



VIA EMAIL

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.¹ 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.² 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.³ 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.⁴

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 rates⁵ and as mentioned before, are also more likely to be affected by gaps in coverage.⁶ 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,



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¹ 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 \(georgetown.edu\)](#)

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

³ 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>

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

⁵ 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)

⁶ 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 \(georgetown.edu\)](#)