

October 4, 2022

Dr. Kevin Olson, Chair, MD
Health Policy & Analytics Division
Delivery Systems Innovation
Health Evidence Review Commission
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Dear Dr. Olson:

We are writing in anticipation of the Health Evidence Review Commission (HERC) meeting on October 6, 2022, during which the commission will review its proposed policy options to guide Commission's use of quality-adjusted life years (QALYs) in meeting materials and decision-making.¹ Our organizations continue to be concerned about the discriminatory implications of the QALY metric that run contrary to federal disability and civil rights laws. We urge the HERC to discontinue its use of QALYs, consistent with the guidance from the U.S. Department of Health and Human Services (HHS) to the State of Oregon when rejecting the state's original waiver application 30 years ago in 1992.

The HERC Should Cease Use of and Reliance on QALYs and Similar Metrics that Discriminate against People with Disabilities and Older Adults

We strongly oppose the use of QALYs in Oregon to set its prioritized list of services and urge the HERC to rescore any condition where QALYs were used to establish a score. For too long, Oregon's Medicaid system has achieved cost savings through systemic discrimination and devaluing of the lives of people with disabilities and chronic disease and has not complied with section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act (ADA). Corrective action must be taken anywhere Oregon's Medicaid program is out of compliance, starting with rescoring conditions.

Oregon's original waiver application in 1992 was denied because HHS found the state's reliance on QALYs to develop its prioritized list of services would violate the ADA. HHS stated, "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

¹ <https://www.oregon.gov/oha/hpa/dsi-herc/pages/meetings-public.aspx>

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).

approved in 1993 when submitted 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

We are concerned that the 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 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, the HERC continues to consider QALY-based analysis in evaluating other factors in the formula.⁵

We are also concerned that 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 loss associated with Chronic Otitis Media (line 476), Bell's Palsy (line 485), Spastic Diplegia (line 491), and certain personality disorders (e.g., line 479).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

⁴ DiPrete B, Coffman D. A Brief History of Health Services Prioritization in Oregon. Oregon Health Services Commission, March 2007.

⁵ Oregon Health Authority. Prioritization Methodology. Accessed September 26, 2022: <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx>

⁶ Oregon Health Authority. Prioritized List of Health Services. Accessed September 26, 2022: <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>

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

The HERC Should Support Oregon’s Health Equity Goals

We urge the HERC to advance health equity by ending its use of QALYs and by influencing the development and use of evidence that is representative of all people living with a condition, regardless of race, color, national origin, sex, age, or disability. We were encouraged by the recent proposed rule issued by the U.S. Department of Health and Human Services, Office for Civil Rights, highlighting the risk of violating existing nondiscrimination laws posed by value assessments that place a lower value on life-extension for a group of individuals based within a protected population or via inappropriate adjustment of clinical end points for a protected population under Section 1557. The concerns that they raised are consistent with the justification HHS provided in denying Oregon’s original waiver application in 1992 as a violation of the ADA.⁸

The use of QALYs is in direct contradiction of Oregon’s own stated health equity values. The 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.”⁹ Most cost-effectiveness analyses rely on data from randomized clinical trials (RCTs) and health utility preference weighting surveys, data sources that primarily rely on inputs from non-disabled, white, Caucasian populations. This systematically biases available therapies to favor covering those that are effective for white people to the detriment of covering treatments effective for people of color and people with disabilities. People of color are disproportionately represented among people with disabilities and multiple co-existing conditions but are poorly represented in the data that drives conclusions about the effectiveness of treatments. The inevitable result is unequal access to care that effectively treats a condition for populations that may respond differently to treatments than the average of those represented in the evidence base.¹⁰

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/>

⁸ <https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html>

⁹ Oregon Health Authority. Health Equity Committee. <https://www.oregon.gov/oha/OEI/Pages/Health-Equity-Committee.aspx>

¹⁰ <https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods>

The HERC Has an Opportunity to Lead the Nation in Development of Alternative Coverage Strategies

When Oregon submitted its original waiver application, its goal was to expand coverage. While we have taken issue with Oregon's restricted benefits using a prioritized list of services, we are pleased that federal law now supports all states to expand coverage to nearly all adults with incomes up to 138% of the Federal Poverty Level by providing states with an enhanced federal matching rate (FMAP) for their expansion populations. In the future, we believe Oregon has a unique opportunity to lead in the development of alternative coverage strategies that expand availability of effective treatments by ceasing to rely on discriminatory metrics and instead relying on assessments of treatment value that recognize the heterogeneity of treatment impact on subpopulations to drive improved health decisions. The goal should not be to restrict coverage to the treatment that works best on average but to ensure beneficiaries receive the treatment that is most effective for them.

We recognize there is not consensus on one metric that would replace the QALY. We also are aware of alternative metrics for assessing the value of treatments that are inherently less discriminatory. The HERC should be at the forefront of identifying innovative metrics for making decisions, recognizing their benefits and limitations for making decisions, and developing methodologies that combine the use of these next generation metrics to communicate to providers and beneficiaries the treatment options that the science supports as most effective for treating a person within a subpopulation. Ultimately, value assessment methodologies will fail people who are not represented in the science. The HERC can address this challenge by leading an effort to explicitly call out the limitations of the data being used to make decisions and identifying the research questions that the field of science should prioritize in its work.

We would encourage the HERC to consult with entities that currently are prioritizing work to capture the burdens and outcomes that matter to people living with a condition or disease and to test and validate alternative methodologies. For example, the National Council on Disability, an independent federal agency advising Congress and the Administration on disability policy, has indicated that it will publish a report on alternatives to QALYs.¹¹ The Patient-Centered Outcomes Research Institute (PCORI) has developed useful resources, including an Economic Resource Center (ERC) through contract with RTI International to provide support in conducting activities related to capturing patient-centered costs and economic impacts for PCORI-funded research.¹² The Innovation and Value Initiative (IVI) is also working to drive innovation in value assessment through collaborative research and partnerships on patient preferences, novel methods of value, and value assessment model development.¹³

Conclusion

¹¹ <https://twitter.com/NatCounDis/status/1551614586171826177?s=20&t=129JEw1ky92ntXnnhXqg1Q>

¹² <https://www.pcori.org/resources/landscape-review-and-summary-patient-and-stakeholder-perspectives-value-health-and-health-care>

¹³ <https://www.thevalueinitiative.org>

We remain concerned that the HERC is unwilling to abandon its use of QALYs, knowing for 30 years that the metric is contrary to federal nondiscrimination laws. There is no excuse for the HERC to continue to delay complying with the 1992 guidance from HHS that QALYs violate the ADA. After 30 years, we expect more from the HERC and believe that it has a role to play in being part of the solution instead of part of the problem.

Thank you for your consideration of our concerns and recommendations.

Sincerely,

Allfocus Technologies, Inc
American Academy of HIV Medicine
American Association of Kidney Patients (AAKP)
Allergy & Asthma Network
Autism Insurance for Oregon
Axis Advocates
CancerCare
Caring Ambassadors Program
Colorado Cross-Disability Coalition
Cystic Fibrosis Research Institute
Disability Policy Consortium
Disability Rights California
Disability Rights Education and Defense Fund (DREDF)
Disability Rights Oregon
Epilepsy Foundation Oregon
Health Hats
healthywomenover50.org
Hepatitis B Foundation
Hepatitis C Association
ICAN, International Cancer Advocacy Network
Krishnan Family Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
M-CM Network
Men's Health Network
MLD Foundation
Rosie Bartel
National Alliance for Hispanic Health
National Disability Rights Network (NDRN)
National Native American AIDS Prevention Center (NNAAPC)
Not Dead Yet
Noona Leavell, M.D., Assistant Professor of Neurology, OHSU ALS and Neuromuscular Disorders Team

Mark O Loveless, MD MHA, FACP, OHSU/PSU School of Public Health
Jesse Larsen, Oregon Health and Science University
Pacific Northwest Bleeding Disorders
Parkinson's Resources of Oregon
Partnership to Fight Chronic Disease
Partnership to Improve Patient Care
Providence
Pulmonary Hypertension Association
RASopathies Network
SEIU Oregon State Council
SYNGAP1 Foundation
The ALS Association
The ALS Association Oregon and SW WA Chapter
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum
The Hepatitis C Mentor and Support Group, Inc. - HCMSG
TSC Alliance
US Hereditary Angioedema Association (HAEA)

cc:

Representative Rob Nosse, Chair, House Interim Committee on Health Care
Senator Deb Patterson, Chair, Senate Interim Committee on Health Care