NATIONAL HEALTH COUNCIL

August 17, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program [CMS-4215-P]

Submitted electronically via regulations.gov

Dear Administrator Oz:

The National Health Council (NHC) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS') proposed rule regarding the Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program. The proposed rule marks an important transition in the Negotiation Program's implementation by moving many policies that have governed initial price applicability years (IPAYs) 2026 through 2028 from program guidance into regulation and establishing several new policies that would apply beginning with IPAY 2029. These include policies addressing fixed-combination drugs that are new formulations, drugs that formerly qualified for the orphan drug exclusion, bona fide marketing of generic drugs and biosimilars, transfers of responsibility following an acquisition, calculation of a 30-day equivalent supply for drugs that are typically administered one time, the temporary floor for small biotech drugs, and consideration of off-label use in determining eligibility and selection for renegotiation. The proposed rule would also codify requirements concerning drug selection, negotiation and renegotiation, patient-focused engagement, evaluation of clinical benefit, and formulary inclusion of selected drugs.

The NHC unites nearly 200 national organizations—including leading patient groups, research institutions, providers, caregivers, and businesses across the health care sector—to drive patient-centered health policy. Representing 200+ million Americans with chronic diseases and disabilities, the NHC strengthens its members' collective influence to expand access to quality, affordable, and equitable health care. The NHC fosters collaboration to shape policies that reflect the needs of patients.

The NHC has engaged extensively with CMS throughout implementation of the Negotiation Program. These efforts have included comments on the guidance governing IPAYs 2026–2028 and related information collections. The NHC has also convened a series of roundtables with CMS and the patient advocacy community to assess and strengthen the agency's patient engagement activities. Those discussions have examined the first two negotiation cycles and, most recently, implementation of the

IPAY 2028 process. They have provided a direct forum for patients, caregivers, and patient organizations to share practical lessons regarding listening sessions, data submissions, educational materials, accessibility, and the use of patient experience information.[1,2,3,4,5]

The NHC welcomes CMS' use of notice-and-comment rulemaking as the Negotiation Program moves beyond the period during which the Inflation Reduction Act directed CMS to implement the program through guidance. Rulemaking offers greater transparency, greater predictability for patients and other stakeholders, and an opportunity for CMS to formally consider and respond to public comments. Codification is particularly important for policies that affect which products are selected, how information is evaluated, how the maximum fair price (MFP) is developed, and how selected drugs remain accessible to beneficiaries. However, codification should not prevent CMS from continuing to evaluate the program as experience develops. The Negotiation Program remains relatively new, the first negotiated prices have only recently taken effect, and Part B implementation is still developing. Significant questions therefore remain regarding how patient information influences negotiations, how plans and providers respond to an MFP, and whether the program produces meaningful and sustainable improvements in access and affordability. The final rule would be strengthened by mechanisms for continued public input, transparent program evaluation, and periodic reconsideration of policies as new evidence and implementation experience become available.[6]

From the patient perspective, the success of the Negotiation Program will by whether the MFP translates into greater affordability and timely, predictable access to selected drugs. Beneficiaries must be able to obtain these drugs, providers and pharmacies must be able and willing to furnish them, and coverage policies should not create new barriers. Successful implementation should also preserve future treatment options and support continue development of therapies and treatment improvements that address

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[1] National Health Council, "NHC Comments on IRA Guidance Response," April 14, 2023, https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-ira-guidance-response/.

[2] National Health Council, "NHC Comments on 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 in 2026 and 2027," July 2, 2024, https://nationalhealthcouncil.org/wp-content/uploads/2024/07/NHC-Comments-RE-IPAY-2027_07.02.24.pdf.

[3] National Health Council, "NHC Comments on Draft Guidance for the Medicare Drug Price Negotiation Program for Initial Price Applicability Year 2028," June 26, 2025.

[4] National Health Council, *Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement* (Washington, DC: National Health Council, March 2024).

[5] National Health Council, *Amplifying the Patient Voice: Reflections and Recommendations from the Second Cycle of CMS Patient Engagement* (Washington, DC: National Health Council, August 2025).

[6] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program," *Federal Register* 91, no. 115 (June 16, 2026): 36236–38.

unmet needs. The NHC's recommendations are intended to improve implementation of the Negotiation Program so that efforts to advance affordability remain responsive to the clinical circumstances, treatment experiences, and outcomes that matter to patients and family caregivers, while preserving meaningful access, treatment choice, and continued development of therapies that address unmet needs.[7]

Summary of Recommendations

The NHC recommends that CMS:

- Finalize a durable regulatory framework for the Negotiation Program while preserving structured opportunities for continued public input, evaluation, and improvement as additional experience becomes available;
- Retain the current policy of treating separately approved or licensed fixed-combination products as separate qualifying single-source drugs, including when an added active ingredient enables a different route of administration, rather than finalizing the proposed fixed-combination drug modification;
- Clarify and strengthen minimum expectations for patient-focused engagement, including adequate notice and preparation time, transparent participant-selection criteria, accessible participation options, opportunities for bi-directional feedback, clear descriptions of the information CMS is seeking, and sufficient time for patient organizations to collect and submit relevant information;
- Provide clear feedback explaining how patient and caregiver input informed CMS' analysis of therapeutic alternatives, outcomes, unmet medical need, therapeutic advance, and other relevant factors;
- Provide a public framework explaining how CMS evaluates and brings together patient experience data, patient-reported outcomes, caregiver perspectives, clinical evidence, real-world evidence, evidence involving Medicare subpopulations, and uncertainty in the available evidence;
- Ensure that evidence is evaluated from rare disease communities, small clinical populations, and patient organizations using standards appropriate to the question, population, and available evidence and does not treat small sample size or qualitative evidence as inherently lacking value;
- Clarify how off-label uses are identified and considered during both negotiation and renegotiation, permit information from patients, clinicians, patient organizations, professional societies, and other credible sources to inform those determinations, and ensure that therapeutic alternatives remain clinically appropriate for the specific use and patient population;
- Strengthen monitoring of access and utilization management for selected drugs under both Part D and, where applicable, Part B, including through public reporting and comparison of access policies before selection, after selection, and after the MFP takes effect;
- Maintain flexibility in the calculation of a 30-day equivalent supply for one-time or episodic therapies to account for full-course treatment costs, duration of benefit

[7] National Health Council, "NHC Comments on Draft Guidance 2028," June 26, 2025, 1–2, 22–23.

for patients, treatment burden, variable dosing, or other factors relevant to patient value;
- Ensure that future MFP-effectuation rulemaking for IPAY 2029 and subsequent years builds on the 2028 Part B effectuation framework and provides stakeholders sufficient notice and opportunity to assess how operational requirements affect patient access;
- Clarify that eligibility for the amended orphan drug exclusion is assessed based on indications approved at the time a drug would otherwise be selected for negotiation, and monitor whether the policy affects continued development for rare disease populations and or the pursuit of additional indications;
- Provide plain-language information accompanying the selected-drug and top negotiation-eligible-drug lists, including how dosage forms, strengths, NDCs, and HCPCS codes are grouped, together with a practical pathway for identifying and correcting objective factual errors;
- Balance protection of proprietary and patient information with sufficient public explanation of the evidence, methodology, and patient-centered considerations that informed the initial offer and final MFP; and
- Apply compliance and enforcement policies in a predictable manner that protects beneficiaries from disruptions, supports timely correction of operational failures, and provides aggregate public information on recurring compliance issues and corrective actions.

The Regulatory Framework Should Remain Responsive to Patient Experience and Implementation Evidence

The NHC supports CMS' proposal to codify core elements of the Negotiation Program in a new part 429 and to codify related Part D requirements in part 423. The transition from annual guidance to regulation can provide greater predictability for patients, patient organizations, manufacturers, plans, providers, and other stakeholders. It can also make the program's policies easier to understand and evaluate across negotiation cycles. Codification can also reduce the risk that foundational policies change without sufficient notice or opportunity for public input.[8]

Several policies proposed for codification, however, rely on methods that have not yet been fully tested and their effects cannot yet be comprehensively evaluated. The first MFPs took effect in 2026, and CMS is still developing the process for MFP effectuation for drugs payable under Part B. It will take time to assess the relationship between negotiated prices and formulary design, provider participation, product availability, treatment switching, and beneficiary out-of-pocket costs. In addition, patient organizations continue to identify opportunities to improve CMS' engagement processes, including the timing and structure of public events, the information available to participants, and the absence of a sufficiently detailed explanation of how patient input affects CMS' negotiation decisions.[9]

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[8] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36236–38.

[9] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36237–38, 36296–97.

The NHC therefore encourages CMS to treat the final rule as a durable foundation rather than the conclusion of policy development. Periodic public evaluation of the Negotiation Program, publication of implementation findings, identification of policies that may require revision, and meaningful opportunities for patients and other stakeholders to comment on future changes would support continued improvement. CMS will likely still need to address operational details through subregulatory guidance. However, policies that materially affect drug selection, grouping, clinical evaluation, patient access, or the responsibilities of program participants warrant continued consideration through transparent processes with adequate public notice.[10,11]

The proposed rule does not codify MFP-effectuation requirements for IPAY 2029 and later years. CMS has since issued draft guidance with substantial operational detail for 2028, including for selected drugs payable under Part B. Because selection, negotiation, effectuation, coverage, reimbursement, and beneficiary access are interconnected, the NHC encourages CMS to use the 2028 framework as the foundation for future rulemaking. CMS should identify material changes sufficiently in advance and allow stakeholders adequate time to assess how those changes interact with the policies finalized through the present rule.[12]

Drug Selection and Publication Processes Should Support Transparency and Timely Patient Participation

CMS proposes to codify the process for identifying qualifying single-source drugs and calculating combined expenditures under Parts B and D. The proposal also addresses how CMS will rank negotiation-eligible drugs and publish the selected-drug list along with a list of up to 30 negotiation-eligible drugs ranked by combined expenditures.

The NHC appreciates CMS' continued efforts to provide patients and other stakeholders greater visibility into the selection process. The NHC encourages the agency to continue publishing at least the 50 highest-ranked negotiation-eligible drugs, consistent with its approach for IPAY 2028.[13] Such a list, provided as early as possible, would help patient organizations anticipate when a therapy relevant to their communities may be selected and begin gathering patient experience information before the formal submission period. This preparation time is particularly important for smaller patient organizations, which may need to notify their communities, identify knowledgeable participants, collect and analyze information, and prepare.

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[10] National Health Council, "NHC Comments on IRA Guidance Response," 1–2, 7–8.

[11] Office of the Assistant Secretary for Planning and Evaluation, *An Evaluation Framework for the Inflation Reduction Act's Medicare Drug Pricing Provisions* (Washington, DC: U.S. Department of Health and Human Services, December 2024).

[12] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36238.; Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Draft Guidance: Manufacturer Effectuation of the Maximum Fair Price in 2028 (July 16, 2026).

[13] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36243–46.

The NHC recognizes that publication of a broader list could create uncertainty or expectations regarding which drugs will ultimately be selected. CMS can address this concern by clearly stating that inclusion on the list does not indicate or guarantee future selection. This clarification would preserve valuable preparation time for patients and other stakeholders and greater insight into the selection methodology without limiting CMS' discretion in subsequent cycles.

Regardless of the number of drugs included, the usefulness of these publications will depend on whether stakeholders can understand how CMS has grouped products and calculated the relevant expenditures. The NHC encourages CMS to accompany the lists with plain-language information identifying the relevant active moiety or ingredient, included dosage forms and strengths, and applicable NDCs and HCPCS codes, as well as an explanation of any material changes from the prior year. This information would be particularly valuable where a product is used across multiple indications, settings, or routes of administration and where the scope of the potential selected drug may not be readily apparent to patients or clinicians.[14]

Because selection and grouping decisions rely on complex product, ownership, claims, and market information, the final process would also benefit from a practical mechanism through which stakeholders can identify factual errors. Such a mechanism need not create a substantive appeal process where review is limited by statute, but it could allow CMS to correct inaccurate product identifiers, ownership information, approval dates, marketing status, or other inputs before those errors affect patient engagement or the negotiation process. Prompt notification to patient communities when a relevant drug is selected would further support meaningful and timely participation.[15]

Fixed-Combination Drug Policy Should Not Discount Meaningful Patient Benefits or Separately Approved Innovation

CMS characterizes its proposal as a narrow modification to its general fixed-combination drug policy. The proposal would apply when products offered by the same New Drug Application or Biologics License Application holder differ because one product includes an additional active moiety or ingredient that creates a new formulation and enables an alternative route of administration. Under the proposal, CMS would identify the potential qualifying single-source drug using all dosage forms and strengths of the shared active moiety or ingredient offered by the same application holder. This grouping would include both the earlier product and the new fixed-combination formulation.
CMS explains that the policy is intended to address program-integrity concerns. Specifically, the agency is concerned that manufacturers could shift utilization toward a new formulation that would otherwise be treated as a separate qualifying single-source

[14] National Health Council, "NHC Comments on Negotiation Program Drug Selection for Initial Price Applicability Year 2028," October 30, 2025, 1–4.

[15] National Health Council, "NHC Comments on Negotiation Program Drug Selection 2028," 2–4.

drug and potentially remain outside negotiation for an additional period. CMS also explains that the proposal has been designed to use objective criteria and public data sources and is narrower than the approach discussed in prior guidance.[16]

The NHC appreciates CMS' efforts to improve the consistency and predictability of the Negotiation Program. However, the NHC urges CMS not to finalize this proposed modification. The agency should instead continue treating separately approved or licensed fixed-combination products as separate qualifying single-source drugs, including when an added active ingredient enables a different route of administration.[17] This recommendation reflects two related concerns: the proposal could discount distinctions established through FDA's scientific and regulatory review, and it may not adequately account for the clinical and practical significance of a new formulation for patients.

FDA's separate approval or licensure of a fixed-combination product reflects a scientific and regulatory review of the product, the evidence supporting its safety and effectiveness, and its conditions of use. The NHC is concerned that CMS' proposed negotiation-specific grouping policy could discount distinctions established through that review even when development of the new product required additional evidence or produced meaningful clinical, functional, access-related, or treatment-experience benefits.[18,19,20] Although CMS indicates that it may consult FDA, the proposed rule would ultimately place CMS in the position of determining, for purposes of negotiation eligibility, that separately approved or licensed products should be treated as the same qualifying single-source drug. The NHC therefore cautions against adopting this approach without a clear statutory basis and a clinical framework that fully accounts for the reasons those products were developed and the practical differences they may create for patients, caregivers, clinicians, and the delivery of care.[21,22]

A change in route of administration can be clinically and experientially significant even where one or more of the active ingredients remains the same. Depending on the product and condition, a new formulation may reduce infusion time, eliminate the need for venous access, lower the risk of administration-related complications, improve tolerability, or support adherence and persistence. It may also make treatment more

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[16] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36236, 36257–61.

[17] National Health Council, "NHC Comments on Draft Guidance 2028," 21–22.

[18] 21 U.S.C. § 355(b), (d).

[19] 42 U.S.C. § 262(a).

[20] 21 C.F.R. § 300.50(a).

[21] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36236, 36257–61.

[22] Social Security Act § 1192(e), 42 U.S.C. § 1320f-1(e).

feasible for patients who cannot reasonably receive the original product because of age, disability, comorbidities, prior complications or mobility limitations. A new formulation may also allow treatment to be administration in a physician office or the home rather than a hospital outpatient department. That flexibility can reduce travel, time away from employment or caregiving responsibilities and caregiver burden.[23,24,25] For patients who travel long distances for care, lack paid leave, rely on hourly employment, have limited transportation, or balance treatment with childcare or other caregiving responsibilities, a substantial reduction in administration times or more accessible sites of care may meaningfully affect their ability to initiate and sustain treatment.[26,27,28]

The NHC has previously encouraged CMS to distinguish between formulation and route-of-administration changes based on whether they represent a meaningful improvement from the patient perspective. However, the current proposal moves in the opposite direction by categorically grouping products in which an added active ingredient enables an alternate route of administration. Because those products may be developed precisely to address treatment burden, site-of-care limitations, adherence challenges, caregiver impact, or barriers faced by patients who cannot readily use an existing formulation, applying the approval or licensure date of the earlier product could accelerate negotiation eligibility in a manner that fails to recognize the distinct evidence, development, and patient value associated with the new therapy.[29,30]

CMS should evaluate the proposed policy based on how new formulations affect patients and caregivers in practice. The assessment should consider whether a new formulation changes the site or frequency of administration, reduces administration time, eliminates invasive access, affects monitoring requirements, and changes safety or tolerability. It should also examine effects on patient or caregiver travel and time

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[23] National Health Council, “NHC Comments on Draft Guidance 2028,” 21–22.

[24] Katie Stewart et al., “Preference for Pharmaceutical Formulation and Treatment Process Attributes,” *Patient Preference and Adherence* 10 (2016): 1385–99, https://doi.org/10.2147/PPA.S101821.

[25] P. M. Overton et al., “Patient Preferences for Subcutaneous versus Intravenous Administration of Treatment for Chronic Immune System Disorders: A Systematic Review,” *Patient Preference and Adherence* 15 (2021): 811–34, https://doi.org/10.2147/PPA.S303279.

[26] Samina Syed, Ben Gerber, and Lisa Sharp, “Traveling Towards Disease: Transportation Barriers to Health Care Access,” *Journal of Community Health* 38, no. 5 (2013): 976–93.

[27] Anne M. Planey et al., “The Intersection of Travel Burdens and Financial Hardship in Cancer Care: A Scoping Review,” *Journal of the National Cancer Institute Monographs* 2024, no. 64 (2024): 112–20.

[28] Aguiar-Ibáñez R, Fotheringham I, Mittal L, Sillah A, Pathak S. Differences Between Intravenous and Subcutaneous Modes of Administration in Oncology from the Patient, Healthcare Provider, and Healthcare System Perspectives: A Systematic Review. Adv Ther. 2024 Dec;41(12):4396-4417. doi: 10.1007/s12325-024-02985-9. Epub 2024 Oct 19. PMID: 39425890.

[29] National Health Council, “NHC Comments on Draft Guidance 2028,” 21–23.

[30] National Health Council, “NHC Comments on Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027,” September 3, 2024, 9–11.

burdens, access in rural or underserved communities, adherence or persistence, and treatment for patients who could not reasonably receive the earlier formulation. Outcomes patients identity as important, including functioning, symptoms, quality of life, and treatment experience, should also inform the analysis. CMS should supplement its proposed technical criteria and public product data with clinical and patient information capable of capturing these effects.[31]

For these reasons, the NHC recommends that CMS retain the existing treatment of separately approved or licensed fixed-combination products rather than establishing a negotiation-specific policy that groups them with an earlier product based on a shared active moiety or ingredient. Preserving separate treatment would better respect FDA's application-based review framework, avoid discounting evidence and investment required to develop a new product, and reduce the risk of creating uncertainty that discourages continued development of formulations and routes of administration that patients may regard as clinically and practically meaningful.[32]

Patient and clinician input will be particularly important because some of the most meaningful effects of a formulation change may not be captured by product labeling or administrative data. Public sources can establish the active ingredients and routes of administration, but they may not explain how a formulation affects time spent receiving treatment, transportation, caregiver responsibilities, pain, anxiety, treatment persistence, or the ability to receive care in a less burdensome setting. The proposed policy should not be finalized without meaningful input from affected patient communities, clinicians, manufacturers, and other stakeholders regarding these real-world differences and the potential effect of the policy on future treatment development and patient access.[33]

If CMS proceeds with finalizing some form of the proposed modification, the final rule should, at minimum, require meaningful consultation with FDA before any grouping determination, a transparent patient-centered review of the clinical and practical differences between the products, and a predictable opportunity for the primary manufacturer, patients, clinicians, and other affected stakeholders to submit relevant evidence before CMS reaches a determination. CMS should also publish a clear explanation of the products considered, the statutory and technical criteria applied, the clinical and patient-experience evidence reviewed, and the basis for its conclusion, while providing a mechanism to correct inaccurate information concerning active ingredients, application holders, approval or licensure status, routes of administration, product availability, or other objective facts.

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[31] National Health Council, "NHC Comments on Draft Guidance 2028," 21–22.

[32] National Health Council, "NHC Comments on Draft Guidance 2028," 21–22.

[33] National Health Council, *The Patient Voice in Value: The National Health Council Patient-Centered Value Assessment Rubric*, accessed July 29, 2026, https://nationalhealthcouncil.org/wp-content/uploads/2024/10/NHC_Patient_Voice_Value-Assesment_v5.pdf.

Finally, if CMS moves forward with this policy despite these concerns, it will be essential to monitor whether it affects continued development of new formulations, routes of administration, or other treatment improvements that reduce burden, improve adherence, expand access, or make therapy feasible for patients who cannot readily use an existing formulation.[34] CMS should report publicly on those effects and revisit the policy if implementation indicates that it is discouraging investment in patient-valued improvements or reducing the availability of less burdensome treatment options.

Implementation of the Amended Orphan Drug Exclusion Should Remain Predictable and Support Continued Development

The NHC appreciates CMS' proposal to codify the orphan drug exclusion as amended by the ORPHAN Cures Act and clarify how it will determine the date from which to measure the seven- and eleven-year periods. The amendment recognizes that developing an additional indication for another rare disease or condition should not, by itself, cause a drug otherwise approved exclusively for rare diseases to lose the exclusion.[35] This change is important for patients because rare disease development often proceeds incrementally across related conditions, disease subtypes, age groups, and other small populations. Preserving the exclusion can support continued research for communities with few or no meaningful treatment options.[36]

The NHC recognizes the need for a workable approach that implements the statutory amendments while providing manufacturers, researchers, patients, and other stakeholders with clear and predictable expectations. Predictability is especially important in rare disease development, where small populations, lengthy evidence-generation timelines, and limited opportunities to recover research and development costs can make decisions about additional indications and continued study particularly sensitive to uncertainty regarding future negotiation eligibility.[37]

A policy that creates uncertainty about the treatment of additional indications could unintentionally discourage research that might extend a therapy's benefits to patients who currently have few or no meaningful treatment options. The NHC therefore encourages CMS to explain clearly the event that triggers loss of the exclusion and the date used to measure time since approval or licensure. The agency should also explain how it will address multiple orphan designations, multiple indications, and changes that

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[34] National Health Council, "NHC Comments on Draft Guidance 2028," 21–23.

[35] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36236, 36261–63.

[36] U.S. Food and Drug Administration, *Rare Diseases: Considerations for the Development of Drugs and Biological Products: Guidance for Industry* (December 2023), 4–19, https://www.fda.gov/media/119757/download.

[37] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36236, 36261–63.

occur between selection cycles.[38,39] In particular, if FDA withdraws a drug's sole non-rare indication, its remaining approved indications would be exclusively for rare diseases or conditions. The drug would therefore appear to satisfy the statutory criteria for the orphan drug exclusion again.[40,41] Consistent with CMS' clarification that withdrawn approvals are not considered in applying the exclusion, the NHC encourages CMS to confirm that eligibility will be assessed based on the indications remaining approved when a drug would otherwise be selected for negotiation. CMS should recognize the exclusion as of the effective date of that withdrawal and explain how any resulting pause in the applicable seven- or eleven-year period operates across selection cycles.

CMS should also monitor whether the framework affects the pursuit or timing of additional indications, evidence generation for very small populations, or continued investment in treatments for rare diseases and serious chronic conditions. The NHC encourages an implementation approach that preserves the statutory protection as intended, provides reasonable reliance on clear agency interpretations, and avoids creating a tradeoff in which development for one patient population discourages research that could benefit another. This is particularly important where a manufacturer is considering whether to undertake the substantial clinical and regulatory work necessary to expand treatment options for an additional rare disease population.[42,43] CMS should also explain how a change in orphan-drug-exclusion status occurring after publication of a negotiation-eligible or selected-drug list would be handled. That explanation should address how a later approval of a non-rare indication or correction to relevant approval or designation information would affect subsequent cycles. Clear treatment of these circumstances would help ensure consistent implementation and reduce uncertainty for rare disease development.

Patient Engagement Should Be Predictable, Accessible, and Connected to Program Decisions

The NHC supports CMS' proposal to codify patient-focused engagement events through which patients, caregivers, patient organizations, clinicians, and other interested parties may provide information concerning selected drugs, therapeutic alternatives, the conditions treated by those products, and patient experiences. By including patient engagement in the regulatory framework, CMS recognizes that patients bring expertise that cannot be replaced by claims data, clinical trials, or manufacturer submissions.

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[38] National Health Council, "NHC Comments on Draft Guidance 2028," 19–21.

[39] U.S. Food and Drug Administration, *Rare Diseases: Considerations for Development*, 4–19.

[40] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36236, 36261–63.

[41] Social Security Act § 1192(e)(3)(A), 42 U.S.C. § 1320f-1(e)(3)(A).

[42] National Health Council, "NHC Comments on Draft Guidance 2028," 19–23.

[43] U.S. Food and Drug Administration, *Rare Diseases: Considerations for Development*, 4–19.

Patients and caregivers can provide information concerning symptoms, functioning, quality of life, treatment burden, administration challenges, side effects, tradeoffs among therapies, unmet needs, and the outcomes that shape whether a treatment is a meaningful option for patients.[44,45,46]

The proposed regulation, however, would leave much of the timing, form, manner, and structure of engagement to CMS' discretion. That flexibility may be necessary because the number and types of drugs selected will vary from year to year, but the absence of minimum expectations can make participation difficult and create substantial differences among negotiation cycles. Patient organizations, particularly smaller organizations and those representing rare or complex conditions, may need time to notify their communities, collect information, analyze existing data, identify knowledgeable participants, and prepare materials that respond to CMS' specific questions. Short timelines or unclear instructions can favor organizations that already possess substantial research and policy capacity while limiting participation by communities whose perspectives may be especially important.[47,48]

The NHC recommends that CMS establish predictable minimum standards for patient-focused engagement either in the final regulation or in an accompanying framework published sufficiently in advance of each negotiation cycle. Those standards could include timely notice of engagement opportunities, accessible plain-language materials describing the purpose of the event and the information CMS is seeking, transparent participant-selection criteria, and sufficient time between publication of the selected-drug list and the deadline for submissions or participation. Multiple participation pathways, including written submissions and remote options, would help accommodate people with disabilities, people with limited English proficiency, individuals with limited access to technology, and patients whose health conditions or caregiving responsibilities make participation in a live event difficult.[49,50,51]

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[44] National Health Council, *Amplifying the Patient Voice* (March 2024), 3–8.

[45] National Health Council, *Amplifying the Patient Voice* (August 2025), 2–6.

[46] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input, Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders* (June 2020), 4–10, https://www.fda.gov/media/139088/download.

[47] National Health Council, *Amplifying the Patient Voice* (August 2025), 2–6.

[48] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Collecting Input*, 4–10.

[49] National Health Council, *Amplifying the Patient Voice* (March 2024), 3–8.

[50] National Health Council, *Amplifying the Patient Voice* (August 2025), 3–6.

[51] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Methods to Identify What Is Important to Patients, Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders* (February 2022).

It will also be important for CMS to distinguish among the different forms of information provided by patients, caregivers, patient organizations, clinicians, researchers, manufacturers, and other stakeholders. Each can offers a valuable, distinct perspective. A patient's account of treatment burden should be recognized as distinct from comparative research or manufacturer-submitting product data. CMS should preserve these distinctions in engagement materials and public summaries so that patient experience remains visible as a distinct source of input.[52]

The NHC continues to encourage CMS to provide greater transparency concerning how patient input affects negotiation. Patients and organizations may invest significant time in developing submissions or participating in public events, yet the published explanation of an MFP may not allow them to determine whether their perspectives influenced CMS' assessment. A meaningful engagement process requires more than an opportunity to speak; it also requires a reasonable connection between the information provided and the decisions being made.[53]

CMS could strengthen the connection between patient input and its decision-making by publishing a plain-language summary of the major patient and caregiver themes received for each selected drug. The summary should explanation of how those themes informed the identification of therapeutic alternatives, selection of outcomes, evaluation of unmet medical need, assessment of therapeutic advance, or adjustment of the starting point. When such information is not incorporated, CMS could briefly explain why. For example, the information may fall outside the statutory framework, duplicate other evidence, be limited by the available methods or evidence, arrive too late to be considered, or otherwise not relevant to the analysis. CMS could prove this account without disclosing confidential information or details of the negotiation.[54]

The NHC's roundtable reports reinforce the need for this feedback. Participants value the opportunity to engage but also seek clearer information about what CMS is asking, how speakers and submissions are selected or reviewed, and how patient input ultimately affects the negotiation process.[55,56]

These findings also support the NHC's recommendation for establishing a more continuous engagement structure that extends beyond drug-specific events. Regular public roundtables, a dedicated patient liaison or ombudsman, and annual discussions of lessons learned could help CMS identify cross-cutting issues and improve engagement over time. Drug-specific events are necessary, but they may not capture recurring barriers affecting multiple patient communities, such as limited preparation

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[52] National Health Council, "NHC Comments on Negotiation Data Elements," 1–12.

[53] National Health Council, *Amplifying the Patient Voice* (March 2024), 3–8.

[54] National Health Council, *Amplifying the Patient Voice* (August 2025), 4–6.

[55] National Health Council, *Amplifying the Patient Voice* (March 2024), 3–8.

[56] National Health Council, *Amplifying the Patient Voice* (August 2025), 2–6.

time, unclear evidence expectations, inaccessible materials, or uncertainty about how input will be used. A continuous structure would allow CMS and patient organizations to address these concerns before the next negotiation cycle begins.[57]

The NHC also encourages CMS to create opportunities for bi-directional feedback, rather than relying exclusively on formats in which participants provide statements without a practical opportunity for CMS to ask follow-up questions, clarify what information would be most useful, or respond to recurring concerns. This type of exchange could make engagement more useful to both CMS and patient communities while preserving broader public participation.

These recommendations are informed by the NHC's direct experience convening CMS and the patient community across multiple negotiation cycles. In January 2024, the NHC held a roundtable with patients, caregivers, patient organizations, and CMS representatives to assess the first cycle of listening sessions and the data-submission process. The NHC convened a second roundtable on June 30, 2025, focused on CMS' patient engagement activities during the second negotiation cycle. A third roundtable held on July 8, 2026, addressed implementation of the IPAY 2028 process. These dialogues have provided CMS with recurring, practical feedback and have reinforced that effective engagement depends not only on whether opportunities are offered, but also on their timing, accessibility, structure, clarity, and connection to agency decision-making.[58,59,60]

Evaluation of Clinical Benefit and Patient Value Should Be Transparent and Multidimensional

The NHC appreciates the broad range of evidence CMS proposes to consider when evaluating a selected drug and its therapeutic alternatives. The framework would recognize clinical outcomes, functioning, symptoms, quality of life, patient experience, caregiver perspectives, treatment complexity, unmet medical need, therapeutic advance, real-world evidence, clinical guidelines, and evidence involving Medicare populations, including people with disabilities and people with end-stage renal disease. This approach has the potential to provide a more complete understanding of patient value than an approach relying exclusively on traditional clinical endpoints or a single measure of value.[61]

Under the proposed framework, CMS would evaluate the statutory factors collectively rather than applying a rigid mathematical formula. This flexible approach recognizes

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[57] National Health Council, *Amplifying the Patient Voice* (March 2024), 7–8.

[58] National Health Council, *Amplifying the Patient Voice* (March 2024), 2–8.

[59] National Health Council, *Amplifying the Patient Voice* (August 2025), 2–7.

[60] National Health Council, *CMS Patient Engagement Roundtable* (July 8, 2026).

[61] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36287–96.

that the relevance and strength of evidence vary by condition, treatment, and patient population, and an overly mechanical framework could fail to capture important differences. At the same time, CMS should clearly explain its approach so stakeholders can understand how the agency reached its conclusion and whether particular evidence materially influenced the preliminary price or MFP.[62,63,64,65]

The NHC recommends that CMS provide a public framework explaining how the agency organizes, evaluates, and brings together the different types of evidence. Such a framework could describe how CMS evaluates qualitative patient evidence alongside clinical studies, how conflicts among evidence sources are resolved, how the agency distinguishes an absence of evidence from evidence that no benefit exists, how uncertainty affects the analysis, and how evidence concerning specific patient subpopulations is incorporated. Greater clarity regarding how an identified therapeutic advance, unmet medical need, reduction in treatment burden, improvement in quality of life, or other patient-centered benefit may support an upward adjustment, downward adjustment, or no adjustment to the starting point would also help stakeholders develop more relevant submissions.[66,67,68]

This framework need not assign a fixed numerical weight to each factor. The NHC recognizes that a flexible qualitative process may be necessary, particularly where evidence is heterogeneous or different considerations point in different directions. However, the process would benefit from being sufficiently clear and reproducible that patients and other stakeholders can understand what information is relevant, how CMS evaluates its quality, and why the evidence supports the resulting conclusion.[69]

The NHC's Patient-Centered Value Assessment Rubric and Rubric to Capture the Patient Voice provide principles for evaluating whether evidence and engagement are patient centered. These principles include patient partnership, transparency, representativeness, diversity, inclusion of outcomes that patients identify as important, use of appropriate patient-centered data sources and methods, and timely incorporation of patient evidence. The final framework would be strengthened by an explanation of how these principles are reflected in the Negotiation Program's evidence review and

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[62] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36287–96.

[63] National Health Council, "NHC Comments on Negotiation Data Elements," 3–10.

[64] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Collecting Input*, 4–10.

[65] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Methods to Identify*.

[66] National Health Council, "NHC Comments RE IPAY 2027," 7–9.

[67] National Health Council, "NHC Comments on Negotiation Data Elements," 9–12.

[68] National Health Council, *Patient-Centered Value Assessment Rubric*.

[69] National Health Council, *Patient-Centered Value Assessment Rubric*.

how patient-generated information is evaluated in relation to other sources.[70,71,72,73,74,75,76]

CMS proposes to prioritize appropriately powered studies and evidence designed around relevant Medicare populations. However, CMS should take particular care when applying conventional evidence standards to rare diseases, small clinical populations, heterogeneous conditions, or patient populations historically underrepresented in research. Although rigorous evidence remains important, conventional expectations for sample size or study design may not be feasible for every condition. Patient organizations may also be able to provide qualitative studies, surveys, registry data, natural-history information, or structured patient experience data that provide important insights in the absence of a randomized clinical trial.[77,78,79]

The NHC encourages CMS to evaluate evidence using standards appropriate to the question being addressed, the evidence available, the characteristics of the population, and the method used. Small sample size need not, by itself, make evidence irrelevant, particularly where the population is small or where the evidence addresses treatment burden, functioning, patient preferences, or other questions that may be best understood through qualitative or mixed methods. Similarly, an absence of large comparative studies need not be treated as evidence that a selected drug provides no meaningful benefit beyond its therapeutic alternatives.[80,81,82]

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[70] National Health Council, “Rubric to Capture the Patient Voice,” accessed July 29, 2026, https://nationalhealthcouncil.org/additional-resources/patient-engagement-rubric/.

[71] National Health Council, “NHC Comments on Negotiation Data Elements,” 6–10.

[72] National Health Council, “Patient-Centered Multi-Criteria Decision Analysis,” accessed July 29, 2026, https://nationalhealthcouncil.org/additional-resources/patient-centered-multi-criteria-decision-analysis/.

[73] U.S. Food and Drug Administration, *Rare Diseases: Considerations for Development*, 4–19.

[74] National Health Council, “NHC Comments on Negotiation Data Elements,” 6–10.

[75] U.S. Food and Drug Administration, *Rare Diseases: Considerations for Development*, 4–19.

[76] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Collecting Input*, 4–10.

[77] National Health Council, “NHC Comments on Negotiation Data Elements,” 10–12.

[78] U.S. Food and Drug Administration, *Rare Diseases: Considerations for Development*, 4–19.

[79] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Collecting Input*, 4–10.

[80] National Health Council, “NHC Comments on Negotiation Data Elements,” 10–12.

[81] National Health Council, “Patient-Centered Multi-Criteria Decision Analysis.”

[82] U.S. Food and Drug Administration, *Rare Diseases: Considerations for Development*, 4–19.

CMS should clarify the distinction between evidence showing that a treatment offers no additional benefit to patients and evidence that is insufficient to determine whether such a benefit exists. A benefit that patients experience may not yet have been systematically studied, included in older clinical guidelines, or captured by the endpoints used in pivotal trials. In these circumstances, CMS should acknowledge the uncertainty rather than treating incomplete evidence as a definitive finding that the benefit does not exist.[83,84]

The NHC supports codification of the statutory protections against discriminatory measures of value. These protections prohibit the use of evidence that assigns less value to extending the life of an elderly, disabled, or terminally ill individual than to extending another individual's life. They also prohibit certain uses of quality-adjusted life years (QALYs). CMS should explain more clearly how it identifies and handles studies that incorporate QALYs or related measures. A publication may contain useful clinical, patient-reported, or comparative evidence alongside a QALY analysis that falls within the statutory prohibition. CMS should clarify when it can separate and consider permissible evidence from a prohibited component. The agency should also explain how it screens for measures that may reproduce similar discriminatory assumptions under another name and what alternative approaches it uses to assess treatment value across multiple dimensions. These explanations would improve confidence that the process does not devalue the lives of people with disabilities, chronic illnesses, or serious health conditions.[85]

Greater transparency about CMS' approach would improve the quality of submissions, allow patient organizations to better direct limited resources, and increase confidence that the Negotiation Program is evaluating value in a manner that reflects the diversity of patient experiences rather than relying primarily on evidence that is easiest to quantify.[86]

Confidentiality and Public Explanation Should Be Balanced to Support Trust and Accountability

The NHC strongly supports appropriate protection of proprietary commercial information, trade secrets, personally identifiable information, and protected health information. Clear and consistently applied safeguards are essential to the integrity of the Negotiation Program and to the willingness of manufacturers, patients, and other stakeholders to provide complete and candid information. Public accountability can be advanced without weakening those protections, and the NHC has therefore encouraged CMS to provide sufficient high-level explanations to enable patients and other stakeholders to understand how clinical evidence, patient experience, and statutory

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[83] National Health Council, "NHC Comments on Negotiation Data Elements," 6–10.

[84] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Methods to Identify*.

[85] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36293–94.

[86] National Health Council, "NHC Comments on Negotiation Data Elements," 1–12.

factors informed the outcome while avoiding disclosure of manufacturer-specific confidential information or details that could allow such information to be inferred.[87]

The proposed rule would codify confidentiality protections and require CMS to provide the primary manufacturer with a concise justification for the written initial offer. For patients and other external stakeholders, however, the public explanation of the final MFP remains the principal means of understanding the outcome. The NHC encourages CMS to use that public explanation to identify the major clinical and patient-experience considerations, the therapeutic alternatives evaluated, material limitations or uncertainty in the evidence, and, in general, how patient input affected the analysis. High-level or aggregated explanations can provide meaningful accountability without disclosing protected information or the details of confidential price exchanges.[88]

CMS should also explain, at a high level, how the initial offer relates to the final MFP. Any explanation should protect proprietary information, confidential negotiation positions, and details from which commercially sensitive information could reasonably be inferred. Using a consisted public template across selected drugs, CMS could indicate whether evidence received later in the process materially changed the agency's assessment of therapeutic benefit, unmet medical need, comparative clinical benefit, or other patient-centered considerations. This explanation could strengthen confidence in the program and help patient organizations understand what information is most useful in future cycles while preserving the confidentiality necessary for a credible negotiation process.[89]

Identification of Therapeutic Alternatives Should Reflect Clinical Practice and Individual Patient Needs

CMS proposes to draw from multiple sources when identifying therapeutic alternatives, including FDA-approved prescribing information, drug classification systems, major drug compendia, widely accepted clinical practice guidelines, CMS-led literature reviews, peer-reviewed evidence, Medicare claims and other data sets, and information submitted by the primary manufacturer and the public. The framework recognizes that a therapeutic alternative may be in the same or a different pharmacologic class, may include a generic drug or biosimilar, and may involve a specific formulation, dosage form, or strength. CMS further proposes to prioritize clinical appropriateness and may consult with FDA, clinicians, patients, patient organizations, and researchers.[90,91,92]

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[87] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36272–73, 36296–97.

[88] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36296–97.

[89] National Health Council, "NHC Comments on IRA Guidance Response," 2–5.

[90] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36287–91.

[91] National Health Council, "NHC Comments on Negotiation Data Elements," 3–10.

[92] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Methods to Identify*.

This broad framework provides an appropriate starting point, but the identification of products that may be used for the same condition does not necessarily establish that those products are clinically comparable or reasonably interchangeable for every patient. Therapies used to treat the same disease may differ in indication, line of therapy, mechanism of action, route and site of administration, dosing frequency, contraindications, safety profile, monitoring requirements, interaction with comorbidities, or suitability for specific patient populations. Prior treatment response, disease severity, progression, genetic or biomarker status, and individual patient preferences may also determine whether a product represents a realistic alternative in clinical practice.[93,94,95]

The NHC therefore encourages CMS to adopt the proposed emphasis on clinical appropriateness at the level of the condition, indication, and relevant patient population rather than relying principally on broad pharmacologic or formulary classifications. A drug within the same class may be inappropriate for a patient because of a contraindication, prior treatment failure, intolerance, interaction with another therapy, or a clinically meaningful difference in administration. Conversely, a therapy in a different class may represent the most relevant alternative for a particular indication or line of treatment. CMS should explain how it accounts for these distinctions when identifying therapeutic alternatives and using those alternatives to inform the starting point for negotiation of the MFP. A therapy that is technically available but not clinically appropriate or realistically usable for the relevant patient population should not disproportionately influence the starting point for negotiation.

Clinical practice guidelines may help CMS assess whether a potential therapeutic alternative is clinically appropriate, but they may not fully reflect current practice or the experiences of all affected patients. Guidelines are updated on different schedules, may not incorporate recently available evidence, may vary across professional societies, and may not always include meaningful patient participation in their development. In some cases, they may also describe several products as treatment options without addressing the circumstances in which one therapy is more appropriate than another. The NHC encourages CMS to consider guidelines as one element of a broader evidence review and to examine the publication or update date of the guideline, the evidence on which it is based, the patient populations represented, the role of patients in its development, and whether subsequent evidence or clinical experience has altered practice.[96,97]

When clinical practice guidelines identify multiple treatment options, CMS' proposed authority to focus on a subset of therapeutic alternatives that are clinically comparable

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[93] National Health Council, "NHC Comments on Negotiation Data Elements," 8–11.

[94] National Health Council, "NHC Comments RE IPAY 2027," 8–9.

[95] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Methods to Identify*.

[96] National Health Council, "NHC Comments on Negotiation Data Elements," 3–10.

[97] U.S. Food and Drug Administration, *Patient-Focused Drug Development: Collecting Input*, 4–10.

may help address some of these concerns. CMS should explain how it applies that authority, including the criteria used to determine clinical comparability and the reasons particular products are included or excluded. The published explanation of the MFP could identify the therapeutic alternatives considered, describe material clinical differences among them, and clarify how those differences affected the starting point and subsequent adjustments. This information would help patients and other stakeholders understand whether the products used in the analysis reflect actual treatment options for a affected populations.

Patient and clinician input will remain particularly valuable in this area. Administrative data may show that two therapies are used for the same condition, but they may not reveal why one treatment was selected, whether another therapy had previously failed, or how administration burden, side effects, functioning, and patient preferences affected the decision. The NHC encourages CMS to use patient-focused engagement and consultation with clinical experts to identify differences that may not be apparent from labeling, claims, or class-level evidence.[98]

Consideration of Off-Label Use Should Be Comprehensive and Consistent

The NHC supports CMS' recognition that off-label use can be relevant to both identification of the conditions for which a selected drug is used and identification of therapeutic alternatives. The proposed definition of off-label would encompass uses that are not FDA-approved indications but are included in evidence-based clinical practice guidelines and constitute medically accepted indications payable under Part B, covered under Part D, or both, taking into account major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination of those sources. CMS proposes considering off-label uses when developing the initial offer and excluding uses intended solely for settings in which the drug is neither payable under Part B nor covered under Part D.[99,100]

Recognition of off-label use is important because such it represents an established and clinically necessary component of care, particularly in oncology, rare diseases, complex conditions, and areas where evidence or clinical practice develops more quickly than product labeling. Excluding clinically important off-label uses from CMS' analysis used to develop the initial offer and MFP could result in an incomplete understanding of the populations receiving a selected drug, the outcomes that matter to those patients, and the therapies that constitute realistic alternatives.[101,102]

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[98] National Health Council, *Amplifying the Patient Voice* (August 2025), 3–6.

[99] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36289–90, 36300–06, 36359–60.

[100] National Health Council, "NHC Comments RE IPAY 2027," 8–9.

[101] National Health Council, "NHC Comments on Negotiation Data Elements," 2–3.

[102] National Health Council, *Amplifying the Patient Voice* (March 2024), 4.

CMS could strengthen the proposed rule by providing additional clarity on how it identifies off-label uses in practice. Guidelines and compendia remain important sources, but clinically accepted uses may emerge before those sources are updated, and some uses may be supported by a combination of literature, specialist consensus, and real-world practice rather than a single authoritative document. The NHC encourages CMS to consider information from patients, patient organizations, clinicians, professional societies, researchers, and other credible sources when determining whether an off-label use warrants inclusion in the analysis.[103]

Greater transparency regarding the threshold for inclusion would also be helpful. CMS could describe how it assesses the strength, consistency, and relevance of evidence supporting an off-label use; how it distinguishes emerging use from broadly accepted clinical practice; and how it treats uses concentrated in a small population or specialized treatment setting. An approach tailored to the question and available evidence will be especially important where the patient population is small and the available evidence necessarily differs from that available for more common conditions.[104] Even when an off-label use is appropriately included, CMS should continue to prioritize the therapeutic alternatives that are most clinically appropriate for that specific use and patient population rather than assuming that all products used for the broader condition are equally relevant.

CMS proposes to exclude an FDA-approved indication or off-label use when the agency determines that the use is intended solely for a setting in which the selected drug is neither payable under Part B nor covered under Part D. The NHC recognizes the rationale for limiting the negotiation analysis to uses to which the MFP may apply. However, in doing so, CMS should account for variation in site-of-care practices, particularly when a therapy is used across multiple settings. A use commonly associated with an inpatient setting may also occur in an outpatient setting for certain patients, and changes in clinical practice may shift administration between settings over time. The final policy would benefit from a transparent explanation of the data and assumptions used to determine that a use occurs solely outside Part B and Part D.[105]

The proposed rule also appears to permit a primary manufacturer to identify an omitted use in its response to the initial offer, after which CMS may consider that use during later exchanges. While that process provides a potential correction mechanism, patient communities and clinicians may also possess relevant information concerning uses that were not initially included. The NHC encourages CMS to establish a pathway through which those stakeholders can identify material omissions early enough for the

[103] National Health Council, “NHC Comments on Negotiation Data Elements,” 2–3.

[104] National Health Council, “NHC Comments on Negotiation Data Elements,” 2–3.

[105] Centers for Medicare & Medicaid Services, “Medicare Drug Price Negotiation Program,” 36289–90.

information to inform development of the initial offer rather than only being considered in later stages of negotiation.[106]

Renegotiation Should Reflect Material Changes in Evidence, Use, and Patient Experience

Because the statute provides for renegotiation under specified circumstances, CMS will need a structured and transparent process for assessing which drugs are eligible and deciding which will undergo renegotiation. Clinical evidence, indications, therapeutic alternatives, utilization, treatment patterns, and patient experience can change materially after the original negotiation, and the MFP may no longer reflect the information available when a later price applicability year begins. Applying consistent policies concerning off-label-use across initial negotiation and renegotiation may improve predictability, provided the process remains sufficiently responsive to new evidence and changes in clinical practice.[107]

CMS should clarify which changes in the factors it evaluates would be considered material for purposes of renegotiation. Such changes may include approval of a new indication, emergence of a clinically accepted off-label use, new comparative-effectiveness evidence, changes in safety information, availability of a new therapeutic alternative, changes in the standard of care, identification of a new biomarker-defined population, or new evidence concerning functioning, quality of life, treatment burden, adherence, caregiver experience, or unmet medical need. Changes in use within an existing indication, such as movement to an earlier line of therapy or expansion to a clinically distinct population, may also be meaningful even when the formal indication remains unchanged.[108]

A process focused too narrowly on regulatory milestones may overlook changes that matter substantially to patients. For example, new real-world evidence may demonstrate that a therapy provides benefits or presents burdens that were not apparent during the initial negotiation. A new route of administration may alter site-of-care needs or treatment burden, while updated guidelines may establish a different place in therapy. The NHC encourages CMS to explain how these developments are evaluated and how the agency distinguishes changes that warrant renegotiation from those that can be addressed through continued monitoring.

How CMS intends to consider off-label use in renegotiation also warrants additional clarification. Where the existence or expansion of an off-label use may affect whether a drug is renegotiation eligible or selected for renegotiation, CMS' review need not depend primarily on whether the primary manufacturer voluntarily submits the information. Patients, clinicians, patient organizations, professional societies,

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[106] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36289–90, 36300–06.

[107] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36298–306.

[108] National Health Council, "NHC Comments on Draft Guidance 2028," 18–21.

researchers, Medicare claims analyses, and other sources may identify clinically important changes. A process that permits these sources to inform CMS' review would provide a more complete understanding of how the selected drug is being used and whether the original negotiation remains responsive to current care.[109]

Patient participation will be as important during renegotiation as during the initial negotiation. By the time of renegotiation, a drug may be used by patients who were not represented during the initial cycle, particularly if the drug has gained a new indication or is being used in a new population. Even where the population is unchanged, additional years of experience may produce new information concerning long-term outcomes, adherence, treatment burden, or access. The NHC recommends that CMS provide a new opportunity for public submissions and patient-focused engagement whenever a drug is selected for renegotiation and tailor that engagement to the changes that prompted reconsideration.[110]

The public explanation accompanying a renegotiated MFP could also identify the material developments since the prior negotiation, describe the new evidence considered, and explain how those developments affected the renegotiated price. Such transparency would allow patients and other stakeholders to understand whether renegotiation responds to current clinical practice rather than mechanically repeating the earlier analysis.

Calculation of a 30-Day Equivalent Supply Should Account for Nontraditional Treatment Patterns

CMS proposes codifying methodologies for calculating a 30-day equivalent supply across dosage to and strengths of a selected drug. For Part B drugs, the general methodology would use the interval between successive claims or prescription drug event records involving the same beneficiary and active moiety or ingredient. When no later claim is available for a beneficiary, CMS would generally use the median interval among the beneficiary's other claims. If no other relevant claims exist, the claim would be excluded in the calculation. CMS also proposes a separate methodology for drugs typically administered only one time, including certain vaccines, gene therapies, and cancer treatments.[111]

A standardized 30-day supply can facilitate application of statutory calculations across therapies with different dosing schedules. However, a 30-day equivalent may not reflect how one-time, episodic, weight-based, loading-dose, or curative therapies that do not resemble a monthly maintenance medication. The NHC encourages CMS to apply the 30-day equivalent as a technical calculation rather than as a clinical characterization of treatment duration, treatment burden, or value.

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[109] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36300–06.

[110] National Health Council, *Amplifying the Patient Voice* (August 2025), 3–6.

[111] Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program," 36236–37, 36274–80.

For therapies administered once or infrequently, a 30-day equivalent can obscure important distinctions between the cost of a single administration, the cost of a complete treatment course, and the duration of expected benefit for patients. It may also fail to capture the need for pretreatment, monitoring, repeat administration, supportive care, or management of adverse events. In other circumstances, claims intervals may reflect clinical deterioration, treatment interruptions, changes in weight, provider scheduling, or access barriers rather than an intended dosing interval.[112]

The final rule would benefit from additional explanation of how the methodology addresses one-time therapies whose effects may extend for years; finite treatment courses lasting substantially less or more than 30 days; loading and maintenance phases; weight- or body-surface-area dosing; variable dosing based on response; retreatment that occurs only when clinically necessary; bundled or shared HCPCS codes; wastage and discarded amounts; changes in site of care; and patients whose claims history is incomplete because of enrollment changes or coverage transitions.[113] Given the diversity of these treatment patterns, the NHC encourages CMS to preserve sufficient flexibility so that the methodology does not inherently devalue the clinical benefit of a one-time or long-duration therapy simply because its treatment pattern does not map neatly to a 30-day period.

CMS separately proposes that a tailored alternative methodology may be used when the standard approach would not produce comparable terms, including where a therapeutic alternative is usually prescribed for a period meaningfully shorter than 30 days. The NHC supports retaining this flexibility and encourages CMS to publish criteria governing when an alternative methodology will be considered. The agency could also explain how clinical expertise and public input will inform those determinations and provide a plain-language description of the methodology used for each affected selected drug.

The relationship between the 30-day equivalent and the starting point also merits transparency. Where a selected drug and its therapeutic alternatives have fundamentally different treatment patterns, expressing both as a 30-day amount may create the appearance of comparability while concealing substantial differences in treatment course, durability, administration burden, or downstream health care use. The NHC encourages CMS to supplement the standardized amount with consideration of the full course of treatment and other relevant clinical and patient-experience factors when evaluating the statutory negotiation factors.

For one-time or long-duration therapies, it may also be useful for the public explanation of the MFP to distinguish clearly among the unit-level MFP, the calculated 30-day equivalent, the anticipated full treatment-course amount, and the assumptions used to connect those figures. Clear communication will reduce the risk that patients, clinicians,

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[112] National Health Council, “NHC Comments on Draft Guidance 2028,” 2–7.

[113] Centers for Medicare & Medicaid Services, “Medicare Drug Price Negotiation Program,” 36274–80.

or policymakers misinterpret the technical calculation as the actual monthly cost or expected duration of treatment.

Part D Formulary Inclusion Must Be Accompanied by Meaningful Access Protections

The NHC supports codification of the requirement that Part D plan formularies include each selected Part D drug for which an MFP is in effect. The proposed regulatory text would preserve the ability of a plan to remove a selected drug when existing formulary-removal and notice requirements are satisfied. Formulary inclusion is an essential foundation, but inclusion alone does not ensure that a beneficiary can obtain a therapy in a timely and affordable manner.[114,115,116]

A selected drug may remain technically included while being placed on a less favorable tier, subjected to prior authorization or step therapy, restricted to a narrow pharmacy network, or made more difficult to access than another product used for the same condition. These policies can affect whether the MFP produces a meaningful affordability benefit for the beneficiary. They can also result in treatment switching, delayed initiation, interruption of stable therapy, or abandonment of treatment.

The NHC appreciates CMS' recognition in prior Negotiation Program guidance that plan practices involving selected drugs may warrant scrutiny, including circumstances in which a selected drug is placed on a non-preferred tier, assigned higher cost sharing than a non-selected drug in the same class, or subjected to more restrictive utilization management. The final rule and related formulary-review processes would be strengthened by a clear statement that selection of a drug or establishment of an MFP, standing alone, does not constitute a clinical rationale for more restrictive utilization management.

CMS should evaluate access policies in a longitudinal manner. Comparing formulary placement and utilization management before selection, after selection, and after the MFP takes effect may help identify changes associated with the Negotiation Program. Review of aggregate trends could also reveal whether plans systematically favor non-

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[114] National Health Council, "NHC Comments RE IPAY 2027," 10–11.

[115] National Health Council, "NHC Comments on Draft Guidance 2028," 14–18.

[116] Medicare Payment Advisory Commission, "Part D Prescription Drug Plans for Beneficiaries in Fee-for-Service Medicare and Medicare Advantage," in *Report to the Congress: Medicare and the Health Care Delivery System* (Washington, DC: MedPAC, June 2025), 195–208.

selected alternatives or impose restrictions that diminish the practical benefit of the MFP.[117,118,119]

The NHC encourages CMS to consider public reporting on formulary tier placement for selected drugs; prior authorization, step therapy, and quantity-limit requirements; changes in those policies over time; rates of denials, exceptions, and appeals; processing times; treatment switching or abandonment, where measurable; differences among beneficiary populations; and corrective actions arising from formulary review. Such reporting could be presented in aggregate to avoid disclosure of proprietary plan information while still providing patients and policymakers with a clearer understanding of whether selected drugs remain accessible.

The use of pharmacologic classes or similar groupings in formulary review will also require careful application. Drugs within the same class are not necessarily interchangeable for every condition or patient. Differences in indication, route of administration, contraindications, prior treatment response, safety, and monitoring can make a higher-cost or selected drug the clinically appropriate option for an individual beneficiary. The NHC encourages CMS to evaluate plan justifications in relation to specific conditions and populations rather than relying exclusively on class-level comparisons.

Accessible exceptions and appeals processes will remain an important safeguard. CMS should provide beneficiaries and prescribers with clear, timely information concerning coverage requirements and the ability to seek an exception when a preferred alternative is not appropriate. Monitoring could therefore include the clarity of plan communications, the availability of expedited review, and whether beneficiaries experience interruptions while an exception or appeal is pending.

Future MFP-Effectuation Rulemaking Should Address the Full Patient Access Pathway

The proposed rule would codify major elements of drug selection, negotiation, and renegotiation, while CMS indicates that requirements governing MFP effectuation for IPAY 2029 and subsequent years will be addressed through future rulemaking. The NHC recognizes that the program is being implemented in stages, but selection, negotiation, effectuation, coverage, reimbursement, and access are interdependent. A negotiated price cannot benefit patients if the operational process for making it available fails at the pharmacy, provider, distributor, plan, or claims-processing level.

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[117] National Health Council, *Amplifying the Patient Voice* (August 2025), 5.

[118] Michael Anne Kyle and Nancy L. Keating, “Prior Authorization and Association With Delayed or Discontinued Prescription Fills,” *Journal of Clinical Oncology* 42, no. 8 (2024): 951–60, https://doi.org/10.1200/JCO.23.01693.

[119] Medicare Payment Advisory Commission, “Part D Prescription Drug Plans,” 195–208.

A coordinated timeline for future rulemaking would allow stakeholders to understand when the remaining policies will be proposed and how they will interact with the present rule. Providing adequate time for stakeholders to review policies will be especially important for Part B drugs, where the effectuation pathway may involve providers purchasing and maintaining inventory, specialty distribution, claims and coding systems, patient coinsurance, and reconciliation between an acquisition price and Medicare payment.

Implementation for Part B drugs raise distinct patient-access concerns. Providers may face cash-flow pressure, uncertainty about acquisition costs, or delays in receiving access to the MFP. If those pressures make providers less willing to stock or administer a selected drug, patients may be redirected to a more distant or intensive site of care, experience delays, or lose access to a clinician familiar with their condition. These effects may be especially significant for people in rural or underserved communities and for patients whose health, mobility, or caregiving responsibilities make travel difficult.[120] Operational or coverage barriers could also create pressure to switch a patient from a selected drug to another therapy for non-clinical reasons, even when the patient is stable on their existing treatment.

The NHC encourages CMS to address these risks through clear operational responsibilities, reliable data exchange, prompt payment or reconciliation, and rapid escalation pathways when a transaction does not function as intended. Future proposals could also include tracking provider participation, site-of-care changes, delays in treatment, and other indicators that the effectuation process is affecting access. CMS should also monitor coverage restrictions and utilization-management requirements applied to selected Part B drugs, where applicable, including whether such requirements become more restrictive after selection or after the MFP takes effect and whether they contribute to treatment switching, delay, or interruption.

CMS should provide beneficiaries with clear information about how the MFP may affect their costs and access to selected drugs. Beneficiaries may not understand the relationship among the MFP, plan-negotiated prices, cost sharing, provider billing, and other program requirements. Plain-language materials should explain what the MFP means, when it applies, and where beneficiaries can seek assistance so they can both understand and benefit from the program's affordability protections.

Bona Fide Marketing Determinations Should Reflect Meaningful and Sustainable Competition

The NHC supports a clear and predictable framework for recognizing generic and biosimilar competition, which can expand treatment options and improve affordability for patients while providing manufacturers and plans with greater certainty regarding the status of a selected drug. Under the proposed framework, CMS would review utilization and sales information and may consider additional public information concerning launch, distribution, patent disputes, and other evidence relevant to whether an

[120] National Health Council, "NHC Comments on Draft Guidance 2028," 2–7.

approved generic or licensed biosimilar is subject to bona fide marketing. The NHC encourages CMS to apply these factors in a manner that recognizes the realities of market entry, including that utilization may develop over time after a credible commercial launch and may vary across products, settings, and patient populations.

Regulatory approval or licensure is an important milestone, but competition patient benefits patients only when the product is commercially available through the channels and settings in which beneficiaries receive care. At the same time, the standard for bona fide marketing should not require mature market penetration or uniform nationwide utilization immediately after launch. Such an approach could delay recognition of legitimate competition and reduce predictability for generic and biosimilar manufacturers. CMS should instead assess whether the available evidence demonstrates a credible and continuing market presence that can reasonably expand access and competition, taking into account the product's launch stage and the characteristics of the market.

CMS should clarify the level and duration of market activity it considers sufficient. The final policy should evaluate the totality of the evidence rather than rely on a single utilization or sales threshold. Relevant factors could include commercial availability, distribution arrangements, supply, utilization trends, provider or pharmacy access, and evidence of a credible launch plan, with appropriate recognition that a recently launched product may satisfy the standard even when early utilization is necessarily limited. Providing manufacturers with clear submission opportunities and timely notice of CMS' determination would further support predictable implementation and allow factual or market developments to be addressed promptly. To reduce the risk that a bona fide marketing determination lags behind meaningful market entry, the NHC encourages CMS to review available evidence at least monthly during periods in which a determination could affect selection or deselection. Alternatively, CMS could establish an alternative cadence that provides comparably timely recognition of legitimate competition.

If CMS continues monitoring after a bona fide marketing determination, it should clearly describe the purpose, cadence, evidence considered, and circumstances that could cause the agency to revisit the determination. A generic drug or biosimilar could enter the market and subsequently experience a prolonged shortage, discontinuation, or significant restriction in distribution. Where a selected drug has been deselected based on competition that later proves unsustainable, the program will need a process that recognizes the resulting change in market conditions. The process should be predictable enough that manufacturers, plans, providers, and patients understand how CMS will respond if the market conditions underlying a prior determination materially change.

Public transparency concerning these determinations could improve confidence in the process while protecting confidential business information. CMS could publish the general basis for a determination, the categories of evidence reviewed, and any subsequent change in status. A mechanism to correct factual errors in product status, ownership, launch information, or market availability would also be valuable.

The related biosimilar-delay process raises similar considerations regarding predictability, competition, and patient access. Delaying selection of a reference product may be appropriate where the statutory criteria indicate a high likelihood that biosimilar competition will enter the market within the applicable timeframe, but the process should provide biosimilar and reference-product manufacturers with clear criteria, meaningful opportunities to submit current information, and timely notice of CMS' determination. In applying the standard, the NHC encourages CMS to consider the totality of available evidence, including anticipated launch timing, regulatory status, manufacturing and distribution planning, litigation, expected supply, and the settings in which beneficiaries are likely to receive treatment, without requiring certainty regarding market entry or mature commercial availability before the statutory delay period has run its course.

When CMS grants an initial or additional delay, continued monitoring can help the agency account for material changes in anticipated market entry while giving affected manufacturers and other stakeholders reasonable certainty for planning purposes. A high-level public explanation of the general basis for the delay, together with timely notice of any later change in status and careful protection of confidential business information, would support accountability without undermining the commercial and regulatory planning necessary to bring biosimilar competition to patients. CMS should also ensure that the timing of its administrative determinations does not effectively shorten the period of delay available under section 1192(f) of the Act. If CMS plans to issue an interim or October determination before the end of the applicable delay period, the agency should explain how later evidence of bona fide marketing can still be considered through the full period provided by statute under section 1192(f) of the Act, 42 U.S.C. § 1320f-1(f).

The Temporary Floor for Small Biotech Drugs Warrants Transparent Implementation and Evaluation

CMS proposes to implement the statutory temporary floor for qualifying small biotech drugs selected for negotiation or renegotiation for IPAYs 2029 and 2030. The proposal includes a process for a primary manufacturer to request consideration, receive a written eligibility determination and calculation information, and submit a suggestion of error concerning the calculation. Where the otherwise applicable ceiling is below the temporary floor, CMS proposes a stepwise methodology to reconcile the two statutory requirements, potentially adjusting the ceiling and, in limited circumstances, setting it equal to the temporary floor.

The NHC recognizes that the temporary floor reflects a statutory effort to account for the distinct circumstances of smaller biotechnology manufacturers, whose research programs and financial sustainability may depend heavily on a limited number of products, while maintaining the broader negotiation framework. From the patient perspective, predictable and faithful implementation of this protection is important because smaller biotechnology companies often develop therapies for serious chronic conditions, rare diseases, and areas of unmet need where continued investment and additional evidence generation can be especially consequential.

Uncertainty about implementation may be particularly consequential for smaller biotechnology manufacturers with narrower portfolios and less ability to absorb financial risk, particularly where their products address serious chronic conditions, rare diseases, or areas in which patients have few meaningful treatment options. Clear edibility criteria, calculation methods, and rules for treatment of corporate relationships would help preserve the intended protection while allowing CMS to evaluate its effects on access and continued development.

CMS should clearly explain how corporate relationships, acquisitions, and changes in ownership affect a drug's eligibility for the temporary floor or calculation of the floor amount. The proposal to issue written determinations and permit suggestions of error offers a useful safeguard. The NHC encourages CMS to provide sufficient explanatory information to allow affected parties to understand the basis for the determination and to correct objective factual or calculation errors.

Because the temporary floor applies only to negotiations and renegotiations for IPAYs 2029 and 2030, evaluation of its effects will also be important. CMS could examine whether the protection provides the predictability intended by Congress, supports continued research and development, and helps preserve the availability of treatments, including whether observed effects differ by disease area or manufacturer characteristics. Such evaluation would be most informative if it considers patient access, unmet medical need, development activity, and the practical experience of qualifying manufacturers in addition to program-level financial measures.

Compliance and Enforcement Should Protect Patients and Support Timely Correction

The NHC has previously emphasized that effective and predictable oversight is necessary to ensure that patients receive access to the MFP and that each program participant understands and can fulfill the obligations within its control. The proposed rule would codify compliance monitoring, record-retention requirements, civil monetary penalties, and notice and appeal procedures. The NHC recognizes that implementation failures may arise at different points in a complex transaction involving manufacturers, plans, pharmacies, providers, distributors, and CMS systems. Clear allocation of responsibility will therefore be important so that corrective action is directed to the appropriate entity and manufacturers or other participants are not held accountable for failures outside their control.

The NHC encourages CMS to apply this authority through a framework that combines accountability with operational clarity, proportionality, reasonable opportunities to cure, and timely remediation. Guidance regarding what constitutes a good-faith compliance effort, how technical or data failures should be reported, how responsibility will be allocated across participating entities, and how an affected entity can promptly correct a problem would reduce uncertainty and encourage early communication rather than defensive or delayed reporting. Enforcement decisions would also be strengthened by distinguishing isolated or inadvertent errors from repeated, knowing, or systemic noncompliance and from recognizing documented efforts to prevent recurrence. Where an operational failure affects beneficiaries, the immediate priority should be restoration

of access and correction of excess cost sharing or other patient harm, with penalties calibrated to the nature, cause, duration, and impact of the underlying conduct.

Public reporting can support oversight without disclosing confidential business information, identifying individual entities, or creating reputational consequences from good-faith errors that are promptly corrected. CMS could publish de-identified, aggregate information on the number and general types of compliance issues, average resolution timelines, corrective actions, and recurring operational challenges by program year, which would help patients and other stakeholders understand whether the program is functioning as intended while allowing CMS and program participants to identify systemic issues that may warrant additional guidance, technical assistance, or policy refinement.

Transfers of Responsibility Must Avoid Disruption to Patients

CMS proposes additional requirements governing transfer of responsibility for the Negotiation Program Agreement when a primary manufacturer is acquired. These requirements would clarify which entity is responsible for submissions, negotiation obligations, MFP availability, and compliance following a change in corporate ownership.

The NHC encourages CMS to prioritize continuity throughout implementation. A transfer of ownership should not interrupt access to the MFP, claims processing, provider or pharmacy reimbursement, required data exchange, or communications to stakeholders. The acquiring entity and prior manufacturer will need clear timelines and responsibilities, and CMS will need complete and timely information concerning product ownership and included NDCs or HCPCS codes.

CMS should also establish a contingency process for transfers that are complex, disputed, or occur close to a program deadline. Key elements would include continuity of program obligations during the transition and timely notification of operational changes to providers, pharmacies, plans, and beneficiaries. These safeguards would protect patients from disruptions caused by uncertainty between corporate entities.

Program Evaluation and Public Reporting Are Essential to Continued Improvement

The NHC encourages CMS to establish an annual public evaluation of the Negotiation Program that extends beyond publication of selected drugs and MFPs. The program's success will depend on whether negotiated prices translate into lower costs and

sustainable access without creating new barriers or reducing the future treatment options available to patients.[121,122,123]

An annual report could address patient and caregiver participation in negotiation and renegotiation; the disease communities and populations represented; major patient-experience themes and how they informed CMS' analysis; formulary placement and utilization-management trends; beneficiary cost sharing and treatment access; exceptions, appeals, and denials; provider participation and availability of Part B drugs; geographic and demographic disparities; generic and biosimilar market availability; effectuation or transaction failures; treatment switching, delay, or abandonment where data permit; stakeholder concerns identified during implementation; and policy or operational changes planned for the next cycle.

The evaluation would be particularly useful if CMS distinguishes between measures of program activity and measures of patient impact. The number of engagement events or submissions received provides information about process, but not whether the process was representative, accessible, or influential. Similarly, publication of an MFP demonstrates completion of negotiation, but not whether beneficiaries obtained the selected drug at an affordable cost or whether coverage and delivery systems created new barriers.

A regular public feedback mechanism could accompany the annual evaluation. Patients, patient organizations, clinicians, providers, plans, manufacturers, and other stakeholders could use the findings to identify recurring issues and propose improvements before the next negotiation cycle. This approach would support the NHC's broader recommendation that codification provide a stable foundation while leaving the program responsive to evidence and experience.[124,125]

Conclusion

The NHC appreciates CMS' continued work to implement the Medicare Drug Price Negotiation Program and its decision to transition major program policies from guidance to notice-and-comment rulemaking. The proposed rule incorporates several elements that can support a more durable and patient-centered framework, including recognition of patient experience, patient-reported outcomes, caregiver perspectives, off-label use,

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[121] National Health Council, "NHC Comments on Draft Guidance 2028," 21–22.

[122] Office of the Assistant Secretary for Planning and Evaluation, *An Evaluation Framework*.

[123] Caelesta Braun and Madalina Busuioc, "Stakeholder Engagement as a Conduit for Regulatory Legitimacy?" *Journal of European Public Policy* 27, no. 11 (2020): 1599–1611, https://doi.org/10.1080/13501763.2020.1817133.

[124] Laura Esmail, Emily Moore, and Alison Rein, "Evaluating Patient and Stakeholder Engagement in Research: Moving from Theory to Practice," *Journal of Comparative Effectiveness Research* 4, no. 2 (2015): 133–45, https://doi.org/10.2217/cer.14.79.

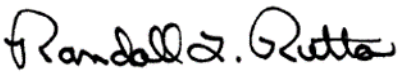
[125] National Health Council, *Amplifying the Patient Voice* (August 2025), 5–6.

Medicare-specific populations, patient-focused engagement, and Part D formulary inclusion.

As CMS finalizes the rule, the NHC encourages continued attention to how these provisions will operate in practice. Translating negotiated prices into improved affordability and access for patients will require transparency providing the use of patient evidence, a patient-centered approach to fixed-combination formulations, comprehensive processes for off-label use and renegotiation, careful treatment of nontraditional dosing patterns, and stronger monitoring of formulary coverage and provider participation. Continued public evaluation and timely rulemaking on MFP effectuation will also be important as the program expands to additional Part B and Part D drugs.

Please do not hesitate to contact Kimberly Beer, Senior Vice President, Policy & External Affairs, at kbeer@nhcouncil.org, or Shion Chang, Assistant Vice President, Policy & Regulatory Affairs, at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail. The NHC looks forward to continuing to work with CMS to improve implementation of the Negotiation Program so that efforts to advance affordability also preserve access, continuity of care, meaningful treatment choice, and continued development of therapies and treatment improvements that address the needs of patients and family caregivers.

Sincerely,



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