NATIONAL HEALTH COUNCIL

October 30, 2025

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

RE: Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act [CMS-10844, OMB 0938-1443]

Dear Administrator Oz:

The National Health Council (NHC) appreciates the opportunity to comment in response to the Negotiation Program Drug Selection for Initial Price Applicability Year (IPAY) 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR).

Created by and for patient organizations more than 100 years ago, the NHC convenes organizations from across the health ecosystem to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, comprehensive, accessible, and sustainable health care. Made up of more than 180 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

General Comments

The NHC acknowledges CMS' effort to refine the ICR structure, definitions, and submission mechanics. Aligning terms with the IPAY 2028 final guidance; clarifying use of the CMS Health Plan Management System (HPMS); and requiring executive-level certification represent meaningful steps toward consistency and accountability. At the same time, the revised ICR remains primarily oriented to manufacturer administrative data and does not yet incorporate the transparency and patient-facing elements necessary to sustain public confidence. The separation of selection (CMS-10844) from negotiation data collection (CMS-10849) clarifies program phases but creates a fragmented reporting experience without an accompanying crosswalk to prevent duplication and promote coherence. The NHC urges CMS to pair the revised forms with plain-language public documentation, a defined error-correction pathway, and an integrated overview that explains how the data collected under each control number will be interpreted and used.

Section-By-Section Comments

The following technical and policy-focused recommendations are intended to help CMS refine the ICR in alignment with statutory intent, patient-centered objectives, and the program's broader commitment to affordability, sustainability, and innovation. These comments are intended to improve clarity, consistency, and operational feasibility while ensuring that the data collection framework advances transparency and patient-centered implementation without avoidable administrative burden.

Small Biotech Exception (SBE) and Related Definitions

The NHC supports the effort to define "Part D 2021 Manufacturer" and "Part B 2021 Manufacturer" and to apply the Internal Revenue Code §52 controlled-group aggregation standard. These clarifications would reduce uncertainty and promote uniformity in manufacturer submissions. CMS should augment these improvements with a transparent, time-bound process for disputing or correcting CMS-populated identifiers and ownership attributions. A publicly documented error-correction protocol with defined timelines for review and adjudication would help prevent downstream coverage and reimbursement issues that ultimately fall on patients and providers. CMS should also explain, in accessible language, how SBE determinations for IPAY 2028 may differ from prior years and how acquisitions after December 31, 2021, interact with eligibility limitations, so that beneficiaries and caregivers can understand why particular products are excluded from negotiation.

Submission Platform, Certification, and Data Integrity

CMS' decision to require HPMS submission and executive-level certification strengthens accountability and promotes consistency across manufacturers. CMS should accompany these requirements with role-based technical assistance for small manufacturers that may have limited HPMS experience. A short, publicly available submission checklist that maps each data element to the relevant guidance section would improve completeness and comparability. To reinforce data integrity, CMS should describe how conflicting data across related entities will be reconciled, how CMS will validate labeler-code associations, and how determinations will be communicated to affected parties before they are relied upon in subsequent program steps. At the same time, CMS should ensure that all proprietary information submitted through HPMS or other electronic communications is protected by robust storage and access controls, with access restricted to authorized staff and only when there is a legitimate programmatic need. Strengthening both data security and administrative transparency will help maintain the integrity of the negotiation process and safeguard stakeholder confidence in the confidentiality of sensitive information.

Controlled-Group and Acquisition Disclosures

Controlled-group disclosures play a critical role in ensuring accurate SBE determinations. CMS should clarify its treatment of historic CGDP arrangements in which labeler codes were listed under another manufacturer's agreement and describe how those arrangements will be validated. For acquisitions after 2021, CMS should outline the documentation it will accept to determine whether the statutory limitation

applies, how affiliate restructurings will be handled, and whether manufacturers will have an opportunity to submit supplemental evidence to confirm correct attribution. These steps would help ensure consistent application across both Part D and Part B tracks.

Public Transparency and Patient-Facing Communication

The revised ICR improves administrative specificity but continues to lack a patient-facing component. CMS should consider publishing an annual plain-language overview describing the SBE determination process and summarizing aggregate outcomes, accompanied by a concise explanation of the statutory framework. The summary should be written for beneficiaries and caregivers and should be accompanied by educational materials that explain how these determinations relate to selection and renegotiation timelines, ensuring accuracy while promoting public understanding. This patient-facing documentation will help prevent confusion at the point of care and strengthen public trust in the program.

Integration with CMS-10849 and Administrative Simplification

The separation of CMS-10844 and CMS-10849 should be supported by an integrated overview that identifies overlapping data elements, explains how submissions under one ICR will be referenced in the other, and specifies where manufacturers may rely on previously submitted information. A brief, CMS-maintained data-element crosswalk shared with participating entities would reduce duplicative work, mitigate inconsistencies, and improve internal analytic coherence, while maintaining the distinct purposes of selection and negotiation phases, and should be implemented within existing administrative capacity to avoid additional burden.

Optional Patient-Centered Context

Although the selection ICR is primarily administrative, CMS should permit optional submission of brief patient-centered context where relevant, such as whether a product addresses a distinct unmet need in populations with limited alternatives or poses unique access challenges in particular sites of care. Allowing manufacturers and patient organizations to provide concise, structured context would better align selection mechanics with the program's overarching goals, provided such information is used for contextual understanding and does not alter statutory eligibility criteria or introduce subjective weighting in SBE determinations.

Error-Correction and Appeal

To prevent patient-level disruption from administrative inaccuracies, CMS should establish a concise and clearly defined window for error correction prior to final SBE determinations, with transparent evidentiary expectations and timelines designed to streamline resolution without introducing additional procedural burden. CMS should also indicate whether and how parties will be notified of preliminary determinations, what documentation will be considered authoritative in resolving conflicts, and how corrected information will flow to downstream systems used for effectuation.

Summary of Changes and Responsiveness to Public Comment

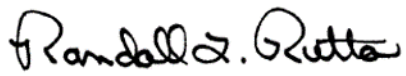
The revised ICR would benefit from a brief synopsis describing the key changes made in response to prior comments and how those changes are expected to improve accuracy, consistency, or feasibility. Publishing such a synopsis would demonstrate responsiveness and further the transparency that beneficiaries and taxpayers expect from a program of this significance.

Conclusion

The NHC values the opportunity to engage with CMS on this important process and remains committed to working together to ensure that Medicare beneficiaries have access to affordable, high-value care.

Thank you again for the opportunity to provide input to CMS on this revised ICR. Please do not hesitate to contact Kimberly Beer, Senior Vice President, Policy & External Affairs at kbeer@nhcouncil.org or Shion Chang, Senior Director, Policy & Regulatory Affairs at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail.

Sincerely,



Randall L. Rutta
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