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Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Summary of CMS Guidance Memorandum

On March 15, 2023, the Centers for Medicare & Medicaid Services (CMS) published a memorandum[1] of proposed initial guidance pertaining to the Medicare Drug Price Negotiation Program (hereafter referred to as the Negotiation Program) as enacted in the Inflation Reduction Act (IRA, P.L. 117-169). The IRA required the Secretary of Health and Human Services (HHS) to implement the Negotiation Program for 2026-2028 through program instruction or other forms of program guidance, rather than notice-and-comment rulemaking.[2] This memorandum is the most comprehensive program guidance to date on the Negotiation Program.

Although CMS is not required to obtain comment from stakeholders in this program guidance, it is voluntarily soliciting comment on certain topics, as noted throughout this summary. C**omments are due by April 14, 2023.** After considering the public comments, CMS will issue revised guidance for initial applicability year 2026.

The organization of this summary follows the section numbers in the CMS memorandum.

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[1] https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf. The CMS materials also included a press release and a fact sheet, with key dates for implementation beyond those provided in guidance from January 11, 2023.

[2] Sections 11001(c) and 11002(c) of the IRA.

Section 10. Introduction

This initial guidance is for implementing the program in its first year, referred to as the initial price applicability year 2026. Per the IRA, CMS will publish the list of the first 10 Medicare Part D drugs[3] selected for negotiation by September 1, 2023. The maximum fair prices (MFPs) for those 10 drugs that result from the negotiations between HHS and those drugs' manufacturers will first apply in Part D for the initial price applicability year 2026 (January 1 through December 31, 2026).

This guidance also specifies requirements on manufacturers of the Medicare Part D drugs selected for negotiation as well as the procedures that may be applicable to those manufacturers, Medicare Part D plans (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs)), and providers and suppliers (including retail pharmacies) that furnish Medicare Part D drugs.

Section 20. Overview

For each initial price applicability year, federal statute in sections 1191 through 1198 of the Social Security Act[4] requires the Secretary to do the following:

- Establish the Negotiation Program (section 1191),
- Publish a list of selected drugs (section 1192),
- Enter into agreements with manufacturers of selected drugs (section 1193),
- Negotiate and, if applicable, renegotiate MFPs for such selected drugs (section 1194),
- Publish MFPs for selected drugs (section 1195),
- Carry out administrative duties and compliance monitoring (section 1196), and
- Enforce civil monetary penalties (CMPs) (section 1197).

Section 1198 establishes limitations on administrative and judicial review.

CMS is seeking comments on nearly all of the provisions in the memorandum, except for most of section 30 pertaining the drug selection process (and thus treated as final) and the excise tax that will be addressed separately by the Treasury Department and Internal Revenue Service (IRS). **The topics that CMS seeks comment on include the following**:

- Terms and conditions contained in the manufacturer agreement, including the manufacturer's and CMS' responsibilities (section 40),
- Approach for considering the manufacturer-reported data elements and evidence about alternative treatments (section 60),
- Process for the offer and counteroffer exchange between CMS and manufacturers (section 60),
- Content of an explanation for the MFP (section 60),
- Method for applying the MFP across different dosage forms and strengths of a selected drug (section 60),
- Dispute resolution process for specific issues not exempt from administrative and judicial review (section 60), and

[3] In this summary, the term "drugs" may refer to both drug products and biological products.
[4] Henceforth, all statutory references are to the Social Security Act unless otherwise specified.

- Processes for compliance monitoring and imposition of CMPs for violations (section 90).

Issues not relevant to initial price applicability year 2026 (for example, selection of Medicare Part B drugs) will be addressed in future guidance.

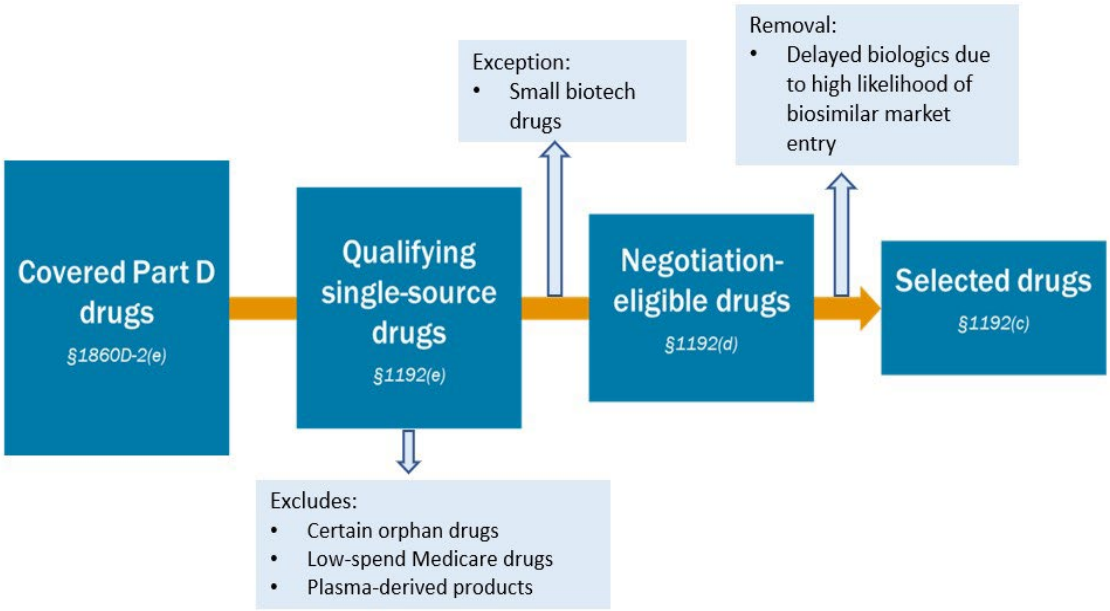
Section 30. Identification of Selected Drugs for Initial Price Applicability Year 2026

CMS is issuing section 30 as final, without a comment solicitation—with the exception of the Small Biotech Exception (SBE) Information Collection Request (ICR), as discussed in section 30.2.1. For initial price applicability year 2026, section 1192 specifies the steps for identifying the following:

- Qualifying single source drugs;
- From qualifying single source drugs, negotiation-eligible drugs—that is, the 50 qualifying single source drugs with the highest total expenditures[5] under Part D, using Part D prescription drug event (PDE) data for dates of service June 1, 2022, to May 31, 2023, and other information described below; and
- From negotiation-eligible drugs, the 10 Part D selected drugs, published on the Secretary's list (no later than September 1, 2023) that will be subject to the negotiation process and ultimately the MFP.

There are some statutory exceptions and exclusions, as described below along with additional details of the foregoing steps.

Figure 1. Process for Selecting Drugs for Negotiation, Initial Price Applicability Year 2026



[5] Total expenditures under Part D of Title XVIII in section 1191(c)(5) are total gross covered prescription drug costs, as defined in section 1860D-15(b)(3). The term gross covered prescription drug costs defined in the Part D regulations at 42 CFR §423.308 is slightly different. CMS has proposed aligning the regulatory definition with the statutory one to "eliminate any potential ambiguity" (87 FR 79611 through 79613).

30.1 Identification of Qualifying Single Source Part D Drugs for Initial Price Applicability Year 2026

Qualifying single source drugs are either of the following:

- A drug product approved by the Food and Drug Administration (FDA)[6] that is not the listed drug for any generic drug and for which at least 7 years have elapsed since the date of its approval; or
- A licensed biological product[7] that is not the reference product for any biosimilar and for which at least 11 years have elapsed since the date of that license.

Potential aggregation across different New Drug Applications (NDA). For purposes of determining whether a qualifying single source drug is a negotiation-eligible drug and applying the exception for small biotech drugs (described later), the statute requires CMS to "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug" (1192(d)(3)(B)).

Accordingly, CMS will aggregate all dosage forms and strengths of the drug with the same active ingredient[8] and the same holder of an NDA or Biologics License Application (BLA). This includes products marketed under different NDAs—as long as the drug uses the same active ingredient from the same NDA holder—including:

(1) Repackaged and relabeled products,
(2) Authorized generic drugs[9] (per 1192(e)(2)(A)), and
(3) Multimarket approval (MMA) products imported under section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On page 8 of the memorandum, CMS gives hypothetical examples demonstrating that drug products under multiple NDAs—using the same active ingredient held by the same entity—would be aggregated together as the same qualifying single source drug, despite those multiple NDAs' different strengths, delivery methods, and even repackaging by another entity. As stated in statute, this includes new formulations of the drug; CMS notes it is aware of new dosage forms or different routes of administration of the same active ingredient that have been submitted by the same NDA/BLA holder and approved under different NDAs/BLAs.

Fixed combination drugs. For a fixed combination drug (21 CFR §300.50) with multiple active ingredients, the distinct combination of those active ingredients will be considered one active ingredient and as its own qualifying single source drug. All formulations of this distinct combination offered by the same NDA/BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug.

[6] Approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act.
[7] Licensed under section 351(a) of Public Health Service Act (PHSA).
[8] In this guidance, CMS also uses the terms "active moiety" as well as "active moiety / active ingredient." For the sake of simplicity, this summary will use the term "active ingredient" to capture those other terms, as well.
[9] Authorized generic drugs are generic drugs that are produced (or authorized to be produced) by the same manufacturer as the brand-name drug, often beginning during the brand-name drug's period of exclusivity (i.e., before other manufacturers can produce a generic version).

Years since approval. To determine the date of approval or licensure for a potential qualifying single source drug with more than one application number from the FDA, CMS intends to use the earliest date of approval of the initial FDA application number assigned to the NDA/BLA holder for the active ingredient—or in the case of fixed combination drugs, for the distinct combination of active ingredients.

The selected drug publication date for initial price applicability year 2026 is September 1, 2023. Thus, for initial price applicability year 2026, to be considered a qualifying single source drug:

- The initial approval for a drug product must have been on or before September 1, 2016, and
- The date of initial licensure for a biological product must have been on or before September 1, 2012.

Generic/biosimilar determination. A brand product that has a generic/biosimilar approved and marketed cannot be considered a qualifying single source drug.[10] CMS will determine this based on FDA reference sources, including the Orange Book and the Purple Book.

The statute lays out the period from which the data will be used in the generic/biosimilar determination. Accordingly, for initial price applicability year 2026, CMS will review PDE data for a generic/biosimilar during the 12-month period from August 16, 2022 to August 15, 2023, using PDE data available on August 16, 2023. A generic/biosimilar will be considered as marketed when that data reveal the manufacturer of that generic/biosimilar has engaged in bona fide marketing of that product.

If any strength or dosage of a potential qualifying single source drug is the listed drug or reference product for one or more generic(s)/biosimilar(s) biological that CMS determines are approved and marketed based on the process described above, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026.[11] CMS will monitor the generic/biosimilar manufacturers to ensure they are engaging in bona fide marketing of the generic/biosimilar (details in section 90.4).

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

Orphan drugs are to be excluded from the list of qualifying single source drugs (1192(e)(3)(A)). Orphan drugs are designated for only one rare disease or condition under section 526 of the FD&C Act and are approved for only an indication (or indications) for such disease or condition. For the orphan drug exclusion, all dosage forms and strengths and different formulations of the drug must meet the criteria for exclusion. For these determinations, CMS will use the FDA Orphan Drug Product designation database and approvals on the FDA website and will consult with FDA as needed. CMS says it is considering whether there are additional actions it can take

[10] That is, a qualifying single source drug cannot be the listed drug for any drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act, and a biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the Public Health Service (PHS) Act.

[11] The apparent corollary is that if drugs/biologics from multiple NDAs but using the same active ingredient had one of those NDAs become a listed drug or reference product, then the listed drug or reference product would not be considered a qualifying single source drug.

in its implementation of the Negotiation Program to best support orphan drug development but, as previously mentioned, CMS is not seeking comment on these provisions in section 30.

30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs

Low-spend Medicare drugs (less than $200 million in combined expenditures under Medicare Parts B and D) are to be excluded from the list of qualifying single source drugs (1192(e)(3)(B)). For initial price applicability year 2026, this will be based on Part D PDE data and Part B claims data with dates of service from June 1, 2022, and ending May 31, 2023 (and as submitted by June 30, 2023), including Part B beneficiary cost sharing.

30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

Plasma-derived products are to be excluded from the list of qualifying single source drugs (1192(e)(3)(C)). A plasma-derived product is a biological derived from human whole blood or plasma, as indicated on the approved product labeling. For these determinations, CMS will rely on the FDA Approved Blood Products website, the FDA Online Label Repository to verify the product is derived from human whole blood or plasma, and consultations with FDA as needed.

30.2 Identification of Negotiation-Eligible Part D Drugs for Initial Price Applicability Year 2026

For identifying the negotiation-eligible drugs (that is, the qualifying single source drugs in the top 50 for Medicare Part D expenditures), CMS will:

- Use Part D PDE data for dates of service June 1, 2022, to May 31, 2023 (as submitted by June 30, 2023) and sum those expenditures;
- Remove the drugs meeting the exception for small biotech drugs (described in 30.2.1);
- Rank the remaining qualifying single source drugs by total expenditures; and
- Identify the top 50 as negotiation-eligible drugs.

30.2.1 Exception for Small Biotech Drugs

For initial price applicability years 2026-2028, small biotech drugs are to be excluded from the list of negotiation-eligible drugs (1192(d)(2)). Based on total Part D expenditures in 2021, the Small Biotech Exception applies to drugs meeting the following criteria:

- The manufacturer that had a Part D Coverage Gap Discount Program agreement (CGDP agreement) in effect for that drug during 2021,
- Part D total expenditures for that drug were not more than 1 percent of all coverage Part D drugs, and
- The drug represented at least 80 percent of the manufacturer's Part D total expenditures, for its drugs with a CGDP agreement, excluding repackers and relabelers.[12]

[12] In statute, the Small Biotech Exception has an aggregation rule to treat certain entities as a single manufacturer (1192(d)(2)(B)(i)). Because CMS does not have this information, manufacturers seeking the Small Biotech Exception must submit the information to be considered for the exception, and only the holder of the NDA/BLA may submit the request for exception. The Small Biotech Exception ICR was published on January 24, 2023, with comments due by March 27, 2023 (88 FR 4184). That ICR applies to initial price applicability year 2026 only,

CMS anticipates the deadline for submitting the Small Biotech Exception ICR, using the CMS Health Plan Management System (HPMS), will be in June 2023 but will publish a specific deadline on CMS' IRA website in the future. Qualifying for the exception for initial price applicability year 2026 does not mean it will apply in initial price applicability years 2027 and 2028; manufacturers must resubmit a request for those other years, with the specific process to be addressed in future guidance.

The memorandum walks through how CMS will use the complete set of 11-digit National Drug Codes (NDC-11s),[13] the members of the manufacturer's control group, and other details for determining eligibility for the Small Biotech Exception.

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026

For selecting the 10 negotiation-eligible drugs subject to negotiation in initial price applicability year 2026, CMS would:

- Rank the negotiation-eligible drugs in order of total Part D expenditures,
- Remove those biologicals with a high likelihood of biosimilar market entry per 1192(b)(1)(C) and 30.3.1 below,
- Select the top 10.

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

The Biosimilar Delay described here is based on 1192(b)(1)(C) and 1192(f), which allows the Secretary to delay—by no more than 2 years—a biological from being selected for negotiation if:

- The Secretary determines there is a high likelihood that a biosimilar will be both licensed (approved by the FDA) and marketed (sold in the marketplace) within 2 years,
- It is an extended-monopoly drug,[14] and
- In the absence of this exception, it would be a selected drug.

Based on the statute, the initial 1-year delay can only be requested by a Biosimilar Manufacturer—that is, not by the manufacturer of the reference biological. This request must be made prior to the selected drug publication date in which the biological product would have been included, or September 1, 2023 for initial price applicability year 2026. Similarly, the second (and final) 1-year delay can only be requested by a Biosimilar Manufacturer prior to the 1-year anniversary of the selected drug publication date in which the biological product would have been included, or September 1, 2024.

because it does not address policies that will be implemented later (for example, accounting for mergers applicable beginning initial price applicability year 2027 and Part B drugs beginning initial price applicability year 2028).

[13] NDC-9 and NDC-11 numbers are identical except for two numbers in NDC-11s that indicate package size. Thus, multiple NDC-11 numbers can aggregate under a single NDC-9 number.

[14] An extended-monopoly drug is a drug that has been on the market for at least 12 and less than 16 years—excluding vaccines licensed under section 351 of the PHSA and selected drugs before initial price applicability year 2030.

Based on the memorandum, the Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the biosimilar or, if the biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by the FDA. The following specifics apply only to the initial Biosimilar Delay for initial price applicability year 2026.

30.3.1.1 Requirements for Granting an Initial Biosimilar Delay Request. The memorandum lists 7 statutory requirements for the Biosimilar Delay, supplemented with CMS guidance to Biosimilar Manufacturers who might submit a request:

1. Without the Biosimilar Delay, the reference drug would be a selected drug (1192(f)(1)(A)).
    - Because drugs eligible for the Biosimilar Delay must be determined by CMS before the publication of the 10 selected drugs, the Biosimilar Manufacturer must submit the request by May 10, 2023, as described below in section 30.3.1.3.
    - Biosimilar Manufacturers who think that a reference drug for their biosimilar may be a selected drug for initial price applicability year 2026 may submit an initial delay request. CMS will disregard the request if the reference drug would not be a selected drug. CMS encourages Biosimilar Manufacturers to consult publicly available data to determine the likelihood that a drug may be selected for negotiation.
2. The reference drug must be an extended-monopoly drug (1192(f)(1)(A)).
    - For initial price applicability year 2026, the drug must have received its initial BLA licensure between January 1, 2010, and January 1, 2014.
3. The biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by the FDA or accepted for review (described below in 30.3.1.2) must identify the reference drug (1192(f)(1)(A)).
    - The licensure application for the biosimilar does not need to include all of the dosage forms, strengths, and indications for which the reference drug has received approval.
4. An initial delay request cannot be granted if more than one year has elapsed since the licensure of the biosimilar and marketing of the biosimilar has not commenced (1192(f)(2)(D)(iii)).
    - If the biosimilar has already received approval by the FDA, the date of that licensure must be on or after September 1, 2022, for a delay to be granted.
    - If the biosimilar is already licensed and marketed by September 1, 2023, the reference drug would by definition no longer be a qualifying single source drug.
    - If the biosimilar was licensed prior to September 1, 2022, and is not marketed before September 1, 2023, then more than one year would have elapsed since the licensure of the biosimilar without its marketing, thus disqualifying the reference drug from the delay request.
5. Per 1192(f)(2)(D)(iv), the Biosimilar Manufacturer cannot be the Reference Manufacturer or treated as the same per the aggregation rule in 1192(f)(1)(C).
    - Under the aggregation rule, all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC), or in a partnership, shall be treated as one manufacturer.
    - Partnership is defined as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or

venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer (1192(f)(1)(C)(ii)).

6. The Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit an initial delay request, or directly or indirectly restricts the quantity of the biosimilar that may be sold in the United States over a specified period of time (1192(f)(2)(D)(iv)).
    - For delay requests with respect to initial price applicability year 2026, CMS will consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the biosimilar that the Biosimilar Manufacturer may sell for any period of time on or after September 1, 2023, as violating this requirement.
7. As described in 30.3.1.2 below, CMS must determine there is a high likelihood that the biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year (1192(f)(1)(A)).

30.3.1.2 High Likelihood. CMS will review Initial Delay Requests to determine if there is a high likelihood that the biosimilar will be licensed and marketed before the date two years after the selected drug publication date for the initial price applicability year (1192(f)(1)(A))—that is, by September 1, 2025, for initial price applicability year 2026. In defining "high likelihood," the statute requires the following two criteria (1192(f)(3)), supplemented with CMS guidance:

- The biosimilar's application for licensure under section 351(k) of the PHS Act has been accepted or approved by the FDA.
    - For initial price applicability year 2026, the biosimilar's application must be accepted or approved by August 15, 2023.
- Clear and convincing evidence submitted by the Biosimilar Manufacturer that the biosimilar will be marketed before September 1, 2025, demonstrating both of the following:
    - That patents related to the reference drug are unlikely to prevent the biosimilar from being marketed, and
    - That the Biosimilar Manufacturer will be operationally ready to market the biosimilar.

With respect to the requirement that patents related to the reference drug be unlikely to prevent the biosimilar from being marketed, CMS will consider the requirement met if any of the following is true, else the Initial Delay Request will be denied:

(1) There are no non-expired approved patent applications relating to the reference drug that are applicable to the biosimilar;
(2) There is any court decision that establishes the invalidity, unenforceability, or non-infringement of any potentially applicable non-expired patent relating to the reference drug that the patent holder asserted was applicable to the biosimilar; or
(3) The Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the biosimilar in one or more dosage form(s), strength(s), and indication(s) before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer.

CMS adds that if the Biosimilar Manufacturer is engaged in active litigation with the Reference Manufacturer regarding the reference product identified in the biosimilar's application, the Initial Delay Request will be denied.

With respect to the requirement that the Biosimilar Manufacturer be operationally ready to market the biosimilar before September 1, 2025, CMS will consider the manufacturer's progress that typically leads up to the marketing of a drug, as evidenced by both of the following:

(1) Disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing a biosimilar before September 1, 2025; and
(2) A manufacturing schedule consistent with the public-facing statements and any revenue expectations.

When assessing whether there is clear and convincing evidence that the biosimilar will be marketed by September 1, 2025, CMS is required by statute to use information from several specific sources (1192(f)(3)(B)):

- All agreements related to the biosimilar filed with the Federal Trade Commission (FTC) or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- The manufacturing schedule for the biosimilar submitted to the FDA during its review of the application for licensure; and
- Required disclosures in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year that pertain to the marketing of the biosimilar, or comparable documentation distributed to shareholders of privately held companies.

CMS notes that its determination of an Initial Biosimilar Delay is not subject to administrative or judicial review, per the statute (1198(2)).

30.3.1.3 Submitting an Initial Biosimilar Delay Request.

CMS says that a Biosimilar Manufacturer should only submit an Initial Delay Request for initial price applicability year 2026 if it meets all of the following:

1. Plans for its biosimilar to be licensed and marketed by September 1, 2025;
2. Believes its request will satisfy the statutory requirements for granting the request, as described in section 30.3.1.1; and
3. Believes its request demonstrates a high likelihood that the biosimilar will be licensed and marketed by September 1, 2025, based on the criteria in section 30.3.1.2.

The memorandum details how Biosimilar Manufacturers may submit their Initial Delay Requests by May 10, 2023. Biosimilar Manufacturers are encouraged to use the template provided in Appendix A of the memorandum (not reproduced or summarized here) for requests intended to be submitted by email. In response, CMS will provide a fillable template for the Initial Delay Request form provided in Appendix B of the memorandum (not reproduced or summarized here).

A complete Initial Delay Request must be uploaded by May 22, 2023, or it will be denied.

30.3.1.4 Process and Timing After Submission of an Initial Biosimilar Delay Request. In this section, CMS describes at length its review process for the Initial Biosimilar Delay Request and some associated key dates. Those key dates are shown below:

Date	Deadline / milestone
11:59 pm PT on May 10, 2023	Deadline for Biosimilar Manufacturer to email CMS regarding intent to submit Initial Delay Request for initial price applicability year 2026
11:59 pm PT on May 22, 2023	Deadline for Biosimilar Manufacturer to submit the documentation for its Initial Delay Request per section 30.3.1.3
June 20, 2023	Deadline for CMS to request follow-up information for a submitted Initial Delay Request, if applicable
July 3, 2023	Deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS, if applicable
11:59 pm PT on August 15, 2023	Deadline for biosimilar licensure application to be accepted for review or approved by FDA; deadline for Biosimilar Manufacturer to submit follow-up information requested by CMS regarding application for licensure
September 1, 2023	Statutory deadline for CMS to publish the selected drug list for initial price applicability year 2026
September 2023	CMS informs each Biosimilar Manufacturer that submitted an Initial Delay Request of the results of such request, in writing; for successful Initial Delay Requests, CMS also informs the Reference Manufacturer
Mid-2024 (specific date in future guidance)	For successful Initial Delay Requests, CMS determines whether the Biosimilar has been licensed and marketed during the initial delay period

30.4 Publication of the Selected Drug List

No later than September 1, 2023, CMS will publish on its IRA webpage the 10 drugs selected for negotiation for initial price applicability year 2026.

Section 40 – Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026

The Secretary must enter into agreements with the manufacturers of selected drugs and negotiate an MFP with the manufacturer of each selected drug.[15]

- **Primary Manufacturer**. If more than one entity meets the statutory definition of manufacturer for a selected drug, CMS intends to designate the entity that holds the NDA(s)/BLA(s) to be "the manufacturer" of the selected drug (hereafter referred to as the Primary Manufacturer[16]).
- **Secondary Manufacturer**. A Secondary Manufacturer is any other entity that meets the statutory definition of manufacturer for a selected drug and that either (1) is listed as a

[15] According to 1191(c)(1), the term "manufacturer" has the meaning given in section 1847A(c)(6)(A).
[16] For the remainder of this summary, this will refer specifically to the Primary Manufacturer of a selected drug for initial price applicability year 2026.

manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer. Secondary Manufacturers include manufacturers of authorized generics and any repackers or relabelers of the selected drug that meet these criteria.

- **Medicare Drug Price Negotiation Program Agreement**. CMS intends to sign a Medicare Drug Price Negotiation Program Agreement (hereafter referred to as the Agreement) with the Primary Manufacturer. CMS believes this aligns with the statutory requirement to determine an MFP with the manufacturer of the selected drug (1193(a)).

Section 40 describes the Agreement and the requirements of the Primary Manufacturer and its participation in the Negotiation Program. CMS does not intend to enter into an agreement with any Secondary Manufacturer but will include several requirements on the Primary Manufacturer that pertain to the Secondary Manufacturer, per 1193(a)(4), including:

- Provide a list of any Secondary Manufacturer(s) and the applicable NDC-11s of the selected drug marketed by each such Secondary Manufacturer(s);
- Collect and report necessary information applicable to any Secondary Manufacturer(s), as described in section 40.2; and
- Ensure that any Secondary Manufacturer(s) make the MFP available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers (1193(a)(1), and sections 40.4 and 80 of the memorandum).

Thus, each Primary Manufacturer will do all of the following, as applicable (with applicable statutory references and reference to where additional guidance is provided in the memorandum):

1. Signs the Agreement with CMS (section 40.1);
2. Collects and reports all data required for negotiation per section 1193(a)(4), including the negotiation data elements (sections 40.2 and 50.1, and Appendix C);
3. Negotiates an MFP with CMS (section 40.3);
4. Ensures the MFP is made available to all MFP-eligible individuals and to pharmacies, mail-order services, and others dispensing the selected drug to those individuals (section 40.4);
5. Responds to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities, and pays any CMPs for violations (section 40.5);[17]
6. Address termination of an agreement (section 40.6); and
7. Address other provisions of the Agreement—for example, if the Primary Manufacturer transfers the NDA(s)/BLA(s) of the selected drug to another entity (section 40.7).

CMS seeks comment on the policies described in section 40, including other ways it might operationalize the statutory requirement to negotiate a single MFP with "the manufacturer" of a selected drug.

[17] Such violations include violating the terms of the Agreement, providing false information, failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but that has since undergone negotiation per 1192(f)(4), or not providing access to the MFP to MFP-eligible individuals, and to the pharmacies, mail order services, and other dispensers that serve them.

40.1 Entrance into an Agreement with CMS

October 1, 2023 is the deadline for the Primary Manufacturer of a selected drug to enter into an agreement with CMS regarding initial price applicability year 2026 (1193(a)). CMS intends to use the CMS HPMS to identify the points of contact and to and store effectuate the Agreement, which will contain the requirements described in sections 40.1 through 40.7 below.

Within 5 days of CMS publishing the list of selected drugs, the Primary Manufacturer of a selected drug that elects to enter into an Agreement with CMS must submit to CMS all names, titles, and contact information for representatives authorized to execute the Agreement and conduct the negotiation. The individual(s) must be legally authorized to bind the Primary Manufacturer to the terms and conditions in the Agreement—at least one of whom must access the CMS HPMS and sign the Agreement by October 1, 2023.

The negotiation period for initial price applicability year 2026 will begin on the earlier of:

1. The date on which the Agreement is executed (that is, signed by both CMS and the Primary Manufacturer) or
2. October 1, 2023.

If an Agreement is fully executed before October 1, 2023, the negotiation period would begin on the date on which the Agreement is signed by the last party to sign it.

If the Agreement is not fully executed by October 1, 2023, then pursuant to 26 USC 5000D(b)(1), a noncompliance period would begin on October 2, 2023, and could result in excise tax liability (see section 90.3). CMS notes that entering into an Agreement is voluntary. CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list for initial price applicability year 2026 is published.

40.2 Submission of Data to Inform Negotiation

Consistent with the statute, after (and only after) entering into the Agreement, the Primary Manufacturer must submit to CMS the following no later than October 2, 2023:

- Information on the non-federal average manufacturer price[18] (non-FAMP) of the selected drug, as described in section 50.1.1; and
- Any information that CMS requires to carry out negotiation, including the factors listed in section 1194(e)(1) of the Act, as described in section 50.1 below (with additional details in Appendix C of the memorandum).

Although data elements may not be submitted prior to execution of the Agreement, Primary Manufacturers will be able to access the data elements template in the CMS HPMS, and CMS believes Primary Manufacturers will be able to gather these data prior to the Agreement being executed. This includes data on products included in the selected drug marketed by any Secondary Manufacturer(s).

[18] At 38 USC 8126(h)(5), the term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary [of Veterans Affairs]), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount.

CMS intends to populate the HPMS with a list of the approved and marketed NDC-11s used to calculate the total expenditures for each selected drug, as described in sections 30.2 and 30.3. A Primary Manufacturer must either:

- Attest that the listed NDC-11s are correct and marketed by the Primary Manufacturer or any Secondary Manufacturer(s) and that no NDC-11s are incorrectly included or missing from the list, or
- Provide any corrections to CMS.

CMS intends to collect this information in the HPMS along with other data elements specified in section 50.1. CMS also intends to require a Primary Manufacturer to report to CMS in writing:

- Any new approved and marketed NDC-11s of the selected drug at least 30 days before the first marketed date for any Primary Manufacturer or Secondary Manufacturer, and
- The delisting of any NDC-11 of the selected drug that is no longer marketed by the Primary Manufacturer or any Secondary Manufacturer(s) within 30 days after its discontinuation.

CMS is seeking comment on this section—specifically, on the requirements that Primary Manufacturers:

- Submit data under section 1193(a)(4), including the factors listed in section 1194(e)(1), for the Primary Manufacturer and any Secondary Manufacturer(s); and
- Report to CMS any new approved and marketed NDC-11s, or discontinued NDC-11s, of the selected drug for the Primary Manufacturer and on behalf of any Secondary Manufacturer(s).

40.2.1 Confidentiality of Proprietary Information

The statute requires CMS to determine which information submitted by a manufacturer is proprietary information of that manufacturer (1193(c)). Information deemed proprietary will only be used by CMS or disclosed to and used by the U.S. Comptroller General (the head of the Government Accountability Office) for purposes of carrying out the Negotiation Program. Proprietary information, including trade secret and confidential commercial or financial information, would also be protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 USC 552(b)(4)).

CMS intends to implement a confidentiality policy that is consistent with existing requirements for protecting proprietary information, such as Exemption 4 of FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating as proprietary any information that does not qualify.

For initial price applicability year 2026, CMS intends to treat the following as proprietary:

- Information on non-FAMP,
- Certain data elements submitted in accordance with section 1194(e)(1) if the information constitutes commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that cannot be found publicly, and

- Research and development costs and recoupment, unit costs of production and distribution, pending patent applications, and market data and revenue and sales volume data, unless the information is already publicly available.

CMS intends to treat the data on prior federal funding and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because they are available publicly.

As described below in section 60.6.1, CMS is required to publish the explanation for the MFP by March 1, 2025 for initial price applicability year 2026. CMS will make high-level comments about the data submitted, without sharing any proprietary information. For example, CMS does not intend to make public the research and development costs reported by a Primary Manufacturer but may say "the manufacturer has recouped its research and development costs."

CMS intends for the confidentiality provisions of the Agreement to survive the Agreement's termination.

CMS is seeking comment on the confidentiality policy described in this section 40.2.1—specifically, on the following:

- Which manufacturer data elements require submission of proprietary information and the basis for such conclusion,
- The type of information that would not be considered proprietary and that CMS could include in the public explanation of MFP, and
- The proper balance between the public's interests in transparency and the protection of business information in this context.

40.2.2 Data Use Provisions and Limitations

Citing section 1193(a)(5), which requires a manufacturer of a selected drug to comply with requirements determined necessary by the Secretary, CMS intends to impose the following requirements on Primary Manufacturers regarding the submission of and use, disclosure and destruction of data and other information received during the negotiation process. CMS states that this aligns with how negotiations are typically conducted by other entities and believes these requirements are in furtherance of the statutory instruction that CMS develop a process that aims to achieve the lowest MFP for each selected drug. According, CMS intends to require that Primary Manufacturers signing the Agreement do the following:

- Use the CMS HPMS;
- Comply with all relevant procedures and policies set forth in the CMS HPMS for utilizing the system;
- Not disclose to the public any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, or any information contained in any concise justification provided with an offer;
- Not disclose to the public any information exchanged verbally during the negotiation period
- Not record (audio or video) any oral conversations with CMS;

- Not use information in the initial offer, including the ceiling price, or the concise justification from the Secretary or any subsequent offer or concise justification, nor information derived from those justifications or offers, for any purposes other than the Medicare Drug Negotiation Program, except as may be required by applicable state or federal law;
- Within 30 days of a determination by CMS that the drug no longer qualifies as a selected drug, destroy all information received from CMS by the Primary Manufacturer during the negotiation period, except as may be required by applicable state or federal law.
    - The Primary Manufacturer must submit a Certificate of Data Destruction to CMS certifying that all information received from CMS during the negotiation period and potential renegotiation period(s), including the initial offer and any subsequent offers, and the concise justification(s), and any written notes or emails pertaining to negotiations (or renegotiations) with CMS, has been destroyed.
    - This Certificate of Data Destruction must be submitted to CMS within 30 days after a determination by CMS that the drug no longer qualifies as a selected drug.

CMS believes these policies will increase the chances of effective and successful negotiation, in furtherance of the statutory instruction that CMS develop a process that aims to achieve the lowest MFP for each selected drug.

CMS seeks comment on this section—specifically on the following:

- The limitations CMS intends put on the use of information in the initial offer, any subsequent offer, and any concise justification;
- Whether there are possible scenarios where a manufacturer might need to disclose this information; and
- The data destruction policies and scenarios where a manufacturer might need to retain certain pieces of information—for example, to comply with state or federal laws.

40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years

CMS intends for the Agreement to include the negotiation process and timeline outlined in statute and in section 60, with the HPMS used to share the initial offer and concise justification, as well as any subsequent offer and justification, and to receive any counteroffer(s) from the Primary Manufacturer.[19]

40.4 Providing Access to the MFP

As previously mentioned and described in greater detail in section 80, the manufacturer of a selected Part D drug subject to an Agreement must provide access to the MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers with respect to such MFP-eligible individuals who are dispensed that drug during a price applicability period.

[19] Although the statute provides for renegotiating the MFP beginning with 2028, CMS plans to release that guidance in the future.

The negotiated prices used by each Part D plan sponsor for selected Part D drugs cannot exceed the applicable MFP plus any dispensing fees, which is the basis for determining beneficiary cost-sharing and for benefit administration at the point of sale. Thus, while section 1193(a)(1)(A) specifies that manufacturers must provide access to the MFP to MFP-eligible individuals, that will be accomplished by Part D plan sponsors without additional steps required of the manufacturer.

CMS also intends to require that the Primary Manufacturer to ensure that entities that dispense drugs to MFP-eligible individuals—pharmacies, mail order services, and other dispensers—have access to the MFP for the selected drug per 1193(a) and as discussed in section 90.2. CMS intends to define "providing access to the MFP" as ensuring that the amount paid by the dispensing entity for the selected drug is no greater than the MFP.

Primary Manufacturers may provide access to the MFP in one of two ways (and which extends to any Secondary Manufacturer):

- Ensuring the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or
- Providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP.

To satisfy the statutory requirements for providing access to the MFP, CMS would require Primary Manufacturers to do the following:

- At least 30 days before the start of the initial price applicability year, submit its process in writing to CMS for making the MFP available.
    - CMS intends to publish these processes on the CMS IRA website.
    - For initial price applicability year 2026, a Primary Manufacturer must send its process for ensuring MFP availability to CMS in writing by December 2, 2025.
- Retain for at least 10 years from the date of sale any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals (see section 90.2).
- Ensure that pharmacies, mail order services, and other dispensers as well as intermediate entities, such as wholesalers, as applicable, are reimbursed timely for the full amount of the difference between their acquisition cost for the selected drug and the MFP within 14 days. Manufacturers or their contracted entities shall not charge any transaction fee for this process.

The Agreement would not restrict the Primary Manufacturer or Secondary Manufacturer(s) from offering a price lower than the MFP.

40.4.1 Nonduplication with 340B Ceiling Price

If the 340B ceiling price is lower than the MFP for a selected drug, the Primary Manufacturer is not required to provide access to the MFP for that drug to MFP-eligible individuals who are eligible to receive that drug at a covered entity, as those terms are described in section 340B(a) of the PHS Act. However, if the MFP is lower than the 340B ceiling price, then the Primary Manufacturer is required to provide the MFP to the covered entity.

40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

Per 1193(a)(5) and as described in section 90, the Primary Manufacturer under an Agreement must comply with requirements determined by CMS to be necessary for administering and monitoring compliance in the program.

40.6. Termination of the Agreement

The Agreement will remain in effect, including through renegotiation (as applicable), until the selected drug is no longer considered a selected drug (section 70) or is terminated by either party.

40.7. Other Provisions in the Agreement

All notices and communications to CMS would be sent via email to IRARebateandNegotiation@cms.hhs.gov.

After entering into an Agreement, if the Primary Manufacturer transfers the NDA(s)/BLA(s) of the selected drug to another entity, CMS will continue to hold the Primary Manufacturer responsible for all requirements of the Agreement and the requirement to provide access to the MFP—unless and until the Primary Manufacturer transfers such requirements to the new holder of the NDA(s)/BLA(s). The Primary Manufacturer would continue to be responsible for any outstanding negotiation rebate liabilities related to the biosimilar delay provision, unless and until such liabilities are transferred to the new holder of the NDA(s)/BLA(s), with notice of any such transfer required to be sent to CMS at least 30 days before the effective date of the transfer.

If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if the invalid or unenforceable provision(s) were eliminated, and without any effect on any other provisions.

Section 50. Negotiation Factors

The Primary Manufacturer of a selected drug is statutorily required (1193(a)(4)), as part of the Agreement, to submit to the Secretary:

(1) Information on the non-FAMP for the selected drug (which is the average price wholesalers pay for the drug distributed to purchasers outside the federal government);[20]
(2) Information the Secretary requires to carry out the negotiation (and renegotiation) process; and
(3) If applicable, information the Secretary requires to apply the rule for delaying the selection and negotiation of biologics for biosimilar market entry.

The CMS guidance points to applicable manufacturer-specific data described in section 1194(e)(1) of the Social Security Act (described in further detail in section 50.1.1) as factors on

[20] Appendix C of this CMS guidance states that CMS intends to define the non-FAMP, in accordance with the definition under section 1194(c)(6), as the average of the non-FAMP (as defined in 38 USC 8126(h)(5)) for the four calendar quarters of the year involved. The non-FAMP unit is to be defined as the package unit, as described at 38 USC 8126(h)(5).

which the Primary Manufacturer will be required to report. CMS is statutorily required to consider as the basis for determining offers and counteroffers in the negotiation process, as applicable to the selected drug, the manufacturer-specific data, as submitted by the manufacturer, and available evidence on therapeutic alternatives to the selected drug.[21]

The guidance specifies that CMS intends to release a Negotiation Data Elements ICR that describes how CMS will collect (and how Primary Manufacturers and members of the public may submit relevant data on) the non-FAMP data, the manufacturer-specific data described in section 1194(e)(1), and the data on available evidence about therapeutic alternatives to the selected drug.

The manufacturer-specific data described in section 50.1 and the data on evidence about therapeutic alternatives described in section 50.2 for drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023.

50.1 Manufacturer-Specific Data

The following are the manufacturer-specific data factors that CMS is required to consider as the basis for determining offers and counteroffers for the MFP of a selected drug:

1. Research and development costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturers;
3. Prior federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer, except costs related to the acquisition of the selected drug would be reported only for the Primary Manufacturer.

The guidance states that for purposes of the required data submissions, the Primary Manufacturer of a selected drug will be responsible for aggregating data from the Primary Manufacturer and any Secondary Manufacturers[22] and reporting such aggregated information.

50.1.1 Non-FAMP Data

For initial price applicability year 2026, the Primary Manufacturer will be required to submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four

[21] Section 1194(e)(1) specifies the manufacturer-specific data that CMS must consider, as submitted by the manufacturer. Section 1194(e)(2) describes the available evidence on therapeutic alternatives that must be considered by CMS.
[22] The CMS guidance specifies the Primary Manufacturer would be required to aggregate such data, including for the non-FAMP, current unit costs of production and distribution, and certain data within market data and revenue and sale volume data.

quarters of calendar year 2021. In the case there is no non-FAMP for the selected drug in calendar year 2021, the Primary Manufacturer will be required to submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of the first full year following market entry of such drug.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

For purposes of negotiating the MFP of a selected drug of a manufacturer, in determining offers and counteroffers, CMS is statutorily required (1194(e)(2)) to consider evidence about alternative treatments to the selected drug, as available:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives (and the costs of such existing therapeutic alternatives);
2. FDA-approved prescribing information for the selected drug and therapeutic alternatives;
3. Comparative effectiveness of the selected drug and therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Information on the evidence about alternative treatments may be submitted by the Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties.

Treatment of Comparative Clinical Effectiveness. Generally note that for factor 3 above (relating to evidence on comparative effectiveness), CMS is statutorily prohibited from using evidence from comparative clinical effectiveness research (such as certain quality-adjusted life years (QALYs)) in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

- Accordingly, the CMS guidance states that entities making submissions should indicate whether the submission contains information from studies that use QALYs in a life-extension context.
- The CMS guidance also states that in the case of a study that clearly separates the prohibited use of QALYs from other evidence that is relevant to the factors listed above, CMS will consider that separate evidence.

CMS is soliciting comment on other metrics that should be excluded from consideration in determining offers and counters because such metrics may treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value.

Considerations taken into account in reviewing evidence. The guidance states that in considering evidence on alternative treatments to a selected drug, CMS will:

- Review literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts;
- Consider the source of the literature, rigor of the study methodology (and if it went through peer review), and relevance of the study to the selected drug and its therapeutic alternative;[23]
- Prioritize research that is methodologically rigorous and with a sufficient sample; and
- Prioritize research with a primary focus on Medicare populations for purposes of considering the impact of the selected drug and alternative treatments on specific populations and patients with unmet medical needs (i.e., factors 3 and 4 above).

Section 60. Negotiation Process

CMS is statutorily required to develop and use a consistent methodology and process for negotiation that "aims to achieve the lowest maximum fair price (MFP) for each selected drug" (1194(b)(1)). The Secretary and Primary Manufacturer of a selected drug are, as specified in statute, to negotiate to determine the MFP with respect to a selected drug, which, unless subject to the renegotiation process, would apply to the drug with respect to each year during the price applicability period (1193(a)). Section 1194 provides for a negotiation process under which:

(1) CMS makes an initial written MFP offer that includes a concise justification of the factors (i.e., the manufacturer-specific data factors and evidence about alternative treatments factors described above) used to develop the initial MFP offer;
(2) The manufacturer must respond in writing (that accepts the initial offer or makes a counteroffer justified by the factors above); and
(3) The Secretary must respond in writing to any such counteroffer.

The Secretary is prohibited from making an offer or accepting a counteroffer that exceeds a ceiling.

60.1. Establishment of a Single Proposed MFP for Negotiation Purposes

CMS interprets the statute as requiring a single price negotiation for a selected drug with respect to its price applicability period, and to accomplish that CMS will:

- Identify a single price to include for each offer and counteroffer in the negotiation process for a selected drug, including in the case of a selected drug with multiple dosage forms and strengths; and
- Base the single price included in the initial offer for a selected drug on the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths as reflected in Medicare Part D utilization during the 12-month period ending May 31, 2023.[24]

[23] A more detailed list of factors to be considered in the review of literature can be found on page 37 of the CMS memorandum.

[24] The guidance states that this methodology was chosen, instead of per unit or per weight-based metric, for a more direct comparison with therapeutic alternatives, which might have different dosage forms, strengths, and frequency of use than the selected drug. See the second paragraph on page 38 of the CMS guidance for an example of how single price would be calculated using the 30-day equivalent methodology.

CMS is soliciting comment on its intended approach to identify a single price for use at each step in the negotiation process, including specifically on:

- The advantages and disadvantages of converting to a price per 30-day equivalent supply; and
- Any other approaches that allow CMS to calculate a single price across dosage forms and strengths and allow for a more direct comparison with therapeutic alternatives.

60.2 Limitations on Offer Amount (Ceiling)

For purposes of negotiating the MFP of a selected drug, CMS is statutorily prohibited (1194(b)(2)(F)(i)) from making an offer (or agreeing to a counteroffer) for an MFP that exceeds the ceiling.

60.2.1 Determination of the Ceiling for the MFP

Section 1194(c) provides that for the initial price applicability year 2026, the MFP ceiling for a selected drug shall be the lower of the following 2 approaches:

- The sum of the plan specific enrollment weighted amounts (as further described in section 60.2.2 below), and
- The applicable percent of the average non-FAMP, which is the average non-FAMP for the selected drug for calendar year 2021, increased by the percentage increase in the consumer price index for all urban consumers (all items, United States city average; CPI-U) from September 2021 to September 2022, multiplied by the applicable percentage.[25]
    - Average non-FAMP is further described in section 60.2.3 below.
    - For initial price applicability year 2026, the applicable percent is:
        - 75 percent for short-monopoly drugs (i.e., selected drugs that have been on the market less than 16 years—thus, after September 1, 2007); or
        - 40 percent for long-monopoly drugs (i.e., selected drugs that have been on the market for at least 16 years—thus, on or before September 1, 2007).

Determining whether to use the sum of the plan specific enrollment weighted amounts or the applicable percent of non-FAMP. CMS will separately calculate a single amount for each methodology, across dosage forms, strengths, and package sizes of the selected drug. To do so, CMS will aggregate the amounts determined for each applicable NDC-11 for the selected drug. The resulting amount from each methodology for the selected drug would be compared, and the lower amount would become the basis for the ceiling for the single MFP of the selected drug.

Using the determined approach for the ceiling:

[25] In the case that there is not an average non-FAMP for a selected drug for calendar year 2021, the applicable percent, with respect to the selected drug, would be of the average non-FAMP for such drug for the first full year following the market entry for such drug, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from December of such first full year following market entry to September 2022.

- CMS intends to ensure the MFP applied to each dosage form and strength does not exceed the ceiling; to do so, CMS will calculate a single ceiling price per 30-day equivalent supply across the NDC-11s for each dosage form and strength of the selected drug to yield dosage form and strength-specific ceilings.
- The guidance also explains how CMS will calculate a single ceiling price per 30-day equivalent supply across all dosage forms and strengths of the selected drug.

60.2.2 Sum of Plan Specific Enrollment Weighted Amounts

Sources of data. To determine the sum of plan specific enrollment weighted amounts for a selected drug for initial price applicability year 2026, CMS plans to use the Part D Event (PDE) file data and Direct and Indirect Remuneration (DIR) data reported by Part D plans to CMS for plan year 2022 (i.e., records for selected drugs with dates of services during CY 2022). Data contained in both sources is reported to CMS at the NDC-11 level.

Method. CMS plans to calculate the sum of plan specific enrollment weighted amounts for each dosage form and strength of the selected drug, and to calculate the sum of plan specific enrollment weighted amounts across dosage forms and strengths of the selected drug. Each calculation would be calculated for a 30-day equivalent supply. Part D plans that have PDE data for the selected drug would be included in the calculations, resulting in plans that have no utilization for the selected drug or that have no enrollment for 2022 being excluded.

To calculate the sum of plan specific enrollment weighted amounts for each dosage form and strength of a selected drug, the guidance specifies that:

- For each part D plan (using the plan's PDE and DIR records for selected drugs with dates of services during 2022), CMS would determine:
    - The price for a 30-day equivalent supply using PDE records,[26] and
    - The total DIR amount for each dosage form and strength.[27]
- For each Part D plan, CMS would determine the plan specific enrollment weighted amount (which would be calculated by multiplying the price for a 30-day equivalent supply of the selected drug, by the ratio of the total number of Part D beneficiaries enrolled in the Part D plan during December 2022, to the total number of individuals enrolled in all Part D plans in such month.
- Then, CMS would sum all of the plan specific enrollment weighted amounts calculated above for all Part D plans.

To calculate the sum of plan specific enrollment weighted amounts for the selected drug <u>across</u> all dosage forms and strengths, the guidance specifies that:

[26] The guidance describes that CMS intends to sum the negotiated price amounts (defined in 42 CFR 423.100) and the estimated rebate at point of sale amounts (ERPOSA) across such PDE records for each NCD-11 of each dosage form and strength. Then CMS would calculate the 30-day equivalent supply for each PDE record, and sum the 30-day equivalent supply across such records for each of the NDC-11s of each dosage form and strength.
[27] The guidance describes that CMS intends to sum the total DIR amounts in the 2022 Detailed DIR Report for all NDC-11s of each dosage form and strength, minus the total ERPOSA (with respect to the PDE record data).

- CMS would use the Part D PDE data for 2022 to calculate (1) the total 30-day equivalent supply for each dosage form and strength of the section drug across all part D plans and (2) the total 30-day equivalent supply of the selected drug across all dosage forms and strengths and all Part D plans.
- For each dosage form and strength of the selected drug, CMS would multiply:
    - The sum of the plan specific enrollment weighted amounts for the dosage form and strength, as calculated above; and
    - The ratio of the total 30-day equivalent supply for the dosage form and strength, to the total 30-day equivalent supply across all dosage forms and strengths of the selected drug, as calculated above.
- Then, CMS would sum the amounts calculated in the previous step.

60.2.3 Average Non-Federal Average Manufacturer Price

To make the average non-FAMP comparable to the sum of plan specific enrollment weighted amounts calculated above in order to determine which method to apply for the ceiling, the guidance provides that CMS will also base the average non-FAMP calculations on a 30-day equivalent supply and use the same data source for weighting both the sum of the plan-specific enrollment weighted amounts and the average non-FAMP.[28]

The guidance describes that CMS intends to first calculate the applicable percent of the average non-FAMP for each dosage form and strength of the selected drug for a 30-day equivalent supply, and would then calculate the applicable percent of the average non-FAMP across dosage forms and strengths of the selected drug for a 30-day equivalent supply. For initial price applicability year 2026, the applicable percent is set in statute and generally varies by monopoly type of the drug (i.e., first approval or licensure date of the drug).

Specific steps are found beginning on page 43 of the CMS guidance, delineating how CMS intends to calculate the applicable percent of the average non-FAMP for each dosage form and strength of the selected drug. Those steps include:

- Deriving amounts for the average non-FAMP to represent the same quantity of the selected drug as in the calculation for the sum of the plan specific enrollment weighted amounts.[29]
- Calculating the non-FAMP per unit for the NDC-11.[30]

[28] To determine the average non-FAMP of a selected drug, the guidance states CMS intends to use the non-FAMP of each NDC-11 for the selected drug (using NDC-11 level unit volume data) for each quarter of calendar year 2021, which is submitted to CMS by the Primary Manufacturer of the selected drug. To determine the 30-day equivalent supply for each NDC-11 of the selected drug, CMS intends to use the 2022 Part D PDE data at the NDC-11, which is submitted to CMS by Part D plan sponsors.
[29] To provide that the average non-FAMP and the sum of plan specific enrollment weighted amounts represent the same quantity of the selected drug, CMS would compare the non-FAMP unit type (e.g., tablet) to the PDE units (i.e., each, milliliter, and grams), and in cases where the units are different, CMS would convert the non-FAMP unit type to the PDE units.
[30] CMS would calculate the non-FAMP per unit by dividing the non-FAMP per package by the total number of units per package for the NDC-11.

- Calculating the average non-FAMP for 2021 for each NDC-11 of the selected drug.[31]
- Calculating the average non-FAMP for NDC-11 for 2021, adjusted for unit volume of dosage form and strength.[32]
- Calculating the average non-FAMP for 2021 for each dosage form and strength, by summing such adjusted average non-FAMP amounts so calculated for each dosage form and strength.
- Applying the CPI-U adjustment[33] to the average non-FAMP in CY 2021 for each dosage form and strength of the selected drug.
- Applying the applicable percent to the 2021 inflation-adjusted average non-FAMP for each dosage form and strength. The guidance specifies that CMS would apply the applicable percent specified in section 1194(c)(1)(C) for the monopoly type determined for the selected drug based on its initial approval date (described in section 30.1).[34] For initial price applicability year 2026:[35]
    - The applicable percent for selected drugs that are short-monopoly drugs or vaccines will be 75 percent.
    - The applicable percent for selected drugs that are long-monopoly drugs will be 40 percent.
- Using the average non-FAMP for CY 2021, as so adjusted for inflation and with the applicable percent applied, to determine the average non-FAMP for 30-day equivalent supply of each dosage form and strength of selected drug.[36]

To calculate the applicable percent of the average non-FAMP across all dosage forms and strengths of the selected drug, the guidance states that CMS would then:

- For each dosage form and strength of the selected drug, multiply the average non-FAMP specific to that dosage form and strength, as calculated above, by the ratio of the total 30-

[31] For each NDC-11 of the selected drug and for each quarter during calendar year 2021, CMS would divide the total unit volume in that quarter by the total unit volume across all four quarters during calendar year 2021, and multiply this quotient by the non-FAMP. If there is not a non-FAMP available for a selected drug for calendar year 2021, CMS would use the non-FAMP and total unit volumes for the quarters of the first full year following the market entry for the drug. CMS would then, for each NDC-11, sum each of CY 2021 quarter amounts.
[32] For each NDC-11 of the selected drug, CMS would multiply the average non-FAMP for the NDC-11 for CY 2021, by the ratio of the total unit volume in calendar year 2021 for that NDC-11 by the total unit volume in calendar year 2021 for all NDC-11s of the same dosage form and strength.
[33] This is specified in section 1194(c)(1)(C)(i). For each dosage form and strength of the selected drug, to adjust for inflation, CMS would multiply the average non-FAMP in CY 2021, by percentage increase in CPI-U (all items; US city average) from September 2021 to September 2022. If there is no non-FAMP available for the dosage form and strength of the selected drug for 2021, CMS would use the percentage increase from December of the first full year following the market entry for that dosage form and strength, in accordance with section 1194(c)(1)(C)(i).
[34] See figure 2 on page 45 of the CMS guidance for a table describing the applicable percentages and the definitions for monopoly types, based on initial approval dates for the drugs, for initial price applicability year 2026.
[35] The extended monopoly type is not discussed for purposes of the applicable percent or for the Negotiation Program. The definition of an extended-monopoly drug under section 1194(c)(4)(B)(ii) excludes a selected drug for which a manufacturer has entered into an agreement with the Secretary with respect to an initial price applicability year that is before 2030.
[36] CMS would multiply the average non-FAMP for CY 2021 for each dosage form and strength of the selected drug, as adjusted for inflation and with the applicable percent applied, by the ratio of the total number of units of that dosage form and strength to the total 30-day equivalent supply for that dosage form and strength.

day equivalent supply for the dosage form and strength to the total 30-day equivalent supply across all dosage forms and strength of the selected drug.
- Sum all of the amounts so calculated across the dosage forms and strengths of the selected drug.

This is the dollar amount that is the applicable percent of the average non-FAMP for the selected drug that would be used for the comparison to determine the ceiling amount.

60.2.4 Selection and Application of the Ceiling for the MFP

The ceiling price for the selected drug will be the lower of (1) the sum of plan specific enrollment weighted amounts (as calculated as described in section 60.2.2) for a selected drug or (2) the applicable percent of the average non-FAMP (as calculated as described in section 60.2.3) for the selected drug. Once it is determined which of the 2 methods is used to determine the ceiling, CMS plans to make sure the MFP, initial offer, and counteroffers, applied across dosage forms and strengths of the selected drug, does not exceed the ceiling price specific to each dosage form and strength. This would be accomplished by comparing such MFP to the ceiling for a 30-day equivalent supply for the dosage form and strength of the drug, calculated as summarized above using the method selected for the ceiling.[37]

60.3 Methodology for Developing an Initial Offer

Section 1194(e) requires CMS to provide an initial offer and justification and requires that such offer and any counteroffers are to consider the factors related to manufacturer-specific data and available evidence about therapeutic alternatives, as discussed above. The guidance specifies how CMS intends to consider evidence about therapeutic alternatives.

60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication

CMS intends to:
- Use FDA-approved prescribing information for the selected drug to identify the FDA-approved indications for the drug.[38]
- For purposes of identifying indications, consider off-label uses that are included in nationally recognized, evidence-based guidelines and recognized by CMS-approved Part D compendia.
- Identify any pharmaceutical therapeutic alternatives for each identified indication of the selected drug. Only alternatives that are covered under Part D or Part B will be considered.
- Prioritize identifying therapeutic alternatives within the same drug class as the selected drug before considering therapeutic alternatives in other drug classes.

[37] If the sum of plan specific enrollment weighted amounts is selected for the ceiling, then see the dosage form and strength specific calculation in step 7 of section 60.2.2 of the guidance. If the applicable percent of the average non-FAMP is selected for the ceiling, then see the dosage form and strength specific calculation in step 9 of section 60.2.3 of the guidance.
[38] Such indications will not include indications excluded from part D coverage or otherwise restricted under section 1860D-2(e)(2) for a selected drug.

60.3.2 Developing a Starting Point for the Initial Offer

Subject to the ceiling price, CMS intends to start with the Part D net price or Average Sales Price (ASP) of the therapeutic alternatives for the selected drug, as applicable, to develop the MFP initial offer.[39] Using Part D PDE data and detailed DIR report data, CMS plans to identify the price (net of price concessions received by a Part D plan or PBM on behalf of the plan) of each identified pharmaceutical therapeutic alternative.[40]

The guidance describes the following scenarios for developing the initial offer for the MFP of a selected drug:

- If there is one therapeutic alternative for the selected drug, CMS would use the net price or ASP, as applicable, of the therapeutic alternative if it is lower than the ceiling.
- If there are multiple therapeutic alternatives, CMS would consider the range of net prices or ASPs, as well as the utilization of, each therapeutic alternative, and the starting point for the initial offer would be within that range, if such starting point would be lower than the ceiling.
- If the selected drug has no therapeutic alternative or if either of the prices from the above 2 scenarios would result in a starting point higher than the ceiling price, CMS would determine the starting point for the initial offer based on the Federal Supply Schedule[41] or "Big Four Agency"[42] price (as described in the footnotes on page 49 of the CMS guidance).
- If the FSS and Big Four prices are above the ceiling price, CMS would use the ceiling price as the starting point for the initial offer.

CMS is soliciting comment on its intended approach to determine a starting point for developing the initial offer—specifically, on the following:

- The advantages and disadvantages of using net prices and ASPs as the starting point for selected drugs with at least one therapeutic alternative and of using the Federal Supply Schedule or Big Four price for selected drugs with no therapeutic alternative or with net prices or ASPs greater than the statutory ceiling;
- Other starting points for the initial offer, including other domestic reference prices (and their disadvantages and advantages); and
- In the event that there are multiple therapeutic alternatives for the selected drug, how to consider the range of net prices and ASPs and utilization of each therapeutic alternative to determine a single starting point for developing the initial offer.

[39] The guidance describes other approaches considered, including using the unit cost of production and distribution, the ceiling price, a domestic reference price, or a "fair profit" price for the selected drug.
[40] The guidance says CMS' reason for taking this approach of considering the price of the selected drug's therapeutic alternative is that it would enable CMS to adjust the initial offer's starting point based on the comparison of the clinical benefit offered by the selected drug compared to that of its therapeutic alternatives. The other potential options considered do not reflect the cost of therapeutic alternatives.
[41] The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government.
[42] The Big Four Agency price is the maximum price that the Department of Veteran's Affairs (VA), Department of Defense (DoD), the Public Health Service, or the Coast Guard is required to pay.

60.3.3 Adjusting the Starting Point Based on Clinical Benefit

CMS intends to adjust the starting point for the initial offer based on the review of the clinical benefit. The resulting adjusted price is referred to as the "preliminary price." CMS will use a qualitative approach and will adjust the starting point upward or downward relative to the clinical benefit of the selected drug compared to its therapeutic alternatives (including based on the unique characteristics of the drug and the patient populations taking the drug).[43]

60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative.

To compare the effectiveness and clinical benefit between a selected drug and its therapeutic alternatives, CMS intends to:

- Identify outcomes to evaluate for each indication of the selected drug, and consider the safety profile of the selected drug and the therapeutic alternative;
- Consider health outcomes, intermediate outcomes, surrogate endpoints, patient-reported outcomes, and patient experience;
- Focus the review of clinical benefit on outcomes of particular importance to the condition or disease being treated by the selected drug;
- Consider the effects on specific populations, as required by section 1194(e)(2)(C);
- Consider if the selected drug fills an unmet medical need;[44] and
- Examine improvements in outcomes with the selected drug as compared to its therapeutic alternative to determine whether a selected drug represents a therapeutic advance.

60.3.3.2 Analysis for Selected Drugs without Therapeutic Alternative

In the case of selected drugs without any therapeutic alternative, CMS intends to adjust the starting point for the initial offer based on the extent to which the selected drug fills an unmet medical need. CMS will consider unmet medical need separately for each indication.

60.3.4 Consideration of Manufacturer-Specific Data

CMS is statutorily required to consider, as the basis for determining the offers and counteroffers, manufacturer-specific data reported by the Primary Manufacturer.[45] The guidance specifies that the initial offer price for negotiation of a selected drug will be the preliminary price, as calculated above and as adjusted to take into account the manufacturer-specific data elements submitted.

The following describes how CMS intends to consider each of the following manufacturer-specific data elements:

[43] To evaluate how the clinical benefit of the selected drug compares to its therapeutic alternatives, CMS intends to use clinical evidence, including data received from the public and manufacturers and data identified through a CMS-led literature review, and may also review Medicare claims or other pharmaceutical drug datasets for utilization patterns, clinical data, or other relevant information, and consult with clinical and academic experts.
[44] The guidance states CMS' intent to define filling an unmet medical need as treating a disease or condition where "very limited or no other treatment options exist".
[45] See section 1194(e)(1). Also, see section 50.1 of the CMS guidance and this summary for further information on the manufacturer-specific data referenced.

Manufacturer-Specific Data Element	How CMS Intends to Consider Element
Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs	CMS will compare the research and development costs and the global, net revenue reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its research and development costs.
Current unit costs of production and distribution of the drug	CMS will consider the relationship between the preliminary price and the unit price of production and distribution.
Prior federal financial support for novel therapeutic discovery and development with respect to the drug	CMS will consider the extent to which the Primary Manufacturer benefited from federal financial support.
Data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug	CMS will consider the length of the available patents and exclusivities before the selected drug may no longer be single source.
Market data and revenue and sales volume data for the drug in the United States	CMS will consider how the data compare to the CMS preliminary price.

60.4 Negotiation Process

The following table outlines the milestones and corresponding dates for the negotiation process for initial price applicability year 2026.[46]

Date	Milestones
October 1, 2023	Statutory deadline for negotiation period to begin.[47]
February 1, 2024	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer.[48]
30 days after receipt of written initial offer from CMS (March 2 if the offer is made on Feb. 1, 2024)	Statutory deadline for the Primary Manufacturer to accept the initial offer or submit a written counteroffer to CMS.[49]
30 days after receipt of the manufacturer counteroffer (April 1 if the manufacturer counteroffer is made on March 2, 2024)	Date by which CMS would provide a written response to the Primary Manufacturer's counteroffer.[50]
From the date that the Primary Manufacturer's written counteroffer is not accepted by CMS through June 30, 2024	If CMS does not accept the Manufacturer's counteroffer, a maximum of 3 possible negotiation meetings (in-person or virtual) between the Manufacturer and CMS. CMS would schedule the first meeting to occur within 30 days of receiving the written counteroffer from the Primary Manufacturer.
July 15, 2024	Date by which CMS would issue a "Notification of Final Maximum Fair Price Offer" to the Primary Manufacturer, if the written initial

[46] Based on the table on page 57 of the CMS guidance.
[47] Section 1191(b)(4) requires the negotiation period for a selected drug to begin on the earlier of the date on which the Primary Manufacturer enters into the Agreement with the Secretary under the Drug Negotiation Program, or, for initial price applicability year 2026, October 1, 2023.
[48] See section 1191(d)(5)(B) and section 1194(b)(2)(B).
[49] See section 1194(b)(2)(C).
[50] See section 1194(b)(2)(D).

	offer or written counteroffer were not accepted and negotiations progressed to negotiation meetings.
July 31, 2024	Date by which the Primary Manufacturer would accept or reject CMS' "Notification of Final Maximum Fair Price Offer," if applicable.
July 31, 2024	Statutory deadline for all negotiations to end. CMS will notify the Primary Manufacturer of any failure to meet the deadline and the possible consequences if there is no agreement for the MFP.
August 1, 2024	Statutory end of negotiation period.
March 1, 2025	CMS publication of explanation of agreed-on MFP.

An agreement for the MFP of a selected drug would be reached if at any point during the negotiation process, the Primary Manufacturer of the selected drug accepts CMS' latest written offer by signing the written offer, or CMS accepts the Primary Manufacturer's counteroffer by countersigning that written counteroffer.

60.4.1 Provision of an Initial Offer and Justification

The written initial offer from CMS is statutorily required (1194(b)(2)(B)) to be made not later than February 1, 2024, and include a concise justification for the offer. The justification would be based on the factors described in section 50 and on the analysis described in section 60.3.

60.4.2 Required Components of a Counteroffer

Not later than 30 days after receipt of the written initial offer from CMS, the Primary Manufacturer of a selected drug must accept the initial offer or submit a written counteroffer. The counteroffer must include justification for the counteroffer based on the factors described in section 50. The CMS guidance provides the counteroffer should:

- Respond to the justification provided in CMS' written initial offer;
- Focus on the manufacturer-specific data factors and evidence on alternative treatments[51] factors and describe the reasons the Primary Manufacturer believes the information submitted by the manufacturer on those factors do not support CMS' initial offer; and
- Include a suggested MFP that is a single price for the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths.[52]

For initial price applicability year 2026, not later than March 1, 2025, CMS is statutorily required (1195(a)(2)) to publish an explanation (further described in section 60.6.1) for the agreed-upon MFP with respect to the manufacturer-specific data factors and evidence on alternative treatments factors described above. The Primary Manufacturer may request that certain details contained in the offer or counteroffer be included in this explanation.

[51] See section 1194(e) of the Act, and sections 50.1 and 50.2 of the CMS guidance and of this summary for the list of factors and further descriptions.
[52] CMS is prohibited under section 1194(b)(2)(F) from accepting a counteroffer that exceeds the ceiling price as specified in section 1194(c).

60.4.3 Negotiation Process After Manufacturer Counteroffer

CMS is statutorily required to respond in writing to a written counteroffer. The CMS guidance states that if CMS' response rejects the counteroffer:

- CMS will provide the Primary Manufacturer of the selected drug with an opportunity to have a negotiation meeting with CMS.
- The Primary Manufacturer and CMS may each request one additional meeting.
- All 3 potential meetings would occur within 30 days after submission of the Primary Manufacturer's counteroffer and ending June 30, 2024.
- The negotiation meetings would be attended by only representatives of the Primary Manufacturer and of CMS, and details discussed during these meetings would not be made public by either CMS or the Primary Manufacturer.[53]

The guidance states that CMS also considered using solely a written offer and counteroffer approach, with CMS submitting a written initial offer and the Primary Manufacturer submitting one written counteroffer, or with each party making up to 2 written offers or counteroffers. However, CMS believes the inclusion of the negotiation meetings in the negotiation process would allow for discussion of new information and would better facilitate the negotiation process than an approach that would rely solely on the exchange of written offers.

CMS is soliciting comments on the proposed drug price negotiation process after the manufacturer counteroffer—specifically, on the advantages and disadvantages of the negotiation process described above, as well as whether there are alternatives that CMS should consider.

60.4.4 Determination that Negotiations Have Finished

For initial price applicability year 2026, all negotiations for the MFP of a selected drug are statutorily required to end not later than August 1, 2024.[54] The CMS guidance states that if negotiation meetings are held, CMS intends to send to the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" by July 15, 2024, and the manufacturer would be required to accept or reject the offer in writing by July 31, 2024.

60.5 Application of the MFP Across Dosage Forms and Strengths

The MFP for a selected drug would reflect a single price for the selected drug per 30-day equivalent supply. To ensure that the MFP is made available to MFP-eligible individuals at the point of sale (and to pharmacies, mail order services, or other dispensers, with respect to such MFP-eligible individuals), CMS intends to publish the MFP at the per unit level for each dosage form and strength associated with the selected drug. The guidance describes a methodology that would take the single MFP across dosage forms and strengths for a 30-day equivalent supply and calculate an MFP per unit for each dosage form and strength of the selected drug, and notes the goal to scale the MFP per unit based on price differentials across dosage forms and strengths.

[53] The guidance states that in the explanation of the agreed upon MFP that must be published by CMS and any other public documents discussing the MFP, CMS may make high-level comments on the data submitted or discussed in negotiation meetings, without sharing any proprietary information.
[54] See section 1194(b)(2)(E) and 1191(d)(2)(B) of the Act.

CMS is considering using the wholesale acquisition cost (WAC) of the selected drug, as follows, in calculating an MFP per unit for each dosage form and strength:

- CMS would convert the WAC per unit cost for each NDC-9 of the selected drug to a WAC per unit cost for each dosage form and strength, which would then be converted into a WAC amount for a 30-day equivalent supply[55] and would allow for the WAC to represent an equivalent amount to the negotiated single MFP.
- For each dosage form and strength of the selected drug, CMS would then use the WAC per 30-day equivalent supply to calculate a WAC price ratio (comparing the WAC per 30-day equivalent supply for each dosage and strength to the WAC per 30-day equivalent supply across dosage forms and strengths of the selected drug).[56]
- CMS would then, for each dosage form and strength of a selected drug, multiply the WAC price ratio for the dosage form and strength by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each dosage form and strength of the selected drug.[57]
- CMS would then convert the MFP for a 30-day equivalent supply of a dosage form and strength to an MFP per unit for a dosage form and strength based on the average number of units in a 30-day equivalent.[58]

CMS is soliciting comment on this potential approach to computing the MFP across dosage forms and strengths of the selected drug. Specifically, CMS seeks comments on:

- The advantages and disadvantages of using WAC in the computation of MFP at the per unit level;
- Any alternative approaches to the application of the MFP across dosage forms and strengths that could accurately and fairly compensate manufacturers and other entities throughout the supply chain; and
- Whether there are other approaches CMS should consider to apply the MFP across dosage forms and strengths that would be feasible, along with the disadvantages and advantages of the approaches. CMS asks for commenters' attention to the potential for disclosure of confidential or proprietary information when considering other approaches.

60.5.1 Application of the MFP to New NDAs/BLAs or NDCs

The guidance states that:

- If, after a qualifying single source drug is selected as a selected drug, the Primary Manufacturer of the selected drug receives approval for an NDA/BLA for the same active

[55] Steps 1-4 on page 58 of the CMS guidance describe in detail how the conversion to the WAC per unit cost for each dosage form and strength and the conversion to a 30-day equivalent supply would be conducted. Step 1 notes that CMS is considering using the WAC unit cost for 2022 to align with data used for calculating the ceiling.
[56] Steps 5-8 on page 59 of the CMS guidance describe in detail how the WAC price ratio for each dosage form and strength would be calculated. For each dosage form and strength, CMS would calculate the ratio of 30-day equivalent supply for the dosage form and strength to the total 30-day equivalent supply across all dosage forms and strengths of the selected drug, and then multiply such ratio by the WAC per 30-day equivalent supply. Then CMS would sum all such amounts so calculated across all dosage forms and strengths of the selected drug. To calculate the WAC price ratio for each dosage form and strength, CMS would divide the WAC per 30-day equivalent supply for each dosage and strength by the WAC per 30-day equivalent supply across dosage forms and strengths of the selected drug.
[57] See step 9 on page 59 of the CMS guidance.
[58] See step 10 on page 59 of the CMS guidance.

ingredient, CMS intends to require that the MFP apply to products marketed pursuant to the newly approved NDA/BLA.

- If, after a qualifying single source drug is selected as a selected drug, the Primary Manufacturer of the selected drug receives approval or licensure for a new drug or biological product or NDC that is marketed pursuant to a supplement to an existing NDA or BLA, CMS intends to require that the MFP apply to such new drug or biological product.

CMS is soliciting comment on how to compute the MFP for a drug or biological product or NDC that is a selected drug and is marketed for the first time, pursuant to an existing or new NDA or BLA, after the drug is selected and an MFP has been agreed.

60.6 Publication of the MFP

For initial price applicability year 2026, not later than September 1, 2024, CMS will publish for each selected drug the MFP agreed on by the Primary Manufacturer of the drug and CMS.[59]

60.6.1 Explanation for the MFP

For initial price applicability year 2026, CMS is required under section 1195(a)(2) to publish an explanation for the MFP by not later than March 1, 2025.

CMS intends that the published explanation will be on the CMS website and would summarize how relevant negotiation factors (i.e., manufacturer-specific data and the evidence about alternative treatments) were considered during the negotiation process. If an agreement for an MFP is not reached for a selected drug, CMS would indicate on the website that an MFP has not been agreed upon. If an agreement is reached after the end of the negotiation period, CMS would indicate on the website the MFP agreed to and accompanying explanation within 30 days of such agreement.

60.7 Exclusion from the Negotiation Process

In accordance with section 1192(c), CMS will not begin or will suspend the negotiation for a selected drug when there is at least one generic/biosimilar competitor product on the market.[60] The drug will continue, though, as specified in section 1192(c)(2), to be considered a selected drug under the Negotiation Program for purposes of the number of negotiation-eligible drugs published on the list for that initial price applicability year.

[59] Section 1191(d)(6) requires this publication and timeline. The guidance specifies that CMS also intends to publish on the CMS website, for each selected drug, the MFP file, the explanation for the MFP, when a drug is no longer a selected drug and the reason for that change, and when an MFP between a Primary Manufacturer and CMS is not agreed upon.

[60] Section 1192(c)(2) specifies that a selected drug is no longer subject to the negotiation process for an initial price applicability year if before or during the negotiation process for such year, the Secretary determines that at least one drug or biological product (1) is approved under section 505(j) of the FD&C Act with at least one dosage form and strength of the selected drug as the listed drug, or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product; and (2) is marketed pursuant to such approval or licensure.

60.8 Establishment of MFPs After the Negotiation Deadline

The guidance specifies that if the Primary Manufacturer of a selected drug would like to agree to an MFP after the end of the negotiation period, the manufacturer must notify CMS in writing that it would like to accept the last offer from CMS. Section 1195(b)(2) requires that if the MFP is determined after the end of the negotiation period, CMS must publish the MFP not later than 30 days after the MFP is determined.

Section 70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

A drug or biological is no longer considered a selected drug for a year when there is at least one generic/biosimilar approved and marketed for the drug or biological (other than authorized generic drugs as defined in section 1192(e)(2), which include certain biological products[61]). Thus, when there is an approved generic drug or licensed biosimilar for which the selected drug is the listed drug or reference biological and the generic or biosimilar has been marketed, the drug's status as a selected drug will terminate.

The timing and conditions under which a drug's status as a selected drug terminates will be determined similar to how CMS determines whether a selected drug has at least one generic/biosimilar approved and marketed for the drug to exclude it from being a qualifying single source drug under section 30.1 (summarized above). CMS will review PDE data to determine whether the manufacturer of the generic or biosimilar has engaged in bona fide marketing.

On a monthly basis, starting with October 2023, CMS will check FDA reference sources, like the Orange Book and Purple Book, to determine whether a selected drug has at least one generic/biosimilar approved and marketed for any strength(s) or dosage form(s) of the selected drugs for initial price applicability year 2026. If CMS finds as part of those monthly checks that a generic/biosimilar has been approved, it will review PDE data with dates of service during the most recent 12-month period to verify bona fide marketing.

A determination that a generic/biosimilar is available on or after the selected drug publication date and before or during the negotiation period for an initial price applicability year results in the removal of the selected drug from the negotiation process for the negotiation period. No MFP will be established for the drug.

For example, for initial price applicability year 2026, should the agency make this determination between September 1, 2023, and August 1, 2024, the drug will remain a selected drug through 2026, but no MFP will apply. Additionally, that selected drug will not be replaced with another selected drug.

[61] Section 1192(e)(2)(B)(ii) applies the rule for authorized generics for listed drugs to a biological product that is approved under section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under different labeling or packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark.

However, if under this example this determination is made between August 2, 2024, and March 31, 2026, for a drug selected for initial price applicability year 2026, then the drug will no longer be a selected drug on January 1, 2027, but the MFP will apply for 2026. Additionally, if the determination is made between April 1, 2026, and March 31, 2027, then the selected drug will stop being a selected drug on January 1, 2028, and the MFP will apply for 2026 and 2027. These rules apply because section 1192(c)(1) mandates that a selected drug included on the list of selected drugs for an initial price applicability year remains a selected drug for that year and each subsequent year that begins before the first year that begins at least 9 months after the date on which CMS determines that generic/biosimilar competition exists.

CMS will publish on its website the determinations that a selected drug has generic/biosimilar competition.

Section 80. MFP Eligible Individuals

The guidance largely codifies the statutory definition of MFP eligible individuals as follows:

- Where a selected drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a Part D PDP or an MA–PD plan (including enrollees in Employer Group Waiver Plans) if coverage is provided under such plan for such selected drug; and/or
- Where the selected drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under Medicare Part B, including an individual who is enrolled in an MA plan under Medicare Part C, if payment may be made under Part B for such selected drug.

Section 90. Manufacturer Compliance and Oversight

90.1 Monitoring of Manufacturer Compliance

Noting that it intends to monitor Primary Manufacturers of selected drugs closely, especially for compliance with terms and conditions of the manufacturer agreements, CMS will provide operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact and other information relevant to the negotiation process. The agency will be tracking and monitoring progress during all steps of the process and directly communicate with Primary Manufacturers, and it intends to issue reminders before deadlines as well as warning letters if necessary. Compliance failures could give rise to excise tax liability or CMPs.

90.2 Monitoring of Access to the MFP

As noted earlier, CMS will require Primary Manufacturers to establish safeguards to ensure the MFP is available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers of units of the selected drug for which there are Secondary Manufacturers. The duty is on the Primary Manufacturer to ensure that access.

The guidance notes several ways the public can be apprised of the MFP for each selected drug, including publication and explanation of the MFPs by CMS and publication by pharmaceutical database companies for pharmaceutical purchasers. **The agency seeks comment** on other ways

it could assist dispensing entities and MFP-eligible individuals to know the MFP for a selected drug and determine whether they are able to access it. CMS notes, with respect to Part D, that each plan sponsor must use a unique Part D processor identification number (RxBIN) and Part D processor control number (RxPCN) combination to identify a Medicare Part D payer. The agency intends to leverage this existing mechanism to ensure a pharmacy can identify at the point of sale whether the individual is an MFP-eligible individual. It also notes that the private sector could leverage its chargeback payment and rebate mechanisms to identify MFP-eligible individuals to provide access to the MFP.

CMS will establish a mechanism by which violations of the access requirement may be reported by beneficiaries, dispensing entities, and other providers and suppliers; they would be able to report instances to the agency where the MFP should have been made available to them but was not. CMS is considering a toll-free telephone line or an dedicated email box to report suspected violations. It would review reports of potential noncompliance and if appropriate impose CMPs. **Comment is sought** on the most effective process, including ways in which the agency could provide technical assistance as well as ways to ensure that MFP-eligible individuals whose cost-sharing was inconsistent with the MFP are made whole.

Instances where dispensers either do not pass through the MFP to MFP-eligible individuals or make MFP available to non-MFP-eligible individuals would also be reported through this mechanism.

On the issue of interaction with prices under the 340B program, CMS indicates that it will work with HRSA to ensure that the MFP is made available to 340B covered entities where appropriate.

CMS seeks comment on other ways it could ensure Primary Manufacturers meet their obligations to ensure that Secondary Manufacturers provide access to MFPs for dispensing entities. CMS is concerned that it is possible for an entity to purchase one or more drug or biological products included in a selected drug from a wholesaler, repackage or relabel those products, and then re-market them pursuant to one or more NDA(s) or BLA(s) included in the selected drug. **Comment is sought** on how to monitor MFP access for these units of the selected drug, including how to identify the other manufacturers that market these selected drugs, and what mechanisms are available to ensure MFP is available for these units of the selected drug.

90.3 Excise Tax on Sale of Designated Drugs During Noncompliance Periods

No guidance is included in this document on the excise tax under 26 USC 5000D. Such guidance will be developed and released by the Treasury Department at a later date.

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

When CMS determines that a generic or biosimilar has been marketed as evidenced by PDE data, it will monitor whether "robust and meaningful competition exists" in the market. See section 60.7 above for a description of the process and timing for the monitoring. The agency may monitor whether the generic or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain, and whether it is available for purchase by community retail pharmacies in sufficient quantities from their wholesale suppliers. CMS will

analyze the share of generic drug or biosimilar units identified in Part D PDE data as a percentage of total units of Part D expenditures. **Comment is sought** on the most effective ways to monitor whether "robust and meaningful competition" exists in the market after a selected drug ceases to be a selected drug.

Section 100. Civil Monetary Penalties

Under section 1197, CMPs may be imposed on the Primary Manufacturer of a selected drug that is subject to a manufacturer agreement for several violations, including the following:

- Failure to provide access to the selected drug at or below the MFP for the year involved to MFP-eligible individuals or to providers of services (including hospitals) and suppliers (including physicians) with respect to those individuals;
- Failure to comply with administrative requirements, including the submission of information, to carry out the Negotiation Program; and
- Knowingly providing false information for purposes of the special aggregation rules and acquisition rules for manufacturers in applying the exception for small biotech drugs during 2026, 2027, and 2028.

CMS largely codifies the statutory provisions in this guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP

The failure by a Primary Manufacturer to provide access to a price that is less than or equal to the MFP to MFP-eligible individuals who are dispensed the selected drug, to pharmacies, mail order services, or other dispensers with respect to MFP-eligible individuals who are dispensed the selected drug or to hospitals, physicians, or other providers or suppliers that furnish or administer the selected drug to MFP-eligible individuals will subject the manufacturer to a CMP. As specified in statute, the CMP would equal 10 times an amount that is equal to the product of—

- the number of units of the drug so furnished, dispensed, or administered (during such year); and
- the difference between—
    - the price for that drug made available (for such year by such manufacturer) to MFP-eligible individuals or a hospital, physician, or other provider or supplier that furnishes or administers the selected drug to an MFP-eligible individual; and
    - the MFP for that drug for such year.

CMS intends to use the net price to acquire the drug for the pharmacy, mail service, or dispenser, excluding any service fees, as the price made available for the selected drug. The agency will conduct such audits as it considers necessary to ensure selected drugs are being offered to MFP-eligible individuals at or below the MFP.

100.2 Violations of the Agreement

A CMP of up to $1 million for each day of a violation may be imposed on a Primary Manufacturer for failure to comply with administrative requirements established by CMS to carry out and monitor compliance with the Negotiation Program, including the provision of information. For example, failure to timely submit non-FAMP information, including such

information for which there is a Secondary Manufacturer, would give rise to a CMP. CMS would count the first day after the applicable data submission deadline and each succeeding day as days of non-compliance until (i) the requisite data is submitted; (ii) the date the drug is no longer a selected drug; or (iii) the Primary Manufacturer terminates the agreement.

Requests for information required to administer or monitor compliance with the Negotiation Program will be documented and include a deadline by which the requested information must be submitted. Failure to provide requested information on or before that deadline will result in a CMP.

CMS also clarifies that the knowing submission of false information by a Primary Manufacturer will also be subject to this CMP. The number of days in which the Primary Manufacturer is in violation of the Agreement will be calculated by counting the day of submission of the false information under the Manufacturer Agreement as the first day of violation with each additional day of violation counted until (i) the day the Primary Manufacturer provides a complete and accurate submission of the required information to CMS; (ii) the day the drug is no longer a selected drug; or (iii) the Primary Manufacturer terminates the agreement.

100.3 Provision of False Information

Small Biotech Exception

As described in section 30.2.1, small biotech drugs are excluded from the definition of negotiation-eligible drugs for initial price applicability years 2026-2028, with special aggregation rules and acquisition rules for manufacturers in applying this exception.

Any manufacturer that knowingly provides false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) for purposes of the Small Biotech Exception will be subject to a CMP equal to $100 million for each item of such false information.

Biosimilar Delay

As described in section 30.3.1, under section 1192(f), CMS may delay—by no more than 2 years—a biological from having an MFP set under the Negotiation Program if the Secretary determines there is a high likelihood that a biosimilar will be both licensed by the FDA and marketed within 2 years. Similar to the Small Biotech Exception, special aggregation rules apply under section 1192(f)(1)(C).

Any biosimilar manufacturer that knowingly provides false information under the procedures to apply the aggregation rule in section 1192(f)(1)(C) would be subject to a CMP equal to $100 million for each item of such false information.

100.4 Notice and Payment Procedures

CMS will provide written notice to manufacturers that violate any of the provisions described in this section. The notice will describe options to either pay or contest the determination that a violation was committed. It will also include other relevant information, such as the basis for the

CMP, the amount owed, deadlines for responses, how to make payment, and information on how to seek a hearing.

A hearing must be requested within 60 days of receipt of the notice; date of receipt is defined to be the calendar day following the day on which the CMP notice is issued. Failure to request a hearing means that the CMP is due on day 60 following the date of receipt (as so defined). CMPs that are not paid may be deducted from any sums owed by the federal government.

Section 110. Part D Formulary Inclusion of Selected Drugs

The statutory mandate for Part D plans to include all selected drugs on their formularies starting in plan year 2026 is codified.

Section 120. Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs

This section of the guidance describes the interaction between the Part D Inflation Rebate Program and selected drugs under the Negotiation Program. This is because the Negotiation Program does not apply to Part B drugs before initial price applicability year 2028. **CMS seeks comment** on whether guidance should be made available for the interaction between the Negotiation Program and the Part B Inflation Rebate Program for years before initial price applicability year 2028.

The Part D Inflation Rebate Program applies to certain Part D drugs that meet the definition of a Part D rebatable drug[62] and that are dispensed under Part D and covered and paid for by Part D plans beginning for each 12-month applicable period, beginning October 1, 2022.[63] The guidance states that whether a drug is a selected drug has no bearing as to whether the drug is also subject to the Part B and Part D inflation rebate programs. However, when a drug's status as a selected drug is terminated due to generic/biosimilar competition, certain components of the inflation rebate formula are recalculated.

Specifically, the Part D Inflation Rebate Program formula requires the determination of a benchmark period manufacturer price for the Part D rebatable drug, which is calculated based on a payment amount benchmark period as well as a benchmark period CPI-U. Different periods apply based on whether or not the drug was approved or licensed on or before October 1, 2021.

When a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period for the drug will be reset to the last year that begins during the selected drug's price applicability period, and the benchmark period CPI-U will be established as January of the last year beginning during the selected drug's price applicability period.

[62]A Part D rebatable drug is any covered Part D drug with one exception—a drug or biological with an average total Part D cost of less than $100 per individual who uses the drug during the 12-month period beginning on October 1, 2022 (referred to as an applicable period), increased for inflation over time.
[63] CMS published initial guidance on both Part B and Part D inflation rebates on February 9, 2023, which includes more specific details on the operation of the Part B and Part D inflation rebate programs. See: https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf and https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.