



NATIONAL HEALTH COUNCIL

May 22, 2023

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

Re: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on Information Collection Request (ICR) on data elements for the drug price negotiation process 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 representative of patient advocacy organizations that are likely to be participating in this data collection process, we are committed to working with CMS to implement the negotiation process in a way that encourages data submission that is meaningful, efficient, and transparent. Our comments are designed to encourage the active involvement of patients and patient advocates in submitting data about selected drugs and their therapeutic alternative(s).

Patient Involvement in Data Submission

Following are some of the comments we submitted in response to the CMS initial guidance on implementing negotiation that are related to data submission by patients and patient advocates. We reiterate them here to stress their importance.

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 and 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 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.

Engaging Patients to Holistically Consider Therapeutic Alternatives

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 the previous guidance may represent a very narrow interpretation and could be re-defined in a way that takes a more holistic view to determine patients’ views on the value of drugs compared to their alternatives. For example, the narrow definition used for “unmet need” could result in misalignment between CMS’ and patients’ views on the value of the drugs and their therapeutic 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. A more thorough approach to patient engagement 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.

In addition, it will be important for CMS to provide clarity on how it evaluated evidence. When CMS reviews therapeutic alternatives, there should be a clear description of what data was considered and how it influenced the final outcome. The goal of this information should be to demonstrate how patient benefits and clinical appropriateness influenced the final decision.

Patient Engagement and Utilizing Patient Experience Data

The NHC urges CMS to prioritize 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 as compared to other factors such as research and development costs. CMS should also articulate how patient experience data influenced initial and final offers.

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 previously mentioned concerns 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 the previous guidance 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 the previous guidance. 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.

Specific Comments in Response to ICR

The NHC recommends that the category of trade association and patient advocacy organization be separated into two categories in question 39. It is important that data from patients and patient advocates be in its own category in order to help the Agency evaluate and prioritize patient-centered data. The types of research and the weight given to different responses may vary greatly between a patient advocacy organization and a trade association representing providers or manufacturers.

In addition, we recommend that the guidance include a definition of patient advocacy organization that makes it clear who qualifies in this category. An example can be found in the National Health Council's [Glossary of Patient Engagement Terms - National Health Council](#):

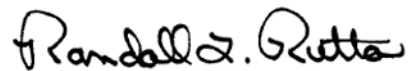
- **Patient advocacy organization:** a 501(c)(3) organization that has a mission to combat a particular disease, disability, or group of diseases and disabilities, or to improve and protect the health of a particular group of people. It engages in programs, such as research, education, advocacy, and service to individuals and communities. It takes a holistic view of the conditions for the patients it represents and seeks universal support from stakeholders for its mission and programs. While a patient advocacy organization may advocate for patient access to care, they do not have prescribing authority; formulary control, responsibility, or decision-making authority; or make drug purchases.

Finally, in the questions regarding evidence about alternative treatments, respondents are asked to certify that the evidence provided does not rely on discriminatory approaches. In the previously issued guidance, CMS stated that they would exclude QALY metrics from data that otherwise factor in QALYs. The NHC appreciates CMS' adherence to the statute and the decision to separate out and exclude such data. However, we are concerned that there may be a lack of clarity among patient groups about this process of utilizing studies that use QALY-related data from secondary sources. This may result in hesitancy to submit certain analyses that are otherwise helpful in establishing the value of a drug or lack of certainty that QALYs have been effectively eliminated from CMS' decisions. Therefore, the NHC requests that CMS offer more clarity into exactly how patients and patient advocates should analyze QALY-based metrics in value-based decisions. This clarity will help patients and patient advocates better respond to the required certification.

Conclusion

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.

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