Timeline: Medicare Drug Price Negotiation Program Final Rule (CMS-4215-F)

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

In accordance with the Inflation Reduction Act of 2022 (IRA), CMS will select up to 20 additional negotiation-eligible drugs covered under Part D and/or payable under Part B for the fourth cycle of negotiations. In addition to the drugs selected for negotiation, CMS may also select drugs negotiated in the first, second, or third cycles of negotiation to be renegotiated, if those selected drugs meet certain eligibility and selection criteria.

Key dates for the Negotiation Program for Initial Price Applicability Year 2029 ("fourth cycle of negotiations")

- **June 16, 2026,** CMS published the Negotiation Program Notice of Proposed Rulemaking (NPRM) (CMS-4215-P) to implement the Negotiation Program for the fourth cycle of the Medicare Drug Price Negotiation Program and initial price applicability years thereafter and to codify policies established in guidance documents. The fourth cycle of negotiations will occur during 2027 and, for drugs where an agreement on a negotiated price is reached, will result in prices that will be effective beginning Jan. 1, 2029. The 60-day public comment period closed on August 17, 2026. CMS also issued proposed revisions to two information collection requests on the data and information the federal government will collect to inform drug selection and drug price negotiation, and these proposed revisions were open for a 60-day public comment period.

- **November 5, 2026,** CMS issued the final rule to implement the Medicare Drug Price Negotiation Program for initial price applicability year 2029 and initial price applicability years thereafter. CMS also issued final revised information collection requests on the data and information the federal government will collect to inform drug selection and drug price negotiation and submitted the collection to the Office of Management and Budget for approval.

- **December 2026,** Deadline for the manufacturer of a biosimilar biological product ("Biosimilar") to submit a request (an "Initial Delay Request") to CMS for initial price applicability year 2029 to delay selection of a negotiation-eligible drug that includes the reference product for such Biosimilar ("Reference Drug"). Deadline for manufacturers to voluntarily submit information to inform renegotiation eligibility and selection.

- **December 2026,** CMS will publish on the CMS public website the specific due date, which will be in January 2027, by which the manufacturer of a biosimilar biological product ("Biosimilar") who timely submitted a request (an "Initial Delay Request") to CMS for initial price applicability year 2029 to delay selection of a negotiation-eligible drug that includes the reference product for such Biosimilar ("Reference Drug") may provide CMS with updated information (if any) regarding the status of the Biosimilar's licensure application submitted to the Food and Drug Administration (FDA).

- **February 1, 2027,** Deadline for CMS to publish the list of up to 20 drugs payable under Part B and/or covered under Part D selected for initial price applicability year 2029, along with any drug(s) selected for renegotiation. CMS will also release the list of the up to 30 top negotiation-eligible drugs based on combined total expenditures under Part B and Part D from which the drugs selected for initial price applicability year 2029 were chosen.

- **February 28, 2027,** Deadline for participating Primary Manufacturers for the fourth cycle of negotiations to sign agreements to participate in the Negotiation Program. Drugs selected for renegotiation (if applicable) have existing Negotiation Program Agreements that remain in effect and include provisions related to renegotiation; therefore, an additional agreement is not required.
- **March 1, 2027,** Deadline for participating Primary Manufacturers to submit manufacturer-specific data to CMS for consideration in the negotiation or renegotiation of a maximum fair price (MFP), and for a Primary Manufacturer to request CMS consider whether the selected drug is eligible for the Temporary Floor for Small Biotech Drugs. In addition, this is the deadline for the public to submit data on selected drugs and potential therapeutic alternative(s), if any, data related to unmet medical need, and data on impacts to specific populations, among other considerations.
- **Spring 2027,** CMS will host patient-focused and clinical-focused public engagement sessions. Specifically, CMS will host patient-focused roundtable events that will be open to patients, patient advocacy organizations, and caregivers to share patient-focused input. CMS will also host at least one town hall meeting focused on clinical considerations related to the selected drugs. Additional information about these public engagement sessions will be shared in the future. CMS will also provide an optional opportunity for participating Primary Manufacturers to meet with CMS to discuss their data submission.
- **June 1, 2027,** Deadline for CMS to send an initial offer of an MFP for a selected drug with a concise justification to each Primary Manufacturer participating in the Negotiation Program.
- **June 2027,** CMS will offer each participating Primary Manufacturer one optional negotiation meeting, which will occur after the initial offer is issued and before the deadline to accept the initial offer or to provide a statutory written counteroffer or renegotiation written counteroffer.
- **July 1, 2027,** Deadline for participating Primary Manufacturers to accept CMS' initial offer or provide a statutory written or renegotiation written counteroffer if desired (if the offer is made by CMS on June 1, 2027). Participating Primary Manufacturers have 30 days from receiving CMS' initial offer to respond.
- **Summer 2027,** CMS will respond to any statutory written or renegotiation written counteroffers from participating Primary Manufacturers within 30 days after receipt of a counteroffer or within 60 days of sharing the initial offer, whichever is later. CMS and participating Primary Manufacturers may engage in up to two additional optional negotiation meetings during the negotiation period, as well as have the opportunity for the written additional price exchanges.
- **September 2027,** CMS will announce a last date within September by which CMS and participating Primary Manufacturers may exchange additional written offers or counteroffers.
- **September 30, 2027,** Deadline for CMS to send a final MFP offer to participating Primary Manufacturers if agreement was not reached during the negotiation meetings or the additional price exchange process.
- **October 31, 2027,** Deadline for participating Primary Manufacturers to accept or reject a final MFP offer from CMS.
- **November 1, 2027,** The negotiation and renegotiation (if applicable) period ends.
- **Fall 2027,** After review for licensure and marketing of any Biosimilar that was included in a successful Initial Delay Request (if applicable) for initial price applicability year 2029, CMS will notify a manufacturer of the Biosimilar in writing if CMS determines the Biosimilar is licensed and marketed. CMS will publish on the CMS public website the specific date by which CMS will provide such written notification.

November 30, 2027, Deadline for CMS to publish any agreed-upon MFPs resulting from the fourth cycle of negotiations and renegotiation(s) (if applicable).

March 1, 2028, Deadline for CMS to publish an explanation of any agreed-upon MFPs resulting from the initial price applicability year 2029 negotiation and renegotiation (if applicable) process. In the interest of balancing transparency and confidentiality, as part of the public explanation of an agreed-upon MFP, CMS will publish a narrative explanation of the negotiation and renegotiation (if applicable) process and certain additional information.

Any information submitted by participating Primary Manufacturers during the negotiation process that constitutes confidential commercial or financial information will be considered proprietary and will be redacted.



January 1, 2029, Any agreed-upon MFPs negotiated for selected drugs and renegotiated for drugs selected for renegotiation (if applicable) for initial price applicability year 2029 become effective.

Additional Resources

- Medicare Drug Price Negotiation Program: **https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program**
- Negotiation Program Final Rule Fact Sheet: **https://www.cms.gov/files/document/negotiation-program-final-rule-fact-sheet.pdf**