



April 14, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd  
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments  
Introduction

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on initial guidance for implementation of the Medicare Drug Price Negotiation Program for initial price applicability year (IPAY) 2026 as established by the Inflation Reduction Act (IRA).

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of more than 155 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

As a patient advocacy organization whose mission is to promote increased patient access to affordable, high-value, sustainable, and equitable health care, we submit these comments regarding the impact of the negotiation program on patients. Our comments are informed by our concern for both patient access and affordability.

The NHC would first like to thank CMS for seeking feedback on the negotiation process guidance, a step that was not explicitly required in the IRA statute. While we would have preferred a more traditional Notice and Comment rulemaking opportunity that would ensure the Agency directly responds to stakeholder feedback, we welcome this opportunity to express our reactions to CMS' thinking on the negotiation program. As overarching priorities, the NHC urges CMS to craft the negotiation process to assure:

- Patient organizations have ample opportunity and ability to provide feedback on the negotiation process;

- CMS communicates how external data was factored into decisions, including methodology used;
- Patients have greater access and affordability of needed medicines; and
- Appropriate guardrails and ongoing oversight processes are established to study the impact of the negotiation program to protect patients and inform refinement of the program.

### **§10: External Data Submission Timing**

The NHC understands the tight timeline for the drug selection and price negotiation processes. However, for patients to fully realize benefits of the negotiation program and to limit unintended consequences, CMS must provide ample time for patients to share data and experiences pertaining to selected drugs. The NHC is concerned that 30 days to submit data after CMS releases the list of drugs to be negotiated is insufficient time for organizations, who do not have research and/or data analysis departments and staff to collect information, to submit data that is most beneficial to CMS. We ask CMS to take the burden of data collection and submission into account as it evaluates the proposed timeframe for data submissions.

The NHC believes that CMS should extend the timeframe for stakeholders to submit requested data. At a minimum, the NHC requests that information can still be submitted throughout the negotiation process and could inform “second/final offer” decisions. CMS must consider the patient voice and perspective as vital to the negotiation process.

### **§50.2 and §60.3.3: Patient Engagement and Utilizing Patient Experience Data**

The NHC has long championed the incorporation of patient perspectives in medical product research, development, and coverage. Patient engagement is an important step to better understand the burden of their condition, desired treatment outcomes, and views on benefits and risks. Driven by the work of the Food and Drug Administration on patient-focused drug development (PFDD), many companies in the biopharmaceutical community have devoted significant resources to better understand patient populations and are working to bring to market products that best suit their needs. While patients will benefit from lower-priced medicines, it is important for CMS to consider the positive impact it can have on PFDD if companies are rewarded for demonstrating that their products represent therapeutic advancements over other products and meet unmet needs identified as the most important to patients.

In addition to our earlier expressed concern about the short timeframe for data submissions, we ask CMS to provide more clarity on how the agency intends to leverage negotiation data elements outlined in §50.2 to ensure that the agency is evaluating these elements with the patients' experiences, preferred outcomes, and needs in mind. For instance, we ask CMS to transparently outline a consistent methodology for how data related to therapeutic alternatives will result in changes to an initial or final offer. As part of this methodology, we ask that CMS ensure data explicitly related to patient value is prioritized. We also ask CMS to emphasize patient experience and value in the evaluation of data.

We applaud CMS's reference to patient experience in its discussion of the clinical benefits of selected drugs and their therapeutic alternatives in § 60.3.3. Defining patient experience in this context and appropriately translating it to a drug's MFP is incredibly important. The NHC urges CMS to consider the following six domains of patient centered engagement and methodological practices as included in the NHC [\*Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem\*](#). The rubric was designed through a multi-stakeholder process to elevate meaningful patient engagement and ensure patient voice inclusion is seen in studies and that engagement includes:

- Patient Partnership;
- Transparency;
- Representativeness;
- Diversity;
- Outcomes Patients Care About;
- Patient-Centered Data Sources and Methods; and
- Timeliness.

Additionally, the NHC urges CMS to prioritize patient experience and patient experience data among the many factors the Agency identifies in the guidance as sources that will inform an initial/final offer. Specifically, CMS should ensure that among the data sets that inform any initial or final offer, patient experience data should have an outsized impact. CMS should also articulate how patient experience data influenced initial and final offers.

The NHC appreciates that CMS will consider evidence about alternative treatments to the selected drug, specifically on the categories included in the statute and identified in the guidance, including whether it is a therapeutic advance, FDA approval, effects on specific populations, and addressing unmet needs.

While we understand CMS must adhere to the requirements of the statute, we feel the approach taken in this guidance may represent a very narrow interpretation and could be defined in a way that takes a more holistic view to determine patients' views on the value of drugs compared to their alternatives. CMS is required to consider evidence about therapeutic alternatives to the selected drug, as available. This includes whether it represents a therapeutic advance; prescribing information; comparative effectiveness, including effects on specific populations; and whether it addresses an unmet need. We encourage CMS to consider what evidence may be needed for each identified category and support the broadest scope of evidence that may be considered. For example, when considering whether a product represents a therapeutic advance, it is important to consider whether the advance is based on outcomes important to patients, including non-clinical outcomes such as productivity or independence. The patient community is well suited to collect and provide this type of information, though a more thorough approach to patient engagement, as explained below, will help CMS better understand a range of elements important to patients to help direct patient organizations toward data that will best suit CMS' needs.

### *Need for Broader, Consistent Patient Engagement*

In addition to the opportunity to submit data, the NHC urges CMS to develop further initiatives to solicit feedback from the patient community. These processes could be comparable to the FDA's work in PFDD.<sup>1</sup>

CMS should develop a patient engagement infrastructure that creates an ongoing dialogue about IRA implementation and systemic issues with those most affected by them. This can include:

- Creating a patient ombudsman charged with oversight of implementation;
- Convening public roundtables of disease or treatment-specific experts from the patient and disability communities for each drug selected for MFP negotiation; and
- An Administrator-level Patient Advisory Committee to provide overall feedback on this program and other work of the Agency.

This infrastructure could help patients and caregivers provide input to CMS about domains that will inform negotiations such as:

- The impact of the condition on patients and their family caregivers, and how it affects their daily activities, physical functions, and quality of life – overall and across key domains: social, physical, emotional, and functional;
- Outcomes that are most important to the patient, both clinical and non-clinical (e.g., goals, daily activities, symptom reduction, or a standard of quality of life);
- Patients' preferences for treatment delivery methods and views on beneficial and negative aspects of treatment effects; and
- Experience on treatment(s) including symptoms and side effects and how the treatment impacts their daily activities, physical functions, and quality of life.

Throughout this process, CMS should be sure to solicit input from diverse communities in order to gain information about the differences among subpopulations and their needs, outcomes, and preferences.

### *NHC Resources*

In addition to the Rubric mentioned above, the NHC has several tools that can help identify and infuse the patient experience into the value discussion. These include the [Patient Experience Mapping Toolbox](#), which was developed to help researchers capture patient experience data more holistically and in a standardized manner across chronic diseases. The Toolbox includes project planning and data collection tools.<sup>2</sup> We have also created a Blueprint for the development of [Patient-Centered Core Impact Sets \(PC-CIS\)](#), which address

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<sup>1</sup> "Externally-Led Patient-Focused Drug Development Meetings." U.S. Food and Drug Administration, FDA, 29 July 2022, <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/externally-led-patient-focused-drugdevelopment-meeting>

<sup>2</sup> All patient-facing tools in the Toolbox were reviewed externally by health literacy experts and refined through patient interviews. To encourage uptake, the Toolbox is made available free for public use.

inconsistencies between what is important to patients and the information that is typically collected in research and care. A PC-CIS is a standardized, patient-derived, and patient-prioritized list of the most important impacts - both clinical and non-clinical - a disease and/or its treatments have on a patient's health and daily life, and that of their family and caregivers.

### **§50.2 and §60.3.3: Utilization of Quality-Adjusted Life-Years (QALYs) in the Negotiation Process**

The NHC greatly appreciates CMS stating that it will not use metrics such as QALYs. Any evidence that values extending the life of some individuals less than extending the life of other individuals based on disability status, age, or other special populations (e.g., children or those of marginalized status, including the patient community of color) is completely inappropriate. All patients deserve to be treated equally, and thus we laud CMS' adherence to the statute and decision to separate out and exclude QALY metrics from data that otherwise factor in QALYs. However, we are concerned that CMS may not effectively eliminate QALYs from analysis by utilizing studies that use QALY-related data from secondary sources, or that CMS may over-exclude analyses that are otherwise helpful in establishing the value of a drug. Therefore, the NHC requests that CMS offer more clarity into exactly how it will exclude QALY-based metrics from analysis of certain evidence in value-based decisions. The NHC also requests that CMS highlight when and how the agency removed QALY-based metrics from consideration in MFP justification documentation.

While it is clear both in the statute and this guidance that QALYs will not be used as a base for evaluations, CMS requests input on what other measures might be appropriate or inappropriate. While the NHC does not have positions on other specific measures, we do think that it is important that CMS not rely on a single metric and look at a wide variety of sources to take a holistic approach to this data. One potential approach to aggregate the different dimensions of value is multi-criteria decision analysis. As discussed in the NHC's 2020 white paper on the topic,<sup>3</sup> patient value is multi-faceted, and any attempts to distill important dimensions of patient value and benefit into a single number is fraught. We recommend the negotiation process leverage metrics that are driven by patient experience data and patient input and are patient-centered.

### **§60: Input Process for Future Program Guidance**

The NHC appreciates the opportunity to comment on initial program guidance for IPAY 2026 and seeks clarification on processes for seeking feedback moving forward. The NHC requests insight on what opportunities CMS plans to put forward for stakeholders to provide formal input into adjusting future program guidance and whether there will be a comment opportunity to inform negotiation for IPAY 2027 and beyond. The NHC believes that CMS may need to reevaluate methodology for various pieces of the negotiation process, including aggregating drugs to determine MFP. The negotiation program is a new policy that is being implemented in a non-traditional manner. As such, the NHC believes CMS should be nimble and responsive to

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<sup>3</sup> <https://nationalhealthcouncil.org/additional-resources/patient-centered-multi-criteria-decision-analysis/>

feedback from stakeholders and the policy is implemented in future years. To do so, CMS should establish a meaningful process for 1) patients and other stakeholder to provide consistent feedback on the experience of IPAY2026 and 2) CMS to evaluate policy decisions made for the initial year of negotiation and incorporate necessary changes quickly for future years.

### **§ 60.6.1 Explanation for the MFP**

The explanation for the MFP will be a critical tool in the continuous improvement of the negotiation program, as well as a tool the patient advocacy community will use to learn and improve our ability to participate in the process. We urge CMS to assure that these explanations are clear, accessible, and transparently available. We also ask that they include critical information about what data was used to develop the MFP and how specifically it was used. We are especially interested in information about how patient experience data was incorporated and weighed against other factors. Including this information in the explanation will help patient advocates develop the most useful data for future negotiations.

We also note that CMS' March 1, 2025 deadline for publishing explanations of 2026 MFPs coincides with deadlines for stakeholders to submit information on selected drugs for IPAY 2027, which will make it difficult for stakeholders to glean insight from the explanations to refine and improve their data. We urge CMS to reevaluate the timeline for releasing the explanation to encourage improved stakeholder submissions.

### **§110: Requirements for Coverage**

While the patient community is incredibly supportive of the Part D redesign and out-of-pocket cap, we understand plans will face higher liability moving forward. These shifting incentives, combined with potentially changed market dynamics created by the negotiation process, make it more important than ever that CMS ensure access to medicines and create guardrails such as limiting burdensome barriers such as prior authorization and step therapy. While some utilization management protocols may be grounded in sound clinical decision making, such as prior authorization to limit drug-to-drug interactions or to prevent overprescribing of potentially addictive medication, the development of such protocols is typically done without much or any patient input, and the rationale for such decisions is not typically made public. By defining coverage requirements more explicitly, CMS reduces the risk of plans denying coverage for products vital to a patient's comprehensive care plan. If a plan is receiving a lower price based on a maximum *fair* price, the benefit should be fully conveyed to beneficiaries through *fair* access. Conversely, it is crucial CMS continuously work to ensure access and remove barriers to both negotiated and non-negotiated drugs that providers and patients agree are necessary and appropriate.

Moving forward, the NHC believes that it will be important for CMS to clearly outline a definition of coverage requirements, either in this guidance and/or in any upcoming Part D regulations and payment rules. Appropriate guardrails should be established to assure that patients are, at the very least, no worse off in terms of access than they previously were.

### **Overarching Comment: Oversight and Continuous Improvement**

Given the significant impact this new program and other changes such as the redesign of the Part D program will have on the drug delivery system, CMS must have proper systems in place to monitor impacts to ensure implementation of the IRA achieves our shared goal of increasing access and affordability for patients. At a minimum, CMS should monitor whether people see the savings they are expecting, whether future plan designs inappropriately restrict access to either negotiated or non-negotiated drugs, including through increased utilization management, and the creation of other barriers to access. And while this guidance only applies to Part D drugs, one additional consideration for the Part B program will be monitoring prescribing behaviors to ensure there are not incentives for providers to prescribe non-negotiated products. Furthermore, CMS should monitor the impact of drug selection criteria to ensure it is not creating disincentives to conduct follow-on research on additional indications or new formulations that can demonstrate additional benefit such as greater adherence or reduced side effects.

CMS has made it clear that this guidance is only for the first year of negotiation, and there likely will be the need for adjustment as the mechanisms are put in place. We recommend CMS undertake a formal process for seeking input from patients on the impacts of IRA implementation soon after full implementation and regularly after that. This will help identify areas of concern such as those listed above and identify any needed adjustment.

### **Additional Comments on Drug Selection**

Although we are aware that you are issuing Section 30 on drug selection as final, we have a few comments we hope CMS will consider as you implement the drug selection process for negotiation.

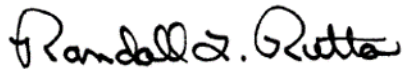
For example, we are concerned about the effects that aggregation of drugs with the same active moiety or active ingredient in the selection process could have on subsequent research. We want to make sure that manufacturers aren't discouraged from developing new indications and forms of administration that may improve patient adherence and/or outcomes. Without appropriate guardrails, CMS' broad definition of drugs eligible for negotiation may discourage these types of improvements. While manufacturers would ideally bring products to market with as many indications as possible, one potential consequence could be a significant delay in initial market entry and access. The NHC is aligned with CMS' desire to eliminate potential gaming of extending patent life or time before negotiation. However, we fear this may be an overly broad approach that does not consider the patient perspective on whether new formulations or forms of administration improve patient care and believe there are better approaches to address this issue. If CMS is unable to reconsider this approach, we request that you undertake future notice and comment processes with adequate time for stakeholders to consider the impact of selection criteria as the negotiation process is implemented.

## Conclusion

The NHC strongly upholds that decisions on value should be driven by the patient perspective. The best results occur when patient organizations can engage and when patients are not limited by policies that restrict access to products that best meet their individual needs. The NHC urges CMS to carefully consider these comments for this and future guidance and allow for patient voices to be heard and emphasized throughout the negotiation process.

The NHC thanks CMS for the opportunity to provide input on this important issue. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these comments in greater detail. He is reachable via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive, slightly slanted style.

Randall L. Rutta  
Chief Executive Officer