

Date: January 11, 2023
To: Interested Parties
From: Centers for Medicare & Medicaid Services Administrator Chiquita Brooks-LaSure
Subject: Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026

Introduction

In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. Among many other provisions, this landmark legislation will lower the cost of health insurance for American families; give peace of mind to 50 million seniors and people with disabilities by placing an annual out-of-pocket cap on Medicare prescription drug costs; build a clean energy economy and reduce harmful pollution; and make the tax code fairer for low- and middle-income Americans.

Further, this historic legislation will permit Medicare to negotiate the price of prescription drugs for the first time. Through this memo, the Centers for Medicare & Medicaid Services (CMS) is taking its first steps toward implementing the Medicare Drug Price Negotiation Program (or “Negotiation Program”), setting the stage for multiple comment opportunities for members of the public, people with Medicare and their families, beneficiary and consumer advocates, pharmaceutical manufacturers, health care providers, and other interested parties. As the law is implemented, with this memo and through opportunities that follow, CMS intends to prioritize transparency and robust engagement among all interested parties.

Summary

The IRA authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare Part B or Part D drugs. For the first year of the Negotiation Program, the Secretary will select 10 Part D high expenditure, single source drugs for negotiation. The maximum fair prices that are negotiated for these drugs will apply beginning in initial price applicability year 2026. The Secretary will select an additional 15 Part D drugs for negotiation for initial price applicability year 2027, 15 Part B or Part D drugs for initial price applicability year 2028, and 20 Part B or Part D drugs for initial price applicability year 2029 and subsequent initial price applicability years.

This memo outlines how CMS will approach implementation of the Negotiation Program of the IRA for initial price applicability year 2026, including the following:

- (1) Engagement with the public;
- (2) Program guidance;
- (3) Information Collection Requests (ICRs) through the Paperwork Reduction Act (PRA) clearance process; and
- (4) A timeline outlining key dates.

Public feedback is critical to the success of the Negotiation Program, and this memo is one tool, among many, CMS will use to ensure interested parties know when and how they can make their voices heard on IRA implementation for initial price applicability year 2026. Plans for implementation of the Negotiation Program in subsequent years are forthcoming.

Public Engagement

CMS will seek feedback and insights from a broad range of interested parties throughout implementation of the IRA, including implementation of the Negotiation Program.

CMS is committed to collaborating with and engaging the public in the policy-making process. CMS will work closely with patients and consumers, Part D plan sponsors and Medicare Advantage organizations, drug manufacturers, hospitals and health care providers, wholesalers, pharmacies, and others. CMS will engage interested parties through national stakeholder calls, quarterly strategic meetings, and monthly technical calls with CMS staff. In addition, members of the public are welcome to share feedback and input in writing by email at: IRAREbateandNegotiation@cms.hhs.gov, and CMS will solicit comment on the draft program guidance and information collection requests discussed below.

Program Guidance

For initial price applicability years 2026 through 2028 of the Negotiation Program, the IRA instructs CMS to implement the Negotiation Program through program instruction and other forms of program guidance. This memo underscores CMS's decision to issue draft guidance for implementation of the Negotiation Program for initial price applicability year 2026 and voluntarily solicit comments on certain topics to allow for public input. CMS will request comment on key elements of the program guidance for the Negotiation Program, including the following:

- a) Terms and conditions contained in the manufacturer agreement, including the manufacturer's and Secretary's responsibilities.
- b) Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments.
- c) Process for the offer and counteroffer exchange between the Secretary and manufacturers.
- d) Content of an explanation for the maximum fair price.
- e) Method for applying the maximum fair price across different dosage forms and strengths of a selected drug.
- f) Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198.
- g) Processes for compliance monitoring and imposition of civil monetary penalties for violations.

Topics that are not relevant to the Negotiation Program for initial price applicability year 2026, such as renegotiation, will not be addressed in the guidance issued by CMS for initial price applicability year 2026. CMS will provide additional information in the future related to any program guidance or rulemaking for initial price applicability years 2027 and beyond.

Data Collection

The Paperwork Reduction Act (PRA) of 1995 is a law governing how federal agencies collect information from the public and requires agencies to plan for the development of new collections of information and the extension of ongoing collections.¹ CMS proposes three new information collection requests (ICRs) related to the Negotiation Program. For each ICR, CMS intends to publish a notice with a 60-day comment period in the Federal Register to announce the proposed ICR and solicit comments. During the public comment period interested parties can review and comment on the proposed draft information collection tool(s) and the supporting statement that explains CMS's need for the data, how the data will be used, frequency and timing of collection, and the estimated public reporting burden. After reviewing and addressing public comments in response to the 60-day notices, CMS intends to publish a notice with a 30-day comment period to announce the submission of the ICR to the Office of Management and Budget (OMB) for review and approval.²

1. **Small Biotech Exception ICR:** In accordance with section 1192(d)(2) of the Social Security Act, as established by the Inflation Reduction Act, CMS will exclude from the term “negotiation-eligible drug,” with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (“small biotech exception”). In identifying such drugs, the statute requires (1) that CMS consider total 2021 Medicare expenditures for the drug, for all Medicare Part B or Part D drugs, as applicable, and for all Medicare qualifying single source drugs of the manufacturer under Part B or all covered Part D drugs for which the manufacturer has an agreement under the Medicare Coverage Gap Discount Program, as applicable, and (2) that all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 be treated as one manufacturer. Accordingly, CMS plans to collect information about a manufacturer's aggregation as a single employer to determine which covered Part D drugs qualify for the small biotech exception. CMS is requesting that only manufacturers who reasonably believe that their covered Part D drug might qualify for the small biotech exception submit these data. Submission will occur in summer 2023 for purposes of determining the selected drug list for initial price applicability year 2026.³
2. **Negotiation Data Elements ICR:** By statute, the manufacturer-specific data to be considered when negotiating the maximum fair price are research and development costs and the recoupment of those costs; unit costs of production and distribution costs; prior federal financial support for novel therapeutic discovery and development; approved and pending patent applications, FDA-recognized exclusivities, and certain other applications and approvals; and market data, and revenue and sales volume data. This ICR will also outline a process for manufacturers and the public to voluntarily submit data regarding the factors related to evidence about alternative treatments described in section 1194(e)(2). CMS is proposing all data submissions will be due October 2, 2023.
3. **Offer and Counteroffer Exchange ICR:** CMS and manufacturers will exchange offers and counteroffers during negotiation, and this package will outline the information that manufacturers must provide in any counteroffers. Manufacturers will submit any counteroffers for the selected drugs for initial price applicability year 2026 in 2024.

Key Dates and Estimated Timeline to Implement the Medicare Drug Price Negotiation Program for Initial Price Applicability Year 2026

- **Winter 2023:** ICR for small biotech exception published with a 60-day notice and public comment period
- **Spring 2023:**
 - Initial guidance for the Medicare Drug Price Negotiation Program initial price applicability year 2026 with a 30-day comment period
 - ICR for small biotech exception submitted to OMB and published with a 30-day notice and public comment period
 - ICR on negotiation data elements published with a 60-day notice and public comment period
 - ICR for negotiation offer and counteroffer exchange published with a 60-day notice and public comment period
- **June 1, 2022-May 31, 2023*:** Time period for total expenditure calculation used in determining negotiation-eligible drugs for initial price applicability year 2026
- **Summer 2023:**
 - Revised guidance for the Medicare Drug Price Negotiation Program initial price applicability year 2026 published
 - Deadline for request by a manufacturer of a biosimilar biological product for a delay in the selection of the reference biological product for negotiation due to high likelihood of biosimilar market entry
 - Deadline for submission to qualify for small biotech exception for initial price applicability year 2026
 - ICR on negotiation offer and counteroffer exchange submitted to OMB and published with a 30-day notice and public comment period
 - ICR for negotiation data elements submitted to OMB and published with a 30-day notice and public comment period
- **September 1, 2023*:** CMS publishes list of 10 Part D selected drugs for initial price applicability year 2026
- **October 1, 2023*:** Deadline for manufacturers of selected drugs to sign an agreement with the Secretary to conduct negotiations
- **October 2, 2023*:** Deadline for manufacturers of selected drugs to submit data elements
- **February 1, 2024*:** CMS sends initial offers of a maximum fair price with a justification to manufacturers, negotiation period begins
- **March 2, 2024*:** Manufacturer has 30 days from when it receives the offer to propose a counteroffer, if desired
- **August 1, 2024*:** Negotiation period ends
- **September 1, 2024*:** CMS publishes maximum fair prices
- **January 1, 2026*:** Price applicability period begins for selected drugs

*Statutory deadline. Please note that non-statutory deadlines may be adjusted by CMS at any time. The steps outlined in this memo are intended to provide an initial overview of CMS actions and opportunities for engagement and feedback during near-term Negotiation Program implementation. CMS is committed to ongoing collaboration with interested parties. For questions, please email IRAREbateandNegotiation@cms.hhs.gov and for more information visit cms.gov/inflation-reduction-act-and-medicare.

¹ More information about the PRA clearance process and requirements can be found at <https://pra.digital.gov>.

² ICRs can be downloaded and comments can be submitted to OMB's website directly (<https://www.reginfo.gov/public/do/PRAMain>) during the 30-day notice for public comment period.

³ Note: This information collection request does not address the statutory limitation on the small biotech exception for manufacturers acquired before 2025, as that provision does not take effect until January 1, 2025, or the single employer status of manufacturers of qualifying Part B drugs, as those drugs cannot be selected for negotiation until initial price applicability year 2028. This information collection request only collects information necessary to implement the small biotech exception for initial price applicability year 2026.