Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Final Rule (CMS-4215-F)

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

On November 5, 2026, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that codifies policies established in guidance documents for the Medicare Drug Price Negotiation Program ("Negotiation Program") for initial price applicability year 2029 and beyond (CMS-4215-F). For initial price applicability years 2026 through 2028 of the Negotiation Program, statute directed CMS to implement the Negotiation Program through program instruction and other forms of program guidance. With this authority expiring, CMS is codifying the Negotiation Program for 2029 and beyond. In addition to codifying these policies, we are establishing new policies to continue implementation of statutory provisions under the Negotiation Program as well as finalizing revisions or clarifications to certain policies previously established to incorporate lessons learned from ongoing experience.[1]

The Negotiation Program final rule is one of several activities that reflect a broader CMS-wide strategy to lower prescription drug costs for people with Medicare. CMS is approaching codification of the Negotiation Program consistent with the goals of achieving greater value for beneficiaries and taxpayers and continuing to foster innovation.

The final rule is effective December 5, 2026.

Background on the Negotiation Program

Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) establish the Negotiation Program to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. Specifically, in accordance with section 1191(c)(3) of the Social Security Act (the Act), MFP means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the MFP negotiated in accordance with section 1194 of the Act, and updated to account for inflation in accordance with section 1195(b) of the Act, as applicable, for such drug and year.

Under the IRA, with respect to each initial price applicability year, CMS will: (1) publish a list of selected drugs for negotiation and renegotiation, if any; (2) enter into agreements with manufacturers of selected drugs that choose to participate; (3) negotiate (or renegotiate) MFPs for such selected drugs; (4) publish any agreed-upon MFPs for selected drugs; (5) carry out administrative and compliance duties; and (6) impose civil monetary penalties (CMPs), when applicable.

CMS will select up to 20 drugs covered under Part D and/or payable under Part B for initial price applicability year 2029 and for each subsequent initial price applicability year. In addition to the drugs selected for negotiation, CMS may also select drugs for renegotiation if selected drugs with an agreed-upon MFP meet certain eligibility and selection criteria.

Codification of the Negotiation Program

In codifying the requirements for the Negotiation Program, CMS builds upon policies established for the first three cycles of negotiations and establishes new requirements for the fourth and future cycles of negotiations with a particular focus on continuing to increase transparency in the Negotiation Program.

[1] Medicare Drug Price Negotiation Program Final Rule (CMS-4215-F). **https://www.federalregister.gov/public-inspection/current**.

The final regulations include, but are not limited to:

- **Identification of Selected Drugs.** Section 1192 of the Act establishes the requirements governing the publication of the selected drug list for an initial price applicability year, the identification of selected drugs, ranking of negotiation-eligible drugs, and the identification of qualifying single source drugs. CMS codifies these policies consistent with statute and guidance for initial price applicability year 2028, with a new policy to clarify how CMS will identify qualifying single source drugs to address potential program integrity concerns posed by specific new formulations. Additionally, CMS clarifies the treatment of withdrawn approvals for indications when identifying whether a drug that formerly qualified for the orphan drug exclusion meets eligibility criteria to be a qualifying single source drug, in accordance with amendments made by the "Working Families Tax Cut" legislation (Pub. L. 119-21).
- **Requirements for Manufacturers of Selected Drugs.** Section 1193(a) of the Act establishes the Negotiation Program Agreement and the requirements for a willing Primary Manufacturer to enter into and sign the Negotiation Program Agreement no later than Feb. 28 following the selected drug publication date. The Negotiation Program Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer considered a selected drug under section 1192(c) of the Act (due to a determination that a generic drug is approved or a biosimilar is licensed and that the generic drug or biosimilar is subject to Bona Fide Marketing) unless it is terminated sooner by the Primary Manufacturer under specified conditions. CMS finalizes additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to another entity. In addition, CMS codifies the timing and process for executing and terminating a Negotiation Program Agreement with CMS and the requirements a willing Primary Manufacturer is subject to upon executing the Negotiation Program Agreement with CMS, including mandatory submission of data to CMS, consistent with statute and guidance for initial price applicability year 2028.
- **Negotiation Factors.** After entering into an Agreement with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug must submit the following information with respect to the selected drug: information on the non-Federal Average Manufacturer Price (non-FAMP) and any information that CMS requires to carry out the Negotiation Program, including but not limited to, information related to the manufacturer-specific factors listed in section 1194(e)(1) of the Act. Additionally, Primary Manufacturers and any interested party may voluntarily submit evidence about the selected drugs and potential therapeutic alternatives as described in section 1194(e)(2) of the Act. In accordance with section 1194(e) of the Act, CMS uses manufacturer-specific data and available evidence about the selected drugs and their therapeutic alternatives as the basis for determining offers and considering counteroffers in the negotiation process. CMS codifies these policies, including submission requirements for Primary Manufacturers, requirements for Primary Manufacturers to update submitted data, and how CMS will consider evidence from comparative effectiveness studies. These policies are consistent with statute and guidance for initial price applicability year 2028.
- **Negotiation Process.** CMS develops and uses a consistent methodology and process for negotiation with the aim of achieving agreement on "the lowest [MFP] for each selected drug" in accordance with section 1194(b)(1) of the Act. The negotiation process includes engagement with Primary Manufacturers and interested parties, including patients; the development and delivery of the written initial offer, including a concise justification, to the Primary Manufacturer of a selected drug; the ability for the Primary Manufacturer to accept an offer or provide a statutory written counteroffer; optional negotiation meetings between CMS and the Primary Manufacturer; additional price exchange opportunities; the conclusion of negotiation, including a final offer sent by CMS to the Primary Manufacturer, where applicable; and the publication of agreed-upon

MFPs and explanations of such MFPs. CMS codifies these policies for the negotiation process, including engagement with Primary Manufacturers and interested parties, the offer and counteroffer process, and the publication and explanation of the MFP. These policies are consistent with statute and guidance for initial price applicability year 2028.

- **Ineligibility for Selection, or Deselection of a Selected Drug Before or During Negotiation, or Following the Negotiation Period.** In accordance with sections 1192(c) and 1192(e) of the Act, a potential qualifying single source drug is not eligible for selection, a selected drug will no longer be subject to the negotiation process, and a selected drug will cease to be a selected drug, subject to certain timing and situations, if CMS determines: (1) the Food and Drug Administration (FDA) has approved a generic drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act that identifies as its reference-listed drug a product that is included in the potential qualifying single source drug or selected drug (as applicable), or FDA has licensed a biosimilar under section 351(k) of the Public Health Service Act that identifies as its reference product a product that is included in the potential qualifying single source drug or selected drug (as applicable); and (2) the generic drug or biosimilar, as applicable, is marketed pursuant to such approval or licensure. CMS codifies provisions regarding its identification of when such generic drug or biosimilar is marketed within the meaning of these statutory requirements ("Bona Fide Marketing"). Further, CMS codifies the criteria, process, and timing related to the determination of ineligibility of a potential qualifying single source drug that would otherwise be eligible for selection and to the determination of the deselection of a selected drug, with additional information provided on the points in time CMS reviews the information to determine if a generic drug is approved or a biosimilar is licensed and that the generic drug or biosimilar is subject to Bona Fide Marketing. CMS also codifies the criteria, process, and timing related to monitoring that the approved generic drug(s) or licensed biosimilar(s) continue to be subject to Bona Fide Marketing for any potential qualifying single source drug(s) that were previously considered ineligible for selection or for any selected drug(s) deselected because CMS determined that a generic drug is approved or a biosimilar is licensed and that generic drug or biosimilar is subject to Bona Fide Marketing. These policies are consistent with statute and build on CMS guidance regarding the timing of review of the information to evaluate whether a generic drug or biosimilar is subject to Bona Fide Marketing.
- **Renegotiation of an MFP.** Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs, the selection of drugs for renegotiation, and the renegotiation process. CMS codifies the criteria CMS will use to determine renegotiation eligibility and selection, the types of information CMS will consider when determining renegotiation eligibility and selection, opportunities and requirements for data submission, and the process for renegotiation, which will remain consistent, to the extent practicable, with the process and methodology used for negotiation. These policies are consistent with statute and guidance for initial price applicability year 2028. For renegotiation with respect to initial price applicability year 2029 and beyond, CMS finalizes its policy to consider the agreed-upon MFP for a drug selected for renegotiation as part of the consideration of section 1194(e)(1) factors.

Strengthening Program Integrity to Address Fixed Combination Drug Loophole

Under policy established for initial price applicability years 2026 through 2028, if a drug is a fixed combination drug with two or more active moieties, active ingredients, or, for a vaccine for infectious disease(s), antigen components, a potential qualifying single source drug is identified using the same distinct combination of active moieties, active ingredients, or antigen components. Under this policy, CMS is aware of a program integrity risk in which a manufacturer may avoid selection of a product or, in the case that such product is a qualifying single source drug that becomes a selected drug, avoid the application of the MFP, by marketing a new formulation of the product that includes, in addition to the active moiety(ies), active ingredient(s), or antigen component(s) in the product, an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the shared active moiety(ies), active ingredient(s), or antigen component(s). In this scenario, CMS is concerned that the fixed combination drug policy established for initial price applicability years 2026 through 2028 would be in tension with

the statutory requirement to identify qualifying single source drugs by aggregating across dosage forms and strengths of the drug, including new formulations of the drug, because CMS would not aggregate the original product and the new formulation containing the additional active moiety, active ingredient, or antigen component that creates a new formulation and enables for an alternative route of administration, even though these may be appropriately understood as different formulations of the same qualifying single source drug for purposes of the Negotiation Program.
To address this program integrity risk and ensure CMS is adhering to the statutory requirement to identify qualifying single source drugs by aggregating across drug dosage forms and strengths, including new formulations, CMS is finalizing its proposed policy regarding treatment of specific fixed combination drugs in CMS' determinations of qualifying single source drugs. Under this policy, if CMS determines that a fixed combination drug with two or more active moiety(ies), active ingredient(s), or, for a vaccine for infectious disease(s), antigen component(s) shares one or more active moiety(ies), active ingredient(s), or antigen component(s) with another drug or biological product with the same New Drug Application (NDA)/Biologics License Application (BLA) holder, and such products differ in active moiety(ies), active ingredient(s), or antigen component(s) due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), CMS will identify a potential qualifying single source drug using all dosage forms and strengths of the drug or biological product with the shared active moiety(ies), active ingredient(s), or antigen component(s) and the same NDA/BLA holder. For example, a product containing active ingredient X plus hyaluronidase will be identified as part of the same potential qualifying single source drug as a product offered by the same BLA holder that contains only active ingredient X, if the inclusion of hyaluronidase creates a new formulation and enables a new route of administration for active ingredient X.

Collection of Information to Inform Drug Selection and Drug Price Negotiation

In conjunction with publication of the final rule, CMS also submitted to OMB for approval revisions to two currently approved information collection packages (OMB 0938-1443 and OMB 0938-1452). These two packages collect information necessary for (1) a Biosimilar Manufacturer to submit a request, prior to the selected drug publication date for an initial price applicability year, for CMS' consideration to delay the inclusion of a Reference Drug on the selected drug list for such given initial price applicability year; (2) a Primary Manufacturer to voluntarily submit information that CMS may consider in determining eligibility and selection of drugs for renegotiation; (3) a Primary Manufacturer to voluntarily submit information to enable CMS to determine if a selected drug is a Small Biotech Drug for purposes of the Temporary Floor for Small Biotech Drugs; (4) Primary Manufacturers of selected drugs to submit information required for the negotiation and renegotiation of the MFP of the selected drug and for Primary Manufacturers and other interested parties to submit optional information about the selected drug and its potential therapeutic alternative(s) for use in negotiation and renegotiation of the MFP of the selected drug; and (5) instructions and a form for a Primary Manufacturer to submit a statutory written counteroffer for negotiation or a renegotiation written counteroffer for renegotiation in the case where the Primary Manufacturer does not accept CMS' written initial offer of an MFP.

Implementing Certain Provisions of the Inflation Reduction Act of 2022

Temporary Floor for Small Biotech Drugs

The exception for Small Biotech Drugs from being considered a negotiation-eligible drug under section 1192 of the Act applied to initial price applicability years 2026, 2027, and 2028. However, the definition of a "Small Biotech Drug" is applicable for the purpose of determining eligibility for the calculation of the Temporary Floor for Small Biotech Drugs, which limits CMS from offering or agreeing to a counteroffer for an MFP below such floor for selected drugs that are qualifying Small Biotech Drugs. The Temporary Floor for Small Biotech Drugs newly applies for initial price applicability years 2029 and 2030 and is included in this final rule. After considering the public comments, CMS is finalizing a modification to the treatment of non-FAMP in the adjusted ceiling calculation for certain selected drugs that are qualifying Small Biotech Drugs.

Negotiated Price for Selected Drugs

Section 11001(b) of the IRA amended section 1860D-2(d)(1) of the Act by adding subparagraph (D), which provides that, for selected drugs with respect to a price applicability period, the negotiated price "used for payment (as described in this subsection) shall be no greater than the [MFP] for such drug…plus any dispensing fees for such drug." CMS is codifying these policies consistent with prior guidance.

IRA Formulary Inclusion Requirement and Successor Regulation Exception

Section 1860D-4(b)(3)(I)(i) of the Act requires that for 2026 and each subsequent year, Part D plans must include each covered Part D drug that is a selected drug on Part D formularies if an MFP is in effect for that drug with respect to that year. Section 1860D-4(b)(3)(I)(ii) of the Act states that nothing in section 1860D-4(b)(3)(I)(i) of the Act shall be construed as prohibiting a Part D plan sponsor from removing a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation. In the Final CY 2026 Part D Redesign Program Instructions, we identified § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation for purposes of section 1860D-4(b)(3)(I)(ii) of the Act. CMS is codifying these policies consistent with prior guidance.

Maximum Fair Price Effectuation for 2028

CMS intends to release final guidance in fall 2026 to implement policies related to manufacturer effectuation of the MFP in 2028 for the Negotiation Program, consistent with the program instruction directive in sections 11001(c) and 11002(c) of the IRA. This guidance will specify the requirements for effectuation of the MFP, including with respect to drugs payable under Part B. CMS intends to codify MFP effectuation policies for 2029 and future years through Negotiation Program rulemaking in calendar year 2027.

Additional Resources

- Medicare Drug Price Negotiation Program: **https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program**
- Medicare Drug Price Negotiation Program Initial Price Applicability Year 2029 Key Milestones and Timeline: **https://www.cms.gov/files/document/negotiation-program-final-rule-timeline.pdf**