April 13, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Re: Oregon Health Plan 1115 Demonstration

Dear Secretary Becerra:

Thank you for the opportunity to submit comments on the Oregon Health Plan 1115 Demonstration. The undersigned organizations represent millions of individuals facing serious, acute and chronic health conditions. We have a unique perspective on what individuals and families need to prevent disease, cure illness and manage chronic health conditions. The diversity of our organizations and the populations we serve enable us to draw upon a wealth of knowledge and expertise that is an invaluable resource regarding any decisions affecting the Medicaid program and the people that it serves. We urge the Department of Health and Human Services (HHS) to make the best use of the recommendations, knowledge and experience our organizations offer here.

Our organizations are committed to ensuring that any changes to the healthcare system achieve coverage that is adequate, affordable and accessible for patients and consumers.[1] We appreciate the focus that the Oregon Health Program has placed on health equity, as well as the changes that the state made in response to the feedback received during the state-level comment period, including the removal of the waiver of retroactive coverage. 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.

However, our organizations remain concerned by certain proposals in this demonstration that would jeopardize access to care for patients. While we appreciate that the state has removed requests to implement a closed formulary and waive the Early and Periodic Screening Diagnosis and Treatment (EPSDT) benefit, our organizations remain concerned that the revised proposals could still create significant barriers to care for the patients we represent. We are opposed to the proposed limitations on coverage of accelerated approval drugs, as this will prevent patients from accessing new and life-saving treatments. Additionally, the continued use of a prioritized list for EPSDT and other services is also a problematic and unnecessary barrier to care for our patients.

Our organizations offer the following comments on the 1115 Demonstration Waiver for the Oregon Health Program.

Continuous Eligibility

Our organizations support the request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Implementing continuous eligibility is an important step in improving health equity, and Oregon's proposed plan for continuous eligibility is already serving as a model for other states interested in improving access to coverage and health equity nationally.[2] Continuous eligibility increases equitable access to care, as studies show that children of color are more likely to be affected by gaps in coverage.[3]

For patients with serious and chronic conditions, a gap in healthcare coverage could mean delays in receiving needed treatments and services that ultimately lead to a worsening of their condition and other negative health outcomes. 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.[4] Our organizations support continuous eligibility as a method to reduce these negative health outcomes for patients and appreciate Oregon's efforts to work towards health equity. We encourage HHS to approve this proposal.

Prescription Drug Coverage

While our organizations appreciate that the state has removed the proposed closed formulary in response to feedback at the state level, we are still strongly opposed to the state's request for authority to exclude drugs approved through the Food and Drug Administration's (FDA) accelerated approval process. Many of the patients that we represent benefit tremendously from accelerated approval drugs and will continue to do so as new medicines come to the market through this process. Removing access to these potentially life-saving treatments will undoubtedly harm patients with serious and chronic illnesses.

In the past decade, many new treatments have been approved through the accelerated approval process that benefit patients. For example:

- The lung cancer survival rate has increased 33% in the past 10 years.[5] Improvements in treatment, including approval and use of targeted therapies, have been an important driver of reduced mortality.[6] Multiple targeted therapies, including therapies that target the epidermal growth factor receptor (EGFR) gene and a mutation in the anaplastic lymphoma kinase (ALK) gene, have come to market through the accelerated approval process.[7,8] For patients who do not have these markers, immunotherapies that target the PD-L1 protein have been an important development in treatment. For example, one immunotherapy approved through accelerated approval process that targets PD-L1 has been found to double the five-year survival

outcomes of patients with non-small cell lung cancer (NSCLC) when compared to chemotherapy treatment and to have less adverse effects on patients than chemotherapy.[9]

- Blood cancer patients have benefitted tremendously from the use of the accelerated approval pathway to bring treatments to market that would not have otherwise been available. Since the introduction of the pathway, 24 drugs for blood cancers have completed their post-market studies after accelerated approval and proven their clinical benefits. Additionally, 18 drugs for blood cancers that are currently available to patients are completing these post-market studies to verify their clinical benefits. This accounts for approximately a third of all blood cancer drugs approved by the FDA, demonstrating that the accelerated approval pathway is a critical lifeline for blood cancer patients and necessary for continued innovation.
- Of the 7,000 rare diseases that have been identified, more than 90% have no FDA-approved treatment.[10] Between 2008 to 2016, 78% of drug approvals for rare disease utilized one or more of the FDA's flexible development approaches, including accelerated approval and the use of surrogate endpoints.[11] [12] Again, these are the potentially life-saving medications that patients could struggle to access under Oregon's proposed limitations.

Our organizations are concerned that Oregon's proposal does not clearly define which drugs with accelerated approval will be limited or excluded, nor does it define the criteria and process for determining clinical efficacy of medications and coverage under Oregon's Medicaid program. This lack of detail prevents our organizations from fully commenting on this proposal and its potential implications on our patient populations. The FDA has a rigorous process for any drug to come to market, and allowing different state Medicaid programs to develop their own standards would risk the creation of duplicative, less rigorous and less transparent processes by different state entities. Proposals like Oregon's could also lead to a patchwork of different coverage policies across the states with significant variation in our patients' access to care based on where they live.

Oregon's proposal also does not include an appeals process for patients to access drugs that they state may choose to exclude. However, even an appeals process or exemptions for certain classes of drugs would not eliminate the barriers to care that for the patients we represent. Appeals processes can cost patients important time while waiting for the medication that they need to be approved, particularly for patients with life-threatening conditions that drugs with accelerated approval can treat. Patients without the resources or health literacy to navigate a complex administrative process may not even attempt an appeal, exacerbating health disparities.

For years, the Medicaid program has had an open formulary to ensure that low-income children, adults, seniors and people with disabilities can access to medications that they need. Oregon's proposal would significantly undermine this critical patient protection and put the care of these populations at risk. Medicaid patients whose drugs are no longer covered will not have the same ability as patients with private coverage to shop around for other health insurance plans, nor are they likely to be able to pay out-of-pocket for medications. Our organizations urge HHS to reject Oregon's request to this limit coverage of accelerated approval drugs.

EPSDT Benefit and Prioritized List

Our organizations appreciate that Oregon is no longer requesting to waive the EPSDT benefit in its Section 1115 demonstration waiver. However, we remain concerned that there will still be significant barriers to accessing EPSDT benefits for children. Oregon has proposed to review and revise the list of medically necessary services that will be available for children, but it is not clear how medical necessity will be defined since this determination is made on an individualized basis. There is also no information

about what the appeals or exceptions process will look like. Patients who need services that are not on the list will likely face challenges in trying to access healthcare, which even the state has acknowledged in their proposal can be "lengthy and burdensome to providers and families." Furthermore, because children of color are enrolled in Medicaid at disproportionately higher rates,[13] they are likely to also be disproportionately affected by these barriers to services, undercutting Oregon's efforts to improve health equity. We urge the state to remove the use of the prioritized list to allow children equitable access to care, in keeping with the purpose of the EPSDT benefit.

We also urge HHS to reconsider allowing Oregon to continue to use the prioritized list for adults as well. The original reasoning behind this list was to enable coverage for more adults before the ACA's Medicaid expansion had gone into effect, but the state now receives federal matching funds for these enrollees and limiting their benefits is not consistent with the objectives of the Medicaid program. There is also no exceptions process for adults to access care outside of the list. Adults should have full access to necessary healthcare services in keeping with the goals of Medicaid.

Investments in Social Determinants of Health (SDOH) Services and Changes to Managed Care
Our organizations appreciate 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 HHS to work with Oregon to develop rates based on all state plan services and supplement those rates by adding health-related social needs services to ensure patients are able to access all the care that they need. We also urge HHS to work with Oregon to establish a plan for oversight to ensure that state plans are correctly recording and reporting administrative expenditures when calculating their medical loss ratios.

Conclusion
Thank you for the opportunity to provide comments on this proposal. Our organizations urge you to approve Oregon's proposal to expand continuous eligibility but reject requests to limit prescription drug coverage and continue to use a prioritized list of EPSDT and other healthcare services.

Sincerely,

American Diabetes Association
American Heart Association
American Kidney Fund
American Lung Association
Arthritis Foundation
Asthma and Allergy Foundation of America
Cancer Support Community
Epilepsy Foundation
Hemophilia Federation of America
Lupus Foundation of America
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
Susan G. Komen

The AIDS Institute
The Leukemia & Lymphoma Society

[1] "Consensus Health Reform Principles." March 9, 2022. Available at: https://www.lung.org/getmedia/0912cd7f-c2f9-4112-aaa6-f54d690d6e65/ppc-coalition-principles-final.pdf
[2] Chomilo, Nathan. Building Racial Equity into the Walls of Minnesota Medicaid. Minnesota Department of Human Services. February 2022. Available at: https://edocs.dhs.state.mn.us/lfserver/Public/DHS-8209A-ENG
[3] 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)
[4] Sugar S, Peters C, De Lew N, Sommers BD. 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 Healthy Policy. April 12, 2021. Available at: https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf
[5] U.S. National Institutes of Health, National Cancer Institute. Recent Trends in SEER Relative Survival Rates, 2000-2018. Available at: SEER Cancer Statistics Review, 1975-2018
[6] John, Ani et al. "Value of Precision Medicine in Advanced Non-Small Cell Lung Cancer: Real-World Outcomes Associated with the Use of Companion Diagnostics." The oncologist vol. 25,11 (2020). Available at: https://pubmed.ncbi.nlm.nih.gov/32627882/; Howlader, Nadia et al. "The Effect of Advances in Lung-Cancer Treatment on Population Mortality." The New England journal of medicine vol. 383,7 (2020). Available at: https://pubmed.ncbi.nlm.nih.gov/32786189/
[7] American Lung Association, EGFR and Lung Cancer. October 28. 2021. Available at: EGFR and Lung Cancer | American Lung Association
[8] American Lung Association, ALK and Lung Cancer. October 28, 2021. Available at: ALK and Lung Cancer | American Lung Association
[9] Reck, Martin et al. "Five-Year Outcomes With Pembrolizumab Versus Chemotherapy for Metastatic Non–Small-Cell Lung Cancer With PD-L1 Tumor Proportion Score ≥ 50%." Journal of Clinical Oncology, 2021. Available at: https://ascopubs.org/doi/full/10.1200/JCO.21.00174
[10] Jennifer Huron, *New Study Investigates the Number of Available Orphan Products, Generics and Biosimilars,* Nat'l Org. for Rare Disorders (Mar. 25, 2021). Available at: https://rarediseases.org/new-study-investigates-the-number-of-available-orphan-products-generics-and-biosimilars/
[11] R. Moscicki, (2016) CDER 2016 Update for Rare Diseases https://www.fda.gov/media/103126/download (Accessed February 19, 2020)
[12] Joshua Lehrer-Graiwer, Linda Yokoshima, Barbara Tong, Ted W. Love, (2020) Accelerated approval of Oxbryta® (voxelotor): A case study on novel endpoint selection in sickle cell disease, *Contemporary Clinical Trials,* https://doi.org/10.1016/j.cct.2020.106161. (https://www.sciencedirect.com/science/article/pii/S1551714420302391)
[13]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)