DRO | Disability Rights Oregon

Submitted via

April 13, 2022

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

Re: Oregon 1115(a) Demonstration Wavier Renewal

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to provide comments on Oregon's application to the Centers for Medicare and Medicaid Services (CMS) regarding its 1115(a) Demonstration Waiver renewal. Disability Rights Oregon (DRO), the protection and advocacy system for Oregon, is writing to express our serious concerns with Oregon's Medicaid program's continued devaluation of the lives of people with disabilities. We urge CMS to reject the Oregon waiver renewal application because it deprioritizes the treatment of people with disabilities, which is in direct contradiction of Oregon's own stated health equity values.

Oregon Health Authority and Oregon Health Policy Board's health equity definition is as follows: "Oregon will have established a health system that creates health equity when all people can reach their full health potential and well-being and are not disadvantaged by their race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances."[1]

To ensure people with disabilities, chronic health conditions, and rare diseases are valued equitably and Oregon's Medicaid program stays true to its own stated values, we encourage CMS to take to the following actions:

1. Bar the use of Quality Adjusted Life Years (QALY) scores in Medicare and Medicaid
2. Not give Oregon the authority to exclude Food and Drug Administration's (FDA) approved drugs
3. Require Oregon to quickly comply with federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) laws

[1] Oregon Health Authority. Health Equity Committee. Accessed April 13, 2022: https://www.oregon.gov/oha/OEI/Pages/Health-Equity-Committee.aspx

**Oregon Must Disallow the Use of QALYs**

First, CMS should advance a consistent policy barring the use of Quality Adjusted Life Years (QALY) scores in Medicare and Medicaid. In doing so, CMS should direct Oregon to stop using the QALY in setting its prioritized list of services and rescore any condition where QALYs were used to establish a score. CMS should evaluate the ways in which Oregon's Medicaid system has achieved cost neutrality while expanding coverage in light of clear evidence of systemic discrimination and devaluing of the lives of people with disabilities and chronic disease to see if Oregon is complying section 504 or the Rehabilitation Act and the Americans with Disabilities Act (ADA). Corrective action must be taken anywhere Oregon's Medicaid program is out of compliance.

Oregon's original waiver application in 1992 was denied because the U.S. Department of Health and Human Services (HHS) found the state's reliance on QALYs to develop its prioritized list of services would violate the 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 ADA."[2] 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.[3] Oregon's waiver was finally approved in 1993 when committed to CMS using a scoring methodology that complied with the ADA, Oregon has reverted to an approach for prioritizing health services for coverage that factors cost-effectiveness and the QALY. Officially, Oregon excluded the survey-based QALY data that triggered the denial of its initial waiver application in 1992. Yet, the voting members of Oregon's Health Policy Commission have the authority to override the results of non-QALY considerations, which they did in over 70% of the cases. The discriminatory outcome for how care is valued and prioritized is the same.[4]

Today, the Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, continues to use QALY-driven data and analysis in the formula for the prioritized list of services. As reconstructed in 2008, Oregon's revised prioritization framework emphasizes preventive services and chronic disease management in order to keep the "population healthy rather than waiting until an individual gets sick before higher cost services are offered to try to restore good health." This focus on preventative care for the healthy population has deprioritized – and in some cases defunded – coverage of health services for individuals living with disabilities, including mental health services for children. Although

[2] The New York Times. Oregon Health Plan is Unfair to the Disabled. Accessed April 13, 2022: https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html
[3] Social Security Act, P.L. 117-39, 1181 (1320) (e).
[4] DiPrete B, Coffman D. A Brief History of Health Services Prioritization in Oregon. Oregon Health Services Commission, March 2007. https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf

Oregon removed a direct and explicit reference to QALYs from its cost-effectiveness framework in 2017, it continues to rely upon the QALY-driven prioritization scores for condition-treatment pairs that were already established at that time. In addition, HERC continues to consider QALY-based analysis in evaluating other factors in the formula.[5]

The HERC does not routinely seek input from patients or individuals impacted by the health conditions in evaluating impact on healthy life or suffering. Instead, commissioners are frequently presented with QALY metrics calculated by entities such as the Institute for Clinical and Economic Review (ICER) as they vote. After a category is determined and weighting factors established, a total score is calculated and reviewed by the HERC, which reserves the right to manually override the scores to move services up or down the prioritized list. A few excluded services for people with disabilities include treatment for hearing impairment, Bell's Palsy, Spastic Diplegia, and certain personality disorders.[6]

Disability experts agree that the QALY is inherently discriminatory and subject to disability rights laws. The National Council on Disability noted that Section 504 and Section 1557 also apply to Medicaid programs because they receive federal financial assistance and that these authorities apply to benefits and reimbursement decisions. Therefore, Medicaid programs should not rely on cost-effectiveness research or reports that are developed using QALYs. They 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.[7]

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

Second, CMS should not give Oregon the authority to exclude Food and Drug Administration's (FDA) approved drugs. The FDA accelerated-approval pathway has a vital purpose. It allows faster access to new drugs for people with serious health conditions. These drugs constitute only about 4 percent of net Medicaid drug spending, yet is the only path to FDA approval many treatments for rare diseases have because there are too few patients to conduct full clinical trials. If CMS allowed Oregon to exclude these FDA-approved drugs it would violate the longstanding federal open-formulary requirement, under which state Medicaid programs must cover nearly all FDA-approved

[5] Oregon Health Authority. Prioritization Methodology. Accessed April 13, 2022: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx
[6] Oregon Health Authority. Prioritized List of Health Services. Accessed April 13, 2022: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx
[7] Disability Rights and Education Defense Fund. Pharmaceutical Analyses Based on the QALY Violate Disability Nondiscrimination Law. September 21, 2021. https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law/

drugs, including those under the accelerated-approval pathway, to ensure beneficiaries have access to needed prescription drugs. The open-formulary protection is a key element of the Medicaid Drug Rebate Program, under which drug manufacturers must provide significant rebates to the federal government and states as a condition of having their drugs covered by Medicaid.

Oregon's request for new authority to exclude drugs approved on the FDA accelerated pathway would further discriminate against the most vulnerable patients. Many treatments for rare diseases are approved via the accelerated approval pathway given the small patient populations in question. Denying coverage of treatments approved via the accelerated approval pathway, whether by use of a prioritized list or by a new state drug review process, would have the impact of subjecting Oregonians with rare and disabling diseases to even more limited access to current and future life-saving care with rare and disabling diseases. Which leaves us asking – what criteria will Oregon use to evaluate treatments? If the federal government approves this request, it could result in some low-income Oregonians losing access to newer, high-cost prescriptions. Oregon's proposal will not yield significant savings for state Medicaid programs the way it hopes but it will create a lower standard of care. The Partnership to Fight Chronic Disease's initial analysis found that, in 2020, accelerated approval drugs accounted for only .4% of the total Medicaid spending in Oregon and, between 2015 and 2020, the category represents just .5% of the total Medicaid spending growth, relative to the 31% growth in total Medicaid spending in the state during the same span.[8] This policy will deny potentially life-saving drugs to people with rare diseases who have little chance of a treatment being approved through the traditional FDA process.

**Oregon Must Comply Quickly with Federal EPSDT Law**

Finally, CMS should require Oregon to quickly comply with the federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) law. Patients and their families must have immediate access to a denial of coverage appeals process that is impartial and not administered by a coordinated care organization or the Oregon Health Authority to determine medical necessity. Oregon must not be allowed to continue to apply the prioritized list to children 21 and under.

**Support Medicaid Coverage for Individuals Leaving Jail and the Oregon State Hospital**

DRO is supportive of expanding Medicaid coverage to individuals transitioning out of jail and the Oregon State Hospital. Coverage during transition will maintain access to care and allow patients to remain stable on the medications that work for them. The current disruption in care

[8] Partnership to Fight Chronic Disease. Quantifying Impact of Accelerated Drugs on Medicaid Spending: De Minimus Impact, Maximum Attention. Accessed April 13, 2022: https://www.fightchronicdisease.org/resources/acceleratedapproval

has led to many individuals decompensating shortly after release and resulting in further encounters with the criminal justice system.

We thank you for the opportunity to comment. Please do not hesitate to reach out for questions or follow up to Meghan Moyer at mmoyer@droregon.org.

Sincerely,

Disability Rights Oregon