



NATIONAL HEALTH COUNCIL

July 2, 2024

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

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

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to the Centers for Medicare & Medicaid Services (CMS) in response to the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (2027 draft guidance).

Created by and for patient organizations more than 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 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.

General Comments

The NHC appreciates CMS' commitment to actively engaging with stakeholders, including patients, consumer advocates, and health experts, in implementing the Medicare Drug Price Negotiation Program (DPNP). We believe that patient-centric engagement is essential to ensure that the negotiation process leads to outcomes that genuinely benefit patients. As noted in our previous communications, while the NHC would prefer 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.¹ And

¹ National Health Council. (2023). NHC comments on IRA guidance response. Retrieved from <https://nationalhealthcouncil.org/wp-content/uploads/2023/04/NHC-IRA-Guidance-Response.pdf>

we appreciated CMS' thorough responses to comments for IPAY 2026 and hope the Agency will replicate this for this comment opportunity. Our comments below highlight specific areas where we believe additional improvements can be made to ensure all Medicare beneficiaries, particularly those with chronic diseases and disabilities, have increased access to affordable, high-value, equitable, and sustainable health care.

Patient Engagement

The NHC recognizes and commends CMS' willingness to improve the listening sessions and the data submission processes. It is encouraging to see CMS' commitment to actively engaging with patients and patient organizations to ensure their voices are heard and considered in the DPNP. The NHC provides the following comments to CMS to improve on the steps it has already taken to date.

Improving the Listening Sessions. In our effort to enhance opportunities for patient input, the NHC held a Roundtable discussion that included patients, caregivers, patient organizations, and CMS representatives. The goal of this Roundtable was to chart a course for improving patient engagement in the DPNP and ultimately in other programs and activities of the Agency. The discussion focused on CMS' 2023 listening sessions during implementation of the first round of negotiations and identified lessons learned to inform future listening sessions and broader patient engagement strategies. Based on the discussions and insights from the Roundtable, the NHC offers the following recommendations to:

Improve Clarity and Communication about the Intent of the Listening Sessions.

- Clarify What Information is Sought from Speakers
- Report on Data Utilization
- Host Educational Webinars Before Listening Sessions
- Market as Stakeholder Listening Sessions if They Have Broader Representation

Improve the Structure of the Listening Sessions.

- Enhance Dialogue-Based Engagement
- Clarify Required Disclosures
- Allow HIPAA Waivers if Feasible
- Clarify Speaker Selection Process
- Allow for Data Submissions After Sessions

Increase Engagement.

- Increase Ways for Stakeholders to Engage
- Provide More Advance Notice
- Enhance Efforts to Engage Diverse Speakers
- Partner with Patient Organizations
- Record Listening Sessions

Improve the Speaker Experience.

- Provide Accommodations
- Allow More Speaking Time and Use a Timer
- Show CMS Representatives on Screen

Our report, [*Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement*](#), offers greater detail and specificity on these recommendations. We also include additional information later in this letter when responding to Section 60.4.

Improving the Data Collection (ICR) Process. The NHC supports the focus on patient-centered data and emphasizes the importance of clear guidelines and support to help patient organizations navigate the data submission process. We appreciate CMS' stated willingness to improve this process to make it more relevant for patients and patient organizations.

We were especially pleased to see CMS indicate that they may make clearer that they are seeking detailed descriptions of what it is like to live with a medical condition treated by the selected drug or its therapeutic alternatives, and the factors that matter most to patients when assessing the value of a drug. We feel this is an optimal use of the ICR process and recommend that this framing also be used as part of the description of the listening sessions.

We also support CMS' potential grouping of questions related to manufacturer input, patient or caregiver experience, clinical experience, and health research, which can streamline the data collection process, aligning information more closely with respondents' areas of expertise. However, it is essential to ensure that the complexity and nuances of patient experiences are not oversimplified. Pilot testing this format with various stakeholders can help identify potential challenges and refine the process accordingly.

To enhance the ICR process, clarifying what qualitative and quantitative information is needed and how it will be used in determining the MFP will help patient organizations better prepare and ensure their data is relevant. Hosting educational webinars to prepare patient groups and stakeholders on information requirements will also be beneficial.

Finally, we encourage CMS to consider a longer time horizon for the submission of data. While some organizations may have access to existing data, others may want to collect new data through surveys or other activities that may be more fit for CMS' needs. Further, if this period is extended beyond the listening sessions, there may be gaps identified during the sessions that can be filled by additional research. While we understand this timing may not allow for the data to be incorporated into CMS' initial offer, it can still be useful during later stages of the negotiation process.

Utilization of Patient Experience Data. The NHC commends CMS for acknowledging the importance of patient experience data in the negotiation process. It is crucial that this data is given significant weight in determining the MFP. Patient

experience data provides valuable insights into how medications impact patients' daily lives, including their ability to manage symptoms, maintain independence, and improve their quality of life.

We urge CMS to consider a broad range of patient experience data, including both clinical and non-clinical outcomes. Factors such as treatment adherence, patient-reported outcomes, and quality of life measures should be integral to the negotiation process. Additionally, CMS should engage with patient organizations to identify the most relevant and impactful data points. By doing so, CMS can ensure that the MFP reflects the true value of medications from the patient's perspective. Furthermore, ongoing dialogue and reporting on how patient engagement information is incorporated into negotiations and establishing a feedback loop with patient organizations will reinforce CMS' commitment to truly patient-centered care.

Clarification on QALY Metrics

The NHC appreciates CMS' commitment to excluding Quality-Adjusted Life Years (QALYs) from the negotiation process as outlined in the 2027 draft guidance. Valuing life differently based on disability status, age, or other special populations is inappropriate. All patients deserve equal treatment, and we applaud CMS' decision to exclude QALY metrics. However, we are concerned about the potential use of studies with QALY-related data from secondary sources or the over-exclusion of valuable analyses. The NHC requests more clarity on how CMS will exclude QALY-based metrics and highlight when they have been removed from consideration in MFP justification documentation. Additionally, we recommend that CMS be more transparent regarding the forms of cost-effectiveness analysis it is considering using, as many approaches are not well understood or tested.

Patient value is multi-faceted and attempts to distill important dimensions of patient value and benefit into a single number are problematic. While QALYs are excluded by statute, CMS should not rely on a single metric and instead use a wide variety of sources for a holistic approach. Multi-criteria decision analysis (MCDA) is one such approach that considers a wide range of factors, including patient preferences and quality of life.² By adopting a holistic approach to value assessment, CMS can ensure that the negotiation process is fair and inclusive of all patient populations.

Continuous Improvement and Feedback Mechanisms

The NHC supports the establishment of a robust infrastructure for continuous patient engagement, including a patient ombudsman and regular public roundtables with patient and disability communities. Continuous improvement is essential for adapting the negotiation program to changing needs and ensuring that it remains effective and patient-centered over time.

Creating a patient ombudsman position would provide patients with a dedicated advocate within CMS who can address their concerns and ensure that their voices are

² National Health Council. (n.d.). Patient-centered multi-criteria decision analysis. Retrieved from <https://nationalhealthcouncil.org/additional-resources/patient-centered-multi-criteria-decision-analysis/>

heard. This role would be instrumental in facilitating ongoing dialogue between CMS and the patient community, helping to identify areas for improvement and ensure that patient feedback is integrated into policy decisions.

Regular public roundtables and advisory committees can also provide valuable insights into the patient experience and help CMS stay informed about emerging issues. These forums should include diverse representation from various patient communities to capture a wide range of perspectives. Additionally, CMS should establish clear processes for incorporating feedback from these engagements into the negotiation program, ensuring that patient input leads to tangible changes.

Comments on Specific Sections of the 2027 Draft Guidance

Transparency and Stakeholder Engagement (Section 30)

The NHC emphasizes the need for CMS to maintain a high level of transparency in its negotiation processes. This includes providing detailed justifications for the MFP and ensuring that patient input, especially through patient listening sessions, is transparently incorporated into decision-making. Moreover, stakeholder engagement should be a continuous process, with CMS actively seeking input from diverse patient organizations and other stakeholders at every stage. Aggregation of stakeholder feedback should be methodical and comprehensive, ensuring that no significant patient perspectives are overlooked. These elements were previously highlighted in our comments in response to the IPAY 2026 guidance, and we continue to stress their importance for the 2027 draft guidance.

Active Moiety and Single Source Qualifying Drugs (Section 30.1)

The NHC remains concerned about the effects that the aggregation of drugs with the same active moiety or active ingredient in the selection process could have on subsequent research.ⁱ We want to ensure that manufacturers are not discouraged from developing new indications, forms of administration, or combination products that may improve patient adherence and 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 aligns 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, combination products, or forms of administration improve patient care.

We believe there are better approaches to address this issue, including using patient engagement to determine whether new formulations, combination products, or routes of administration are considered by patients to be important improvements. For example, innovations in biologic drugs used to reduce inflammation in autoimmune diseases like arthritis have made injections much less painful, significantly improving the quality of life for patients. Similarly, long-acting insulin analogs provide more stable blood sugar control and reduce the number of daily injections needed for diabetes patients. Extended-release psychotropic formulations for mental health conditions improve

treatment adherence and overall patient outcomes by reducing the frequency of dosing. Combination products, such as fixed-dose combinations for hypertension or HIV, simplify treatment regimens and enhance adherence.

Such innovations underscore the importance of encouraging new forms of administration, combination products, and other advancements that enhance patient experience and adherence. Therefore, incorporating robust patient engagement practices is essential to accurately capture the value and necessity of these advancements from the patient's perspective. This ensures that the negotiation process genuinely aligns with patient needs and preferences, ultimately leading to better health outcomes and improved quality of life.

Medicare Transaction Facilitator (Section 40.4.1)

The NHC appreciates the opportunity to provide feedback on the role of the Medicare Transaction Facilitator (MTF) within the Medicare DPNP. The MTF plays a critical role in ensuring that the negotiated MFPs are effectively implemented and that all stakeholders, including patients, manufacturers, and dispensing entities, experience minimal disruption during the transition. To achieve this, it is essential that the MTF operates with consistency, uniformity, and transparency while ensuring robust data security measures.

Standardization and uniformity are essential for the nearly 70,000 pharmacies that bill for Medicare Part D.ⁱⁱ Implementing a standardized process will streamline operations, reduce administrative burdens, and enhance patient access to the program. By ensuring consistency and transparency, CMS can facilitate the efficient and equitable implementation of the MFPs, enabling all parties involved to operate smoothly and effectively. This approach will ultimately lead to better patient outcomes and reduced administrative burdens for manufacturers and dispensing entities.

To maintain impartiality and integrity, it is crucial to consider the nature of any potential conflicts of interest from entities involved in the pharmaceutical supply chain. These conflicts can significantly influence formularies and patient access to medications.ⁱⁱⁱ Transparency and careful evaluation of these conflicts are essential to ensure trust and fairness in the process for all stakeholders. By prioritizing transparency and conflict mitigation, CMS can help ensure that the MTF operates in a manner that is trusted by all stakeholders and that the negotiation outcomes are unbiased and equitable. Ensuring that the selected MTF does not have inappropriate conflicting business interests is vital for maintaining stakeholder confidence.

The NHC supports prioritizing specific MTF functions that can yield immediate benefits and alleviate the burdens faced by beneficiaries, manufacturers, and dispensing entities. Timely reimbursement is of critical importance to ensure uninterrupted access to essential drugs for beneficiaries. When pharmacies are compelled to hold onto funds for extended periods as part of the retrospective payment process, it can strain their financial resources, potentially leading to difficulties in maintaining sufficient medication supplies and disrupting patient access.^{iv} This delay or uncertainty in reimbursement

may result in increased costs, potentially impacting patients through higher co-pays or out-of-pocket expenses, potentially limiting their ability to afford necessary medications.^v

The NHC also underscores the utmost importance of implementing robust data security measures to safeguard patient data throughout the MTF process. To this end, we recommend that CMS clarify that the MTF is designated as a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), ensuring full compliance with patient data privacy and security laws. The NHC recommends the implementation of advanced encryption to secure all data exchanges and prevent unauthorized access to sensitive patient information. Additionally, strict access controls should be implemented to restrict data access exclusively to authorized personnel, fortifying data confidentiality. It is also crucial to maintain comprehensive data audit trails to monitor data access and modifications, enhancing accountability and data integrity. Furthermore, conducting regular security audits and assessments is essential to systematically identify vulnerabilities and proactively address them. The NHC firmly believes that these security measures will not only protect patient data but also foster trust in the MTF process among all stakeholders involved.

Evaluation Criteria and Patient-Centered Metrics (Section 50.2)

The NHC reemphasizes the need for comprehensive evaluation criteria that prioritize patient-centered metrics. These metrics should include patient-reported outcomes, quality of life measures, and other indicators that reflect the real-world impact of medications on patients' lives. The inclusion of such metrics will ensure that the negotiation process genuinely reflects the value of treatments from the patient's perspective.

To this end, the NHC recommends that CMS consider non-QALY-related models that focus on the quality of evidence and strength of recommendations, which can provide a more nuanced and patient-centered assessment of treatment value. Furthermore, the NHC suggests that CMS utilize the NHC's patient principles and rubric as a checklist to ensure that any methodology considered is patient-centered. The [National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem](#) was developed through a multi-stakeholder process to elevate meaningful patient engagement. This rubric encompasses seven domains of patient-centered engagement and methodological practices: 1) patient partnership; 2) transparency; 3) representativeness; 4) diversity; 5) outcomes patients care about; 6) patient-centered data sources and methods; and 7) timeliness. By incorporating these domains, CMS can prioritize patient experience data in the negotiation process and develop a standardized methodology for incorporating this data into decision-making. This methodology should outline how patient experience data will be collected, analyzed, and weighted against other factors, such as research and development costs. Transparency in this process is essential to build trust and ensure that patient perspectives are genuinely influencing the outcomes.

Standardized Methodology and Real-World Evidence (Section 50.4)

We also highlight the importance of a standardized methodology for applying therapeutic alternatives data, as outlined in Section 50.4. The methodology should be

transparent and consistent, leveraging real-world evidence to provide a comprehensive understanding of treatment benefits and risks. This approach aligns with our previous calls for a holistic evaluation that incorporates diverse data sources and patient experiences.

Use of Clinical Guidelines (Section 50.6)

Clinical guidelines provide evidence-based recommendations that can help ensure treatments align with the best available scientific evidence. **The NHC supports CMS' use of these guidelines as one of many evidence sources to ensure therapies are selected and valued based on clinical efficacy and appropriateness for patients.** Emphasizing clinical guidelines and other evidence-based recommendations helps prevent the inappropriate use of cost considerations as the primary driver of decision-making, which could undermine patient care by prioritizing cheaper treatments that may not be the most effective or suitable for patient needs. CMS should balance the use of clinical guidelines with patient-centered outcomes and real-world evidence and ensure evidence is as current as possible to keep the negotiation process focused on what is best for patients. **As CMS works to achieve this balance, the NHC would like to emphasize several limitations associated clinical guidelines:**

- **Off-Label Usage:** Clinical guidelines typically do not cover off-label uses of medications, which can be significant for many patient populations, especially those with rare or complex conditions. Off-label usage often emerges from real-world clinical practice and patient experiences, which might not be reflected in the guidelines. It is crucial to consider how off-label uses will be evaluated and incorporated into the negotiation process. Ignoring these uses could lead to decisions that do not fully capture the value of a medication for all patients. CMS should develop a framework to evaluate and include off-label uses in the negotiation process. This could involve consulting with clinical experts, patient organizations, and reviewing peer-reviewed literature and real-world evidence that supports off-label use cases.
- **Pace of Guideline Updates:** The process for updating clinical guidelines can be slow, often lagging behind the latest clinical research and real-world evidence. This delay can result in outdated recommendations that do not reflect current best practices or emerging treatment options. CMS should ensure that the negotiation process is flexible enough to incorporate new evidence and adapt to changes in clinical practice swiftly. CMS should establish mechanisms to expedite the integration of new clinical evidence into the guidelines used for negotiation. This could involve setting up rapid review panels or interim updates to guidelines based on emerging data.
- **Lack of Patient Input:** Clinical guidelines often lack robust patient input, focusing predominantly on clinical outcomes rather than patient-centered outcomes such as quality of life, treatment adherence, and patient preferences. Incorporating patient perspectives into the guideline development process is essential to ensure that the recommendations reflect what matters most to patients. CMS should work with stakeholders to increase patient involvement in guideline development and consider patient-reported outcomes in the negotiation process and ensure that patient-centered outcomes are given significant weight

in the evaluation of treatments. There are some notable instances of clinical guidelines developed in collaboration with patient organizations that emphasize patient-centered outcomes in atrial fibrillation and arthritis (specifically osteoarthritis and juvenile idiopathic arthritis) that showcase models of how patient engagement can enhance the development and implementation of clinical guidelines.^{vi,vii,viii}

Patient Engagement during the Negotiation Process (Section 60.4)

The NHC appreciates CMS' detailed outline in Section 60.4 regarding the patient-focused listening sessions and the overall negotiation process for determining the MFP. We commend CMS for its commitment to improving these sessions and provide the following detailed recommendations.

First, CMS should specify the type of information it seeks from speakers during patient-focused events. Clear communication about the objectives and desired outcomes will help participants prepare more effectively and contribute valuable insights. For example, CMS could outline the specific aspects of patient experiences and therapeutic alternatives it is interested in, which will enable participants to provide more targeted and relevant input. It is also essential for CMS to report on how the patient engagement information and qualitative data collected during these sessions are incorporated into the negotiations. This transparency will build trust and demonstrate that patient voices are genuinely influencing the outcomes, which can lead to greater and more representative participation moving forward. Hosting educational webinars in advance of the listening sessions can further ensure stakeholders are well-prepared. These webinars can provide detailed information on the structure of the sessions, the types of data CMS is seeking, and how this data will be used in the negotiation process. If CMS continues to include stakeholders other than patients, they should be marketed as stakeholder listening sessions. This will make it clear that the outreach includes all members of a disease community, including patients, caregivers, and practitioners. This inclusive approach will help gather a diverse range of perspectives and experiences, enriching the data collected.

CMS should focus on creating opportunities for real-time dialogue with smaller groups of patients rather than merely holding listen-only events. This approach can help gather deeper insights and foster a more interactive and engaging approach. For instance, roundtable discussions and focus groups could facilitate more meaningful interactions among participants. The required disclosures should be clarified in a manner that explains why they are needed and how they affect the testimony. This will help participants understand the necessity of these disclosures and provide informed consent. CMS should also allow patients and speakers the ability to waive HIPAA requirements, if legally permissible. This flexibility can facilitate more open and honest sharing of experiences, which is crucial for understanding the real-world impact of medications. Additionally, CMS should clearly communicate the process for selecting speakers and ensure diversity in the selection process to include a broad spectrum of voices and perspectives. Allowing for data submissions after the listening sessions can enable participants to provide additional insights that may arise from the discussions, ensuring that all relevant information is captured.

CMS should increase ways for patients and other relevant stakeholders to engage, such as through written statements or recorded testimonies for those who cannot participate in live sessions due to job constraints, privacy concerns, or lack of broadband access. Providing more advance notice for listening sessions will allow organizations time to identify relevant patients and conduct surveys to gather insights. Enhancing efforts to engage speakers from diverse backgrounds is essential, and this can be achieved by working with the Office of Minority Health and minority-led patient organizations to ensure that the sessions reflect the diversity of the patient population. Partnering with patient organizations to monitor the program's impact, especially on access to treatments, will help ensure that the program is meeting its goals. Recording the listening sessions will allow stakeholders to review the testimony and ensure that all voices are heard and considered. Sharing redacted transcripts can help maintain transparency while protecting privacy.

To improve the speaker experience, CMS should provide accommodations for patients with disabilities and non-native English speakers to ensure that all participants can engage fully. This includes providing translation services, accessible venues, and other necessary support. Allowing speakers more time (at least five minutes) and including a timer on the Zoom screen to help manage pacing can make the experience more comfortable and effective, ensuring that participants do not feel rushed and can share their experiences thoroughly. Showing CMS representatives on the Zoom screen can make speakers feel more comfortable and ensure they feel heard. This visual presence can help build rapport and foster a sense of engagement and interaction.

Explanation for the MFP (Section 60.6.1)

It is crucial that CMS provides clear and detailed explanations for the MFP, explicitly explaining how patient listening sessions and patient-submitted data are utilized. Transparency in these justifications will build trust and ensure that the negotiation outcomes are genuinely patient-centered. The NHC urges CMS to release the justifications for 2026 before starting the 2027 process, despite the statutory timeline requiring publication by March 1 of the year prior to the initial price applicability year. Early release will allow for better preparation and more informed stakeholder engagement. Furthermore, CMS might also consider releasing a template for these explanations in advance and soliciting feedback on that template to ensure the information meets the guidance's transparency goals.

Part D Formulary Inclusion of Selected Drugs (Section 110)

Finally, we reiterate our concerns regarding Part D formulary inclusion of selected drugs, as expressed in our previous letters. Ensuring that negotiated drugs are included in formularies without undue restrictions is critical for maintaining patient access to essential medications. Additionally, it is important to consider how negotiation could impact access to competitors of selected drugs, potentially affecting the overall availability of effective treatments.

To protect patients from potential negative consequences of the negotiation program, such as increased utilization management or formulary restrictions, CMS should establish clear guardrails and conduct ongoing oversight. It is essential that the

negotiation process does not inadvertently create barriers to accessing necessary medications. Patients must be assured that cost-saving measures will not come at the expense of their health and well-being.

One key area of concern is the potential for increased utilization management practices, such as prior authorization and step therapy, which can delay or deny access to necessary treatments.^{ix,x,xi,xii,xiii,xiv} CMS should establish stringent guidelines to ensure that these practices are not used excessively or inappropriately. Additionally, CMS should monitor the impact of these practices on patient access and adjust policies as needed to protect patients from undue burden.

CMS' recent interoperability and prior authorization final rule emphasizes the need for streamlined prior authorization processes and enhanced transparency, which was supported by many stakeholders, including patient organizations, providers, health plans, and pharmaceutical groups.^{xv} The NHC urges CMS to consider developing parallel rules specifically for prescription drugs to ensure comprehensive coverage and protection for patients.

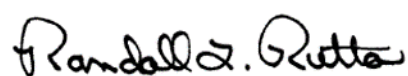
Ongoing oversight is critical to ensuring that the goals of the negotiation program are achieved without compromising patient care. CMS should implement a robust monitoring system to track the program's impact on drug prices, access, and patient outcomes. This includes collecting data on utilization management practices, formulary changes, and patient experiences. Patient organizations are willing and able to assist in collecting information from their populations to share with CMS if the appropriate structure is established to allow for this reporting. Regular reporting and public transparency will help identify any unintended consequences and allow for timely corrective actions.

Conclusion

The NHC strongly believes that a patient-centered approach is vital for the success of the DPNP. We urge CMS to consider these recommendations to ensure that the program not only achieves cost savings but also enhances access to high-value, life-saving medications for Medicare beneficiaries.

We appreciate the opportunity to provide input on this important issue and look forward to continuing our collaboration with CMS. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, at egascho@nhcouncil.org if you have any questions or require further information.

Sincerely,



Randall L. Rutta
Chief Executive Officer

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^{xv} Medicare and Medicaid programs; patient protection and Affordable Care Act; advancing interoperability and improving prior authorization processes for Medicare Advantage organizations, Medicaid managed care plans, state Medicaid agencies, Children's Health Insurance Program (CHIP) agencies and CHIP managed care entities, issuers of qualified health plans on the federally-facilitated exchanges, Merit-based Incentive Payment System (MIPS) eligible clinicians, and eligible hospitals and critical access hospitals in the Medicare Promoting Interoperability Program, 89 Fed. Reg. 8758 (2023) (to be codified at 42 C.F.R. pts. 422, 431, 435, 438, 440, 457, and 45 CFR pt. 156). <https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability>