

May 23, 2024

Gail Mizner, MD
Board Chair
Prescription Drug Affordability Board
c/o Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Dear Dr. Mizner and Members of the Board:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Colorado Prescription Drug Affordability Board's ongoing affordability review activities. Our comments follow letters sent to the Board urging it to avoid policies that would potentially discriminate by relying on discriminatory measures such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment, as well as encouraging the Board to include patients and people with disabilities throughout its decision-making process.¹ I am writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations related to its use of discriminatory value assessments and to request robust engagement of patients and people with disabilities.

As background, PIPC has been very concerned that the legislative provisions governing the use of QALYs and similar measures in legislation creating the Prescription Drug Affordability Board may be interpreted narrowly. The Board's recent conversation with the Program on Regulation, Therapeutics and Law (PORTAL) indicates to us that the Board is relying heavily on entities like PORTAL that view measures like QALYs and evLYGs as the gold standard, despite concerns shared by patients and people with disabilities. In response to the Board's questions to PORTAL related to foreign health systems, we would emphasize that referencing other countries is contrary to federal laws governing disability discrimination. PIPC and others have commented on proposed federal policies that would reference prices in other countries, raising concerns that such a policy would import discriminatory standards from other countries, and lead directly to lack of access to needed treatments for many Americans.² While Germany is often raised, we encourage the Board to review PIPC's paper on the German system in which we discussed its limited use of evidence, inappropriate comparators and endpoints, exclusion of health outcomes that are important to patients, and failure to capture heterogeneity of patient populations.³ PIPC would encourage the Board to also reference the work of the National Council on Disability, an independent federal agency advising Congress and the administration

¹ https://drive.google.com/file/d/1TarE5xF9h2vRU-0V55PkbGa3_9YJKNSD/view?usp=share_link

² https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_stakeholder_comment_on_importing_qalys.pdf

³ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/germany_draft_2022_9-21_edited_clean.pdf

on disability policy, which has consistently recommended against referencing foreign prices in comments related to a proposed international pricing index,⁴ Most Favored Nation policy,⁵ and federal legislation.⁶ The NCD’s recommendations against reliance on cost effectiveness are largely reflected in the new federal regulations discussed below, providing increased clarity on the prohibited use of discriminatory value assessments.

I am pleased to share that on May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, a law protecting the rights of people with disabilities in programs and activities receiving federal financial assistance.⁷ In response to the proposed rule last year, PIPC joined 100 organizations and individuals on a letter supporting agency rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.⁸

The U.S. Department of Health and Human Services’ rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don’t rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating, “The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment.” As you may be aware, section 1182 of the ACA bars Medicare’s use of QALYs and similar measures that discount the value of a life because of an individual’s disability. PIPC was pleased the final rules governing Section 504 would be interpreted as broader than section 1182.

The agency referenced both § 84.56 and § 84.57 as relevant to entities receiving federal financial assistance, which includes state Medicaid programs. For example, the agency stated, “Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as §

⁴ <https://www.ncd.gov/2020/08/05/ncd-statement-on-harm-of-using-international-pricing-index-for-u-s-prescription-drug-pricing/>

⁵ <https://www.ncd.gov/letters/2021-01-15-ncd-letter-to-cms-on-most-favored-nation-rule/>

⁶ <https://www.ncd.gov/letters/2021-04-29-ncd-letter-to-house-committees-with-concerns-regarding-h-r-3/>

⁷ 89 FR 40066 at https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

⁸ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf

84.56’s prohibition of discrimination based on biases or stereotypes about a patient’s disability, among others.” Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. As PIPC and others noted in its comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.⁹ Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

In summary, the new rules clarify that recipients of federal financial assistance, including Medicaid programs, may not rely on measures like QALYs.

Alternatively, PIPC recommends:

- The Board should engage directly with patients and people with disabilities to learn about their real-world experiences, consistent with recommendations from experts in the patient and disability communities.^{10,11,12,13}
- The Board should collaborate directly with the patient and disability communities to solicit information. For example, we share the concerns of Colorado advocates that the Board did not develop its survey for patients in collaboration with patients.^{14,15}
- The Board should avoid referencing prices in other countries.
- The Board should respond to new federal regulations by making its process and decisions transparent, especially related to its use of value assessments. We hope that the evidentiary basis for its decisions will be made public in a manner that is accessible and clear.

Thank you for your consideration of our comments.

⁹ Ne’eman Et. Al, “Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic,” October 2022, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504>.

¹⁰ <https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf>

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<https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf>

¹² <https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf>

¹³ <https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/>

¹⁴ <https://drive.google.com/file/d/1oYGIPVVLrXL7ZXeu-eZ2vLZEunPhzN3u/view>

¹⁵ <https://drive.google.com/file/d/1hF5-4Lxf5IHNNHMunRVm-fBaDt6QF-M3/view>

Sincerely,



Tony Coelho
Chairman
Partnership to Improve Patient Care