turner et. al, “Parsing Interindividual Drug Variability: An Emerging Role For Systems Pharmacology,” 7 Wiley Interdiscip. Rev. Syst. Biol. Med. 221-41 (2015); Mullins et. al, “Persistence, Switching, And Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, And Citalopram,” 25 Pharmacotherapy 660-67 (2005).

<sup>10</sup> See, e.g., Happeet. al, “A Systematic Literature Review Assessing The Directional Impact Of Managed Care Formulary Restrictions On Medication Adherence, Clinical Outcomes, Economic Outcomes, And Health Care Resource Utilization,” 20 Manag. Care Spec. Pharm. 677-84 (2014).

<sup>11</sup> See, e.g., USC Schaffer, “Medicaid Access Restrictions on Psychiatric Drugs: Penny-Wise or Pound Foolish?” (Feb. 2015), <http://healthpolicy.usc.edu/documents/USC%20Issue%20Brief%20No.%202%20Final.pdf> (indicating increased incarceration rates associated with certain access restrictions); Lu, et. al, “Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness,” 48 Medical Care 4 (Jan. 2010) (finding that while a prior authorization policy in Maine Medicaid was associated with a marked decrease in rates of initiation of bipolar treatments associated with reduction in initiation of nonpreferred agents, the policy had no discernable impact on rates of switching therapy among patients currently on treatment); Farley, et al., “Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications,” 30 Clinical Therapeutics 1524 (April 2008) (showing, for a group of Medicaid patients with schizophrenia who were subject to a prior authorization policy for atypical antipsychotic medications, significant increases in per member per month outpatient expenditures far exceeded the associated savings in a typical antipsychotic expenditures).

- Clinical benefits have not been assessed;
- The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives.”<sup>12</sup>

This language (contained in section 3b of the waiver request) reflects OHA’s misguided attempt to target for exclusion drugs that enter the market through FDA’s accelerated approval pathway.<sup>13</sup> This statutory pathway authorizes FDA to approve a product that treats “a serious or life threatening condition . . . upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit . . . taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative therapies.”<sup>14</sup>

Under the law, FDA must find “substantial evidence” of the drug’s effectiveness, and the applicant must have conducted one or more “adequate and well-controlled studies,”<sup>15</sup> just like drugs approved outside this pathway. Indeed, medicines approved through the accelerated pathway are those that FDA has determined meet the key requirements of safety and efficacy, and that FDA believes should be approved on an expedited basis because they are needed to treat “serious and life-threatening” diseases and conditions.

Existing literature supports this characterization. Researchers at Tufts University, for example, found that drugs cleared through FDA’s expedited review process “offered larger health gains, compared to drugs approved through conventional review processes.”<sup>16</sup> Notwithstanding these health benefits, OHA wishes to target these drugs for formulary exclusion.

While accelerated approval drugs represent the cutting edge of treatment—and meet the exacting FDA approval standards required under law—the proposal would permit OHA to exclude these drugs from coverage on the grounds, for example, that their clinical benefit was established through studies that rely on surrogate endpoints.<sup>17</sup> This exclusion criterion reflects OHA’s misunderstanding of the nature and purpose of validated surrogate endpoints. Under the Food, Drug, and Cosmetic Act (FDCA), FDA can base an accelerated approval “upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the

---

<sup>12</sup> *Id.* at 10.

<sup>13</sup> *Id.* (“Many drugs coming to market through the FDA’s accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints.”).

<sup>14</sup> 21 U.S.C. § 356.

<sup>15</sup> 21 U.S.C. § 355.

<sup>16</sup> James D. Chambers et al., “Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process,” 36 Health Affairs 1408-1415 (Aug. 2017), <http://content.healthaffairs.org/content/36/8/1408.abstract>.

<sup>17</sup> The Commonwealth also includes another criterion, “Primary endpoints in clinical trials have not been achieved.” This criterion is somewhat confusing, since primary endpoints are endpoints that FDA deems essential to establish effectiveness, thus it is not clear that any approved drugs exist for which “primary endpoints in clinical trials have not been achieved.” *See, e.g.*, FDA, Draft Guidance for Industry, Multiple Endpoints in Clinical Trials, at 2 (January 2017).

condition and the availability or lack of alternative treatments.”<sup>18</sup> FDA explains in its guidance that the accelerated approval process requires “that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. This judgment does not represent either a ‘lower standard’ or one inconsistent with section 505(d) of the act [i.e. FDA criteria for refusing applications, including the “substantial evidence” standard].”<sup>19</sup> FDA is the expert agency for determining products’ safety and efficacy, including those receiving accelerated approvals. CMS should not undermine its sister agency by allowing OHA to second-guess FDA by broadly rejecting coverage for products used for their FDA-approved indications.

If the waiver were granted, it would allow OHA to exclude many drugs that received accelerated approval and that thousands of patients, including Oregon Health Plan beneficiaries, depend on for the treatment of severe and life-threatening conditions.

In addition to noting the serious risks for patients who rely on these innovative medications, it is worth pointing out additional problems with OHA’s exclusion criteria. For example, the proposed criterion that “[c]linical benefits have not been assessed” actually does not apply to any FDA approved drug (under either the accelerated or traditional pathways); the criterion is a misguided attempt to target drugs that have been approved based on clinical studies using surrogate endpoints to predict a clinically meaningful benefit. Also, the criterion that that “drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives” is overly broad and could in fact be applied by OHA to exclude from coverage almost any drug. U.S. law does not require a demonstration of “incremental benefit” for product approval. Instead, drugs are approved if they are “safe and effective,” whether the drug receives approval under the traditional or the accelerated pathway.

#### B. An Exceptions Process is No Panacea

The proposal would allow patients to obtain excluded drugs through an exceptions process. However, exceptions procedures for non-formulary drugs, like utilization management restrictions for on-formulary drugs, can lead to a decrease in patient adherence and an increase in overall system cost and inefficiencies. Such burdensome administrative processes can deter or prevent patients from taking medication altogether. Moreover, several studies conducted with Medicaid beneficiaries suggest other ways in which utilization management controls like prior authorization can backfire—for example, by increasing certain costs of outpatient care that outweigh the per-member savings gained by limiting drug utilization.<sup>20</sup> Even where utilization

---

<sup>18</sup> 21 U.S.C. 356(c)(1)(A).

<sup>19</sup> FDA, “New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval,” 57 Fed. Reg. 58942, 58944 (Dec. 11, 1992).

<sup>20</sup> Farley, et al., “Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications,” 30 *Clinical Therapeutics* 1524 (April 2008) (“Among patients with schizophrenia, the PA policy was associated with a \$19.62 per member per month (PMPM) decrease in atypical antipsychotic expenditures and a \$2.20 PMPM increase in typical antipsychotic expenditures (both,  $P < 0.001$ ). Among the same patients with schizophrenia, however, the reduction in atypical antipsychotic expenditures was accompanied by a \$31.59 PMPM increase in expenditures for outpatient services ( $P < 0.001$ ).”).

management is successful in switching patients to lower-cost sales channels or lower-tier medications, such changes do not always result in greater cost savings overall.<sup>21</sup>

Clinical judgement exercised within the bounds of accepted medical practice ought to take precedent over a payer’s cost considerations in decisions about an individual’s care. This is especially true because there is no conclusive evidence that administrative barriers such as prior authorization or step therapy reduce long-term health care costs—and such restrictions may in fact result in higher costs due to possible adverse reactions or other treatment that may be required as the result of nonadherence. For these reasons, applying a blanket exclusion restriction to FDA approved therapies used for their approved indications, not to mention cutting-edge therapies approved through accelerated approval, and forcing patients and providers to rely on an exceptions process to access medically necessary drugs would be a step in the wrong direction, creating new barriers for patients rather than supporting prescriber decision making and pioneering drug development. Pfizer believes that existing utilization management tools provide OHA sufficient control over pharmacy spending. Given the limitations noted above, we believe these tools ought to be applied efficiently and judiciously, in a manner consistent with sound policy and the framework of existing law.

### **III. Granting OHA’s request would be inconsistent with FDA’s authority to grant accelerated approvals.**

Congress explained how it envisioned FDA’s role in the extensive “findings” and “sense of Congress” provisions included in Section 901 of the Food and Drug Administration Safety and Innovation Act (FDASIA), a bipartisan reform in 2012 that amended the federal Food Drug and Cosmetic Act (FDCA) to codify the accelerated approval pathway. Congress addressed both how it saw FDA’s role as a steward of medical innovation as well as the importance of the expedited approval framework to realizing FDA’s duty and purpose:

[FDA] serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation’s strategy to address serious or life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs. [. . .] FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate.<sup>22</sup>

FDA has recognized this statutory mandate through public statements, such as in a 2015 white paper in which FDA declared: “finding effective treatments for rare diseases is a public health priority, and FDA has brought to bear all of its drug review and technical assistance tools

---

<sup>21</sup> See, e.g., Martin, et. al, “Impact of a Novel Cost-Saving Pharmacy Program on Pregabalin use and Health Care Costs,” 22 J. Managed Care & Specialty Pharmacy 132 (Feb. 2016).

<sup>22</sup> Pub. L. 112–114, title IX, §901(a), July 9, 2012, as amended by Pub. L. 114-255, div. A, title III, §3101(b)(1), Dec. 13, 2016, 130 Stat. 1156.

to assist the development of new treatments for these conditions.”<sup>23</sup> FDA also acknowledged that Congress built on this framework through the passage of the 21<sup>st</sup> Century Cures Act:

With [21<sup>st</sup> Century Cures,] great progress has been made towards our shared goal of advancing regulatory science so that we can continue to speed the discovery, development, and delivery of medical products to prevent and cure disease and improve health while sustaining the evidence framework that enables assurance to the public of the safety and effectiveness of medical products.<sup>24</sup>

As these sources indicate, FDA’s role as contemplated by Congress is to apply FDA’s technical expertise to speed the development and approval of safe and effective medicines—including drugs that treat serious conditions and fill an unmet need. FDA exercises tools for regulatory flexibility in service of this mission. Congress has recognized that it is because of FDA’s expertise that FDA is able to use these tools to promote (and not hamper) the development and approval of safe and effective medicines.

OHA’s proposed section 1115 waiver request would undercut FDA’s role, by substituting the judgement of OHA for that of FDA.<sup>25</sup> We think that Congress never would have intended such an outcome, as it would conflict with the statutory framework Congress devised under FDCA and its amendments.

As courts have described, section 1115 allows CMS to exercise its own wisdom to determine whether a state experiment in social services programs and benefits should be allowed: Congress “intended that the Secretary would ‘selectively approve[]’ state projects,” and gave the HHS Secretary “plenary authority to reject State projects and to require States to modify projects to make them more consistent with federal requirements, less likely to harm recipients, and more likely to further the goals of the Social Security Act.”<sup>26</sup>

Moreover, OHA’s proposed 1115 waiver would violate a core principle of statutory interpretation—that where potential conflicts exist between two federal statutes, one should adopt “the interpretation that preserves the principal purposes of each.”<sup>27</sup> If the two laws cannot be reconciled, courts generally give effect to the “later-enacted, more specific statute.”<sup>28</sup> Here, OHA’s proposed 1115 waiver would usurp FDA’s authority and contradict the aims of FDCA in creating a cutting-edge legal framework for the exercise of FDA technical expertise.

---

<sup>23</sup> FDA White Paper, FDA and Accelerating the Development of New Pharmaceutical Therapies, 7-8 (March 23, 2015).

<sup>24</sup> 21<sup>st</sup> Century Cures Act; Making Progress on Shared Goals for patients, FDA Commissioner Dr. Robert M. Califf, FDA Voice, December 13, 2016.

<sup>25</sup> Waiver request at 9 (“Massachusetts seeks the ability to use its own rigorous review process, in partnership with the University of Massachusetts Medical School, to determine coverage of new drugs and to guarantee that patients access clinically proven, efficacious drugs.”).

<sup>26</sup> Beno v. Shalala, 30 F.3d 1057, 1069 (9th Cir. 1994)(internal citations omitted).

<sup>27</sup> See, e.g., SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc., 211 F.3d 21, 27-28 (2d. Cir. 2000).

<sup>28</sup> Hawaii v. Trump, 859 F.3d 741, 778 (9th Cir. 2017).

\*\*\*

Again, Pfizer appreciates the opportunity to comment on OHA's proposed 1115 waiver renewal and amendment application. If you have questions or need additional information, please contact Tom Brownlie at [thomas.brownlie@pfizer.com](mailto:thomas.brownlie@pfizer.com).

Joyce Rogers

A handwritten signature in cursive script that reads "Joyce Rogers".

Vice President  
U.S. Policy and Public Affairs



January 3, 2022

To whom it may concern:

I am writing on behalf of Cascade AIDS Project (CAP) and the undersigned organizations to submit public comment on Oregon's draft 1115 Medicaid Demonstration Waiver application.

Founded in 1985 as a grassroots response to the AIDS crisis, CAP is now the oldest and largest HIV-services provider in Oregon. We and our allies are deeply concerned by the proposal in Oregon's draft application to adopt a closed formulary approach, and **we urge the state to commit in the application to maintaining open access to HIV treatment medications.**

Although we understand the reasons for adopting a closed formulary, this approach is not appropriate for HIV treatment medications, for a number of reasons:

- (1) HIV is a highly individual disease. Different people living with HIV have different treatment needs based on their specific medical history and the resistance(s) to medication that may have developed in their bodies. As a result, people living with HIV and their healthcare providers need maximum flexibility to select an HIV treatment regimen that is right for them.
- (2) HIV disproportionately impacts people who are also experiencing challenges such as homelessness, mental illness, and/or substance-use disorder. Members of this population may need simpler, more manageable HIV treatment regimens (e.g., single-tablet regimens) to remain adherent to their medications, but closed formularies can restrict access to those regimens by not factoring social determinants of health into decision-making on coverage.
- (3) Utilization-management techniques used in a closed-formulary approach, such as prior-authorization requirements, can cause abandonment of treatment, especially for those already at risk of falling out of care. For people living with HIV, in particular, the consequences can be disastrous: Medication non-adherence can lead not only to poor health outcomes, but also to permanent resistance to a drug or entire class of drugs.
- (4) People who are living with HIV and in successful treatment cannot transmit the virus through sex. However, if people fall out of care, as utilization management can cause them to do, they can spread HIV to their sexual partners. Adherence is, therefore, a public-health issue as well as an individual one.

**Chief Executive Officer**

Tyler TerMeer, PhD

**Board of Directors**

**President**

Karol Collymore  
Nike

**Vice President**

William E. Spigner  
Nike

**Secretary**

Miguel Villarreal  
Kaiser Permanente

**Treasurer**

Edwin Kietzman  
Smart Foodservice  
Warehouse Stores

**Member at Large**

Kris Young  
Nike

**Tracy A. Curtis**

Wells Fargo Bank

**Eric Garcia**

Multnomah County

**Daniel Guilfoyle**

Native American Youth &  
Family Center (NAYA)

**Andy Jamison-LeGere**

OnPoint Community Credit  
Union

**Jordan Olson**

Community Volunteer

**Rhodes Perry**

Rhodes Perry Consulting, LLC

t > 503 223 5907

f > 503 223 6437

capnw.org

520 Northwest Davis Street, Suite 215 Portland, Oregon 97209

For all these reasons, it is considered best practice to ensure access to HIV treatment medications, even within a closed-formulary approach. This is why **antiretrovirals are designated as a drug class “of clinical concern” within Medicare Part D, requiring Part D plans to cover all drugs within that class** (rather than only two or more drugs, as for most classes). It’s also why the federal agencies responsible for ending the HIV epidemic direct states to “design their prescription drug formularies to minimize potential barriers presented by utilization management techniques so that Medicaid...beneficiaries can readily access all [HIV] regimens.”<sup>1</sup> Several states, including California, Colorado, and Illinois, have gone so far as to codify in statute protections from utilization-management techniques for Medicaid members living with HIV.

Oregon currently includes all U.S. Food and Drug Administration-approved HIV drugs on its Preferred Drug List, and the above-average health outcomes of Oregonians living with HIV reflects such public policies. Ensuring access to HIV treatment medications bolsters not just Oregon’s efforts to end the HIV epidemic, but the state’s commitment to eliminating health inequities as well, because Black, Latinx, and Indigenous Oregonians are more likely to be living with HIV, and more likely to experience poor HIV health outcomes (e.g., viral non-suppression). We hope that Oregon will remain aligned with best practice and the state’s own strategic goals by **committing in its 1115 waiver application to maintain open access to HIV treatment medications.**

Sincerely,

Jonathan Frochtz wajg  
Public Policy & Grants Manager, CAP



<sup>1</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf>



January 7, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
Oregon Health Authority  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Comments on Oregon Health Plan 1115 Demonstration Waiver Application for Renewal

Dear Ms. Hatfield:

We appreciate this opportunity to provide comments as the Oregon Health Plan (OHP) applies to the Centers for Medicare & Medicaid Services (CMS) for a new five-year Medicaid waiver, known as the 1115 Demonstration. We hope that the state will incorporate the perspectives of people with disabilities that disproportionately are impacted by the state's prioritized list of services by barring the use of the discriminatory quality-adjusted life year (QALY) as a consideration; by ensuring that individuals with disabilities and significant health conditions do not face discrimination in accessing suicide prevention services; and by discontinuing the EPSDT waiver that too often fails to give children the care they need.

As you know, in 1992, Oregon submitted a waiver application relying on the QALY to prioritize services for coverage that was denied by the U.S. Department of Health and Human Services as "discriminatory and inconsistent with the Americans with Disabilities Act."<sup>1</sup> The waiver was later approved in 1993, after committing to changes for ADA compliance. Despite ADA concerns, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost effectiveness and the QALY. Officially, Oregon excluded the survey-based QALY data that triggered denial of its initial waiver application in 1992. Yet, the voting members of Oregon's Health Policy Commission have authority to

---

<sup>1</sup> <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

override the results of non-QALY considerations, which they did in over 70% of the cases. The discriminatory outcome for how care is valued and prioritized is the same.<sup>2</sup>

Today, the Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, continues to use QALY-driven data and analysis in the formula for the prioritized list of services. As reconstructed in 2008, Oregon's revised prioritization framework emphasizes preventive services and chronic disease management in order to keep the "population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health." This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. Although Oregon removed a direct and explicit reference to QALYs from its cost-effectiveness framework in 2017, it continues to rely upon the QALY-driven prioritization scores for condition-treatment pairs that were already established at that time. In addition, HERC continues to consider QALY-based analysis in evaluating other factors in the formula.<sup>3</sup>

The HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by entities such as the Institute for Clinical and Economic Review (ICER) as they vote. After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list. A few excluded services for people with disabilities include treatment for hearing impairment, Bell's Palsy, Spastic Diplegia, and certain personality disorders.<sup>4</sup>

Oregon also chooses to provide coverage for some services that aren't on the list at all. For instance, it is the policy of the state of Oregon to provide Medicaid coverage of physician-assisted suicide, including counseling and lethal prescriptions. It has been reported that OHP patients who have been denied coverage of potentially life-extending health services that were "below the line" have been advised by OHP that physician assisted suicide is a covered alternative.<sup>5</sup> This outcome – preference for assisted suicide over treatment – is the direct result of the state's discriminatory policies and is clearly unethical and in violation of disability and civil rights protections.

The ethical challenges of Oregon's use of discriminatory metrics to ration services it will cover are exacerbated for children. Oregon is the only state with an EPSDT waiver. In every other state, under Federal law, Medicaid includes a critical benefit for children and adolescents under the age of 21, called "Early and Periodic Screening, Diagnostic and Treatment" (EPSDT) to ensure that they receive "age-appropriate screening, preventive services, and treatment services that are medically necessary to correct or ameliorate any identified conditions – the right care to the right child at the right time in the right setting." Critically, the EPSDT provision requires comprehensive coverage of health services for children – *regardless of whether or not such services are otherwise covered* under the state

---

<sup>2</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf>

<sup>3</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx>

<sup>4</sup> <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>

<sup>5</sup> <https://abcnews.go.com/Health/story?id=5517492&page=1>

Medicaid plan for adults ages 21 and older – to make certain that rationing is not imposed for this vulnerable population.<sup>6</sup> Even still, Oregon’s Section 1115 Medicaid waiver includes a provision authorizing it to withhold medically necessary care from children over the age of one if it is “below the line” on its “Prioritized List” of health services. A few examples include noncoverage of treatment for selective mutism, conduct disorder, recurrent ear infections, minor burns, and pica.

We believe it is time to end this failed experiment of relying on discrimination to ration care. Our specific recommendations are as follows:

**1. Full Compliance with EPSDT**

The provision allowing Oregon to “[r]estrict coverage for treatment services identified during Early and Periodic Screening, Diagnosis and Treatment (EPSDT) to those services that are consistent with the prioritized list of health services for individuals above age one” should be removed. Oregon should comply fully with EPSDT, to ensure that all EPSDT-eligible children receive the medically necessary care that Congress intended, without rationing.

**2. Prohibit the Use of Discriminatory QALY Measures**

The waiver should include a provision explicitly renouncing use of discriminatory measures such as QALYs, such as this:

“Prohibition on Reliance on Discriminatory Measures. The state shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per- quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs.”

**3. Non-discrimination in Suicide Prevention Services**

The waiver should include a provision affirming that patients with disabilities who express a desire to harm or kill themselves in a medical setting, even when they qualify for lethal drugs under Oregon’s “Death with Dignity Act,” will be provided with the same harm and suicide prevention services<sup>7</sup> as the general public. No patient should ever be placed under pressure – intentional or otherwise – to die by suicide because of the subjective judgments on the value of their lives or an inability to find coverage for medically indicated care, treatments, or therapies.

---

<sup>6</sup> <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>

<sup>7</sup> The term “harm and suicide prevention services” includes screening, diagnosis, psychiatric treatment, therapy, counseling, and other services whose purpose is the detection and treatment of suicidal ideation and tendencies and the causes thereof, including depression, mental disorders, and lack of access to rehabilitative and supportive care.

We appreciate the opportunity to comment.

Sincerely,

[Disability Policy Consortium](#)

[Disability Rights California](#)

[Disability Rights Education and Defense Fund](#)

[Not Dead Yet](#)

[Patients Rights Action Fund](#)

[Partnership to Improve Patient Care](#)

[The Coelho Center for Disability Law, Policy, and Innovation](#)



**BY ELECTRONIC DELIVERY**

January 7, 2022

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, 5th Floor, E65  
Salem, OR 97301

**RE: Application for Renewal and Amendment Oregon Health  
Plan, Section 1115 Demonstration Waiver**

Dear Director Allen:

The Rare Disease Company Coalition (RDCC) appreciates the opportunity to provide comments on the state of Oregon's application for a section 1115 Demonstration Waiver. We appreciate the state's intention to be responsive to the community feedback and request the state consider our serious concerns with the potential impact of the demonstration waiver on the discovery and development of new medicines, particularly on treatments and cures for patients with rare diseases who currently have limited or no treatment options.

In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people. There are 7,000 identified rare diseases that impact an estimated 25 to 30 million Americans. These diseases are devastating and often life-threatening: 80 percent of rare diseases are genetic in origin, 50 percent impact children, and 30 percent of those children will not live to see their 5th birthday. While only 7 percent of rare diseases have an FDA-approved treatment, the 20 life science companies comprising the RDCC are committed to continuing to change these statistics by discovering, developing, and delivering rare disease treatments for patients. Our goal is to inform policymakers of the unique challenges—and promises—we face in taking these rare disease drugs from research through development, approval, manufacturing, to delivery to patients. Collectively, Coalition members invested over \$4.5 billion in R&D in 2020; have brought 36 treatments to market to date, the majority of which are first-to-market therapies; and are presently working on more than 225 rare disease development programs, many of which would be first-to-market therapies if approved. We are focused on working to meet the needs of rare disease patients with currently limited or no treatment options.

The RDCC has significant concerns with the Oregon Health Authority's (OHA) request to establish a closed formulary for the state's Medicaid program that could limit coverage to one drug for each therapeutic class and would exclude drugs approved via the Accelerated Approval pathway. We believe a closed formulary is not in the best interest of patient health, particularly for patients with rare disease, and that this proposal would curtail innovation in the discovery and

development of new treatments. We believe this could potentially deny Medicaid patients access to important medical advances.

Our specific concerns are as follows:

### **Oregon's 1115 Demonstration Waiver would impact innovation for rare disease treatments and cures**

Rare diseases present specific challenges - such as small population sizes, or slow, irreversible, and variable disease progression - that make it difficult to study in some cases using clinical measures as endpoints. The Accelerated Approval pathway is a critical tool, well-suited to recognize these unique circumstances. If these drugs are not covered by state Medicaid programs thereby limiting patient access, manufacturers have little incentive to pursue research and development in rare diseases, as an already small (rare) population becomes smaller.

Oregon's approach simply does not align with the intent of the Accelerated Approval pathway to expedite access to rare disease treatments for patients with serious conditions, especially for diseases that have limited or no treatment options. We are concerned about the impact to these patients and the broader impact on the entire rare disease community, regardless of payor, because we believe the OHA 1115 Demonstration Waiver would effectively disincentivize and curtail research and development for the treatment of certain rare diseases. Ultimately, this approach would punish patients who are forced to suffer as their disease progresses while continuing to wait for a treatment. For example, the Accelerated Approval pathway can be credited for changing the trajectory of scientific advancement for HIV/AIDS and for oncology. We also note that a significant proportion of rare disease patients are children who are on Medicaid and while the Oregon waiver would maintain an open formulary for children, we note that these children would potentially lose access to these drugs when they reach adulthood.

### **Oregon's 1115 Demonstration Waiver would undermine the intent of the Accelerated Approval pathway and FDA's role as the sole arbiter of determining safety and efficacy**

We believe that subjecting medicines that are approved via the FDA Accelerated Approval pathway to additional scrutiny based on their pathway for approval undermines the purpose of the Accelerated Approval pathway and disregards its benefits to patients with unmet medical needs, including those with rare diseases. Targeting Accelerated Approval therapies could deprive patients who suffer from certain conditions the important, safe, and effective therapies they need. In many cases, these therapies are the only effective course of treatment for their disease.

By law (21 U.S.C. § 356(e)(2)), the FDA must find "substantial evidence of effectiveness" to approve any drug, including drugs approved via the Accelerated Approval pathway. The Accelerated Approval pathway is a targeted and robust, science-based pathway established by Congress and the FDA to speed the availability of new therapies to patients with serious conditions,<sup>1</sup> especially when there are no available alternatives, while preserving the FDA's

---

<sup>1</sup> Serious condition is defined as: "...a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is

rigorous standards for safety and effectiveness. In 1992, the FDA established a new expedited pathway to speed approval of medicines that treat serious conditions and address an unmet need, later codified by Congress in 1997.<sup>2</sup> In 2012, Congress passed the Food and Drug Administration Safety Innovations Act (FDASIA) that amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow the FDA to reinforce and enhance the Accelerated Approval pathway in FDASIA and encouraging broader applicability for rare disease.<sup>3</sup> The Accelerated Approval pathway has been credited with significant advances in the treatment of life-threatening diseases where patients have limited or no treatment options. Historically, this pathway has been used primarily for oncology drugs with 174 oncology accelerated approvals through June 30, 2021.<sup>4</sup> In fact, from 2010-2020, 85 percent of the agency's accelerated approvals have been for oncology indications.<sup>5</sup> We believe this can be a critical pathway for rare diseases as well.

The FDA's Accelerated Approval pathway is a well-established, proven, regulated path forward for certain drugs that rely on the use of surrogate or intermediate clinical endpoints to determine the effectiveness of a therapy. Surrogate endpoints are imperative to getting rare disease treatments to patients as there is limited disease knowledge and small populations so determining a clinical endpoint is rarely feasible. Congress, the FDA, and the scientific community have all recognized the important role of surrogate endpoints as relevant and reliable biomarkers to assess effectiveness in certain circumstances, particularly for slowly progressing, debilitating diseases where verification of clinical benefit may take many years.<sup>6</sup>

Both Congress and the FDA have been clear in affirming that accelerated approval does not diminish or compromise FDA's stringent approval standards. Notably, the FDA has maintained that prescription drugs and biologics approved under the Accelerated Approval pathway must meet clinically meaningful endpoints and that the benefits of the treatment must outweigh the risks of treatment, finding that *"Approval...requires ... that the effect shown be, in the judgment of the agency, clinically meaningful, and of such importance as to outweigh the risks of treatment. This judgment does not represent either a "lower standard" or one inconsistent with section 505(d) of the act, but rather an assessment about whether different types of data show that the same statutory standard has been met."*<sup>7</sup>

The FDA has noted that the Accelerated Approval pathway "ensure[s] that therapies for serious

---

persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one." 21 CFR 312.300(b)(1); <https://www.fda.gov/media/86377/download>

<sup>2</sup> <https://www.govinfo.gov/content/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf>

<sup>3</sup> <https://www.govinfo.gov/content/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>

<sup>4</sup> CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint (As of June 30, 2021). Accessed December 22, 2021. <https://www.fda.gov/media/151146/download>

<sup>5</sup> See Friends of Cancer Res., Optimizing the Use of Accelerated Approval 3(2020) ("FOCR Report"), [https://friendsofcancerresearch.org/sites/default/files/2020-11/Optimizing\\_the\\_Use\\_of\\_Accelerated\\_Approval-2020.pdf](https://friendsofcancerresearch.org/sites/default/files/2020-11/Optimizing_the_Use_of_Accelerated_Approval-2020.pdf) (stating that 84% of accelerated approval drugs from 2010 to 2019 were for oncology indications); CDER Drug and Biologic Accelerated Approvals, supra note 72 (stating that FDA has granted 253 accelerated approvals as of December 31, 2020, of which 9 were approved after June 30, 2020 and 7 were for oncology drugs); see also Julia A. Beaver & Richard Pazdur, "Dangling" Accelerated Approvals in Oncology, 384 New Eng. J. of Med. e68(1), 1 (May 2021) ("[A]pproximately 85% of accelerated approvals in the past 10 years have been granted in oncology.").

<sup>6</sup> <https://www.fda.gov/news-events/fda-voices/delivering-promising-new-medicines-without-sacrificing-safety-and-efficacy>

<sup>7</sup> 57 Fed. Reg. at 58944.

conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks."<sup>8</sup> The Agency has also emphasized that the accelerated approval procedures "are intended to provide expedited marketing of drugs for patients suffering from such [serious or life-threatening] illnesses when the drugs provide meaningful therapeutic advantage over existing treatment"<sup>9</sup> and that "it is in the public interest to make promising new treatments available at the earliest possible point in time for use in life-threatening and serious illnesses."<sup>10</sup>

Oregon's interest in making determinations that would deny coverage for drugs "with limited or inadequate evidence of clinical efficacy" based on the state's own review process is particularly troublesome. We believe it is inappropriate for OHA to substitute its own judgement for determinations related to clinical efficacy of drugs that have been reviewed and approved by the FDA. The FDA remains the gold standard for drug safety and efficacy. Moreover, Oregon's efforts to supplant FDA authority go beyond just excluding Accelerated Approved drugs. Oregon's request would seek to exclude drugs with "no incremental clinical benefit within its therapeutic class, compared to existing alternatives." FDA's drug approval framework does not require evidence of an "incremental benefit" over existing therapies for a demonstration of safety and efficacy. Overall, such an approach implies that Oregon is better suited to review drugs than the scientists and disease experts at the FDA. Establishing such a framework undermines the important, independent authority of the FDA as the sole arbiter of safety and efficacy.

### **Closed formularies are not in the best interests of rare disease patients with limited to no treatment options**

We have great concerns that Oregon's proposal to cover as few as one drug per therapeutic class would seriously jeopardize the health of patients and would hinder access to quality of care for the most vulnerable patients, especially those with rare, life-threatening diseases. For many therapeutic classes, such restrictions could leave impacted Medicaid beneficiaries without access to the physician-prescribed medicine deemed most appropriate. Given the heterogeneity within patient populations and the advancement of precision medicine, providing access to a wide variety of drug options is foundational to appropriate patient care. One formulary agent may not produce the intended therapeutic outcome or have the same side effects across patient types which could be detrimental to Medicaid patients in Oregon, particularly those with rare diseases. The Oregon approach would also provide fewer protections for Medicaid beneficiaries. For example, it does not provide any access protections or require its closed formulary to adhere to the Essential Health Benefits benchmark standards. We also note this approach would not align with the interests of CMS in consistency across programs – specifically Medicaid and Medicare – given the Medicare Part D coverage requirement of at least 2 drugs per drug category/class.

### **Oregon's 1115 Demonstration waiver is not consistent with foundational Medicaid policies.**

---

<sup>8</sup> FDA. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics. May 2014

<sup>9</sup> 57 Fed. Reg. 58942.

<sup>10</sup> 57 Fed. Reg. at 58944

The Medicaid Drug Rebate program represents a carefully balanced compromise made by Congress under the Omnibus Reconciliation Act of 1990 to ensure the federal government has access to the lowest available price for covered outpatient prescription medicines – via a statutorily mandated rebate – while also ensuring that manufacturers’ products would be accessible to Medicaid recipients if medically necessary and subject to statutorily defined access restrictions. The Oregon demonstration waiver would disrupt this long-term, successful Medicaid policy that has facilitated access to medicines for beneficiaries with a fiscally prudent approach.

We note that severely limiting beneficiary access to physician-prescribed medicines in the Medicaid program has already been rejected by the Centers for Medicare and Medicaid Services (CMS). In 2017, the Commonwealth of Massachusetts proposed a closed formulary with at least one drug per class, with the intent to exclude drugs approved through the FDA’s Accelerated Approval process. These policies were firmly rejected by CMS, indicating that a state cannot simply opt out of the Medicaid Rebate Program, and not provide access to “covered outpatient drugs” for which a manufacturer has a signed National Rebate Agreement.<sup>11</sup> Of note, the same day that CMS responded to the Massachusetts waiver amendment, the agency issued “State Release No. 185,” which underscored the fact that drugs approved through the FDA’s expedited approval processes “must be covered by state Medicaid programs, if the drug meets the definition of “covered outpatient drug” as found in Section 1927 of the Social Security Act”<sup>12</sup> and the Manufacturer has a signed Medicaid National Rebate agreement. We believe these policies demonstrate continued support by CMS for patient access to medicines facilitated by the Medicaid Drug Rebate Program.

### **This approach would not promote the elimination of health disparities nor the achievement of health equity**

OHA’s approach to establish a closed formulary for adults and to not cover drugs approved via the Accelerated Approval pathway is in direct conflict with the state’s purported goal of the 1115 Demonstration waiver: “to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon.” The Health Equity Committee, a subcommittee of the Oregon Health Policy Board (OHPB) was tasked with coordinating and developing policy that proactively promotes the elimination of health disparities and the achievement of health equity for all people in Oregon and the state has a goal of “eradicating health inequities by 2030.” This is an admirable goal for the state, as 27% of the state’s population is considered low-income, below 200% of the Federal Poverty Level. However, rather than making progress toward Oregon’s goal of eradicating health disparities, Oregon’s proposed closed formulary would likely create additional health disparities for rare disease patients, especially those who are also part of racial and/or ethnic minority group. Without the ability to have coverage of a medicine that may not be included in Oregon’s closed formulary, these issues will be exacerbated and could result in poor health outcomes and increased costs of care, rather than achieving the state’s goals of eliminating health disparities and the achievement of health equity for all people in Oregon. Individuals with rare diseases tend to report common concerns that result from being underserved, such as a long road to diagnosis, limited treatment

---

<sup>11</sup> CMS letter to Asst. Secretary Tsai, MassHealth, June 27, 2018.

<sup>12</sup> CMS State Release No. 185, June 27, 2018.

options, and a need for research to better understand their medical condition.<sup>13</sup> Rare diseases are disproportionately prevalent among some racial and ethnic minority groups. These patients may also face greater disease burden, earlier age of disease onset, and/or complex sets of comorbidities that limit the safety and effectiveness of older treatment options. We believe the Oregon approach sends a message to patients with high unmet needs that their lives are not worth the investment; we strongly oppose that sentiment.

### **Oregon's 1115 Demonstration Waiver would have a limited budgetary impact**

Historical claims analysis suggests that a closed formulary would not be likely to yield significant savings to OHA. From 2007 to 2018, Accelerated Approval drugs account for less than 1% of overall Medicaid spending while often representing the only treatment options available for beneficiaries.<sup>14</sup> The same analysis continues to conclude that “[l]imiting Medicaid coverage for accelerated approval drugs would have a devastating impact on patients benefiting from these treatments while having a de minimis impact on spending.”<sup>15</sup>

Thank you for the opportunity to submit comments on the OHA's section 1115 Demonstration Waiver Renewal and Amendment application. The RDCC is greatly concerned about the impact of the proposed closed formulary provisions on the rare disease community and we respectfully request your reconsideration of this proposal.

Should you have any questions, please feel free to contact Patroski Lawson, Interim Executive Director of the RDCC at [patroski@kpmgroupdc.com](mailto:patroski@kpmgroupdc.com)

Sincerely,  
Patroski Lawson

---

<sup>13</sup> Barriers To Rare Disease Diagnosis, Care and Treatment In The US: A 30-Year Comparative Analysis, NORD 2020, [https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report\\_FNL-2.pdf](https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report_FNL-2.pdf)

<sup>14</sup> Am J Manag Care. 2021;27(6):e178e180. <https://doi.org/10.37765/ajmc.2021.88596>

<sup>15</sup> Am J Manag Care. 2021;27(6):e178e180. <https://doi.org/10.37765/ajmc.2021.88596>



January 7, 2022

Mr. Patrick Allen  
Director  
Oregon Health Authority  
Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Dear Director Allen,

Traverse Therapeutics, Inc. (Traverse) appreciates the opportunity to provide comments on Oregon Health Authority's draft Section 1115 waiver and applauds the state for its innovative approaches. However, if the waiver is submitted and approved by the Centers for Medicare and Medicaid (CMS) as proposed, Traverse is concerned about two provisions: 1) limiting drug access to patients for therapies approved through the Federal Food and Drug Administration's (FDA) accelerated approval pathway; 2) enacting a closed formulary. We urge the state to revise its waiver request and remove these provisions before formally submitting to CMS.

Traverse is a small biotechnology company based in San Diego, exclusively focused on identifying, developing, and delivering life-changing therapies to people living with rare disease. We have three approved products that are used by patients each day to treat rare nephrology and hepatology conditions. We also have late-stage research and development (R&D) programs with first-in-class potential for rare kidney conditions, and ongoing discovery efforts partnered with the National Institutes of Health (NIH) and leading patient advocacy organizations.

While millions of Americans have a rare disease or live with someone who does, the patient population living with any given rare disease is very small, even miniscule. By definition, rare disease patient populations are less than 200,000 people residing in the U.S., and in many cases are much smaller – one of our therapies serves under 100 U.S.-based patients. People with rare disease face unique challenges and often have very

**Traverse Therapeutics, Inc.**

3611 Valley Centre Drive, Suite 300, San Diego, CA 92130  
888-969-7879 | [traverse.com](http://traverse.com) | @TraverseRare    

limited treatment options.<sup>1</sup> The complex nature of rare diseases combined with small patient populations presents a unique set of challenges to developing treatments for rare diseases and facilitating their access. In fact, 95% of the approximately 7,000 known rare diseases still have no treatment available.<sup>2</sup> Yet, for the 5% of patients that have the hope that comes with an FDA-approved treatment for their condition, it is likely that treatment was approved via the accelerated approval pathway due to the unmet need and burden of the disease.

Travere writes to express concerns and ask the state to reconsider the following two provisions included in its draft waiver request:

**Limits to Drugs Approved Via Accelerated Approval Would Decrease Access for Rare Disease Patients That Already Have Very Limited Options**

Travere, and others, are deeply concerned about the state's proposal to use its own review process to determine coverage of new drugs. If this proposal moves forward, Oregon could exclude drugs approved through FDA's accelerated approval process from its formulary. This would be devastating for the state's rare disease community as "accelerated approval offers a valuable source of hope," according to the National Organization for Rare Disorders.<sup>3</sup> Additionally, the draft waiver proposes to use discretion of drugs when certain conditions, like only "surrogate endpoints have been reported." Surrogate endpoints are a crucial aspect of the FDA accelerated approval pathway that help allow patients access to life-changing medicine when there is an unmet need, without sacrificing safety and efficacy. In sum, Travere disagrees with the state's interpretation of the intent of the 21<sup>st</sup> Century Cures Act.

In 2018, CMS notes in *State Release 185* that these drugs must be covered by the Medicaid program if there is a signed Medicaid National Rebate Agreement, but it also reaffirms that these drugs go through the same rigorous approval as drugs through the traditional approval process. *State Release 185* notes,

"Drugs granted accelerated approval by FDA under the process described in 506(c) of the FDCA are approved under section 505(c) of the FDCA and must meet the same statutory evidentiary standards for safety and effectiveness as those granted traditional approvals. See section 506(e)(2) of the FDCA. Thus, as noted above, at the time a product is granted accelerated approval, FDA has based such an approval on a determination that the drug has an effect on a

---

<sup>1</sup> See, e.g., Gina Kolata, *'It Will Consume Your Life': 4 Families Take On Rare Diseases*, N.Y. TIMES, July 7, 2020, <https://www.nytimes.com/2020/07/07/health/rare-diseases.html>.

<sup>2</sup> Rare Diseases Clinical Research Network, National Institutes of Health, available at <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=126>.

<sup>3</sup> [https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report\\_Accelerated-Approval\\_FNL.pdf](https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf)

surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint other than survival or irreversible morbidity.”<sup>4</sup>

Drugs approved via the accelerated approval pathway are a lifeline for the more than 95% of rare disease patients that do not yet have access to an FDA-approved treatment. If Oregon moves forward with circumventing the FDA process, which is considered to be the “gold standard” for review and efficacy of drugs, there would likely be unequal treatment and worsened health outcomes for patients already dealing with serious, life-threatening diseases. More is explained in the extensive findings and sense of Congress provisions of the *Food Drug Administration Safety and Innovation Act*, §901:

“[FDA] serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation’s strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.”

Drugs approved through the accelerated approval pathway are subject to a demanding standard of review — demonstration of “substantial evidence” of effectiveness.<sup>5</sup> In fact, studies have found that certain drugs reviewed under the accelerated approval processes have offered greater medical gains than drugs reviewed through the FDA’s traditional, lengthier process.<sup>6</sup> Importantly, for drugs granted accelerated approval, post-approval confirmatory trials or studies are required as part of the regulatory process to verify and describe the anticipated clinical benefit.<sup>7</sup> If the confirmatory trial fails to verify benefit, the FDA has the authority to withdraw approval and has done so when needed.<sup>8</sup>

Furthermore, if the goal of this section of the waiver is to save costs or improve care, we believe that is misguided. According to Medicaid claims data from 2007 to 2018, accelerated approval drugs only accounted for less than 1 percent of Medicaid spending.<sup>9</sup> For the impacted families living with rare disease, “...downstream access concerns have emerged that could be chilling the appetite for investing in accelerated approval programs and [leave] patients without access to beneficial treatment,” according to the EveryLife Foundation for Rare Diseases.<sup>10</sup>

---

<sup>4</sup> *State Release 185*, CMS, June 27, 2018.

<sup>5</sup> 21 U.S.C § 355(d)(5).

<sup>6</sup> Chambers, et al., *Drugs Cleared Through the FDA’s Expedited Review Offer Greater Gains Than Drugs Approved by Conventional Process*, Health Affairs Vol. 36, No. 8, 2017.

<sup>7</sup> FDA. *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics*. May 2014.

<sup>8</sup> FDA. *Delivering Promising New Medicines Without Sacrificing Safety and Efficacy*. FDA Voices: Perspectives from FDA Leadership and Experts. August 2019.

<sup>9</sup> <https://www.fightchronicdisease.org/sites/default/files/FINAL%20Quantifying%20Impact%20-%20White%20Paper%20v6.pdf>

<sup>10</sup> <https://everylifefoundation.org/events-schedule/scientific-workshop/>

## **Closed Drug Formularies Harm Rare Disease Patient Care**

Travere is also concerned about the state using a closed formulary approach and the impact that would have on rare disease patients that rely on Medicaid. If Oregon proceeds with covering one drug per therapeutic class, patient care and well-being would be severely compromised. It is not uncommon for rare disease patients to take multiple drugs to manage their condition. The decision on the best course of treatment should remain between the provider and patient, not the state's Medicaid program.

Medicaid is a lifeline for many rare disease patients and families. There could be many unintended consequences to the overall health of patients in Oregon if access is limited to only certain medications through a closed formulary approach. For example, medication adherence would likely decrease leading to worsened health outcomes.<sup>11</sup> Additionally, we believe a closed formulary approach will only further exacerbate disparities in care that could lead to delays and worsened health outcomes. We urge Oregon to reconsider this approach and prioritize rare disease patients living in the state.

## **Conclusion**

Travere strongly encourages the Oregon Health Authority to protect the core objectives of the Medicaid program and refrain from moving forward with the proposed outlined provisions above. Rare disease patients in the state rely on the Medicaid program for access to their needed treatments and care. We urge Oregon to revise its proposal before submitting to CMS and we look forward to working with you to advocate for better outcomes for all rare disease patients and families living in the state. If you have any questions, please do not hesitate to contact me or Rose Gallagher at 315-263-8463 or by email at [rose.gallagher@travere.com](mailto:rose.gallagher@travere.com).

Sincerely,



Christopher Porter  
Vice President  
Government Affairs and Policy  
Travere Therapeutics, Inc.

---

<sup>11</sup> <https://www.imcp.org/doi/pdf/10.18553/imcp.2014.20.7.677>



January 6, 2022

Oregon Health Authority  
Health Systems Division  
Health Policy & Analytics Medicaid Waiver Team  
500 Summer Street NE, E65  
Salem, OR 97301

Re: Response to 2022-2027 Medicaid 1115 Demonstration Application

To the Health Policy & Analytics Medicaid Waiver Team:

This letter is in response to OHA's 2022-2027 Medicaid 1115 Demonstration Application proposal.

First, a brief description of who we are: New Narrative is a non-profit agency established in 1977 which provides mental health treatment services, housing programs, and peer support and mentoring services to adults with persistent and severe mental illness. We serve over 1,500 program participants each year and provide housing for 261 beds. Over 52% of our funding comes from Medicaid.

In recent years we've been expanding our programming to address social determinants of health (SDOH) in areas including housing, life skills training, transition into adulthood, equity and inclusion, improved access to services, and peer support. We have been expanding our funding sources beyond Medicaid in order to provide these services that positively impact SDOH because they are not covered by Medicaid in the traditional "medical necessity" model. We believe that wellness is supported by services that impact a wide array of SDOH beyond clinical health care and behavioral health care treatments within the medical model. Our vision is that program participants seeking services can thrive and live the life they choose, not just survive.

We are pleased to see that improving SDOH is the focus of the OHA 2022-2027 Medicaid Demonstration Application and would like to address each section of the proposal:

**I. Maximizing coverage through the Oregon Health Plan**

We support initiatives that will move Oregon closer to a **universal health plan** available to all, particularly traditionally disenfranchised populations. This focus aligns with our values of equity and inclusion.

In addition to the proposed strategies regarding extended OHP coverage for children under 6, continuous OHP enrollment for people ages 6 and up, and an expedited OHP enrollment path for SNAP benefit applicants, we particularly support the following additional proposals based on our values, mission, and experiences with our program participants:

1. Developing commercial insurance market reforms to improve coverage continuity and access to health care through the Oregon Health Insurance Marketplace and making it *easier to navigate the transition* from Medicaid to commercial coverage.
2. Continuing the implementation of Cover All People to support coverage for all individuals regardless of immigration status. We believe it is a violation of our basic values of equity and

8915 SW Center St. Tigard, OR 97223 Tel 503.726.3690 Fax 503.726.3691  
NewNarrativePDX.org



inclusion and simply the value of human life to exclude individuals from coverage who do not have legal status in the U.S. but are here anyway to find a better life for themselves and their families. Our agency not only supports providing them with services, but also assisting them to find a path to legal residency so as to remove other barriers that impact their SDOH, such as jobs and housing.

3. Streamlining the OHP application process and making it easier and faster with initiatives such as allowing applicants to self-attest to their income and aligning the timing of eligibility renewal for OHP with other benefits such as SNAP and TNAF.

## II. Improving Health Outcomes by Streamlining Life and Coverage Transitions

We at New Narrative strongly believe that SDOH have a profound impact on the quality of the health and well-being of our program participants. This is why over the last decade we have expanded our services beyond traditional mental health services to provide a wide variety of housing programs, life skills training, education and job support, and peer support and mentoring to provide socialization and a sense of community. We have found that life transitions such as incarceration, aging out of foster care, loss of employment, and discharge from prolonged hospital stays, to name a few, often disrupt the fragile support systems of our disenfranchised and vulnerable program participants. We strongly support the following proposals:

1. Provide continuous Medicaid coverage for people in custody, including the State Hospital and juvenile corrections. Currently, funding for our services is often interrupted when our program participants are transitioning from jail or from OSH which handicaps our ability to provide optimal care and sometimes a delay in admission into our programs.
2. Retain child eligibility levels for youth up to age 26, even if they don't have special needs. We have found that many young adults from age 18-25 who have come from at-risk and vulnerable families are simply not prepared for independence and require additional services and support to transition to adulthood.
3. Allocating funding to SDOH transition services to support members during life transitions. For example, we are currently piloting a Transition Team to support program participants transitioning in and out of residential treatment to help them find work and housing. This is funded by a one-time grant, so we will need additional funding beyond the first year. We advocate allocation of Medicaid funding to support such teams.
4. The expansion and funding of infrastructure at the community level for programming and capacity building needed to support services that improve SDOH ***outside of the medical model***. One example is our NorthStar Clubhouse which is part of the network of Clubhouse International, a model that supports mental health recovery, community engagement, and re-entry into employment. This is a highly successful program in terms of impact and outcomes for program participants and for the community but severely underfunded in Oregon and not billable under Medicaid. ***We very strongly believe that funding only services defined as "medically necessary" severely limits the potential for positive outcomes and thriving communities.***

## III. Value-Based Global Budget

We support shifting resources to fund a value-based system that supports program participants as their health improves, not just when they are at the highest acuity of illness. We strongly advocate that a

higher percentage of funding being funneled to the community providers who actually perform the front-line services, and less funding being allowed for heavily layered bureaucracy in the CCO and county mental health organizations and system. We urge consideration of the following:

1. Ensuring that CCOs provide payment rates to community providers that are based on realistic, current economic realities such as the supply and demand of the labor force – the largest operating cost of any community provider – along with annual COLA increases in provider service contracts. Labor rates are skyrocketing for community providers who are hamstrung by static contracts that don't adjust for labor rate inflation and consumer price indices and don't allow for a reasonable operating overhead percentage. It is also a mistake to base rates on past spending given the current economic realities and the shift to covering services in support of SDOH.
2. A closed formulary could likely cause some problems for psychiatry, especially with the SPMI population. It is common that participants receive little to no benefit from the first- or second-line medications, and it requires trial and error of medications with less evidence. Sometimes when the right medication is found, it could be lifesaving. If a closed formulary is implemented, special consideration must be given to psychiatry, especially for the SPMI population, to ensure that we have access to a wide selection of medications and a simple, quick process to get authorization outside of the formulary. Burdening providers with the paperwork and bureaucracy of prior authorizations takes precious time away from expensive psychiatrists and psychiatric nurse practitioners, but more importantly, delays patient care and access. This could lead to negatives outcomes and increased system costs (e.g. hospitalizations).

#### **IV. Incentivizing Equitable Care**

We support strategies that enable equitable care including improving cultural responsiveness, mitigate social stigmas and the harm of racism, and create equitable access. These strategies are in complete alignment with our mission and values. However, the issue with incentive measures is that they are often not what actually enables the desired outcome. Some comments and questions on the proposed strategies:

1. **Restructure the Quality Incentive Program into two complementary components to reserve space for upstream work focused on equity:**
  - a. One proposal in this section is to measure and incentivize “Meaningful Language Access to Culturally Responsive Health Care Services.” Assuming that the CCO scorecards will become the service provider scorecards, this puts the burden on the community providers to find or possibly develop said services. Where is the funding for this coming from? Even if funding is available, culturally responsive services are somewhat limited in the state. Where is the effort and investment in the development of culturally responsive services? How are we attracting culturally specific talent to this state? It appears it's all on the backs of community providers who have inadequate resources to make it happen.
  - b. Most of the “Upstream Health Equity Metrics” apply to children. What about upstream metrics for the adult population being served? Why just children?
2. **Redistribute decision-making power to communities:** We encourage OHA to push for membership on the Health Equity Quality Metrics Committee to include a significant number of representatives from community non-profit agencies that are boots-on-the-ground service



providers who have a front-line view of the served populations, challenges, and socioeconomic realities.

- 3. Rethink the incentive structure to better advance equity:** It appears that OHA is trying to incent outcomes by paying the CCOs incentives across a variety of priorities; our concerns center around whether these incentives are actually passed on to frontline community providers, and if this new policy stance guarantees that there will be material pass through of funds to organizations where they are needed most. We also question the logic that the cost savings realized by the CCO model and the manner in which they were generated in the past 5 years are a net positive to our system; Oregon continues to experience some of the lowest ratings in the country in terms of access to care and quality of care, with the current staffing crisis in the sector demonstrating the latest iteration of the flow on effects of cost saving incentives. We advocate that whatever model is utilized takes into consideration that the CCO model must regulate cost responsibly and ensures providers are funded in a meaningful way to actually deliver services and produce materials results within our most vulnerable populations.

## V. Focused Equity Investments

We consider this section of the Medicaid Waiver Application to be the most exciting and promising in that it indicates strong support for funding services that improve SDOH. Our comments on the subsections of this area are as follows:

- 1. Invest federal funds toward infrastructure to support health equity interventions:** We believe that it is imperative that community organizations doing the actual front-line work receive funding to build capacity to serve our program participants with equitable and culturally appropriate programs that support improved SDOH and improved access to services. This could include such things as premium funding for bi-lingual staff including clinical and peer support, training for more culturally appropriate services, housing support, employment programs, and programs that support healthy community engagement, to name a few. Our sole concern about this part of the application is that the community investment collaboratives (CICs) may become another layer of bureaucracy that prevents adequate funding from flowing to front-line services providers. Creating statewide systems to support this proposal may help with communications, allocation, and establishing standards, but it may also add administrative burden that wastes funds and capacity and results in inadequate funding to front-line providers.
- 2. Invest Federal Funds in community-led health equity interventions and statewide initiatives:** We support the concept of local management of CCO community funds. Our main concern here is the mechanism by which the CICs receive, manage, and distribute CCO community funds. We need a system that minimizes bureaucracy and administrative burden and provides more funding directly to front-line community providers.
- 3. Grant community-led collaboratives resources to invest in health equity:** We strongly support additional federal investment to support health equity investment (HEI) grants. We are particularly in favor of a non-competitive process with requests for proposal that address



identified community needs. The examples of proposed HEIs that we are prepared to implement and/or to expand are increasing housing inventory, providing more housing supports and services, improving homeless/houseless outreach, increasing access to social and mental health supports, expanding culturally and linguistically responsive work force, and dismantling structural racism as well as destigmatizing mental health conditions. We have spent the last decade, and particularly the last five years, developing programs and defining our mission and values in all of these areas. Our concern in this area is that after the initial grant period the grants are renewable or that there is other funding made available for on-going support of these programs.

***In summary, we at New Narrative support and are encouraged by the emphasis on funding services that improve SDOH and health equity outlined in this waiver application. The focus on SDOH is in alignment with our mission and vision and the needs of our communities here in Oregon and in our nation. We ask that minimization of administrative burden and bureaucratic layers become a priority in the implementation of these initiatives. We also ask that prioritization be given to making sure that as much funding as possible goes to the actual front-line community providers who are directly serving these populations and making an impact in communities throughout the state.***

Sincerely,

A handwritten signature in black ink that reads 'Julie Ibrahim'.

Julie Ibrahim, LPC  
Interim CEO

January 7<sup>th</sup>, 2021

Health Policy and Analytics Medicaid Waiver Renewal Team

Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

Re: Medicaid 1115 Waiver

Currently there are six Regional Health Equity Coalitions (RHECs) in the state of Oregon that cover 11 out of the 36 counties, and the Confederated Tribes of Warm Springs, including urban, rural and frontier regions (see below “About Regional Health Equity Coalitions”). RHECs involvement in the Medicaid waiver process has been with community and health equity at the forefront because we work firsthand with historically underserved populations and see the impact of inequities in our communities. We believe that community is the ultimate accountability point.

We also keep seeing firsthand, as we know has been the case for centuries, the ways that systems create and deliver the outcomes they are designed to. <sup>1</sup>These systems and institutions have been created to benefit a select group of people over time, while communities of color experience avoidable inequities due to structural racism (Agénor, et. al, 2017), and without intentional structural changes we are bound to keep repeating and perpetuating these inequities.

Through the legislative session, the passage of HB 3353, and through the waiver proposal drafting process the RHECs have advocated for targeted financial investments in community health equity, as well as clear sideboards and accountability points for entities who comprise the system. In recent meetings we have heard the OHA waiver team say they support a statewide oversight committee and the community investment collaboratives (CIC) model. The RHECs also support these two important interventions, and we have submitted public testimony advocating for them because they were designed to specifically address health inequities because *current efforts and investments are not working for our communities*. While the OHA waiver team expresses support, there is no financial allocation in the concept papers of the proposal to reflect that commitment, including how sideboards and accountability from OHA, CCOs, and other entities will be measured. Without a strong independent point of accountability for the asks in HB 3353, it falls on us RHECs to continually keep knocking on the doors of those in power to make small changes.

**We ask for the following changes to reflect HB 3353’s work towards equity, and to demonstrate the necessary shifts in power and resources to address health inequities:**

- 1.) **The commitment from OHA to have a line item in CCO budgets for the 3% regardless of ‘additional’ future federal funding.** That funding needs to be accounted for in the CCOs annual rates and contract rate sheets. We seek a clear request that the identified 3% of investments in health equity and SDOH be recognized as medical expenditures, we see this as a key to making these investments intentional and sustainable.

---

<sup>1</sup> Agénor, M., Bailey, Z.D, Bassett, M.T., Graves, J., Krieger, N., Linos, N. (2017). Structural Racism and Health Inequities in the USA: Evidence and Interventions. *Lancet*, 389, pp. 1453-63.

Section 2(1)(a) of HB 3353 explicitly says, “Require a coordinated care organization to spend up to three percent of its global budget on investments:

- “(A)(i) In programs or services that improve health equity by addressing the preventable differences in the burden of disease, injury or violence or in opportunities to achieve optimal health that are experienced by socially disadvantaged populations;
- “(ii) In community-based programs addressing the social determinants of health;
- “(iii) In efforts to diversify care locations; or
- “(iv) In programs or services that improve the overall health of the community”

**The OHA’s draft application does not outline how these funds will be accounted for within the CCO budget.**

- a. Please also include in the waiver concept that these funding allocations will be accounted for in the annual CCO rate development process (published here <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/OHP-Rates.aspx> ) and Contract Rate Sheets and that the funding available should be outlined in each CCO’s rate sheets.
- b. The most current rates are published here: <https://www.oregon.gov/oha/HPA/ANALYTICS/OHPRates/Oregon-CY22-Rate-Certification-CCO-Rates-Final-20211001.pdf> )

2.) **The waiver concept papers also need to include that a state-level oversight committee**, as established by HB 3353, will be charged with overseeing the 3% global budget spend and that the state-level oversight committee be housed in the Oregon Health Authority Office of Equity and Inclusion, as called for in HB3353.

The RHECs have collectively participated in and co-developed many OHA housed committees, from committees charged with Community Health Improvement Plans, Rules Advisory Committees, the PartnerSHIP, and many others. These models, while asking for the labor of communities most impacted to make recommendations on possible solutions, ultimately the decision making and execution is left to the state. **We ask there be a distribution of power more representative of the work that shapes these decisions via clear policies, practices, and procedures as defined by the oversight committee.**

Section 3 (6) of HB 3353 The authority shall convene an oversight committee in consultation with the office within the authority that is charged with ensuring equity and inclusion. The oversight committee shall be composed of members who represent the regional and demographic diversity of this state based on statistical evidence compiled by the authority about medical assistance recipients. The oversight committee shall:

- “(a) Evaluate the impact of expenditures described in subsection (2) of this section on promoting health equity and improving the social determinants of health in the communities served by each coordinated care organization;
- “(b) Recommend best practices and criteria for investments described in subsection (2) of this section; and

“(c) Resolve any disputes between the authority and a coordinated care organization over what qualifies as an expenditure under subsection a (2) of this section.

- 3.) The way the regional Community Investment Collaboratives CIC model is being designed, is for them to be directed by organizations, or members of organizations, that serve local priority populations that are underserved in communities served by the coordinated care organization, and should also be funded by any additional federal funds that are leveraged for these services.
  - a. **Please clarify that Community Investment Collaboratives will be independently funded with additional funds leveraged from the federal government.**
  - b. **As independent entities they will communicate with the oversight committee and have clear dispute process in the event of a dispute between CCOs, the CICs, and OHA.**
  
- 4.) **Please clarify should the Federal Government allow duplicate investment from the CIC and CCOs, then the State wide Oversight Committee will resolve disputes between these entities.**

Please show your support in this effort in redesigning the system and shifting power and resources to communities through clearly outlined and responsible allocation of funds and accountability.

Sincerely,

Reina Estimo  
Rez Active representing Confederated Tribes of Warm Springs

Roberto Gamboa and Norma Ramirez  
Eastern Oregon Health Equity Alliance (EOHEA) representing Malheur & Umatilla Counties

Esther Kim  
Oregon Health Equity Alliance (OHEA) representing Clackamas, Multnomah & Washington Counties

Liliana Lachino  
Mid-Columbia Health Equity Advocates (MCHEA) representing Columbia Gorge Counties

Seynabou Niang  
Linn Benton Health Equity Alliance (LBHEA) representing Linn & Benton Counties

Annie Valtierra-Sanchez  
SO Health-E representing Jackson & Josephine Counties

### **About Regional Health Equity Coalitions**

Regional Health Equity Coalitions (RHECs) are autonomous, community-led, groups whose backbone organizations are non-governmental in nature. They work to identify the most pressing health equity issues in the state and find creative solutions to address root causes of barriers to health and wellness through policy, system and environment changes.

There are six RHECs in Oregon that represent 11 Oregon counties and the Confederated Tribes of Warm Springs, including urban, rural and frontier regions. There is RHEC representation for Confederated Tribes of Warm Springs, as well as the following counties: Linn, Benton, Multnomah, Washington, Clackamas, Hood River, Wasco, Jackson, Jefferson, Malheur and Umatilla.

January 4, 2022

To: Oregon Health Policy Board  
RE: Medicaid 1115 Waiver Application

Dear Members of the Oregon Health Policy Board,

Comagine Health appreciates the opportunity to provide comments on the renewal of Oregon's Medicaid 1115 waiver for the 2022-2027 demonstration period. Comagine Health is a national, nonprofit health care consulting organization. We work collaboratively with patients, providers, payers, and other stakeholders to reimagine, redesign and implement sustainable improvements in the health care system. In 2017, HealthInsight and Q Corp approved a merger of the two organizations and their operations in Oregon. The following year, HealthInsight announced a merger with Qualis Health to become Comagine Health. For more than 40 years, Qualis Health and HealthInsight (Q Corp) have independently provided quality improvement services, care management services, and quality health care consulting in Oregon. Today, we are proud to continue supporting Oregon's health care quality initiatives as Comagine Health.

We are encouraged that the waiver application's primary goal is to advance health equity, which is closely aligned with Comagine Health's mission, vision, and values. In late 2021, the Comagine Health Board of Directors identified four areas of strategic focus that will provide direction for our priorities in the years to come. These focus areas are as follows:

1. Health Equity
2. Transition to Value
3. Disproportionally Impacted Populations
4. Community-Oriented Public Health

These priorities build upon the strategic work of Comagine Health's Oregon Community Board in 2020. Ultimately, the Board created a *Social Determinants of Health Strategic Vision* based on the Centers for Disease Control place-based framework that outlines five key areas: Economic Stability, Education, Social and Community Context, Health and Healthcare, and Neighborhood and Built Environment. We are committed to identifying, measuring, and working with our partners to improve the social determinants of health that affect a broad array of health risks and outcomes.

Comagine Health fully supports the Oregon Health Authority's approach to the waiver renewal. We must address health inequities in both the health system and communities, we need to increase access to and consistency of Medicaid coverage, and we need to contain costs through providing high-quality and equitable health care. Given our interest in helping drive health care quality in these areas, we have provided the following specific comments in support of OHA's submission.

Reimagining health care,  
**together.**

Office (503) 279-0100  
Fax (503) 279-0190

650 NE Holladay Street  
Suite 1700  
Portland, OR 97232  
[comagine.org](http://comagine.org)

## **from Section I: Program Description -- Subsection 3. Proposed Changes (p15)**

### **3.1 Maximize OHP Coverage (p15)**

#### **Strategy 1: Provide continuous enrollment for children until their 6th birthday**

#### **Strategy 2: Establish two-year continuous OHP enrollment for people ages 6 and up**

Comagine Health strongly supports continuous enrollment of children and adults in the Oregon Health Plan. Fluctuating coverage can increase health risks to individuals impacted in this process and reduces capacity to provide preventive care. Comagine Health is a partner with OHA in monitoring health outcomes for Medicaid beneficiaries. We have maintained an All Payer Claims Database (APCD) in Oregon since 2010 that allows us to track cost, utilization, and quality indicators in three markets: Commercial, Medicare, and Medicaid. Our APCD can connect claims on individuals through changes in their insurance provider's market type and their coverage across insurance companies. As a result, we have observed that many individuals are covered by the Oregon Health Plan one month but not the next. Our carefully prepared cost and quality reports require a minimum number of months of coverage within a year and the frequent loss of Medicaid coverage affects the completeness and accuracy of our measure results and reports. More importantly, fluctuating coverage can increase health risks to individuals impacted in this process.

### **3.2 Improving Health Outcomes by Streamlining Life and Coverage Transitions (p17)**

#### **Strategy 2: Retain child eligibility levels and benefit package for Youth with Special Health Care Needs (YSHCN) up to age 26**

We support Oregon extending OHP coverage to age 26 and retaining eligibility levels of 305% Federal Poverty Level to support smooth transitions from pediatric to adult health care. The best way to avoid expensive emergency department and hospital visits is to maintain continuous and reliable access to outpatient providers and effective medications.

#### **Strategy 3: Provide a defined set of SDOH services based on transition-related criteria to support vulnerable populations in need during transitions**

Comagine Health supports Oregon covering specific Social Determinants of Health (SDOH) benefits for vulnerable populations and life status transitions, including but not limited to, homelessness, change in government-operated insurance plans, youth with special health care needs, and those leaving foster care. Evidence indicates that managing environmental risks to health upstream decreases downstream healthcare costs. Further, inequitable access to housing, transportation, food, employment services, and increased exposure to wildfire, ice storms, and heat domes perpetuates inequitable health outcomes.



**Strategy 4: Expand the infrastructure needed to support access to services using providers outside of the medical model**

**Strategy 5: Obtain expenditure authority to support implementation capacity at the community level, including payments for provider and community-based organizations (CBO) infrastructure and capacity building**

Comagine Health supports expanding funding of community-based organizations and traditional health workers (THWs). These partners have demonstrated their important role in reaching communities disproportionately impacted by chronic disease and access barriers. Expanding resources to support capacity building for CBO infrastructure and delivery of services by THWs is essential to addressing the limitations of the current delivery system. Through our long history of working with community partners to improve clinical-community coordination, bi-directional referral processes, and capacity building to deliver and sustain evidence-based services, we have seen the challenges encountered by CBO and clinical partners in scaling effective models. Referral and reimbursement models for services delivered by CBOs need to account for their varying capacity and expertise to engage with the relevant technology and regulations, and bill for these services. Comagine Health is currently collaborating with clinical and community partners to build and test umbrella network hubs to reduce CBOs' administrative burden for delivering chronic disease self-management education programs and care coordination services. Comagine Health has a long history of helping CBOs build capacity to deliver evidence-based chronic disease prevention and management programs, implement bi-directional referral with healthcare partners, and identify and implement reimbursement opportunities made available by Medicaid and Medicare. Comagine Health is invested in building workforce capacity among THWs to engage patients in community-based services and the delivery of evidence-based programs. Our *Social Determinants of Health Strategic Vision* articulates how we can support clinical-community connections through data linkage, technical assistance, and convening.

### **3.4 Incentivizing Equitable Care (p34)**

**Strategy 1: Restructure the Quality Incentive Program into two complementary components to reserve space for upstream work focused on equity: a) a small set of “upstream” metrics focused on factors affecting health equity, and b) a set of “downstream” metrics that focuses on traditional quality and access measures**

**Strategy 2: Redistribute decision-making power to communities**

Comagine Health strongly supports the proposed emphasis of health equity measures of historically disadvantaged populations. We have been working for years in collaboration with local, state and federal public health partners to assist CBOs with improving their infrastructure and ability to collect data on social determinants of health, and their effectiveness in exchanging data with clinical providers. These data points include client assessments, available health-related services, online appointment scheduling, client retention and progress over course of participation in an intervention, and closed-loop visit follow-up outcomes. In addition to collecting and reporting the traditional health quality measures, Comagine Health is beginning to process data on equity measures related to race, ethnicity, language, disability status, gender, and sexual orientation.

### **3.5 Focused Equity Investments**

**Strategy 1: Invest federal funds toward infrastructure to support health equity interventions**

**Strategy 2: Invest federal funds in community-led health equity interventions and statewide initiatives**

**Strategy 3: Grant community-led collaboratives resources to invest in health equity**

Comagine Health supports the proposal to build community collaboratives to address health inequity. CBOs are frequently beholden to relying on grant funding to close the gap between need and service delivery. This is an inconsistent and tenuous mechanism that does not build the capacity needed for ongoing service delivery at scale. Through our work with CBOs, we see great opportunity for OHA to help communities both invest locally in infrastructures that respond to their unique challenges while also bridging to state level backbone systems. Currently, Comagine Health is convening clinical and community based partners interested in participating in Connect Oregon<sup>1</sup>, Community Information Exchange to develop and test standardized workflows and guidelines for referral to evidence based self-management programs with the goal of building a use case that can inform referral to other services these partners deliver. One of the most significant challenges these efforts encounter is ensuring consistent resources for service delivery and managing the administrative elements of acquiring reimbursement.

---

<sup>1</sup> <https://oregon.uniteus.com/>

### **3.6 Align with Tribal Partners' Priorities**

We support efforts to strengthen Alaska Native/American Indian voice, as identified and prioritized by Tribal partners. If approved by Tribal partners, this work may include: removing prior authorization requirements; extending the current Uncompensated Care program; converting the Special Diabetes Program for Indians (SDPI) to a Medicaid benefit; reimbursing for Tribal best-practices; and providing payment for currently unreimbursed Social Determinants of Health services.

#### **Summary**

The opportunity to link clinical and community-based services to analyze outcomes for applicable patients is significant. It will be important to ensure equity is a leading principle throughout the framing of the issue and questions posed for study. Equity should also remain at the forefront when selecting representation and assembling key tables as this crucial work unfolds. Comagine Health has spent many years working with diverse clinical and community stakeholders to solve complex systems issues to improve community health.

Oregon has made considerable and measurable progress in its health system transformation efforts. We fully support the State's renewal application to build on that progress through the 2022-2027 demonstration period. Thank you for the opportunity to submit comments. Please email me at [rgibson@comagine.org](mailto:rgibson@comagine.org) if you would like additional information.

Sincerely,

Richard Gibson, MD - Physician Informaticist



January 7, 2022

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

**Subject: Support for Oregon’s Draft Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Application**

Dear Director Allen:

Unite Us writes in strong support of Oregon Health Authority’s draft 1115 Waiver Renewal and Amendment application.

This comprehensive Waiver application appropriately recognizes that working upstream is the path of the equity agenda. The Waiver builds on Oregon’s innovative efforts made possible through previous Waivers and furthers Oregon’s commitment to health equity through important reforms, which include expanding covered benefits to include services that address social determinants, incentivizing CCOs to address upstream drivers of health through equity-focused quality metrics, and driving community-centric health investments and governance structures.

Unite Us believes the Waiver application could be further strengthened by recognizing and incorporating the ongoing and planned work of OHA, the CCOs, and community-based partners across the state to build the infrastructure required for community information exchange (CIE).

Over the last 2 years, significant statewide advancement has been made on CIE. These include smarter, more precise definitions of the term and greater awareness as to core components of CIE: shared statewide technology, community-driven governance across diverse sets of network partners, and data and reporting to support network maturation, population health initiatives, and policy and government budgeting decisions. CIE in Oregon, sustained with new long-term financing that maximizes federal drawdown, is now primed to be the shared infrastructure upon which many of the efforts outlined in this Waiver should be built.

In particular, Unite Us encourages OHA to:

- Recognize the CIE Workgroup established by OHA in December of 2021;
- Recognize CIE as the central infrastructure required to advance the equity agenda;
- Consider the overlaps of ongoing CIE work in Oregon with those proposed in this waiver, including existing CIE governance structures and the Community Investment Collaboratives; and
- Use this Waiver opportunity, coupled with administrative claiming opportunities, to communicate intent to build long-term sustainable financing of the CIE.



## **Background on Unite Us and Connect Oregon**

Since 2013, Unite Us has been the national leader in deploying community-wide care coordination infrastructure to meaningfully connect health and social care providers in a common ecosystem and to help address social determinants of health. Our goal is to ensure every individual, no matter who they are or where they live, can access the critical services they need to live happy and healthy lives.

We help community partners – payers and providers, private and public, large and small – work together in new ways to identify and address unmet social needs. To support these network partners, we have deployed our community engagement process in more than 42 states. Our coordinated care networks demonstrate that a robust, collaborative, and holistic community-wide approach to identifying and addressing unmet social needs not only improves individual health and quality of life, but also improves community health, reduces healthcare costs and utilization, and promotes health equity. Network partners leverage the Unite Us platform to securely share information required to coordinate care through closed-loop referrals. If enabled, partners are also able to streamline the billing and invoicing of services from CBOs to payers. A suite of data as well as centralized care coordination services make up the end-to-end solution available to network partners.

In Oregon, Connect Oregon is the network, powered by Unite Us, of organizations participating in community information exchange. Unite Us is currently contracted by 12 of the 16 CCOs to serve 35 of the 36 Oregon counties. In addition to the CCOs, health providers (including large systems and FQHCs), CACs, CBOs, and county-based programs are partners. Further, Oregon Health Leadership Council serves as statewide convener of the CCOs, and 211info operates as a coordination center for the network. OHA currently recognizes Connect Oregon as a Community Information Exchange (CIE).

Given these partnerships in place, the history and the trajectory of this work, and an expansive overlap in values and mission, Unite Us respectfully submits the following comments as a committed partner and advocate for the impact envisioned through OHA's waiver proposal.

**Unite Us is excited to support OHA's 1115 Waiver renewal and amendment which critically expands policy levers to incentivize and enable upstream health approaches focused on equity.** Among the provisions applauded, we highlight the following:

### **1. The Waiver supports individuals experiencing life transitions and disruptions through comprehensive SDOH-related benefits.**

Unite Us applauds OHA's expenditure authority requests for 1) CCOs, to provide covered SDOH services for populations experiencing transitional events, such as reentry from the criminal justice system or the impacts of extreme climate change, and for 2) community-based organizations (CBOs), to support their implementation capacity through infrastructure and capacity-building spending flexibility. These requests will lay the foundation for critical health reforms that emphasize and reward preventative, upstream approaches to care delivery.

Covered SDOH transition services will importantly help individuals more easily access expanded health-related services that meet their basic needs in areas such as housing, food, and employment assistance.

These SDOH benefits will help OHA standardize and streamline the delivery of services that address SDOH, which often reflect and reinforce entrenched health inequities. These benefits can ultimately be offered to additional populations beyond those experiencing life transitions and disruptions.

Importantly, this strategy will drive healthcare dollars to CBOs and community providers who have historically supported the whole-person health of Medicaid members without receiving reimbursement for their services. These dollars will drive sustainable funding and capacity for CBOs, targeting resources toward prevention and directly into communities where the most vulnerable and marginalized individuals often receive their care.

Unite Us works with CBOs on a daily basis. We applaud that this waiver acknowledges the disruption and change management that will be required of CBOs; this initiative presents a massive change to their normal workflows with the added benefit of Medicaid reimbursement. The implementation capacity funds for CBOs and aligned Community Investment Collaboratives (CICs) will be critical for supporting CBOs through this transition. These funds are essential for setting up the necessary infrastructure system that allows for tracking the delivery of services, payment and billing, reporting, and monitoring outcomes.

***To further strengthen this proposal, Unite Us recommends:***

Early CBO/Payer Alignment. We encourage OHA to ensure close collaboration with CBOs and community leaders when developing requirements for CBO participation, reimbursement, and reporting. This can help prevent undue administrative burden for community providers and to ensure the reimbursement process is not over-medicalized for CBOs that are not resourced to process and submit traditional medical claims. For example, OHA should ensure that their state reporting requirements for CCOs do not undermine the ability of CBOs to easily submit invoices for reimbursement. For example, California requires health plans to submit all data on Community Supports in standard encounter format, which forces plans to require traditional medical claims from CBOs so they can properly report back to the state. It's important to acknowledge that this transition will be difficult for CBOs operating with limited overhead spending, and so OHA's requirements should ensure that the transition to billing for social services is as simple and efficient as possible. CCOs should allow CBO providers to submit reimbursement requests in invoice form if that is the best process for them, and encourage use of an invoice portal as an alternative to traditional claims reporting.

In addition, OHA should ensure that vetting processes for CBO providers is distinct from the vetting process in place of medical providers. Background checks on CBO staff and other aspects of the traditional credentialing process may preclude important and trusted CBOs from participating in the initiative, and OHA should explore alternatives that are uniquely suited to vet CBOs.

Clear Standards to Drive Quality. In order to reduce duplicative efforts and minimize the number of systems and solutions that providers need to learn and adopt, SDOH transition services payments and infrastructure investments should build upon existing CIE efforts across the state, which include social needs screenings, closed-loop referrals, social care outcomes data collection and reporting functions.

OHA can ensure that all CIE solutions meet the same single set of standards to allow for standardized data collection and streamlined care coordination efforts across the state. Just as OHA has encouraged MMIS and APCD to align with REALD regulations as required by statute, so should that be encouraged with a CIE solution.

Establishing appropriate privacy, security and billing compliance requirements SDOH referral and reimbursement technology must also be emphasized here. Information exchange between partners must occur in order to ensure care coordination and the adoption of trauma-informed approaches to addressing health-related social needs; but this information sharing must occur pursuant to HITRUST Certification and compliance with HIPAA, 42 CFR Part 2, FERPA, and other pertinent regulations. The assurance of privacy and compliance enables the trust upon which any integrated solution is built and upon which equity is achieved.

Shared, Publicly-Sponsored, CBO Billing Systems. Billing systems adopted and/or procured by and/or for CBOs participating in reimbursement arrangements with CCOs should be seen as shared infrastructure. The burden should not be placed on CBOs nor community investment collaboratives that lack technical capacity to build and/or procure their own billing systems. Further, it is important for CBO payments to be linked to closed loop referral infrastructure in order to link outcomes with reimbursement and monitor population outcomes.

If viewed as shared infrastructure, OHA may consider an Advanced Planning Document (APD) as a mechanism for securing federal match funding (75-90%) for statewide CBO referral and reimbursement technology, while continuing to finance SDOH payments to CBOs via waiver requests. Continued federal investment in SDOH services combined with a publicly-privately funded foundational referral technology presents a sustainable strategy for financing such systems in the long-term – ensuring that individuals’ upstream needs are being met and that CBOs are being paid for their valuable services.

## **2. The Waiver aligns financial incentives in the healthcare delivery system to drive community health and health equity improvements.**

Unite Us celebrates OHA’s commitments in this waiver around redesigning financial incentives in the healthcare system to shift resources towards and reward prevention and population health. We applaud the regulatory and policy levers outlined, including a) value-based global budgets for CCOs, b) 3% allocation of CCO population health budgets towards health equity investments with 30% designated for community investment collaboratives, and c) flexibility around CCO’s ability to count health-related spending as part of their medical load when calculating MLR.

As described by OHA, Unite Us believes that these requirements/levers will “flip” financial incentives in Oregon’s healthcare delivery system – CCOs will be accountable for and rewarded by improvements in whole-person health outcomes, health equity, prevention, and care

coordination rather than being financially rewarded when members are sick and access more care.

Unite Us agrees with and celebrates OHA's recognition that entrenched inequities, power imbalances, and systemic racism in and resulting from the health system cannot be undone unless financial incentives link market power to health equity and community health improvements. At Unite Us, we're working with communities and our funded healthcare partners to shift investments upstream and into community health through community health infrastructure – we will continue supporting and elevating the efforts of OHA alongside our work in communities.

### **3. The Waiver holds CCOs accountable for health equity through quality metrics.**

Unite Us supports OHA's proposal to redesign the Oregon Health Plan Quality Incentive Program with dedicated upstream metrics focused on equity as well as to better integrate community member decision-making power through the new Health Equity Quality Metrics Committee (HEQMC).

In particular, Unite Us celebrates the new health equity upstream metric titled "Social Determinants of Health: Social Needs Screening and Referral," which incentivizes more CCO members having their social needs acknowledged and addressed.

With this metric in place, OHA is building a comprehensive healthcare delivery system that seeks to address members' social determinants of health through population health and prevention strategies, which include connecting members to services that address their social needs.

The new upstream metrics, coupled with the new HEQMC, will enable OHA to iterate and improve its social determinant strategy in the long term.

OHA and the HEQMC should also consider the role of analytical tools to identify opportunities where proactive outreach could drive social care service delivery. Supported as a shared service and run out of OHA, risk scoring mechanisms and proactive human services outreach can be essential components of a forward-looking strategy to achieve health equity.

### **Conclusion & Unite Us Support for Oregon's Waiver**

This 1115 waiver will allow OR to implement innovative and long-lasting equity initiatives within the healthcare delivery system.

These proposals will drive sustainability for the CBO provider network, financially reward CCOs for delivering holistic care that keeps members healthy and in their communities, and incentivize more equitable outcomes with new quality standards.

We recommend that OHA continue to build upon efforts already underway across the state, including the CIE efforts and its governance approaches, to avoid conflicting solutions when possible.

If you have any questions or if there is any additional information Unite Us can provide, please do not hesitate to contact me at [read@uniteus.com](mailto:read@uniteus.com).

Thank you for the opportunity to submit comments, and for your continued leadership and support to provide more holistic and equitable care in Oregon and nationally.

Sincerely,

/s/ Read Holman

Read Holman  
Policy Director, Government and Regulatory Affairs  
Unite Us  
[read@uniteus.com](mailto:read@uniteus.com)