

April 11, 2022

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

Re: Oregon Waiver Renewal Application

Dear Administrator Brooks-LaSure:

We are writing to comment on the Oregon application to the Centers for Medicare and Medicaid Services (CMS) for its 1115(a) Demonstration Waiver renewal. We urge CMS to reject the Oregon waiver renewal application so that the state has an opportunity to reconsider their reliance on flawed decision-making standards. While we appreciate the state's focus on health equity and its decision not to request continuation of the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) waiver that subjects children to a prioritized list of services denying access to medically necessary care, we are concerned that the state's waiver renewal application will entrench health inequality and further deny or delay care to people with disabilities and chronic conditions. The state's defense of its use of the quality-adjusted life year (QALY) metric and effort to exclude FDA-approved drugs from coverage are inconsistent with its stated goals of health equity.

CMS Should Advance a Consistent Policy Barring Use of QALYs in Medicare and Medicaid

As you know, Oregon's original waiver application in 1992 was denied because the U.S. Department of Health and Human Services (HHS) found that the state's reliance on QALYs to develop its prioritized list of services would violate the Americans with Disabilities Act (ADA). The Secretary expressed concern 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."¹ In 2010, Congress barred the use of QALYs in Medicare, indicating a consistent policy across Medicare and Medicaid that QALY-based value assessments were not appropriate for use in decisions related to coverage, reimbursement, and incentive programs.²

¹ In 1992, the HHS Secretary wrote this opinion referencing the letter from HHS to Oregon denying its waiver application. See the opinion at <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>. In its letter, Secretary Sullivan said. "The Americans with Disabilities Act, which was passed with the President's strong support and which went into effect last month, leaves no question that those with disabilities must enjoy the same treatment under the law as other Americans. Oregon's proposal does not meet that test, and we must return it for further work." See excerpts of the 1992 HHS letter to Oregon's Governor at <https://olis.oregonlegislature.gov/liz/2022R1/Downloads/PublicTestimonyDocument/37716>.

² Social Security Act, P.L. 117-39, 1181 (1320) (e).

Despite HHS's 1992 decision that the use of QALYs would be in violation of the ADA, Oregon continued to include the QALY in its methodology to determine its prioritized list of services. Oregon defended its continued use of QALYs in response to concerns from patients and people with disabilities. The state claimed that "QALYs currently play only a minor role in decisions by the Health Evidence Review Commission, usually in comparing two treatments for the same condition." While the state does not believe QALYs are used to discriminate against people with disabilities, the state acknowledged their use to determine cost effectiveness, to prefer treatments that QALYs deem to be cost effective, and to force patients to take low-cost treatments before a more costly service. We would add that when a service is not covered on the Prioritized List — it is not subject to appeals or a review of medical necessity — it is simply denied. The use of an inherently discriminatory metric of cost effectiveness is not appropriate to make decisions in federal programs that impact access to care for people with disabilities, especially when people have no way to appeal those decisions.

Oregon asserts that the Prioritized List takes into account the values and preferences of providers and members. Yet, there is substantial evidence that the values and preferences of people with disabilities are not reflected in QALY-based value assessments. The National Council on Disability (NCD) — an independent federal agency charged with advising the President, Congress, and other federal agencies regarding policies, programs, practices, and procedures that affect people with disabilities — published a report in 2019 titled *Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series*. The report provided recommendations to Congress and the administration emphasizing that its health care policies should not reference or rely on the QALY metric.³

QALYs are Subject to Disability Rights Laws

Disability experts agree that the QALY is inherently discriminatory and subject to disability rights laws. The NCD noted that Section 504 and Section 1557 also apply to Medicaid programs because they receive federal financial assistance and that authorities in these Sections apply to benefits and reimbursement decisions. Therefore, Medicaid programs should not rely on cost-effectiveness research or reports that are developed using QALYs. NCD further noted that covered health insurance programs 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 illnesses. The Disability Rights Education and Defense Fund similarly concluded that the use of QALYs discriminates in violation of disability nondiscrimination laws.⁴

³ The NCD report states, "Disability rights advocates are rightly concerned that these preferences are not based on an accurate understanding of what it is like to have a disability, but on stereotypes and a lack of understanding about disabilities." See

https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

⁴ <https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law/>

Oregon’s Waiver Threatens to Entrench Health Inequities by Relying on QALYs

Advocacy organizations representing patients in communities of color have synthesized the evidence on QALY-based value assessments, finding that the QALY’s “methodological flaws become more pronounced when trying to understand the value of a treatment for a populations [*sic*] not represented to a statistically significant degree in the clinical trials or the peer-reviewed literature, including, but not limited to Latinx populations, persons of African descent, and Asian-Pacific Islander and Native American populations.”⁵ The NCD has also recognized that health disparities for people with disabilities are exacerbated for those who are disabled and a person of color.⁶ The health equity implications of using QALYs are further intensified during situations in which patients cannot find coverage of medically-indicated care, treatments, or services but are able to find coverage under Oregon’s “Death with Dignity Act.” Health equity is further challenged when people who cannot afford commercial insurance are subject to highly restrictive coverage under a prioritized list without an opportunity to appeal for medical necessity. Reference to QALYs to restrict covered services under a prioritized list can only serve to increase, not decrease, the health inequity that Oregon seeks to address as part of its waiver.

Oregon touted efforts to selectively reprioritize or add specific treatments brought to its attention, a tactic that is not likely to improve health equity. People living with disabilities and chronic conditions in the most underserved communities are less likely to access the resources needed to fight for coverage, call for reprioritization, or request consideration of a service not listed. Hurdles to receiving medically necessary care will most impact the very communities that Oregon claims to prioritize for care.

Oregon Should Not be Given Authority to Exclude FDA-Approved Drugs

Oregon’s request for new authority to exclude drugs approved on the Food and Drug Administration’s (FDA) Accelerated Approval Program would further discriminate against the most vulnerable patients. Many novel treatments for rare diseases are approved via the Accelerated Approval Program given the small patient populations in question. Denying coverage of treatments approved via the Accelerated Approval Program — whether by use of a prioritized list or by a new state drug review process — would subject Oregonians with rare and disabling diseases to even more limited access to current and future life-saving care. Under the Medicaid Drug Rebate Program (MDRP), FDA-approved drugs with a rebate agreement are required for coverage in state Medicaid programs, a policy that has served to protect vulnerable patients and people with disabilities from discrimination. Oregon should not have the ability to override the FDA’s authority and circumvent the existing laws governing the MDRP. Oregon’s request for this authority raises further concerns about the waiver renewal’s potential to increase reliance on discriminatory QALYs and similarly flawed data as part of

⁵ <https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods>

⁶ https://www.ncd.gov/sites/default/files/NCD_Health_Equity_Framework.pdf

Oregon's proposed drug reviews, especially considering their foundational goal for this policy seems to be cutting costs, not achieving access to new treatments.

Oregon Should Quickly Comply with the Federal EPSDT Law

While we appreciate that Oregon will not continue its EPSDT waiver, we are concerned that the phase out period ends in 2024. The discriminatory implications of the Prioritized List's reliance on QALYs are exacerbated when children are subject to its limited coverage, contrary to the federal law requiring coverage of medically necessary services for covered children. We would urge the state to expedite its efforts to phase out its EPSDT waiver to come into compliance with the federal law so that children are not subject to discrimination and denied coverage of medically necessary care.

Medicaid Expansion Impacts Justification for Oregon's Medicaid Waiver

In 2010, the Affordable Care Act (ACA) expanded Medicaid eligibility with the federal government providing 100 percent of the cost to cover newly eligible enrollees — until the end of 2016, dropping to 90 percent in 2020 — so that, going forward, states will only cover 10 percent of enrollee costs, which is considerably less than what states paid for Medicaid-eligible enrollees under pre-ACA criteria. This change is a significant increase in federal support from the early 1990s when Oregon initially sought its Medicaid waiver. CMS should reject the Oregon waiver in light of increased federal support for coverage of newly eligible enrollees and the discriminatory nature of the Prioritized List.

In closing, we urge CMS to reject Oregon's waiver renewal application, in accordance with its decision in 1992. A consistent policy across Medicare and Medicaid barring the use of QALYs will serve to improve health equity, access to medically necessary care, and compliance with disability rights laws.

Sincerely,

Accessia Health
Aimed Alliance
Allergy & Asthma Network
Allfocus Technologies, Inc.
Alliance for Aging Research
Alliance for Patient Access
The ALS Association
American Academy of Medical Ethics
American Association of Kidney Patients
American Association of People with Disabilities
American Behcet's Disease Association
The Arc of the United States
Autism Insurance for Oregon

Autism Society of America
Axis Advocacy
The Bonnell Foundation: Living with cystic fibrosis
Buscher Consulting
CancerCare
Center for Autism and Related Disorders
Coalition of State Rheumatology Organizations
Tony Coelho
Color of Crohn's and Chronic Illness
Cystic Fibrosis Research Institute
Deaf Health Coalition
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Policy Consortium
Disability Rights Education & Defense Fund
Epilepsy Foundation
Euthanasia Prevention Coalition-US
Genetic Alliance
Global Liver Institute
GO2 Foundation for Lung Cancer
Headache and Migraine Policy Forum
Health Hats
HealthHIV
Hypertrophic Cardiomyopathy Association
ICAN, International Cancer Advocacy Network
International Foundation for AiArthritis
Islamic Civic Engagement Project
Justice in Aging
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
The Mended Hearts, Inc.
Men's Health Network
MLD Foundation
National Minority Quality Forum
National Organization of Nurses with Disabilities
Not Dead Yet
NTM Info & Research
Partnership to Fight Chronic Disease
Partnership to Improve Patient Care
Patients' Rights Action Fund
Physicians for Compassionate Care
Preventive Cardiovascular Nurses Association
PXE International
The Salvador E. Alvarez Institute for Non-Violence

Texas Rare Alliance
TSC Alliance