HIV + HEP
POLICY INSTITUTE

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 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.[1] 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.[2]

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.[3]

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.[4]

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

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[1] "Medicaid and HIV," Kaiser Family Foundation, updated October 1, 2019, accessed January 6, 2022, https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/.

[2] *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.

[3] *National HIV/AIDS Strategy for the United States: 2022–2025*, White House, 2021, p. 16.

[4] *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).[5]

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

[5] *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."[6]

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.

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[6] *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,

Carl E. Schmid II
Executive Director