April 13, 2022

Submitted via the Federal Medicaid.gov Portal

Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Oregon Health Plan 1115(a) Demonstration Waiver renewal application

Dear Administrator Brooks-LaSure,

We are writing on behalf of the Federal AIDS Policy Partnership - HIV Health Care Access Working Group (HHCAWG) and allied organizations. HHCAWG is a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV- and hepatitis C-related health care and support services. We are writing regarding Oregon's Section 1115 Demonstration Waiver renewal application and offer the following comments.

Many people living with HIV rely on Medicaid as a main source of coverage. Forty-two percent of adults living with HIV are covered by Medicaid, compared to just thirteen percent of the general population.[1] Ensuring access to effective HIV care, treatment, and support through the Medicaid program is important to the health of people living with HIV and to public health. When HIV is effectively managed and individuals stay engaged in treatment and virally suppressed, there is no risk of sexual transmission.[2] HHCAWG writes to express our support for a number of Oregon Health Plan's (OHP) innovative proposals to address health equity, as well as our concerns about Oregon's proposed waiver related to accelerated approval drugs.

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[1] Kaiser Family Foundation, *Medicaid and HIV* (Oct. 1, 2019), available at: https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/.
[2] R. Eisinger, C. Dieffenbach, A. Fauci, HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable, 321 JAMA 451 (2019), doi:10.1001/jama.2018.21167.

1. CMS should approve Oregon's proposals to expand continuous enrollment

We strongly support Oregon's commitment to achieving greater health equity, including through: (a) establishing two-year continuous enrollment for people ages six and up and (b) providing continuous enrollment for children until their sixth birthday.

a. CMS should approve Oregon's proposal to provide two-year continuous enrollment for people ages six and up

We support Oregon's proposal to establish two-year continuous enrollment for people ages six and up. Continuous enrollment is a critical tool to ensure access to and continuity of care for people living with HIV. The 2022 National HIV/AIDS Strategy sets forth an ambitious goal of ending the HIV epidemic in the United States by 2030.[3] In order to achieve that goal, the Strategy calls for ensuring that people with HIV have adequate community and medical support. This includes ensuring that people living with HIV have access to consistent insurance coverage.

As stated in Oregon's proposal, inappropriate or untimely disenrollment may be the result of systemic barriers that disproportionately harm people and communities of color. Research supports that the challenges associated with Medicaid disenrollment disproportionately harm low-income people[4] and people living with disabilities,[5] as these groups are more likely to rely on Medicaid to receive care.

Black and Hispanic/Latinx adults are almost twice as likely as white adults to have income under 200% of the federal poverty level (FPL), thereby making them more likely to rely on Medicaid.[6] Importantly, Black and Hispanic/Latinx adults are also more likely to live with HIV.[7] In 2019, Black people comprised just 13.4% of the U.S. population but 40.3% of people living with HIV in the United States.[8] Hispanic and Latinx people accounted for 18.5% of the U.S. population but of 24.7% of people living with HIV in the United States.[9] Recognizing these intersecting disparities, we know that inappropriate disenrollment and churn harm low-income communities and communities of color that are already disproportionately impacted by HIV.

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[3] National HIV/AIDS Strategy (2022-2025), available at: https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf.

[4] R. Rudowitz, R. Garfield, & E. Hinton, *10 Things to Know about Medicaid: Setting the Facts Straight* (Mar. 6, 2019), available at: https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/.

[5] M. Musumeci & K. Orgera, *People with Disabilities Are At Risk of Losing Medicaid Coverage Without the ACA Expansion* (Nov. 2, 2020), available at: https://www.kff.org/medicaid/issue-brief/people-with-disabilities-are-at-risk-of-losing-medicaid-coverage-without-the-aca-expansion/.

[6] Jesse C. Baumgartner, et al., *Racial and Ethnic Inequities in Health Care Coverage and Access, 2013–2019* (Jun. 9, 2021), available at: https://www.commonwealthfund.org/publications/issue-briefs/2021/jun/racial-ethnic-inequities-health-care-coverage-access-2013-2019.

[7] HIV.gov, *What is the Impact of HIV on Racial and Ethnic Minorities in the U.S.?* (2022), available at: https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities.

[8] *Id.*

[9] *Id.*

Minimizing coverage gaps, including through the implementation of continuous enrollment provisions, improves the health outcomes for people living with HIV. Oregon's own data shows that continuous enrollment helps stabilize coverage and prevent coverage gaps. In the first two years of the pandemic, federal guidelines required states to provide continuous enrollment as a precondition to receive enhanced federal Medicaid.[10] According to their waiver, Oregon's uninsured rate dropped from 6% to 4.6%, and the uninsured rate for Black Oregonians dropped from 8% to 5% during years 2019-2021. Ultimately, Oregon's proposal to provide continuous coverage has the opportunity to lessen churn and improve the health outcomes for people living with HIV.

i. Continuous enrollment improves the health outcome for people living with HIV

The lack of continuous enrollment can result in the temporary loss of Medicaid coverage, also known as "churn." Churn is when enrollees disenroll and then reenroll in Medicaid in a short period of time. Churn typically happens amongst Medicaid enrollees who have fluctuating income levels. Because these individuals' income levels may intermittently fall above or below the Medicaid eligibility line, they face repeated disruptions in care. Research shows that churn is associated with negative health outcomes.[11] Adults who lose Medicaid coverage are more likely to defer medical care, lessening their use of preventive and primary care services, and to have more emergency room visits.[12]

Reducing Medicaid churn is especially important for people living with HIV, among whom Medicaid is the largest source of health.[13] When Medicaid coverage is disrupted, patients lose access to vital treatment. People living with HIV usually take daily medication called antiretroviral therapy (ART).[14] When ART is taken as prescribed, it can suppress viral load, prevent disease progression, and reduce the risk of transmission. ART non-persistence – defined by not taking ART for at least two days – has precarious effects on health, including higher mortality and

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[10] Kaiser Family Foundation, *States Are Planning for the End of the Continuous Enrollment Requirement in Medicaid After the COVID-19 Public Health Emergency Expires, But Many Have Not Made Key Decisions* (Mar. 16, 2022), available at: https://www.kff.org/medicaid/press-release/states-are-planning-for-the-end-of-the-continuous-enrollment-requirement-in-medicaid-after-the-covid-19-public-health-emergency-expires-but-many-have-not-made-key-decisions/.

[11] Bradley Corralo, et al., Kaiser Family Foundation, *Medicaid Enrollment Churn and Implications for Continuous Coverage Policies* (Dec. 14. 2021), available at: https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-churn-and-implications-for-continuous-coverage-policies/.

[12] S. Sugar, et al., Assistant Secretary for Planning and Evaluation Office of Health Policy, *Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic* (Apr. 12, 2021), available at: https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf.

[13] Kaiser Family Foundation, *Medicaid and HIV* (Oct. 1, 2019), available at: https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/.

[14] Centers for Disease Control and Prevention, *What is HIV Treatment?* (2021), available at: https://www.cdc.gov/hiv/basics/livingwithhiv/treatment.html.

morbidity rates.[15] Low-income people who lose their coverage are more likely to miss their doctor appointments and dosages.[16] Lack of insurance coverage has been associated with failure to achieve virus suppression while stable insurance coverage has been associated with consistent ART use.[17]

Furthermore, deferring regular medical care is especially detrimental for people living with HIV. People living with HIV benefit from a continuity of care, usually made possible by seeing providers with whom they have established relationships. The continuity of care and strong patient-provider relationships increase the likelihood of medication adherence and timely treatment of common HIV-related comorbidities.[18] Therefore, unnecessary loss of coverage is detrimental to the health outcomes of people living with HIV.

ii. Gaps in Medicaid coverage hinder the implementation of safe and effective prevention interventions for people at risk for HIV

Not only does churn negatively impact the health outcomes of people living with HIV, but it also negatively impacts access to prevention for people at risk for HIV. One of the best ways to prevent HIV for people at high risk for HIV is using pre-exposure prophylaxis (PrEP), medication that is highly effective in preventing HIV acquisition.[19] When used as prescribed, PrEP reduces the risk of contracting HIV from sex by about 99%.[20] In 2019, the U.S. Preventive Services Task Force (USPSTF) found that PrEP's role in decreasing the risk of HIV infection in persons at risk of HIV infection was a substantial benefit.[21] As a result, Medicaid expansion plans and most private health plans are required to cover PrEP without additional cost sharing.[22] Unfortunately, despite its high effectiveness, PrEP use is less common in communities that can most benefit from PrEP, such as communities of color and transgender communities.[23] A key barrier that prevents people from

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[15] Marya Gwadz, et al., *Stopping, Starting, and Sustaining HIV Antiretroviral Therapy: a Mixed-Methods Exploration Among African American/Black and Latino Long-Term Survivors of HIV in an Urban Context*, BMC Public Health (2021).
[16] Anne K. Monroe, et al., *Factors Associated With Gaps in Medicaid Enrollment Among People With HIV and the Effect of Gaps in Viral Suppression*, JAIDS Journal of Acquired Immune Deficiency Syndromes, Aug. 1, 2018, at 413-420.
[17] *Id.*
[18] C. Chu & P. Selwyn, *An Epidemic in Evolution: The Need for New Models of HIV Care in the Chronic Disease Era*, Journal of Urban Health: Bulletin of the New York Academy of Medicine, Vol. 88, No. 3, available at: doi:10.1007/s11524-011-9552-y.
[19] Centers for Disease Control and Prevention, *How effective is PrEP?*, available at: https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html.
[20] *Id*.
[21] U.S. Preventive Services Task Force, *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis* (Jun. 11, 2019), available at: https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.
[22] Centers for Disease Control and Prevention, *PrEP for HIV Prevention in the U.S.*, available at: https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html.
[23] Pedro Botti Carneiro, et al., *Demographic, Clinical Guideline Criteria, Medicaid Expansion and State of Residency: A Multilevel Analysis of Prep Use On A Large US Sample*, BMJ Open (2021), available at: https://bmjopen.bmj.com/content/bmjopen/12/2/e055487.full.pdf.

taking PrEP is lack of insurance coverage.[24] Moreover, for PrEP to be maximally effective, patients must adhere to the PrEP regimen schedule.[25] With gaps in coverage due to churn, people may not be able to afford PrEP or may discontinue their regimen, placing them at increased risk of acquiring HIV. Therefore, to ensure appropriate access to PrEP, it is important that Oregon be able to offer continuous enrollment to its members.

b. CMS should approve Oregon's proposal to provide continuous enrollment for children until their sixth birthday

We also support unlimited continuous enrollment for children until their sixth birthday. Like adults, Medicaid enables children from low-income families to maintain life-saving medical coverage. Continuous enrollment for children helps improve their health status and wellbeing in the short and long term, including children living with HIV and other chronic conditions. It allows children to develop a relationship with their primary care provider at a young age, which is especially important for children living with a disability and children living with chronic illnesses.[26] Children with consistent coverage are less likely to skip annual physicals and routine preventive visits, which helps the providers detect serious illness early.[27] Medicaid coverage is also associated with decreased avoidable hospitalizations and child mortality.[28]

On the other hand, children with disruptions to their coverage are more likely to have delayed care and unmet medical needs. Disruption in coverage can have long lasting effects on the health outcomes of children,[29] and parents and caregivers may incur expensive medical bills if an emergency arises.[30] Continuous enrollment in children promotes health equity by limiting gaps in coverage and improve the lives of both children and their families.

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[24] L. Garrison & J. Harberer, *Pre-exposure Prophylaxis Uptake, Adherence, and Persistence: A Narrative Review of Interventions in the U.S.*, American Journal of Preventative Medicine (2021), available at: https://doi.org/10.1016/j.amepre.2021.04.036.

[25] Ya-Lin A. Huang, et al., *Persistence with Human Immunodeficiency Virus Pre-exposure Prophylaxis in the United States, 2012–2017* (2022), Clinical Infectious Disease, available at: https://DOI: 10.1093/cid/ciaa037.

[26] Community Catalyst New England Alliance for Children's Health, *Beyond Enrollment: Ensuring Stable Coverage for Children in Medicaid and CHIP* (2013), available at: http://neach.communitycatalyst.org/issue/connecting/asset/Childrens-Insurance-Churn-8-12-13.pdf.

[27] *Id.*

[28] J. Paradise, *The Impact of the Children's Health Insurance Program (CHIP): What Does the Research Tell Us?*, Kaiser Family Foundation (2014), available at: https://www.kff.org/medicaid/issue-brief/the-impact-of-the-childrens-health-insurance-program-chip-what-does-the-research-tell-us/.

[29] Tricia Brooks & Allexa Gardner, *Continuous Coverage in Medicaid and CHIP*, Georgetown University Health Policy Institute Center for Children and Families (2021), available at: https://ccf.georgetown.edu/wp-content/uploads/2021/07/Continuous-Coverage-Medicaid-CHIP-final.pdf.

[30] Community Catalyst New England Alliance for Children's Health, *Beyond Enrollment: Ensuring Stable Coverage for Children in Medicaid and CHIP* (2013), available at: http://neach.communitycatalyst.org/issue/connecting/asset/Childrens-Insurance-Churn-8-12-13.pdf.

2. **CMS should approve Oregon's proposal to provide pre-release coverage to people in carceral settings**

We support Oregon's proposal to extend Medicaid coverage to individuals in prison and jail pre-release. Specifically, Oregon proposes extending full access to Medicaid benefits to all youth otherwise eligible for Medicaid in county or local juvenile detention facilities throughout the duration of their involvement; full benefits and Coordinated Care Organization (CCO) enrollment for OHP members in jail or a local correction facility, including those awaiting adjudication; and limited benefits and CCO enrollment and transition services 90 days pre-release for OHP members in prison.

Health insurance coverage is a critical resource for justice-involved individuals living with HIV. Individuals in carceral settings are 5 to 7 times more likely to have HIV than the general population.[31] Many people learn of their HIV diagnosis for the first time while they are in prison or jail.[32] Furthermore, HIV infection in carceral settings reflects the same racial disparities that we see both in the HIV epidemic more broadly and in the criminal justice system; Black men who are incarcerated are 5 times more likely to be diagnosed with HIV that white men who are incarcerated.[33] Unfortunately, access to HIV care post-release is often inadequate because of poor linkage to care, resulting in poor health outcomes over time.[34]

Appropriate access to care during and following incarceration, especially in the initial weeks and months following release, is crucial. People are in a period of significant transition and the likelihood of disruption is high. Despite Medicaid being, as explained by the Department's Assistant Secretary for Planning and Evaluation (ASPE) "a key source of coverage for this high needs, high risk population, facilitating access to much needed physical and behavioral health services,"[35] justice-involved individuals face complex barriers to accessing care upon release. Medicaid enrollment and coverage reinstatement delays, difficulties establishing care, and challenges relaying medical histories are common. Health risks are further exacerbated by difficulties meeting basic health-related social needs, such as housing. Research shows that newly-released individuals with HIV present to emergency rooms in far higher numbers than the general population, for reasons that may be preventable through outpatient care.[36]

Extending Medicaid coverage to incarcerated individuals prior to release has the potential to improve continuity of care post-release by: allowing for the resolution of administrative issues

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[31] *Prisons and Jail*, The Center for HIV Law and Policy, https://www.hivlawandpolicy.org/issues/prisons-and-jails.
[32] *Id*.
[33] Shufang Sun, Natasha Crooks, Rebecca Kemnitz & Ryan P. Westergaard, Re-entry experiences of Black men living with HIV/AIDS after release from prison: Intersectionality and implications for care, 211 Social Science & Medicine 78 (2018), doi: 10.1016/j.socscimed.2018.06.003.
[34] Benjamin Ammon, et al., *HIV Care After Jail: Low Rates of Engagement in a Vulnerable Population*, 95 J of Urban Health 488 (2018), doi:10.1007/s11524-018-0231-0; David Alain Wohl & David Loren Rosen, *Inadequate HIV care after incarceration: case closed*, 5 The Lancet E64 (2018), doi:10.1016/s2352-3018(17)30210-2.
[35] Jhamirah Howard, et al., ASPE Issue Brief: The Importance of Medicaid Coverage for Criminal Justice Involved Individuals Reentering Their Communities, 6 (2016), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//146076/MedicaidJustice.pdf.
[36] Alfredo G. Puing, Xilong Li, Josiah Rich & Ank E. Nihawan, *Emergency department utilization by people living with HIV released from jail in the US South*, 8 Health & Justice (2020), doi:10.1186/s40352-020-00118-2.

related to enrollment and reinstatement of care early in the process, prior to release; allowing transitions of care to be streamlined and immediate, without harmful disruptions in care and treatment; and allowing community providers and coordinators to establish relationships with members and access critical health and treatment information prior to release. Additionally, pre-release coverage may also allow HIV-negative individuals access to critical prevention tools, like PrEP, that may not otherwise be available in correctional settings. As of 2019, HIV prevention medication had not been integrated into any correctional setting.[37] Research suggests, however, that people leaving prison may be especially vulnerable to HIV infection.[38] Moreover, the recent market approval of a long-acting injectable HIV prevention medication improves the ability to reduce risk of HIV acquisition in preparation for reentry. Pre-release coverage has the potential to greatly improve continuity of care for individuals living with HIV post-release. We encourage CMS to approve this proposal.

3. CMS should approve Oregon's proposals addressing social determinants of health

We strongly support Oregon's proposals addressing social determinants of health (SDOH), including providing a set of SDOH services to support vulnerable populations during transitions, incentivizing SDOH services through the Quality Incentive Program and through rate-setting, and making health equity investments through community-led collaboratives.

When individuals living with HIV are able to effectively access the supports and treatment needed to remain virally suppressed, they experience better health outcomes and cannot sexually transmit HIV.[39] Access to effective treatment is heavily dependent, however, on social risk factors, including homelessness,[40] food insecurity,[41] and unemployment,[42] that disproportionately affect people living with HIV. These risk factors can create significant barriers to care. For instance, food-insecure individuals must make difficult choices between obtaining food and securing other necessities such as medical care, which can interfere with adherence to regular medication use or attendance at outpatient appointments.[43] The barriers then ultimately result in negative health outcomes. For example, a recent systematic review found that in 94% of studies, homelessness

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[37] Lauren Brinkley-Rubinstein, et al., *The Path to Implementation of HIV Pre-exposure Prophylaxis for People Involved in Criminal Justice Systems*, 15 Curr HIV/AIDS Rep 93 (2018), doi:10.1007/s11904-018-0389-9.
[38] Jack Stone, et al., *Incarceration history and risk of HIV and hepatitis C virus acquisition among people who inject drugs: a systematic review and meta-analysis*, 18 Lancet Infect. Dis. 1397 (2018), doi:10.1016/S1473-3099(18)30469-9.
[39] Robert W. Eisinger, et al., *HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable*, 321 JAMA 451 (2019). doi:10.1001/jama.2018.21167.
[40] People experiencing homelessness are significantly more likely than the general population to be living with HIV. Kinna Thakarar et al., *Homelessness, HIV, and Incomplete Viral Suppression*, J Health Care Poor Underserved, 2016 Feb; 27(1). doi:10.1353/hpu.2016.0020
[41] Food insecurity is highly prevalent among people living with HIV, even in well-resourced cities. Aranka Anema, et al., *Food insecurity and HIV/AIDS: current knowledge, gaps, and research priorities*, Curr HIV/AIDS Rep. 2009;6(4):224-231. doi:10.1007/s11904-009-0030-z
[42] People living with HIV are disproportionately likely to be unemployed. Liza M Conyers, et al., *A Critical Review of Health, Social, and Prevention Outcomes Associated With Employment for People Living With HIV*, AIDS Educ Prev, 2017 Oct;29(5). doi: 10.1521/aeap.2017.29.5.475.
[43] Sheri Weiser, et al., *Conceptual framework for understanding the bidirectional links between food insecurity and HIV/AIDS*, Am J Clin Nutr, 2011 Dec;94(6). doi: 10.3945/ajcn.111.012070.

was associated with worse HIV medical outcomes, such as increased viral load and increased mortality.[44] Food insecurity is similarly associated with worse medical outcomes, with current research indicating that food insecure people living with HIV are substantially less likely to have achieved viral suppression than those who are food secure.[45]

Oregon's proposed SDOH initiatives hold significant promise to improve health outcomes for people living with HIV. We urge CMS to approve Oregon's proposals because they will: (1) directly connect vulnerable populations, including people living with HIV, to needed SDOH services; (2) incentivize CCOs to make additional investments in SDOH services going forward; and (3) invest in community organizations addressing SDOH, reducing future need for acute clinical treatment for all populations, including people living with HIV.

a. *CMS should approve Oregon's proposals to directly connect vulnerable populations, including people living with HIV, to needed SDOH services*

HHCAWG supports Oregon's plan to provide a defined set of SDOH services to certain populations identified as vulnerable based on transition-related criteria. The transitions Oregon identifies, such as experiencing homelessness or housing insecurity, disproportionately impact people living with HIV and can significantly disrupt access to consistent treatment and care.[46] Connecting people to responsive services such as housing, food assistance, and employment supports will help eliminate barriers to care and improve outcomes. For example, medically-tailored food supports, such as medically-tailored meals, have been shown to decrease hospitalizations by ten percentage points and increase medication adherence from a baseline of 47% up to 70% for people living with HIV.[47] Similarly, when individuals living with HIV receive supportive housing placements, they are twice as likely as those without such supports to have an undetectable viral load after 12 months of treatment.[48]

Given the importance of these services, we are heartened by Oregon's proposal to invest in them in such a robust fashion. We therefore urge CMS to approve these investments. Additionally, we suggest that Oregon and CMS consider expanding on this proposal by working to provide additional funding for these services over the full five-year demonstration period, rather than phasing down funding beginning in year three. By providing funding for transition services throughout the waiver period, Oregon would ensure that CCOs have adequate time to build community partnerships and capabilities and to identify the most effective interventions.

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[44] Angela A. Aidala, et al., *Housing Status, Medical Care, and Health Outcomes Among People Living With HIV/AIDS: A Systematic Review*, 106 Am J Pub Health, e1, e5 (2016). doi:10.2105/AJPH.2015.302905
[45] Seth C. Kalichman, et al., *Health and treatment implications of food insufficiency among people living with HIV/AID*S, Atlanta, Georgia. J Urban Health, 2010;87(4). doi:10.1007/s11524-010-9446-4
[46] Angela A. Aidala, et al., *Housing Status, Medical Care, and Health Outcomes Among People Living With HIV/AIDS: A Systematic Review*, 106 Am. J. Public Health, e1, e5 (2016). doi:10.2105/AJPH.2015.302905
[47] Kartika Palar, et al., *Comprehensive and Medically Appropriate Food Support Is Associated with Improved HIV and Diabetes Health*, J Urban Health, 94(1), 87–99 (2017). https://doi.org/10.1007/s11524-016-0129-7
[48] David Buchanan, et al., *The health impact of supportive housing for HIV-positive homeless patients: a randomized controlled trial*, Am J Public Health. 2009 Nov; 99 Suppl 3(Suppl 3): S675-80. doi: 10.2105/AJPH.2008.137810.

Furthermore, it is critical to recognize that, given the importance of SDOH services, existing inequities may deepen if the services do not reach all those who could benefit from them. For many communities, equitable access can depend on the availability of culturally responsive care. For example, peer supports have proven effective in the context of HIV care and are associated with superior retention in care.[49] For this reason, HHCAWG encourages CMS to approve Oregon's proposal requesting the ability to provide some of these transition services to members using Traditional Health Workers, including community health workers and peer support specialists. HHCAWG also urges the approval of Oregon's request for flexibility in reimbursement for SDOH services in fee-for-service Medicaid, which will ensure that programs outside the CCO model, including tribal health programs, receive reimbursement for providing these needed services.

b. *CMS should approve Oregon's proposals incentivizing CCOs to make additional investments in SDOH services going forward, ensuring continued access to these services for populations such as people living with HIV*

In several recent proposals, CMS has recognized that a wide array of factors can impact plan decision-making around SDOH, and that an effective approach will use a variety of supports and incentives to achieve change. For instance, in its 2021 SDOH guidance to state health officials, CMS suggested that states use incentive payments and quality review strategies to reward managed care organizations for investing in SDOH services.[50] Additionally, in its recent Advance Notice of Methodological Changes for Calendar Year 2023, CMS proposed development of Star Ratings measures in the Medicare Advantage program relating to SDOH in order to promote screening, referral, and payment for SDOH services.[51]

We therefore urge CMS, in line with its past actions, to approve Oregon's proposals incentivizing CCOs to make additional investments in SDOH services going forward, including:

- *Inclusion of a Social Needs Screening Metric in the Quality Incentive Program*
  Adding a measure to the Quality Incentive Program incentivizing social needs screenings will help drive CCO behavior and incentivize SDOH investments. A social needs screening will give CCOs the information and motivation to connect members to needed SDOH services. If screening reveals unmet needs among plan members, it may encourage CCOs to provide SDOH services or referrals to community-based organizations (CBOs).

- *Inclusion of Health-Related Services and Population Health Spending as Medical Spending for Capitation*

[49] Rigmor Berg, et al., *The effectiveness of peer-support for people living with HIV: A systematic review and meta-analysis*, PLoS ONE 16(6): e0252623 (2021). https://doi.org/10.1371/journal.pone.0252623
[50] Centers for Medicare & Medicaid Services, *Opportunities in Medicaid and CHIP to Address Social Determinants of Health (SDOH)*, Department of Health and Human Services (Jan. 2021), available at: https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf
[51] Centers for Medicare & Medicaid Services, *Calendar Year (CY) 2023 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies*, Department of Health and Human Services (Feb. 2022), available at: https://www.cms.gov/files/document/2023-advance-notice.pdf

We also support Oregon's inclusion of CCOs' health-related services spending, including population health spending that improves health equity, as medical spending for purposes of capitation. This will help to ensure these investments do not negatively impact CCOs' future rates and to incentivize CCOs to provide critical SDOH services.

c. *CMS should approve Oregon's proposals investing in community organizations addressing SDOH, reducing future need for acute clinical treatment*

CBOs play a powerful role in addressing SDOH, but their impact can be disrupted by various barriers. CBOs can identify and address "upstream" issues like food insecurity or housing instability before they give rise to a need for acute treatment. They can also be effective "downstream" referral partners for payers and providers, as they can respond to individual patients who present for treatment with social needs. The effectiveness of CBOs is limited, however, by factors such as funding constraints, administrative burdens associated with navigating patient privacy and other laws, and a need to develop additional infrastructure to scale up delivery of services.[52]

For this reason, we urge CMS to support Oregon's proposal requiring CCOs to invest at least 3% of their budgets for population health toward health equity investments, of which at least 30% would be directed to community investment collaboratives. These investments will help CBOs build capacity through technical assistance or grants to support training and leadership development. Similar investments have been effective elsewhere. For instance, Massachusetts has used its 1115 waiver to launch its Social Services Organization Preparation Fund, which supports infrastructure costs for community organizations, enabling these organizations to partner effectively with Medicaid Accountable Care Organizations to provide housing and nutrition supports. Massachusetts noted in its recent 1115 waiver request that this program has been highly successful and requested its extension.[53] Massachusetts' success shows the promise of Oregon's proposed investments in community organizations.

4. CMS should deny Oregon's proposal to waive coverage of drugs that have gone through the FDA's accelerated approval process

In contrast to our support for other aspects of Oregon's proposal, HHCAWG strongly disagrees with Oregon's proposed waiver of accelerated approval drugs. This provision would allow the state to waive coverage of certain drugs that have gone through the FDA's accelerated approval process, while still being allowed to receive generous rebates from manufacturers through the Medicaid Drug Rebate Program. This section of Oregon's proposal is both unlawful and harmful to patients, especially those who require access to new specialty drugs.

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[52] *See, e.g., Mainstreaming Produce Prescriptions: A Policy Strategy Report*, Center for Health Law and Policy Innovation (Mar. 11-12 2021).

[53] Executive Office of Health and Human Services, *MassHealth Section 1115 Demonstration Extension Request*, Commonwealth of Massachusetts (Dec. 2021), available at: https://www.mass.gov/doc/1115-waiver-extension-request/download

a. Oregon's proposal to waive coverage of accelerated approval drugs is incompatible with federal law

The Medicaid Drug Rebate Program requires all drug manufacturers to provide rebates to the state and federal government as a condition of having their drugs covered on Medicaid. The program reduces state and federal spending, while still ensuring that Medicaid beneficiaries can access the drugs they need.[54] Formulary requirements for states in the Medicaid Drug Rebate Program are outlined in Section 1927 of the Social Security Act, codified at 42 U.S.C. § 1396r-8. Notably, Section 1927 is not found in the list of waivable provisions under Section 1115 authority.[55] In 2018, CMS affirmed that Section 1927 is not waivable by rejecting Massachusetts' Section 1115 proposal to create a closed formulary.[56] By failing to cover a subset of medically-necessary drugs, Oregon is proposing to operate a version of a closed formulary, which is incompatible with the advantages associated with the Medicaid Drug Rebate Program.

Furthermore, approval of any waiver to deny access to drugs that have gone through the accelerated approval process is incompatible with the goals of the Medicaid program. The primary objective of Medicaid is to "furnish medical assistance to…citizens."[57] This proposal clearly restricts the scope of assistance that would be available to beneficiaries of the Oregon Medicaid program. Therefore, Oregon's waiver is inappropriate and incompatible with federal law.

b. Oregon's proposal to waive coverage of accelerated approval drugs is harmful to Medicaid enrollees, including people living with HIV and other chronic conditions

Oregon's proposal to restrict access to drugs that have gone through the FDA's accelerated approval process has the potential to seriously harm Medicaid enrollees who require access to these drugs. Under this proposal, the state would review accelerated approval drugs for sufficient evidence of clinical efficacy, in order to determine whether they should be excluded from the formulary. However, the state does not indicate the criteria that would be used during review process, leading to a potentially high number of accelerated approval drugs being excluded.

Notably, the FDA's accelerated approval process was created in 1992, in response to the HIV epidemic.[58] The goal of this process is to allow expedited access to life-saving drugs and to address unmet medical need. To allow Oregon to impede this process could be potentially devastating to individuals living with HIV or other chronic diseases. Additionally, this is a particularly short-sighted proposal as we enter the third year of a global pandemic, when treatment innovation is

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[54] *See* Edwin Park, Ctr. for Children & Families, Geo. Univ. Health Policy Inst., *How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs*, 5 The Future of Children's Health Coverage 1, 1 (2019).

[55] Social Security Act § 1115(a)(1), 42 U.S.C. § 1315(a) (2012).

[56] *See* Letter from Tim Hill, Acting Dir., Ctr. for Medicaid & CHIP Servs. U.S. Ctrs. for Medicare & Medicaid Servs., to Daniel Tsai, Assistant Sec'y, MassHealth, Exec. Office of Health & Human Servs. (Jun. 27, 2018).

[57] *Stewart v. Azar,* 313 F. Supp. 3d 237, 243 (D.D.C. 2018).

[58] Food and Drug Administration Modernization and Accountability Act of 1997, S. Rep. 105-43, at 16 (1997); *see also* U.S. Food and Drug Administration, *The History of FDA's Role in Preventing the Spread of HIV/AIDS* (March 2019), available at: https://www.fda.gov/about-fda/fda-history-exhibits/history-fdas-role-preventing-spread-hivaids ("The ACTUP protest publicized patients' concerns to improve access to emergent therapies and pushed FDA to promulgate new accelerated approval regulations to accompany new treatment regulations for Investigational New Drugs implemented in 1987, both of which enabled desperately ill patients access to promising new therapies.").

moving rapidly in response to the urgency created by specific conditions. On balance, CMS should deny Oregon's proposed waiver of accelerated approval drugs.

We have included numerous citations to supporting research, including internet links. We direct CMS to each of the materials we have cited, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If CMS is not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

Thank you for the opportunity to provide feedback and for your thoughtful consideration of these comments. If you have further questions, please reach out to HHCAWG co-chairs Maryanne Tomazic (mtomazic@law.harvard.edu) with the Center for Health Law and Policy Innovation and Rachel Klein (rklein@taimail.org) with The AIDS Institute.

Respectfully submitted by the undersigned organizations:

AHF
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation Chicago
American Academy of HIV Medicine
APLA Health
Center for Health Law and Policy Innovation
Community Access National Network - CANN
Community Research Initiative, Inc. (CRI)
HealthHIV
HIV+Hepatitis Policy Institute
HIV Dental Alliance
HIV Medicine Association
iHealth
International Association of Providers of AIDS Care
NASTAD
Positive Women's Network-USA
Prevention Access Campaign
San Francisco AIDS Foundation
SisterLove, Inc.
The AIDS Institute
Vivent Health