NATIONAL HEALTH COUNCIL

September 3, 2024

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

**RE: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) Forms (CMS-10849, OMB 0938-1452)**

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) Forms (CMS-10849, OMB 0938-1452) (IRA 2027 Drug Price Negotiation ICR).

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 170 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.

The NHC appreciates CMS' efforts to gather patient-centered data as part of this ICR and its commitment to making the process more relevant for patients and patient organizations. We are pleased to see several of our recommendations, such as the grouping of questions by respondent type, the inclusion of questions requesting detailed descriptions of what it is like to live with a medical condition treated by a selected drug or its therapeutic alternatives, and the focus on factors that matter most to patients when assessing the value of a drug, reflected in the ICR. While we acknowledge these improvements, it is important to note that some aspects of the data collection process may remain challenging. Of note, the reduction in word count limits across multiple instances in the ICR may restrict stakeholders' ability to provide comprehensive and nuanced insights into the holistic value of drugs. The NHC suggests that CMS reconsider these constraints to allow for more detailed and meaningful responses.

Overall, while the NHC appreciates CMS' intent to streamline the data submission process and make it more accessible, we encourage ongoing dialogue and adjustments to ensure that the process remains patient-centered, efficient, and capable of capturing the full spectrum of information necessary to inform meaningful drug price negotiations.

While most of our comments are focused on the questions in the patient and caregiver section, we note that CMS states that any and all parties can comment on any and all questions, so we have included select questions we think are particularly important to the patient community.

**Manufacturer-Focused Input**

***Question 30: Off-Label Use*.** CMS has appropriately highlighted the significance of off-label use information, providing a specific avenue for manufacturers to submit data on off-label uses supported by evidence-based guidelines listed in CMS-recognized Part D compendia. Off-label use is particularly relevant to patients, as it often represents an option for those who may not respond to standard treatments or who have conditions for which no approved therapies exist. Patients and caregivers are directly impacted by the availability and accessibility of off-label uses, as these can offer life-changing, and sometimes lifesaving, treatment alternatives. Given the critical role that off-label use can play in patient care, it is essential that the data submitted is clear and consistent. However, the question could benefit from additional guidance on the format for submitting this information to ensure consistency and ease of review. Providing a standardized format for submissions would improve the clarity and consistency of the data collected, making it easier for CMS to evaluate the data provided. For patients, ensuring that off-label use information is accurately captured and evaluated can mean better access to effective treatments and more informed decision-making by health care providers.

***Question 34: Therapeutic Advance and Unmet Medical Need.*** This question emphasizes the need to understand the therapeutic advances and unmet medical needs addressed by the selected drug, which are crucial for evaluating its value. However, the question could be improved by explicitly requesting data on the relative improvement over existing therapies and specific metrics used to define "therapeutic advance." Additionally, CMS can request patient experience data that demonstrates the unmet medical needs are based on outcomes that matter to the patient population.

***Question 35: Specific Populations and Patient Experience*.** By asking about specific populations and patient experiences, CMS ensures that the evaluation process includes diverse patient perspectives and real-world outcomes. However, the question could be enhanced by explicitly requesting data on health disparities and the impact of social determinants of health on treatment outcomes. Including specific prompts for information on health disparities and social determinants of health would provide a more comprehensive understanding of how different populations are affected by the selected drug. Furthermore, question 35b could be improved by asking about the side effects that are typically experienced by certain populations but not others, and how these differences impact patient experience and the use of the drug. This would help CMS

better understand the varied effects of the drug across diverse groups and inform more tailored approaches to patient care.

***Question 36: Dossier Submission*.** Allowing for the submission of a dossier provides manufacturers with the opportunity to present comprehensive, structured evidence supporting their responses. However, clear guidelines on the preferred format and content of the dossier are necessary to ensure consistency and completeness. Providing a template or detailed guidance on the expected structure and content of the dossier, including specific sections and data types, would facilitate more uniform and comprehensive submissions.

**Patient- or Caregiver-Focused Input**

The NHC appreciates the effort CMS has made to rethink the framing of questions in this section, where input is sought from individuals with direct lived experience. Gathering insights from patients and caregivers is essential to ensuring that the Medicare Drug Price Negotiation Program reflects real-world experiences and addresses the needs of those most impacted by these decisions. Overall, we believe this question set represents a meaningful step forward in terms of understandability and approachability, which are key factors in encouraging meaningful participation from everyday people.

A central focus of our feedback is on the practical usability of these questions for the average person – those who may not have prior experience with formal data collection or survey participation. While the questions have been thoughtfully framed, it is crucial that they are presented in a way that is clear, concise, and easily navigable. The substantial number of questions in this section may pose a barrier for some patients who may become overwhelmed. To help overcome this issue and ensure patients respond, the NHC recommends that CMS state as clearly and often as possible that it is not required to answer all questions and that the language used in this section be free of jargon and technical terms that could create barriers to understanding. Ensuring that the questions are truly patient-friendly will maximize the quality and depth of the responses CMS receives from patients and caregivers. To further enhance this effort, the NHC recommends that CMS directly involve patients in reviewing the final format and phrasing of these questions before they are fully implemented. Although this ICR process serves as a key step in refining the questions, real-world feedback from those who will actually be answering them is invaluable in identifying potential issues and ensuring that the questions are as accessible as possible.

The NHC appreciates the use of a conditional logic format in the questions, where separate paths are provided based on respondents' answers (i.e., whether they select yes or no). This method can streamline the experience for respondents by ensuring they are only asked relevant questions. However, the success of this format heavily depends on the overall approachability of the ICR portal – how intuitive and user-friendly it is. The NHC observed significant frustration with the portal during the IPAY 2026 process, where many participants found it difficult to navigate or understand how to properly submit their input. We strongly urge CMS to address these issues in the IPAY 2027 portal to ensure that all participants, regardless of their familiarity with technology or

survey formats, can contribute their insights without unnecessary difficulty. Additionally, CMS must ensure that this technology is accessible for people with disabilities.

Finally, the NHC recommends that CMS incorporate feedback from a diverse group of patients and caregivers during the design and testing phases of the ICR portal. This real-world user feedback is crucial for identifying potential challenges and ensuring that the final platform is accessible to all, particularly those who may not be technologically proficient or who have limited experience with similar data collection efforts.

***Question 38: Background*.** The structured approach of gathering whether patients or caregivers have experience with the selected drug provides a clear starting point for collecting relevant information. However, there should be an option for respondents to elaborate on why the selected drug was chosen over others initially, including the role of health care providers in that decision.

***Question 39: Information on Your Condition(s) or Condition(s) of Someone You Care For.*** The questions comprehensively cover the daily impact of the condition, its progression, management priorities, and challenges faced. This allows for a detailed understanding of the patient's journey. We particularly appreciate the focus on how symptoms may impact daily living such as work, family, and/or hobbies. We recommend adding education to this list of examples, as it is also critical to know how the patient's education is affected by their condition, which can in turn affect their employment.

We also recommend a more explicit addressing of the emotional and mental health impacts of managing chronic conditions. Adding questions about the emotional and mental health impacts of the condition would provide a more holistic view of the patient's experience.

***Question 40: Information on the Current Medication to Treat Your Condition.*** These questions effectively capture patient experiences with current medications, including benefits, drawbacks, and factors influencing the choice of medication. However, a more comprehensive understanding of patient experiences could be achieved by addressing additional factors that influence medication efficacy, access, management, and the broader context of patient care.

First, the NHC recommends adding a question that asks whether there are any symptoms that impact the patient's daily life but are not adequately addressed by their current treatment. This would provide insight into areas where existing therapies may fall short and highlight unmet needs from the patient's perspective.

Access to medication is a critical issue that encompasses several interconnected factors, including formulary design, utilization management practices, affordability, and availability. These issues significantly influence whether patients can obtain and maintain their prescribed treatments. For example, formulary restrictions, such as medications not being covered or requiring prior authorization, may impact the

timeliness and ease with which patients can access their prescribed treatments.[1,2,3,4,5,6] The NHC suggests expanding the current question about "whether your local pharmacy could get it" to explore these access barriers more thoroughly. Additionally, the question about local pharmacies should be expanded to include other types of pharmacies, particularly as a significant number of patients now receive their medications through home delivery services; CMS should consider collecting data on any access barriers associated with home delivery pharmacies.

Additionally, the NHC recommends including questions that explore challenges related to the cost of medications, insurance coverage decisions, and availability through pharmacies, such as shortages or supply chain issues. Directly asking patients and caregivers if they have encountered any of these access issues – whether related to cost, insurance coverage, utilization management, or availability – can provide valuable insights into the factors influencing patient access to medications. Identifying these issues is essential not only for understanding current challenges but also for monitoring and improving the implementation of the Medicare Drug Price Negotiation Program.

Furthermore, it is crucial to understand how patients perceive the communication and support they receive from health care providers regarding the management of their medications. Including a question about the quality of communication and support when discussing medication options, especially in the context of overcoming access barriers, could provide valuable insights into the patient experience. This information can help identify areas where health care providers might improve their communication strategies to better assist patients in navigating challenges related to access, affordability, and availability of medications.

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[1] Jacobsen, G., Leonard, F., Sciupac, E., and Rapoport, R. (2024). What do Medicare beneficiaries value about their coverage? Findings from the Commonwealth Fund 2024 value of Medicare survey. Retrieved from https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage

[2] American Medical Association. (2023). 2022 AMA prior authorization (PA) physician survey. Retrieved from https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

[3] Kyle, M. and Keating, N. (2023). Prior authorization and association with delayed or discontinued prescription fills. *Journal of Clinical Oncology, 42(8)*. https://doi.org/10.1200/JCO.23.01693

[4] Chino, F., Baez, A., Elkins, I., Aviki, E., Ghazal, L., and Thom, B. (2023). The patient experience of prior authorization for cancer care. *JAMA Network Open, 6(10)*. doi: 10.1001/jamanetworkopen.2023.38182

[5] Jew, O., Okawa, J., Barbieri, J., McCaffrey, J., Hayward, E., and Werth, V. (2021). Evaluating the impact of prior authorizations with complex dermatological conditions. *Journal of the American Academy of Dermatology, 83(6)*, 1674-1680. doi: 10.1016/j.jaad.2020.06.998

[6] American College of Cardiology. (2017). Barriers to new medications for cardiovascular disease: insights from CardioSurve. Retrieved from https://www.acc.org/latest-in-cardiology/articles/2017/02/21/12/42/barriers-to-new-medications-for-cardiovascular-disease-insights-from-cardiosurve?__hstc=117268889.c6acac5669d4f1e6063a774e6d96c6b5.1716560813145.1716560813145.1716560813145.1&__hssc=117268889.1.1716560813145&__hsfp=3523199817

By expanding the scope of these questions to include these critical factors, CMS can gain a more comprehensive understanding of the real-world challenges that patients face in managing their conditions with their current medications. This, in turn, will allow for a more patient-centered approach to evaluating treatment effectiveness and ensuring that the Medicare Drug Price Negotiation Program better addresses the needs of those it serves.

***Question 41: Information on the Medication(s) Used in the Past to Treat Your Condition.*** The historical perspective on past medications provides valuable insights into treatment pathways and reasons for changing therapies. However, to gain a more comprehensive understanding of patient experiences, it is important to explore how these transitions have impacted overall condition management, particularly in the context of access considerations related to prior authorization and step therapy.

As with current medications, CMS should collect information on whether patients experienced difficulties accessing past treatments due to prior authorization requirements or step therapy protocols. Step therapy is a utilization management process where patients are required to try an alternative treatment before gaining access to the prescribed medication. Understanding these considerations is important for assessing continuity of care and understanding the factors that may influence patient transitions between medications.

Additionally, the NHC recommends including questions that explore how these access challenges were communicated and managed by health care providers. This could provide valuable insights into the patient experience during transitions in therapy and help identify areas where additional support or improved communication might alleviate some of the burdens associated with navigating complex formulary and utilization management processes. By ensuring that this information is collected for both current and past medications, CMS can develop a more patient-centered understanding of the real-world challenges that patients encounter, particularly when transitioning between treatments. This comprehensive approach will better inform the Medicare Drug Price Negotiation Program and help ensure that it addresses the full spectrum of patient needs.

***Question 42: Additional Information.*** The open-ended nature of this question allows respondents to provide unique and qualitative data that may not be captured in structured questions. However, clear guidance on the types of additional information that might be most useful could help respondents provide more focused and relevant insights. Providing examples or categories of useful additional information (e.g., specific barriers to access, additional side effects not previously mentioned) could help respondents provide more targeted feedback.

***Question 43: Visual Representations.*** Allowing for visual representations such as tables, charts, and graphs can enhance the clarity and impact of the information provided. However, ensuring respondents have clear instructions on how to create and submit these visuals in a format that is useful for CMS' review process is essential. Including detailed instructions and examples of effective visual representations would help respondents provide more useful and standardized submissions.

***Question 44: Demographic Questions.*** Collecting demographic information is essential for contextualizing patient responses and ensuring that the diverse experiences of different population groups are considered in the evaluation. However, the current demographic categories may not capture all aspects of diversity that can impact patient experiences. To enhance the comprehensiveness of the demographic data collected, the NHC recommends several key additions and adjustments:

1. **Inclusion of a "Prefer Not to Answer" Option:** For each demographic field, there should be an option for respondents to select "prefer not to answer." This ensures that respondents can maintain their privacy and comfort while participating in the survey.
2. **Separate Demographic Information for Caregivers:** For respondents who are caregivers, CMS should include an option to complete demographic information for both the caregiver and the person receiving the treatment. This would provide valuable insights into how caregiver demographics might influence the caregiving experience and the patient's treatment outcomes.
3. **Urban, Suburban, or Rural Living Environment:** The NHC suggests adding a question that asks whether the respondent lives in an urban, suburban, or rural area. This information is crucial as access to health care resources, including medications, can vary significantly based on geographic location.
4. **Gender or Gender Identity:** The demographic section should include a question about gender identity. This would provide a more inclusive understanding of how gender-related factors might impact patient experiences with treatment.
5. **Expanded Race/Ethnicity Categories:** The current race and ethnicity categories are quite basic. Aligning these categories with the more granular standards used by the Office of Management and Budget (OMB) is recommended.[7] This approach would allow for a more nuanced understanding of how different racial and ethnic groups experience health care and access to medications, and it may create better research and data with more consistent data collection across the federal government.
6. **Inclusion of Socioeconomic Status and Education Level:** Expanding the demographic questions to include socioeconomic status and education level would provide a more comprehensive view of how these factors influence patient experiences. Differences in income, educational attainment, and occupational status can all impact access to care, treatment adherence, and health outcomes. Furthermore, including questions that address housing and food insecurity can provide insight into the social drivers of health that affect patient experiences. Understanding the stability of basic needs like housing and food can reveal underlying challenges that impact health outcomes and access to care, further informing CMS' evaluation of treatment effectiveness and patient support needs.
7. **Primary Language Utilized:** To better understand communication needs and potential barriers, the NHC recommends including a question about the primary

[7] Office of Management and Budget, "Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity," *89 Fed. Reg. 18530* (2024) (to be codified at 44 C.F.R. pts. 1, 2, and 3). https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and

language spoken by respondents. This information would help identify language access issues and ensure that communication about treatment options is effective and inclusive.

**Clinical-Focused Experience**

***Question 45: Background Questions.*** The NHC appreciates CMS' efforts to gather background information on health care providers prescribing the treatment. To enhance the value of this data, we recommend expanding this section to include additional demographic information about both the providers and the patients they serve. For instance, while Question 45a1 asks about the area of specialization, practice type, and practice site, it would be beneficial to also collect information on the demographics of the provider's patient population. Furthermore, we suggest including questions about the providers' own demographic characteristics, such as age, race/ethnicity, gender or gender identity, and geographic location. Collecting this information would enable CMS to analyze and compare prescribing practices across different groups of providers, leading to a deeper understanding of how demographic factors may influence treatment decisions and outcomes.

***Question 46: Treatment-related Questions.*** The NHC appreciates CMS' focus on understanding treatment goals, outcomes, and clinical practices related to the selected drug. To improve the quality and relevance of responses, we offer the following recommendations.

When asking about treatment goals, CMS should provide specific prompts, such as whether the goal is disease remission, symptom management, or quality of life improvement. This structured approach will help respondents provide more comprehensive and comparable answers.

For outcomes and assessments of improvement, CMS should clarify the types of outcomes being referred to – whether clinical, functional, or patient-reported. We recommend prioritizing outcomes that matter most to patients, including impacts on daily living and quality of life. Respondents should also specify the thresholds that indicate meaningful change, whether through clinical markers or patient-centered outcomes. This will ensure the evaluation captures what is truly important to patients. To better understand variability in treatment effectiveness, CMS should provide examples of subpopulations that may experience different outcomes, such as those based on age, comorbidities, or genetic factors.

The NHC also recommends including questions about utilization management practices like prior authorization and step therapy, as these may influence treatment access and patient outcomes. Gathering this information from both patients and providers is essential, as both parties often deal with these coverage issues. Therefore, we suggest incorporating these questions into the broader assessment, including Questions 40 and 41.

Finally, CMS should ask respondents to explain how evidence-based clinical practice guidelines are applied in practice, particularly when there is divergence from standard

recommendations or when guidelines lag behind current practice. Understanding these nuances will help contextualize the clinical decision-making process.

***Question 47: Treatment-related Questions.*** The NHC appreciates CMS' emphasis on understanding how the selected drug fits into current treatment paradigms, as this is crucial for ensuring that the Medicare Drug Price Negotiation Program accurately reflects real-world clinical practices and patient needs. To enhance the evaluation, we suggest reframing the benefit-risk assessment questions to focus on how patients perceive the trade-offs between benefits and risks, providing valuable insights into patient priorities and preferences for a truly patient-centered approach.

In considering the selected drug as a treatment option or comparing it to alternatives, it is important for respondents to specify the clinical scenarios, patient characteristics, or prior treatment failures that typically lead to the drug's use. This should include considerations of efficacy, safety, patient preferences, cost-effectiveness, and factors related to prior authorization or step therapy protocols, which will clarify the drug's role within the broader therapeutic landscape.

CMS should also prompt respondents to elaborate on the relative importance of various factors such as efficacy, safety, administration route, patient characteristics, and cost in treatment selection. This will capture the nuanced trade-offs that influence both clinician and patient decisions. To better understand variability in clinical practice, CMS should seek examples of how real-world prescribing may differ from clinical guidelines, including any debates or uncertainties that might affect drug selection.

Lastly, when discussing patient subgroups that may benefit more or face greater risks, it is essential to include considerations of health disparities, genetic factors, and comorbid conditions. This will help CMS gain a comprehensive understanding of the drug's differential impact across diverse populations, ensuring more equitable and effective health care outcomes.

***Question 48: Health Equity and Patient Experience.*** The NHC strongly supports the inclusion of considerations related to health equity and patient experience in the evaluation of selected drugs. Addressing health equity is essential to ensuring that all patients, regardless of their background or socioeconomic status, have access to effective treatments.

We recommend that CMS offer more specific sub-questions, similar to other questions in the document, aimed at prioritizing the identification of health disparities that may affect access to and outcomes from the selected drug. This includes considering social determinants of health, such as income, education, geographic location, and race/ethnicity, which can influence both the availability of the drug and the effectiveness of its use. By focusing on these factors, CMS can better understand how different patient populations may experience varying levels of access to the selected drug and its therapeutic alternatives.

Additionally, it is important to assess whether there are specific barriers that patients from underserved communities might face in accessing the selected drug. These could

include cost, insurance coverage limitations, availability of the drug in certain geographic areas, or cultural and language barriers that could affect a patient's ability to understand and adhere to treatment recommendations.

The NHC also encourages CMS to incorporate patient-reported outcomes and experiences into the evaluation process. These insights can provide a more comprehensive understanding of how the drug impacts daily life, including the ability to manage symptoms, maintain independence, and improve overall quality of life. By integrating these patient-centered measures, CMS can ensure that the evaluation process reflects the real-world experiences of those who rely on the selected drug.

***Question 49: Therapeutic Advance and Unmet Medical Need.*** When considering whether the selected drug represents a therapeutic advance, the NHC recommends that CMS take into account both clinical and patient-centered outcomes. This includes evaluating improvements in efficacy, safety, quality of life, and the ability to manage daily living activities. Additionally, it is important to assess whether the drug provides benefits over existing therapies in terms of reducing treatment burden, improving adherence, and offering new modes of administration that may be more patient friendly.

To better align with patient-centered care, the NHC suggests reframing the concept of unmet medical needs to focus on the impacts that are most important to patients. This includes asking respondents to identify and prioritize the outcomes and challenges that matter most to their patients, thereby ensuring that the evaluation reflects the real-world needs and preferences of those who use the drug.

**Research-Focused Experience**

***Question 54: Comparative Clinical Evidence.*** The NHC acknowledges the importance of robust methodologies and frameworks in evaluating the clinical comparative effectiveness of the selected drug and its therapeutic alternatives. To ensure that CMS' evaluation process is comprehensive and patient-centered, the NHC offers the following recommendations.

Regarding relevant clinical outcome measures, the NHC believes it is essential to consider both clinical efficacy and safety outcomes, as well as patient-reported outcomes that reflect quality of life, treatment burden, and functional status. By including these measures, CMS can ensure that the evaluation process captures the full impact of the drug on patients' lives.

In terms of specific evidence, the NHC encourages CMS to gather data from a variety of sources, including head-to-head trials, pragmatic clinical trials, and real-world studies that provide insights into the drug's performance in diverse patient populations. Additionally, it is important to consider evidence that highlights differences in outcomes among subpopulations, particularly those that are often underrepresented in clinical trials.

***Question 55: Specific Populations and Patient Experience.*** The NHC strongly supports the emphasis on understanding patient experiences and the impact of the

selected drug on specific populations. This approach is vital to ensuring that all relevant patient perspectives are considered in the evaluation process.

Regarding patient experiences, the NHC recommends that CMS collect evidence related to patient priorities and preferences, including how patients perceive the benefits and drawbacks of the selected drug compared to its therapeutic alternatives. This should include insights into the treatment burden, the overall impact on quality of life, and how the drug influences daily activities and well-being. Additionally, patient-reported outcomes should be emphasized, as they provide a direct measure of the drug's effectiveness from the patient's perspective.

For specific populations or subgroups, the NHC suggests that CMS identify and assess how different patient subgroups, such as those defined by age, race, ethnicity, socioeconomic status, or comorbid conditions, are impacted by the selected drug and its alternatives. Understanding how these groups experience the drug's benefits and risks will provide a more comprehensive picture of its effectiveness and safety across diverse populations. Studies focusing on health disparities and differential outcomes should be prioritized to ensure that the evaluation process addresses the needs of all patients.

Regarding considerations of access, health equity, and disparities, the NHC suggests that CMS explore factors affecting access, including cost, availability, insurance design, and social determinants of health, which may influence the use of the selected drug in different populations.

**Other Public Input**

The NHC recognizes that this section provides an opportunity for any other interested parties to contribute additional public input on the evaluation process. In this context, we emphasize the importance of a comprehensive approach that fully captures the selected drug's broader impact on patient care. We recommend that CMS consider the full range of indications for which the drug is used, including both FDA-approved and off-label indications supported by clinical evidence. This broader perspective will ensure that the evaluation process reflects the drug's significance in treating conditions with high unmet needs, as reported by patients and caregivers.

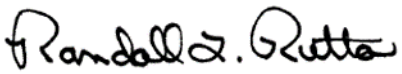
For all interested parties providing input, it is crucial for CMS to consider a wide range of evidence, including real-world data, patient-reported outcomes, and studies focusing on health disparities. These considerations are essential for understanding how different populations, particularly those that are underserved or marginalized, experience the benefits and risks associated with the drug. By incorporating these insights, CMS can better promote health equity and improve outcomes for all Medicare beneficiaries.

Moreover, the use of visual representations, such as patient experience maps and data on health equity impacts, can provide valuable insights into how the drug affects diverse populations. The NHC encourages CMS to include such visual aids in its evaluation to enhance understanding and support more informed decision-making.

**Conclusion**

The NHC appreciates the opportunity to provide input on the IRA 2027 Drug Price Negotiation ICR. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, at egascho@nhcouncil.org if you or your staff would like to discuss these comments in greater detail.

Sincerely,



Randall L. Rutta
Chief Executive Officer