April 14, 2023

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services (CMS)
Baltimore, MD

RE: Response to Solicitation for Comments, Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026

Dear Dr. Seshamani,

Thank you for the opportunity to comment* on the Medicare Drug Price Negotiation Program. As researchers with expertise in pharmacoeconomics, health economics and policy, we have been studying trends in drug pricing and payment models in order to improve patient access to effective treatments, while creating incentives for U.S. manufacturers of health technologies to continue innovating. Our comments draw on our experiences and perspectives developed in that research. We share a mission to measurably improve the value for money accruing from pharmaceuticals and other health technologies, through evidence-based policy solutions, research excellence, and public-private partnerships.

As CMS begins building a new program that relies in part on health economic principles to implement the Medicare Drug Price Negotiation Program, we recommend incorporating several key elements to promote the program's success. Our recommendations have the goal of building public confidence and stakeholder buy-in through rigor and reliable application to CMS decision-making. As described in greater detail below, we recommend that CMS:

- Establish explicit methodological standards to ensure the rigor of research, evidence reviews, and assessments;
- Describe a methodology for applying evidence to pricing decisions that places the greatest weight on added clinical benefit and contextual factors, such as unmet medical need;
- Create a transparent process to:
    a. solicit input from patients, physicians, and academic researchers with expertise on issues such as choice of comparators and outcomes;
    b. describe to stakeholders how they are their input will be considered in proposed decisions.

Therefore, we provide the following comments and recommendations that we believe would be helpful to consider as your office continues to advance efforts for Drug Price Negotiation through the Medicare Program:

1. **Current CMS Position:** *Apply adjustments by the manufacturer-specific factors outlined in the law to determine the initial offer price.*

   Our Recommendation: Place greater emphasis on the clinical benefit factors (e.g. survival, rate of cure), as prioritized with input from the patient community affected, rather than manufacturer-specific factors. Manufacturer-specific factors would lean more towards a cost-plus pricing model, which rewards less efficient firms rather than those providing the most benefit to patients. This is particularly important given vertical integration of PBMs, insurers and pharmacies, which already have an incentive to share data with their rebate-conferring drug company partners. These will be the only entities controlling this essential information, which is necessary for evaluating the drug company's value claims. Such information and data analytic asymmetries will only expand and grow more problematic, making it nearly impossible for payors and government entities to engage in independent auditing.

   In contrast, a clinical benefit factor-based negotiation process provides CMS with the ability to reward efficiency and clinical benefit, which ultimately reduces costs and benefit patients. Transparent incorporation of benefits will lead to pricing models that align better with the value of the technology to Medicare beneficiaries and American taxpayers.

2. **Current CMS Position:** *Engage members of the public (including people with Medicare, consumer advocates, prescription drug companies, Medicare Advantage and Part D plans, health care providers and pharmacies, and other interested parties) on key policies, make requests for information, and inform the public on other implementation timelines and milestones.*

   Our Recommendation: A stakeholder engagement process should provide input on the priorities and activities of the drug price negotiation methodology and decision-making.[1] Adopt a deliberative, continuous, and transparent process to engage the stakeholders (i.e., those mentioned above in your current position) *as well as* patients affected by the treatments under review, experts in pharmacoeconomics, health economics, and outcomes research and policy. These experts have diverse perspectives to identify and evaluate evidence that can provide insight into the negotiation process that the other listed stakeholders may lack.

[1] Lakdawalla DN, Neumann PJ, Wilensky GR. Health Technology Assessment in the U.S. – A Vision for the Future. Los Angeles: USC Schaeffer Center, 2021. Accessed at: https://healthpolicy.usc.edu/research/health-technology-assessment-in-the-u-s-a-vision-for-the-future/.

3. **Current CMS Position:** *CMS intends to consider health outcomes, intermediate outcomes, surrogate endpoints, patient-reported outcomes, and patient experience when reviewing the clinical benefit of the selected drugs and its therapeutic alternative(s).*

   Our Recommendation: Ensure evidence on clinical benefit and unmet need reflects perspectives and experiences important to patients, as well as their caregivers, clinicians, and society, including selection of therapeutic alternatives, outcomes, and unmet needs. Given variation in evidence sources, weight should be applied to those factors most important to patients, caregivers, clinicians, and society. CMS can leverage real-world data (e.g., payer claims, patient registries, and electronic health records) and patient-centered outcomes research (e.g., mixed-methods) approaches to capture this information. There are multiple frameworks available to incorporate multi-stakeholder perspectives.[2]

   In addition, we encourage CMS to evaluate the potential role for measurements of value beyond clinical benefit and unmet need. We recognize that the Inflation Reduction Act creates some limitations to this by focusing on comparative effectiveness research and mandatory ceiling price discounts unconnected to value measurement, but we also believe that any price negotiation should be conducted transparently and linked to a drug's value for money to the extent possible.[3] While the Affordable Care Act, and Inflation Reduction Act, have prohibited the use of traditional economic measures of value, such as the quality-adjusted life year (QALY), because they assign less value to life extensions for patients with disability and severe disease, recent advances in value assessment may provide alternative pathways forward. For example, the Generalized Risk-adjusted Cost-Effectiveness (GRACE) framework offers an empirical pathway to evaluating price relative to value for all patients without bias for inequities.[4] CMS should launch a dialogue with relevant stakeholders to discuss potential approaches to broader consideration of value measures, consistent with past recommendations of several expert panels.[1,3,5]

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[2] McQueen RB, Mendola ND, Jakab I, Bennett J, Nair KV, Németh B, Inotai A, Kaló Z. Framework for Patient Experience Value Elements in Rare Disease: A Case Study Demonstrating the Applicability of Combined Qualitative and Quantitative Methods. Pharmacoecon Open. 2023 Mar;7(2):217-228.

[3] Goldman DG, Grogan G, Lakdawalla D, Liden B, Shafrin J, Than KS, Trish E. Mitigating the Inflation Reduction Act's Potential Adverse Impacts on the Prescription Drug Market. Schaeffer Center White Paper Series. Los Angeles: Leonard D. Schaeffer for Health Policy & Economics, April 2023.

[4] Lakdawalla DN, Phelps CE. Health Technology Assessment With Diminishing Returns to Health: The Generalized Risk-Adjusted Cost-Effectiveness (GRACE) Approach. Value Health. 2021 Feb;24(2):244-249. doi: 10.1016/j.jval.2020.10.003. Epub 2021 Jan 12. PMID: 33518031.

[5] Rimber BK, Harper H, Witte ON. Promoting Value, Affordability and Innovation in Cancer Drug Treatment. A Report from the President of the United States from the President's Cancer Panel. Bethesda, MD: President's Cancer Panel; 2018 March.

4. **Current CMS Position:** *CMS intends to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer-review, study limitations and degree of uncertainty of conclusions, to ensure integrity of the contributing data within the negotiation process (page 37).*

   Our Recommendation: Establish rigorous and more detailed standards for evidence relied upon in both the literature review and all third-party submitted data, as well as CMS's own "internal analytics." While CMS indicates that it intends to employ rigorous standards, CMS does not indicate what these standards will be, what methods will be used to establish them, or if they will apply to internal analyses conducted by CMS. Other organizations, including the International Society for Pharmacoeconomics & Outcomes Research (ISPOR), the International Society for Pharmacoepidemiology (ISPE), and a recent Health Technology Assessment Panel Report co-published by the Aspen Institute and USC Schaeffer Center provide specific guidance on methods that are rigorous and could apply to drug price negotiation analytics.

5. **Current CMS Position:** *CMS intends for the published explanation of Maximum Fair Price (MFP) to summarize how relevant negotiation factors were considered during the negotiation process.*

   Our Recommendation: The explanation of Maximum Fair Price (MFP) should be thorough and released as early as possible to enhance the predictability and transparency of the process. Such thoroughness should specify that CMS will include in its public announcement of the MFP:
   - How it selected the therapeutic alternatives;
   - How the various factors were weighed;
   - How stakeholders were engaged;
   - How evidence was considered;
   - How types of outcomes were considered;
   - How unmet need was defined;
   - And, which priority populations were considered.

Thank you for your time and consideration of these issues as we as a nation continue to explore the programmatic structure of Medical Drug Price Negotiation.

Sincerely,

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**The information contained in this letter to CMS represents the ideas and opinions of the signed individuals, and does not necessarily represent the positions of their home institutions – Geisel School of Medicine at Dartmouth, Johns Hopkins Bloomberg School of Public Health, Pennsylvania State University, Tufts University, University of Chicago, University of Colorado, University of Maryland School of Pharmacy, University of Rochester, University of Southern California, USC Leonard D. Schaeffer Center for Health Policy & Economics, University of Utah, University of Washington, Virginia Commonwealth University.*