PIPC Partnership to Improve Patient Care

August 17, 2026

Submitted Electronically: *https://www.regulations.gov/docket/CMS-2026-CMS-2026-2080.*

Chris Klomp
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 212440-1850

Re: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program (CMS–4215–P)

Dear Deputy Administrator Klomp:

Thank you for this opportunity to comment on the Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Proposed Rule. We have worked collaboratively with organizations representing patients and people with disabilities to amplify the perspectives of those with lived experience in the implementation of the Medicare Drug Price Negotiation Program. Our comments focus on the agency's approach to patient engagement, CMS' consideration of patient-centered outcomes, and the agency's use of value assessments – all of which inform the agency's judgements about clinical effectiveness, unmet medical need, and therapeutic alternatives per the statute's § 1194(e)(2).

We appreciate CMS' ongoing efforts to build a public engagement strategy and are encouraged that the process will continue to solicit input from patients and people with disabilities. However, we are concerned that the strategy outlined in the proposed rule does not seem to have evolved from past years. In particular, CMS' process has not provided a level of robust engagement and transparency that would allow patients and people with disabilities to trust that their voices were heard in the process and that different patients' needs were considered.

We are also concerned that, though the proposed rule acknowledges the statutory ban on the Quality-Adjusted Life Year, there are no clear parameters limiting studies and evidence built on this highly discriminatory metric, when, in past round of negotiation, we have seen data cited that is derived from QALY-based studies.[1]

[1] https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-negotiated-prices

Therefore, we are pleased to share the following recommendations:

- CMS should avoid **one-size fits all value metrics such as the QALY.**
- CMS should develop a formalized process to ensure **continuous, robust engagement** of patients and people with disabilities at multiple levels.
- **Where high-quality patient data exists, like FDA Voice of the Patient Reports, CMS should use it**.
- Using patient insights, CMS should **clearly communicate how it intends to use the input it receives,** and how that input is reflected in the final negotiated prices.
- CMS should solicit input from **a variety of patients who rely on the treatments in question, including those in rural areas** to ensure representation of the diversity of the patients and communities affected by the topic.
- CMS should ensure that opportunities for patient engagement are **accessible**.
- To gauge both successes and challenges, CMS should establish a structured process for **continuous review and assessment** of its engagement strategy and its holistic processes.

Since CMS released its initial guidance on the Medicare Drug Price Negotiation Program in 2023, comments – including input from many patient and disability organizations – have urged the agency to build the program around three pillars: (1) meaningful, early, and ongoing engagement with patients and people with disabilities, including through a dedicated program ombudsman; (2) patient-centered evidentiary standards, including full transparency about the evidence CMS relies upon; and (3) an explicit, enforceable rejection of QALYs and other cost-effectiveness measures that devalue older, disabled, or seriously ill patients.[2] Unfortunately, these recommendations have remained unaddressed. This is particularly concerning as the program moves from implementation via guidance to a formal rule-making process. It is imperative that CMS use this inflection point to refine its processes and prioritize the patients and people with disabilities that this rulemaking will ultimately impact the most.

CMS should avoid one-size-fits-all value metrics.

It is now widely recognized that traditional methods and metrics of value assessment such as the QALY have significant shortcomings. This has led to well-intentioned development of other measures and approaches that seek to address some of the QALYs core shortcomings (in particular, its implications for discrimination and its lack of patient-centeredness). However, each approach comes with tradeoffs, need for improvement, and inherent methodological weaknesses as they typically rely on similar health utilities that reflect a fundamental bias against

[2]Partnership to Improve Patient Care, supra note 4.

people with disabilities and the value of health improvement. No patient is average, and no measure of value should assume so.

Prior law, including the Affordable Care Act, bars use of QALYs and similar measures

PIPC remains concerned that the proposed rule retains a narrow framing around consideration of cost-effectiveness that precludes direct consideration of the QALY, but leaves the door open to QALY-based studies and similar metrics of cost effectiveness that conflict with patient-centeredness and can bias how comparative clinical outcomes are evaluated. CMS states that it will evaluate information on cost-effectiveness metrics in accordance with the Inflation Reduction Act (IRA) section 1194(e)(2), as well as with the Affordable Care Act (ACA) section 1182(e) of Title XI of the Act." This reference to the IRA's statutory language bars CMS from using "information that treats extending the life of individuals in these populations as of lower value." Combined, these provisions comprehensively prohibit the use of the QALY and similar measures that "discount the value of a life because of an individual's disability" and we urge CMS to review the data on which it relies using the broad scope intended by statute.

While we appreciate the guidance's reaffirmed commitment to excluding use of QALYs in the Negotiation Program, we remain concerned that use of the QALY is just one of several ways that value assessments can discriminate against patients and devalue those with unique health needs and circumstances. The final rules implementing Section 504 of the Rehabilitation Act[3] and Section 1557 of the ACA[4] both acknowledge the potential for value assessments to discriminate. In fact, the rule explicitly barred use of "any measure, assessment, or tool that discounts the value of life extension on the basis of disability 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 any aid, benefit, or service, including the terms or conditions under which they are made available."[5] It also clarified that "discounting the value of quality of life on the basis of disability for purposes of denying or limiting medical treatment to a qualified individual with a disability would likely violate § 84.56." The agency also 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 § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others." Taken together, HHS interpreted the obligations of entities receiving federal financial assistance to be

[3] HHS, "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance," May 9, 2024, https://www.federalregister.gov/documents/2024/05/09/2024- 09237/nondiscrimination-on-the-basis-of-disability-in-programs-or-activities-receiving-federal-financial

[4] CMS, "Nondiscrimination in Health Programs and Activities," May 6, 2024, https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health- programs-and-activities

[5] 89 FR 40066, § 84.57

broader than the ACA's QALY ban because it prohibits unequal access and prohibits discriminatory value assessment. This language clarifies that the final rule holistically is intended to be interpreted in a manner that is consistent with, and broader than, the law barring the use of QALYs and similar measures in Medicare.[6]

The aim of these statutory and regulatory protections is not to encourage workarounds, but to ensure that measures used in federal programs do not disadvantage individuals based on age, disability, or health status. As discussed on the Senate floor, the spirit of these provisions was to protect vulnerable populations from policies that "set national practice standards or coverage restrictions" and to ensure that research used in such decisions is grounded in meaningful clinical outcomes.[7] Without transparency and clear limitations around value assessment methods, there is a heightened risk that discriminatory methodologies — like QALYs or similar tools — will enter the negotiation process without detection or accountability.

The data used to value health care may be discriminatory or fail to represent real-world experiences of patients and people with disabilities.

We urge CMS to strengthen patient protections in its rulemaking by complying with the spirit as well as the letter of the law, and to consider whether the evidence used in its decision-making was developed in a manner that reliably represents the population of patients and people with disabilities impacted. Value assessments are only as good as the outcomes they value and the data used in their development. Therefore, we urge the agency to consider the following factors:

- **Health utilities**: Also known as Health State Utility Value (HSUV), they mark the health-related quality of life (HrQOL) of a patient with a specific disease. A numeric valuation is applied to a health state based on preference of being in that state relative to perfect health, assigning a number between 0 and 1 to various conditions a person's health could be in (often called "health states" in which 0=death and 1=optimal health). They are typically derived from surveys asking how much, on average, someone prefers one health state compared to another. Health states typically represent degrees of impairment (not the disability or condition) such as active disease, response, remission, or mild, moderate and severe. Shortcomings include:
    - Survey data relies on average perspectives of quality of life in a health state, which are biased, inaccurate and almost never replicable. For example, there is

[6] https://www.pipcpatients.org/resources/hhs-finalizes-the-regulations-on-section-504-of-the-rehab-act-clarifying-rules-for-nondiscrimination

[7] Colloquy by Senators Baucus, Enzi, Conrad, Hatch, Carper and Menendez. "Comparative Effectiveness Research Funds." Congressional Record 155:24 (February 6, 2009) p. S. 1796.

significant research on the bias against disability among the public[8] and among providers[9].

- The identified health states are typically not disease or condition specific, often surveying health from the lens of mild, moderate or severe (such as the EQ- 5D6) and only accounting for health improvements that move between these broad states.
- Health utilities typically give a lower value to people living below optimal health. For example, extending the life for person living at a .5, such as with multiple sclerosis, is worth half of a person at a 1.

- **Disability weights**: Disability weights quantify health losses relating to non-fatal outcomes, expressed as years lived with disability (YLD). They typically have a value between 0 (equivalent to full health) and 1 (equivalent to death). For example, living 10 years with a 10 percent reduction in HRQoL is a disability weight of 0.10 – equal to losing one full year of good health (e.g., by dying one year before the life expectancy). Severity of condition (morbidity) and its death rate (mortality) are expressed as the number of healthy life years lost. Shortcomings include:
  - Disability weights are elicited by surveys, often of participants that do not have experience in the studied health state. Surveys are subject to bias against disability.
  - Disability weights from different studies are often not comparable, coming from different countries or populations with differing perceptions of disease and disability.
  - Assuming same weights to different aspects of quality of life as representative of all people risks being applicable to none.[10] Triathletes may highly weigh physical function. Academics may weigh mental acuity.
- **Health outcomes data**: Cost effectiveness analysis requires data on health outcomes to measure cost of gaining health. A product's "value" combines clinical effectiveness (impact of intervention on select health outcomes) and economic value (impact of intervention on healthcare resource use and costs). Shortcomings include:
  - Patient-centered outcomes and societal value are often ignored. For example, methods may not incorporate data on economic or social consequences such as loss of ability to work or caregiver effects.

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[8] Ari Ne'eman et. al., "Identifying And Exploring Bias In Public Opinion On Scarce Resource Allocation During The COVID-19 Pandemic," *Health Affairs* Vol. 41 No. 10 (October, 2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00504

[9] Lisa I. Iezzoni et. al., "Physicians' Perceptions of People With Disability and Their Health Care," *Health Affairs* Vol. 40 No. 2 (February, 2021), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01452

[10] Anirban Basu & David Meltzer, "Value of Information on Preference Heterogeneity and Individualized Care," *Medical Decision Making* Vol. 27 No. 2 (March-April 2027), https://pubmed.ncbi.nlm.nih.gov/17409362/

  - Reliance on average estimates based on generic survey data obscures important differences in clinical needs and preferences, particularly complex diseases and those from underrepresented communities. [11]
- **Real-World Implications**: New methodologies for cost effectiveness analysis are abundant but untested. While recognition of flaws inherent in historic methods for assessing treatment value is driving innovation, literature on almost every method underscores need for extensive detailed data on patients' risk profiles, co-existing conditions, and other relevant factors currently lacking and challenging to obtain. Investment in data is needed.

Every value assessment measure has tradeoffs.

There has been longstanding protection against the use of discriminatory value assessment tools in statute. Therefore, we are concerned that CMS' draft guidance explicitly expressed interest in using alternative approaches as part of drug price negotiations. Every cost effectiveness measure has tradeoffs between conditions advantaged and disadvantaged:

- **Quality-adjusted life year (QALY):** Less value to life-extending treatments among patients whose baseline health-related quality of life is low, particularly people living with disabilities. More value to treatments achieving maximum quality of life.
- **Equal value of life year gained (evLYG)**: Less value to treatments improving quality of life in extended life years. Same value as QALYs for treatments that do not extend life years regardless of quality-of-life improvements. More value to treatments extending life years.
- **Generalized Cost Effectiveness Analysis (GCEA):** Less value to treatments for common conditions to manage symptoms. More value to treatments for severe and disabling conditions.
- **Generalized risk-adjusted cost effectiveness (GRACE):** Less value to treatments for common conditions to manage symptoms. More value to treatments for severe and disabling conditions.
- **Disability adjusted life year (DALY):** Less value to treatments for people with disabilities due to focus on life years lost. More value to conditions leading to an early death without treatment.
- **Health years in total (HYT):** Less value to treatments that improve quality of life without increasing life expectancy. More value to treatments that extend life.
- **Life years gained (LYG):** Less value to treatments for patients with fewer years left to live (e.g., older adults or those with disabling conditions) and for largely non-fatal conditions

[11] Michael J DiStefano et. al., "Alternative approaches to measuring value: an update on innovative methods in the context of the United States Medicare drug price negotiation program," *Expert Review of Pharmacoeconomics & Outcomes Research* Vol. 24 No. 2 (February 2024), https://pubmed.ncbi.nlm.nih.gov/37961908/

(e.g., blindness, depression, rheumatoid arthritis. More value to treatments extending life.

We urge CMS to avoid use of one-size-fits-all value metrics, like the QALY or evLYG, as part of its decision-making, consistent with current Medicare law and regulations governing nondiscrimination. CMS should also identify and be transparent about the types and sources of research, data, and assessments considered in its decision-making process — including requiring disclosure of whether submitted evidence relies on cost-effectiveness measures such as QALYs, evLYG, or similar metrics. In addition, CMS should ensure it and other entities are exercising adequate oversight over the Medicare Drug Price Negotiation Program to ensure decisions do not rely on data from studies relying on one-size fits all metrics, like the QALY or evLYG.

Engaging Patients and People with Disabilities

To this point, CMS's process has not provided a level of robust engagement and transparency that would allow patients and people with disabilities to trust that their voices were heard in the process and that different patients' needs were considered. In 2024, PIPC developed a literature review drawing on robust engagement frameworks from leading organizations including National Health Council (NHC), the Patient-Centered Outcomes Research Institute (PCORI), the PATIENTS Program at the University of Maryland, the Innovation and Value Initiative (IVI), and AcademyHealth. These recommendations to CMS prioritized authentically involving patients and people with disabilities in agency decisions, including a formalized process to ensure continuous, robust engagement of patients and people with disabilities at multiple levels and using patient insights to clearly communicate how CMS uses input it receives, and how that input is reflected in the final negotiated prices. The explanations provided by CMS and limited changes from the guidance to proposed rule do not reflect these recommendations, remaining vague in terms of how information was used in decision-making, which is especially concerning knowing that many of the cited studies use QALYs and reflect patient populations outside the U.S. or outside the populations receiving Medicare benefits.

Since CMS released its initial guidance on the Medicare Drug Price Negotiation Program in 2023, comments have urged the agency to build the program around three pillars: (1) meaningful, early, and ongoing engagement with patients and people with disabilities, including through a dedicated program ombudsman; (2) patient-centered evidentiary standards, including full transparency about the evidence CMS relies upon; and (3) an explicit, enforceable rejection of QALYs and other cost-effectiveness measures that devalue older, disabled, or seriously ill patients.[12]

[12]Partnership to Improve Patient Care, supra note 4.

It is clear both from the MFP explanations released by CMS and the limited changes to the guidance that patient input has not been meaningfully heard and incorporated. In the recent document, CMS proposed a change to the treatment of fixed dose combination (FDC) products, which would aggregate all products as one under negotiation regardless of dosage or strength. Patients often prioritize different methods of administration – for example a subcutaneous administration can allow a patient to spend significantly less time in a hospital setting compared to an infused treatment. This is meaningful for a patient undergoing ongoing treatments for conditions like cancer. This policy sweeps newer products into negotiation when they otherwise wouldn't be eligible, even if patients view them as offering significant improvement in their care. We have concern that if this policy is finalized, it will devalue and therefore discourage development of, more patient-friendly versions of critical treatments, leaving patients with fewer options. We would urge CMS not to finalize their proposed policy on FDC products in the proposed rule and to have robust conversations with patients about this topic before moving forward to ensure their voices are heard and incorporated in a policy that will deeply impact them.

Where high quality patient-reported outcomes data exists, CMS should prioritize its incorporation in its process for determining MFPs.

For many of the drugs reviewed by CMS to date, high-quality patient experience data exists and was omitted in the explanations for development of maximum fair prices, including some developed in partnership with CMS's colleagues at the FDA and by PCORI, an entity that was formed for and is dedicated to doing the exact type of patient centered research that should be feeding CMS's decision-making processes.

PIPC conducted in-depth reviews of CMS's Maximum Fair Prices explanation documents for three products - Ibrance, Otezla, and Vraylar[13] - to determine whether CMS was actively using patient-reported outcomes and patient experience data in their process. Unfortunately, this review showed us that evidence on patient priorities was limited. Patient experience data appeared in only 10% of the Ibrance references, 16% of the Otezla references, and 11% of the Vraylar references. When this data did exist, it focused on symptoms and quality of life but omitted key issues of concern for patients, like treatment burden, side effects, and caregiver impact.

We hoped to see in our review that patients actively influenced the research being used, but found only 12 evidence sources from all three combined products that described how patient

[13] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_blog_apx_8.17_final.pdf

involvement impacted the study or findings. The majority of research gave no indication that patients were active participants.

All three reports have FDA Voice of the Patient reports on the conditions which they treat. Despite these high-quality reports developed by a sister federal agency existing, CMS did not cite them consistently. Only one of the three drugs, Otezla, cited the patient focused drug development process at all, and it cited just to the FDA's general webpage on the psoriasis meeting, so it is unclear if the Voice of the Patient report was used.

PCORI research also exists on all three of the conditions these drugs exist to treat, but it was entirely omitted from the report. PCORI's mandate is to produce high-quality comparative clinical-effectiveness research, the exact type of research CMS should be reviewing when making its price determinations, so it is deeply disappointing to see that PCORI's work has not informed CMS' process.

It was even more disappointing to see that despite the omission of PCORI funded research and FDA Voice of the Patient Reports, cost-effectiveness assessments were cited from the Institute for Clinical and Economic Review (ICER) and the National Institute for Health and Care Excellence (NICE). The primary purpose of these reports is not to determine clinical effectiveness using patient-centered data but to assess cost effectiveness relying on a QALY-based methodology. The fact that these resources were included is inconsistent with legal restrictions on use of QALYs and similar measures. We also have no way to assess the weight it was given based on the explanations.

We urge CMS to ensure moving forward that it is more heavily weighing research that provided high-quality patient experience data and clinical-effectiveness data. This will be essential to making sure patients' needs and experiences are factored into CMS's decision-making around MFPs. Further, the agency should provide full transparency into the external value assessments that it relies on in the process so that patients, caregivers and other stakeholders can understand what evidence and outcomes were considered, how the evidence informed the final decisions, and the organizations with which CMS is partnering.

Using patient insights, CMS should clearly communicate how it intends to use the input it receives, and how that input is reflected in the final negotiated prices.

While CMS hosts public engagement events and asks stakeholders to submit data on selected drugs, the agency has not clearly explained how that input is used or how it will feed CMS' eventual conclusions. The process of collecting stakeholder input is critical, but equally important is ensuring that the information is meaningfully incorporated into decision-making.

It is challenging for patients and caregivers managing complex conditions to provide the time and preparation needed to participate in these meetings. It is important that, if they are doing so, CMS values their input and provides a clear process both for how they can engage and how their input will be incorporated in the process.

As we have proposed in the past, we encourage CMS to employ a cyclical approach, wherein patient engagement helps CMS communicate how it intends to use the information submitted by stakeholders on selected drugs and therapeutic alternatives. It is critical that this information is communicated to stakeholders to ensure they are prepared to provide appropriate feedback at public engagement events. CMS should be very explicit and transparent about the information it is seeking from patients and people with disabilities and how that input will influence decisions.

CMS should ensure that opportunities for patient engagement are accessible.

Entities that focus on patient-centered research, including IVI and PCORI have emphasized the significance of allocating dedicated funds and resources to support and compensate patient engagement. We concur with this perspective and recommend CMS take responsibility for providing the necessary resources to ensure that patient engagement opportunities are accessible. Most of these individuals take time off from work and routine caregiving duties to lend their expertise. Resources should be provided for their needed expertise in such a process. Patient and disability advocates have echoed these sentiments, urging CMS to allocate resources such as financial assistance, accessible materials, disability-friendly meeting arrangements, and extended input and comment periods.

It will also be critical that CMS provide accessible materials, emphasizing the use of plain language and health literacy principles to ensure patient understanding and inclusivity.

Additionally, communication with executive branch agencies can often be challenging due to bureaucracy and the need for institutional knowledge to communicate effectively. We would again recommend streamlining the process for initiating dialogue, such as by creating an ombudsman or a clearly identified point of contact to better support patient engagement.

CMS should establish a structured process for continuous review and assessment of its holistic process and stakeholder engagement strategy.

At this point, CMS is several years into the negotiation program. Despite patient stakeholders pointing out consistent issues with CMS's patient engagement process and practices and its selection of research to feed its decision-making, CMS has not meaningfully altered its process.

The proposed rule is nearly identical to the several rounds of guidance on the Medicare negotiation program that we have seen previously.

PIPC would urge CMS to commit to continuous learning, refining its patient engagement strategy and promoting equal access to care as part of a structured assessment of what works and what does not work, in collaboration with engaged patients and people with disabilities. A process to do this should be written into regulations ensuring the processes that tokenize patients and that do not fully incorporate patient experience data do not become the norm in the Medicare Negotiation Program.

Conclusion

We urge CMS to continue refining its implementation of the Medicare Drug Price Negotiation Program to strengthen its alignment with existing law governing the use of value assessments, to meaningfully incorporate patient-centered research, and to ensure meaningful, continuous engagement with patients and people with disabilities. While we appreciate the steps CMS has taken to formalize an engagement strategy, further action is needed to ensure that patient voices are not only heard but integrated into decision-making, and that the agency relies on high-quality, representative sources of evidence. We appreciate CMS' consideration of our recommendations, offering a holistic approach to improving patient engagement across the agency. Embracing these recommendations will not only strengthen CMS' relationship with stakeholders but also pave the way for more effective delivery of quality health care, ultimately benefiting patients and the health care system.

Sincerely,

Tony Coelho

Tony Coelho
Chairman
Partnership to Improve Patient Care