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Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program [CMS-4215-P] Proposed Rule Summary

On June 16, 2026, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register (91 FR 36236) a proposed rule to codify the Medicare Drug Price Negotiation Program ("Negotiation Program") and establish certain new policies for the Negotiation Program and the Medicare Prescription Drug Benefit Program as required by the Inflation Reduction Act of 2022 (IRA, P.L. 117-169).[1] CMS also proposes a modification to the fixed combination drug policy. **Comments are due by 5pm on August 17, 2026.**

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[1] Along with the public inspection version of the rule released June 12, 2026, CMS also published a press release, a fact sheet about the proposed rule, and a separate fact sheet on the timeline of key dates for the Negotiation Program for Initial Price Applicability Year 2029, the fourth cycle of negotiations.

I. Executive Summary and Background

A. Executive Summary

In a new part 429,[2] the proposed rule would codify CMS' final guidance[3] for the Negotiation Program established at sections 1191 through 1198 of the Social Security Act ("the Act") by the IRA and amended by the Working Families Tax Cut (WFTC) legislation (P.L. 119-21, July 4, 2025). With modifications at part 423, the proposed rule would codify other policies affecting the Medicare Prescription Drug Benefit Program based on section 11001(b) of the IRA—that is, provisions affecting Medicare Part D and related interactions.

In addition, CMS proposes the following:

- §429.125(b)(4)(i) would clarify treatment of new formulations. Specifically, if CMS determines that products with the same holder of the New Drug Application (NDA)/Biologics License Application (BLA) differ in active moiety(ies)/active ingredient(s)[4] due to the inclusion of an active ingredient that creates a new formulation and enables an alternative route of administration, CMS will identify the potential qualifying single source drug using all dosage forms and strengths of the shared ingredient(s) offered by the same NDA/BLA holder.
- §429.125(c)(3)(i) would clarify how CMS would identify the day from which to measure the 7- and 11-year time since approval and licensure periods for drugs that formerly qualified for the Orphan Drug Exclusion.
- §429.130 would codify CMS' process and schedule for reviewing information to determine if the manufacturer of a generic drug or biosimilar that is approved or licensed, respectively, is engaged in Bona Fide Marketing (as defined in §429.20).
- §429.210(c) would provide additional details on the Primary Manufacturer transfer of responsibility for requirements of the Negotiation Program Agreement to an acquiring entity.
- §429.415(a)(2) would explain how CMS would calculate the 30-day equivalent supply for a selected drug that is typically administered one time (for example, some vaccines, gene therapies, and cancer therapies).
- §429.440 would explain how CMS would implement the Temporary Floor for Small Biotech Drugs for initial price applicability years (IPAYs) 2029 and 2030.
- §§429.605 and 429.610 would clarify when off-label use would be considered for renegotiation eligibility and selection, by aligning the renegotiation eligibility and selection policies for off-label use with the initial offer development process.

Unless specified otherwise, the proposals would apply beginning with IPAY 2029—for example, for the selection of drugs and the negotiation of maximum fair prices (MFPs) for IPAY 2029 that

[2] In this summary, references to a regulatory section or part are in title 42, CFR, unless specified otherwise.
[3] CMS, "Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028," September 30, 2025, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.
[4] Henceforth, for simplicity throughout this summary, "active ingredient" is generally used rather than "active moiety(ies)/active ingredient(s)," etc.

will take place during calendar year 2027. CMS anticipates publishing the final version of this rule in Fall 2026, soon enough for the final requirements to apply to policies for IPAY 2029 and all subsequent years. The program guidance for IPAYs 2026, 2027, and 2028 remains applicable and is not superseded by this proposed rule for those years. Revisions pertaining to drugs selected for IPAYs 2026, 2027, and 2028 would be addressed through publication of revised guidance.

The exclusion for small biotech drugs from what is otherwise a negotiation-eligible drug ended in IPAY 2028 and is therefore not codified in this rule. However, the definition of an eligible small biotech drug for purposes of calculating the temporary floor on the MFP for small biotech drugs under section 1194(d) of the Act is included in this proposed rule (as described in section II.E.2).

B. Background

CMS reviews the legislative and implementation history of the Negotiation Program, under which CMS negotiates maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. With respect to each initial price applicability year (IPAY), the IRA requires CMS to:

- Publish a list of selected drugs;
- Enter into agreements with manufacturers of selected drugs;
- Negotiate MFPs for such selected drugs;
- Publish MFPs for selected drugs;
- Carry out administrative duties and compliance monitoring; and
- Impose applicable civil monetary penalties (CMPs).

For IPAY 2028 onward, the IRA requires CMS to:

- Determine renegotiation-eligible drugs;
- Determine whether to select drugs for renegotiation; and
- Renegotiate the MFP for any drug selected for renegotiation.

Additionally, CMS notes that the WFTC legislation modified the requirements for a drug to qualify for the Orphan Drug Exclusion and described the treatment of former orphan drugs.

C. Severability

CMS emphasizes its intent that if any provision of the rule, once finalized, is held to be invalid, unenforceable, etc., that provision shall be severable and not affect the remainder of the rule.

II. Proposed Requirements for the Medicare Drug Price Negotiation Program

A. General Provisions

1. Basis and Scope (§429.10)

Proposed §429.10 states that part 429 implements sections 1191 through 1198 of the Act and sections 11001 and 11002 of the IRA, which set forth the requirements of the Medicare Drug Price Negotiation Program, requiring the Secretary to negotiate and renegotiate Medicare prices for certain high expenditure, single source drugs and biological products.

Proposed §429.10(c) provides a statement on severability, elaborated on in the preamble—that if any provision of part 429 is to be held invalid or unenforceable, such provision would be severable from part 429 and the invalidity or unenforceability would not affect other provisions. CMS says that although the provisions in part 429 are intended to comprehensively implement the Negotiation Program, each of the provisions is a distinct, severable provision that could operate independently.

2. Definitions (§429.20)

According to CMS, the proposed rule would codify definitions consistent with those in sections 1191 through 1198 of the Act or in the Negotiation Program Guidance, along with new definitions based on policies described later. This summary does not repeat the 80-plus definitions provided in both the preamble and the regulatory text. Rather, selected proposed definitions are described as they relate to a provision in summary sections below.

3. Limitation on Review (§429.30)

Section 1198 of the Act establishes that there shall be no administrative or judicial review of any of the following:

- The determination of a unit of a drug or biological product,
- The selection of drugs,
- The determination of negotiation-eligible drugs,
- The determination of qualifying single source drugs,
- The application of the Biosimilar Delay,
- The determination of an MFP,
- The determination of renegotiation-eligible drugs, and
- The selection of renegotiation-eligible drugs.

CMS proposes to codify these limitations on review at proposed §429.30.

B. Identification of Selected Drugs (§§429.100 through 429.135)

Section 1192 of the Act establishes the requirements governing the publication of the list of selected drugs for an IPAY, the identification of selected drugs, ranking of negotiation-eligible drugs, and the identification of qualifying single source drugs. Beginning with IPAY 2029, CMS

proposes to codify these steps at §§429.100 through 429.135—specifically, codifying the policies for identification of selected drugs described in sections 30 and 40.2 of the Negotiation Program Guidance, subject to proposed modifications noted below.

The order of program operations would be as follows for each IPAY beginning with 2029:

- Qualifying single source drugs. CMS would identify qualifying single source drugs, excluding certain drugs as proposed under §429.125(e)).
- Negotiation-eligible drugs. From the list of qualifying single source drugs, CMS would identify negotiation-eligible drugs using total expenditures under Medicare Part B or Part D (as calculated under proposed §429.120), to identify qualifying single source drugs that are Part B high spend drugs, Part D high spend drugs, or both (as proposed in §429.115). As proposed in §429.105(a), CMS would rank these negotiation-eligible drugs for according to the total expenditures.
- Selected drugs. In proposed §429.105(c), CMS would select[5] up to 20 negotiation-eligible drugs with the highest total expenditures under Medicare Part B and Part D for negotiation and publish the list of selected drugs for negotiation (proposed at §429.100).[6]

In addition, CMS proposes to publish a list of up to 30 top negotiation-eligible drugs (including the up to 20 selected drugs) ranked by combined total expenditures under Part B and Part D, described in greater detail below and as shown in Figure 1 on the next page.

1. Publication of the Selected Drug List (§429.100)

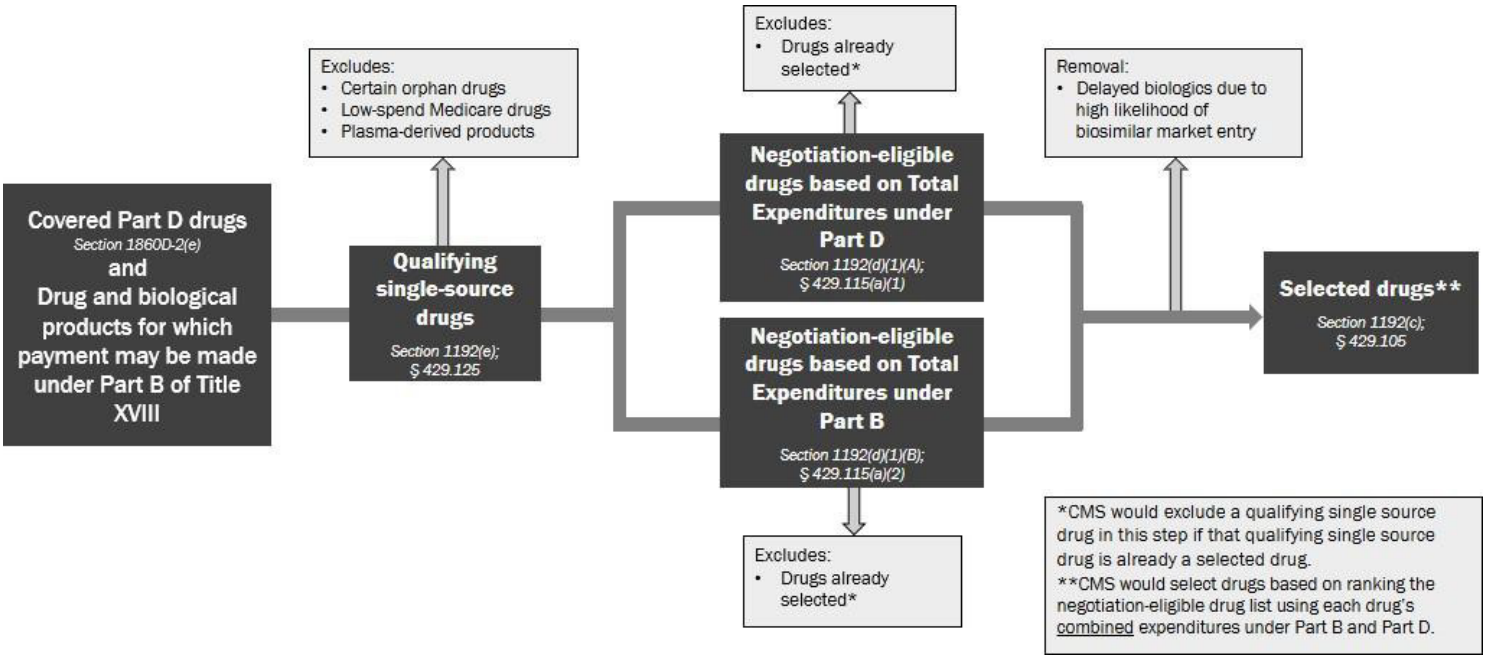
For IPAYs beginning 2029, section 1192(a)(4) of the Act requires that, not later than the selected drug publication date, the Secretary shall select and publish a list of 20 negotiation-eligible drugs. Proposed §429.20 defines the term "selected drug publication date" to have the meaning set forth in section 1191(b)(3)—that is, February 1 of the year that begins 2 years prior to such IPAY.

At §429.100(a), CMS would codify the requirement at section 1192(c)(1) that each drug included on the selected drug list for an IPAY is a selected drug with respect to such initial price applicability year and each subsequent year unless CMS makes a determination under proposed §429.135(a) that such drug will be deselected (see discussion in section II.B.6.d). Section 429.100(b) would codify the requirement that CMS publish the selected drug list (and the drugs selected for renegotiation, if any) no later than the selected drug publication date. For example, for IPAY 2029, this information would be published no later than February 1, 2027.

[5] In accordance with section 1192(a) of the Act and subject to the section 1192(f), which permits the delay in the selection and negotiation of biological products for biosimilar market entry when certain requirements are met consistent with proposed §429.110, hereinafter "Biosimilar Delay."

[6] CMS may also select drugs for renegotiation based on criteria in proposed §429.610 (see section II.G.3 below).

Figure 1: Diagram of Proposed Process for Selecting Drugs for Negotiation for IPAYs Beginning 2029



For each selected drug, CMS is proposing at §429.100(b)(3)(i) to add to the MFP file[7] no later than the selected drug publication date the active moiety, active ingredient, antigen component, or, in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at §429.125(b)(4), the distinct combination of active moieties, active ingredients, or antigen components identified as set forth in proposed §429.125(b). For a potential qualifying single source drug identified under §429.125(b)(4)(i), the agency is proposing to publish the shared active ingredient identified under §429.125(b)(4)(i), plus any additional active ingredient included in new formulations.

Section 429.100(b)(4)(i) would take the same approach for each drug selected for renegotiation, except CMS would publish the active ingredient previously identified for the IPAY for which the drug was originally selected for negotiation. Proposed §429.100(b)(3)(ii) and (b)(4)(ii) would add to the MFP file no later than the selected drug publication date the NDC-11s identified in accordance with §429.100(c)(1) and any corresponding NDC-9s and HCPCS codes for the selected drug and the drug selected for renegotiation.[8] For drugs selected for renegotiation, the

[7] The MFP file refers to the Maximum Fair Price Layout file, which contains the list of National Drug Codes (NDCs) associated with the selected drug list. For any selected drugs for which CMS and participating drug companies have agreed upon negotiated prices under the Medicare Drug Price Negotiation Program, the file also contains the single negotiated price for a 30-day equivalent supply, NDC-9 per unit price, and NDC-11 per package price, as well as other important information regarding updates to the NDCs and MFPs. Selected Drugs and Negotiated Prices | CMS

[8] Each drug is represented by a particular 11-digit National Drug Code (NDC-11). This HIPAA-standardized 5-4-2 format (Labeler Code – Product Code – Package Code) is used by Federal and commercial entities for medical

NDC-11s (and corresponding NDC-9s and HCPCS codes) added to the MFP file would also reflect information previously submitted by the Primary Manufacturer, including submissions in accordance with proposed §429.100.

At §429.100(c), the agency proposes the process for identifying the list of NDC-11s described above. As proposed at §429.100(f), the agency's list of NDC-11s would be used in the administration of the Negotiation Program. Section §429.100(c)(1) outlines first identifying NDC-11s associated with the NDA(s)/BLA(s) of the selected drug. CMS would compile all NDC-11s belonging to the selected drug associated with HCPCS codes that appear on NDC-HCPCS code crosswalks published by CMS for the most recent quarter in the total expenditures measurement period (as defined in proposed §429.20), as well as all NDC-11s belonging to the selected drug that had Part D prescription drug event (PDE) utilization in the total expenditures measurement period. The agency would also identify any additional NDC-11s associated with the NDA(s)/BLA(s) of the selected drug as found in recent updates of the NDC Structured Product Labeling (SPL) Data Elements file (NSDE) file or the NDC Directory (including its NDC Excluded Drugs Database file).

In section 30.4 of the Negotiation Program Guidance, CMS stated that it will remove any NDC-11s for which CMS has evidence suggesting a lack of coverage under Part D and Part B. Based on lessons learned from policy implementation in IPAYs 2026 through 2028, CMS is proposing to remove such requirement for initial price applicability year 2029 and subsequent years. Starting with a more comprehensive list of NDC-11s "holds utility" for CMS and Primary Manufacturers by reducing the number of NDC-11s a Primary Manufacturer must identify as missing from the list, as required in proposed §429.100(d)(1). CMS would publish the selected drug list, as well as the list of drugs selected for renegotiation, in a form and manner of CMS' choosing, which may be on the CMS website.

CMS is proposing at §429.100(c)(2) to transmit the list of NDC-11s identified at proposed §429.100(c)(1) to the Primary Manufacturer. At proposed §429.100(c)(3), the agency may revise the list of NDC-11s of each selected drug, including using information submitted by the Primary Manufacturer under proposed §429.100.

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(4)(B) of the Act and under the Negotiation Program Agreement (set forth in proposed §429.200 and described in section II.C.1), CMS proposes in §429.100(d) that a Primary Manufacturer must review the list of NDC-11s provided by CMS and provide information on each NDC-11 on the list as a part of their data submission. Specifically, a Primary Manufacturer must review the list of NDC-11s and provide proposed revisions to the list by:

- Adding any NDC-11s associated with the NDA(s)/BLA(s) of the selected drug that do not appear on the agency's list of NDC-11s of the selected drug, including any missing NDC-11s of a Secondary Manufacturer; and
- Providing identifying information for any NDC-11 that appears on the list of NDC-11s, including any NDC-11s added by the Primary Manufacturer, on whether NDC-11(s):

billing. The associated 9-digit format typically excludes the 2-digit packaging data and is used in health IT systems to identify a medication regardless of its packaging size. Associated Healthcare Common Procedure Coding System (HCPCS) codes (e.g., J-codes) can map to multiple NDC-9 drug variations and different NDC-11 package sizes.

- Are for products distributed by or under the name of a private label distributor;
- Are not manufactured, marketed, controlled or sold by the Primary Manufacturer or a Secondary Manufacturer;
- Represent a sample package;
- Represent an inner package or an outer package; and
- Whether an NDC-11 has been discontinued.

Under section 1193(a)(5) of the Act and proposed §429.200, CMS proposes at §429.100(e) that a Primary Manufacturer has an ongoing obligation to report, at least 30 calendar days prior to the change taking effect, any changes to the information provided in §429.100(d) to ensure the list of NDC-11s of the selected drug remains complete and accurate. For example, under proposed §429.100(e), a Primary Manufacturer must report to CMS any new NDC-11s of the selected drug at least 30 days prior to their first marketed date by or on behalf of the Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug. Failure to provide timely reporting of changes to the list of NDC-11s of the selected drug may be considered a violation of the Negotiation Program Agreement under section 1193(a)(5) of the Act and proposed §429.200(b).

In response to recommendations by interested parties for greater transparency and in accordance with policy established in the Negotiation Program Guidance, CMS published a list of the 50 top negotiation-eligible drugs for IPAY 2028 (including the 15 selected drugs for IPAY 2028). For IPAY 2029 and subsequent years, CMS is proposing to publish a list of the up to 30 top negotiation-eligible drugs (including the up to 20 selected drugs) ranked by combined total expenditures under Part B and Part D, as determined under proposed §429.105(a), and information on the NDC-9s, NDC-11s, and HCPCS codes for these negotiation-eligible drugs, as applicable and to the extent feasible. CMS describes why the agency is proposing to reduce its published list from 50 to 30 drugs—that previously publishing negotiation-eligible drugs with rankings lower than 30 (that is, #31 through #50) provided less meaningful transparency into the drug selection process, providing little insight into the criteria and conditions that were material to the identification of the selected drug list for that IPAY.

Consistent with prior policy, CMS proposes that the list of top drugs based on combined total expenditures would reflect the removal of negotiation-eligible drugs that qualify for the Biosimilar Delay.

2. Selection of Drugs for Negotiation (§429.105)

CMS reviews statutory requirements for the Secretary to:

- Rank negotiation-eligible drugs, according to the total expenditures for such drugs under Medicare Parts B and D, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date) for which data are available.
- Select from such ranked drugs for the IPAY the negotiation-eligible drugs with the highest such rankings.

CMS is proposing at §429.105 to select 20 (or all, if such number is less than 20) negotiation-eligible drugs for negotiation for each IPAY as follows:

- Under proposed §429.105(a), CMS would rank the list of negotiation-eligible drugs identified at proposed §429.115 based combined total expenditures under both Part B and Part D in descending order.[9]
- Under proposed §429.105(b), CMS would remove any biological products that qualify for delayed selection under section 1192(f) of the Act, as proposed at §429.110 and described in section II.B.3.
- Under proposed §429.105(c), CMS would select for negotiation the 20 (or all, if such number is less than 20) highest ranked negotiation-eligible drugs remaining on the ranked list for the IPAY.

Under the Negotiation Program Guidance for IPAYs 2026, 2027, and 2028, in the event that (1) two or more negotiation-eligible drugs had the same total expenditures to the dollar and (2) such total expenditures were the 10th or 15th highest among negotiation-eligible drugs for the IPAY, CMS will rank those negotiation-eligible drugs based on which drug had the earlier approval or licensure date associated with the earliest-approved FDA application belonging to the NDA/BLA holder and containing the drug's active ingredient. In the proposed rule, the agency is proposing to modify the methodology. Specifically, to determine whether two or more negotiation-eligible drugs have the same total expenditures and such total expenditures are the 20th highest among negotiation-eligible drugs (or the highest, if the number is less than 20), CMS would evaluate such total expenditures to the cent, rather than to the dollar as under prior policy. The agency believes that determining total expenditures to the cent, rather than the dollar, is more precise for purposes of determining the selected drug list. For such drugs with the same combined total expenditures under Part B and Part D to the cent, CMS would continue to rank those negotiation-eligible drugs based on which drug has the earliest-approved FDA application belonging to the NDA/BLA holder and containing the drug's active ingredient and select based on that ranking.

3. Request for a Biosimilar Delay (§429.110)

a. Overview of the Requirements for a Delay in the Selection and Negotiation of Certain Biological Products with High Likelihood of Biosimilar Market Entry

Section 1192(b)(1)(C) of the Act requires the Secretary to remove from the ranked list of negotiation-eligible drugs (described in proposed §429.105 and section II.B.2. of the proposed rule) any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. The manufacturer of a biosimilar biological product (defined at proposed §429.20 as the "Biosimilar Manufacturer" of a Biosimilar) may submit a request, prior to the selected drug publication date for an IPAY, for CMS to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (defined at proposed §429.20 as a "Reference Drug") on the selected drug list for such given IPAY (a "Biosimilar Delay"). A "Biosimilar Delay Request" can be "Initial" or "Additional," which together may result in a delay of two years for a biosimilar to be included on the selected drug list.

[9] The proposed methodology for the calculation of total expenditures under Part B and total expenditures under Part D is described in proposed §429.120 and section II.B.5.

In this section of the proposed rule, CMS proposes to codify its policies and requirements related to biosimilar delay requests at §429.110(a) – (i).

At proposed paragraph (a), for purposes of this section, all references to "marketed" or "marketing" mean Bona Fide Marketing as defined in § 429.20 and set forth at § 429.130(a).[10] At proposed paragraph (b), a Biosimilar Manufacturer may submit a request, prior to the selected drug publication date, to delay the inclusion of a Reference Drug from the selected drug list for: (1) One initial price applicability year based on the criteria specified in paragraph (c)(as discussed below); (2) A second initial price applicability year after such first initial price applicability year based on the criteria specified in paragraph (e) of this section. Such submissions must meet the form and manner requirements under proposed paragraph (f) (as discussed below). CMS notes that, concurrent with the proposed rule, the agency is separately proposing revisions to the information a manufacturer must currently submit as part of an Initial Delay Request (see section IV, Information Collection Request).

As discussed in more detail in the II.B.3.b. and II.B.3.c. that follow below, proposed paragraphs (c) through (f) address requirements for granting a Biosimilar Delay Request. Proposed paragraphs (h) and (i) address issues related to failure of the biosimilar to be licensed and marketed following a successful delay request.

Finally, CMS notes that, consistent with section 1198(2) of the Act, there would no administrative or judicial review of CMS' determinations regarding a Biosimilar Delay Request in proposed §429.110.

b. Requirements for Granting a Biosimilar Delay Request (§429.110(c) through (f))

Under statute, Biosimilar Delay Requests can only be submitted by the Biosimilar Manufacturer,[11] not a third party. Additionally, the statute requires the Biosimilar Manufacturer to make the request prior to the selected drug publication date for the IPAY for which the Biosimilar Manufacturer is requesting a Biosimilar Delay.

For both an Initial Delay Request and an Additional Delay Request, certain requirements must be met for CMS to grant such requests. These requirements are included in proposed §429.110(c) for an Initial Delay Request and proposed §429.110(e) for an Additional Delay Request.

For an Initial Delay Request, first, CMS would review whether the biosimilar meets the definition of an extended monopoly drug (pursuant to Section 1192(f)(1)(A) of the Act and, as described in proposed §429.110(c)(1)(i)).[12]

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[10] Bona Fide Marketing is discussed in more detail in section II.B.6.d. of the proposed rule preamble and this summary.

[11] As defined at proposed §429.20.

[12] For Initial Delay Requests, this means that the Reference Drug must have received its initial BLA licensure at least 12 years, but fewer than 16 years, prior to the start of the relevant IPAY. Selected drugs for which a manufacturer had an agreement under the Negotiation Program for an IPAY prior to 2030 are excluded from the definition of extended-monopoly drugs.

Next, CMS proposes to ascertain that the biosimilar that is the subject of the Initial Delay Request meets additional statutory requirements (largely proposed to be codified at specific subsections of §429.110(c)(1)):

- The Reference Drug must include the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved or accepted for review by FDA (section 1192(f)(1)(A) of the Act),
- Not more than one year has elapsed since the licensure of the Biosimilar and its marketing (section 1192(f)(2)(D)(iii) of the Act),
- The Biosimilar Manufacturer is not the same as the Reference Manufacturer and is not to be treated as being the same under section 1192(f)(1)(C) of the Act (section 1192(f)(2)(D)(iv) of the Act), and
- There is no agreement between the Biosimilar Manufacturer and the Reference Manufacturer that incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request, or that directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time (section 1192(f)(2)(D)(iv) of the Act).

If these requirements are met, CMS would then determine there is a high likelihood,[13] as required in section 1194(f)(1)(A) of the Act, that the Biosimilar will be licensed and marketed before the date that is two years after the statutorily defined selected drug publication date for the IPAY for which the Reference Drug would be included on the selected drug list, absent a successful Initial Delay Request. CMS proposes at §429.110(d)(1) that the agency will specify the due date by which the application for licensure must be accepted for review or approved by the FDA.

To demonstrate clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, CMS proposes at §429.110(d)(2) that the Biosimilar Delay Request must include information to demonstrate that:

- Patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed; specifically proposing at §429.110(d)(2)(i)(A) through (D) that the Biosimilar Manufacturer must demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline through any of four pathways specified, and
- The Biosimilar Manufacturer will be operationally ready to market the Biosimilar. CMS asserts that these requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date. Here, CMS proposes to consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug.

CMS proposes at §429.110(f) that a Biosimilar Manufacturer may submit to CMS a request for a Biosimilar Delay at the time and in a form and manner specified by the agency, by no later than the date specified by CMS. Inclusive in this submission would be information to support CMS' determinations described above. In paragraph (f)(1)(i) through (iii) and in the preamble narrative, CMS provides a non-exhaustive list of "clear and convincing evidence" of

[13] "High likelihood" is defined at proposed §429.110(d).

documentation that would lead the agency to conclude that a biosimilar would have a "high likelihood" of being marketed before the "high likelihood deadline." Such information must include:

- All agreements related to the Biosimilar filed with the Federal Trade Commission (FTC) or the Assistant Attorney General under subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- To the extent available, the manufacturing schedule for the Biosimilar submitted to FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and
- To the extent available, the Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (for example, in filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the 2 years, as applicable) before marketing of a Biosimilar.

CMS also proposes at §429.110(f)(2) that the agency may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request.

CMS proposes at §429.110(g)(1) that it would issue a notice of determination in writing, on or after the selected drug publication date for the IPAY by a specific date to be set forth by CMS, to the Biosimilar Manufacturer that requested the Initial Delay Request regarding whether the request was successful or unsuccessful. CMS provides details regarding the content and timing of the proposed notification.

Under proposed (g)(2): CMS publishes the number of Reference Drugs that would have been selected drugs for the applicable initial price applicability year absent the successful Biosimilar Delay Requests as part of publishing the selected drug list (as set forth in § 429.100).

Under proposed (g)(3), for successful delay requests, CMS provides in writing...a notice of determination to the Biosimilar Manufacturer of CMS' determination as to whether the Biosimilar is or is not licensed and marketed during the Initial Delay Period or the Second Delay Period, as applicable.

CMS similarly proposes procedures, content, and timelines for a Biosimilar Manufacturer's Additional Delay Request (if the manufacturer chooses to request an additional delay) consistent with the statutory requirements at sections 1192(f)(2)(B)(i)(I) and (iii) of the Act. These items would be codified at §429.110(e), §429.110(f), and §429.110(g), if finalized. Many of these elements parallel the procedures and decision points intrinsic to the Initial Delay Request. CMS proposes the notification processes related to the Additional Delay Request at §429.110(g).

c. Review for Failure of the Biosimilar to be Licensed and Marketed; Rebate Owed for Failure of a Biosimilar to be Licensed and Marketed (§429.110(h) through (i))

CMS proposes a process (at §429.110(h)(1) and (2), in accordance with applicable subsections of section 1192(f) of the Act)[14] to determine whether a Biosimilar Manufacturer that received a one- or two-year delay of Medicare drug price negotiation successfully brings its biosimilar to market within the approved delay period. If the biosimilar is not licensed and marketed during the initial delay period, the manufacturer may request an additional delay; otherwise, the reference biologic will be added to the negotiated drug selection list for the next applicable year. If the biosimilar fails to launch during an approved Additional Delay period, the reference drug will be selected two years later than originally scheduled.

Under proposed §429.110(i), if CMS has delayed negotiation due to a successful delay request and subsequently determines that the biosimilar was not marketed and the Reference Manufacturer agrees to an MFP, the reference drug manufacturer must pay a rebate to compensate Medicare for the lost savings that would have resulted from application of the Maximum Fair Price (MFP). For Part D drugs, the rebate equals 75 percent of the difference between the Average Manufacturer Price (AMP) and the MFP multiplied by utilization (per section 1192(f)(4)(B)(i) of the Act and as described in proposed §429.110(i)(4)(ii)); for Part B drugs, it equals 80 percent of the difference between the Part B payment amount and the MFP multiplied by utilization (per section 1192(f)(4)(B)(ii) of the Act and as described in proposed §429.110(i)(4)(iii)). Special rules apply for products covered under both Parts B and D and for drugs that become long-monopoly drugs during the delay, in which case an inflation-adjusted percentage of non-Federal Average Manufacturer Price (non-FAMP) replaces the negotiated MFP in the rebate calculation. CMS would use the MFP ultimately negotiated for the reference drug to calculate rebates for all delayed years, and rebate payments would be deposited into the appropriate Medicare trust funds, with future rulemaking specifying the operational details for notification and payment. In accordance with statute and as described in proposed §429.110(i)(3), the rebates paid for drugs payable under Part B would be deposited in the Federal Supplementary Medical Insurance Trust Fund.[15] The rebates paid for drugs covered under Part D would be deposited in the Medicare Prescription Drug Account.[16] CMS proposes to specify a form and manner for the administration of rebates, including the timing and mechanism for notifying manufacturers when a rebate is owed and the process for payment, in future rulemaking.

4. Identification of Negotiation-Eligible Drugs (§429.115)

Section 1192(d)(1) of the Act requires that a "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an IPAY, a qualifying single-source drug, as defined in section 1192(e) of the Act, that is a high-expenditure drug under Part B or Part D.[17]

[14] §429.110(h)(3) of this proposed rule's regulation text describes the disposition of rebates paid by the Reference Manufacturer, but this material is not discussed in the preamble.
[15] As established under section 1841 of the Act.
[16] As established under section 1860D-16 of the Act, which is within the Federal Supplementary Medical Insurance Trust Fund.
[17] High-expenditure Part B drugs are defined at section 1192(d)(1)(B) of the Act; high-expenditure Part D drugs are defined at section 1192(d)(1)(A).

CMS proposes to codify the statutory requirements at §429.115; the agency describes in the preamble language of this proposed rule the detailed steps it would take to make determinations of negotiation eligibility for drugs covered under Parts B and D; the agency proposes to repeat each step for drugs covered under Parts B and D until it has identified 50 Part D high-spend drugs and Part B high-spend drugs, respectively. These drugs, identified in accordance with proposed §429.115(a)(1) and (a)(2), respectively, would be the negotiation-eligible drugs for the IPAY.

5. Calculation of Total Expenditures (§429.120)

CMS proposes at §§429.105(a), 429.115(a), and 429.125(e)(2) to calculate total expenditures under Part B and Part D as a step in the processes for identifying selected drugs, negotiation-eligible drugs, and drugs eligible for the low-spend Medicare drug exclusion, respectively. Section 1191(c)(5) of the Act defines the term "total expenditures" to include, in the case of expenditures with respect to Part D, the total gross covered prescription drug costs (as defined in section 1860D-15(b)(3) of the Act). In the case of "total expenditures" with respect to Part B, section 1191(c)(5) of the Act specifies that such term excludes expenditures for a drug or biological product that are bundled or packaged into the payment for another service. CMS proposes its methodology for calculating total expenditures for each Part D drug (using PDE data) and Part B drug (using Part B claims data and Medicare Advantage (MA) encounter data) at §429.120(a) and §429.120(b), respectively. Given that 54 percent of Medicare beneficiaries were enrolled in MA plans as of 2025, and in response to comments the agency received on its draft guidance for IPAY 2028, CMS devotes a considerable amount of time describing how it will use MA encounter data in calculating total expenditures for Part B drugs, recapping policies currently in place for the Medicare Drug Price Negotiation Program.

6. Identification of Qualifying Single-Source Drugs (§429.125)

Section 1192(e)(1) of the Act requires that the term "qualifying single source drugs" means a covered Part D drug (as defined in section 1860D-2(e) of the Act) that is described in section 1192(e)(1)(A) or section 1192(e)(1)(B) of the Act, or a drug or biological product for which payment may be made under Part B of title XVIII that is described in section 1192(e)(1)(A) or section 1192(e)(1)(B) of the Act. CMS proposes at §429.125(a)(1) to codify the requirements in section 1192(e)(1)(A) of that Act that, for *drug* products, a qualifying single-source drug is a drug covered under Part D, payable under Part B, or both:

- That is approved under section 505(c) of the FD&C Act and marketed pursuant to such approval;
- For which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the date of such approval; and
- That is not 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.

CMS similarly proposes at §429.125(a)(2) to codify the requirements in section 1192(e)(1)(B) of the Act that, for *biological* products, a qualifying single-source drug is a drug covered under Part D, payable under Part B, or both:

- That is licensed under section 351(a) of the Public Health Service Act ("PHS Act") and marketed pursuant to such licensure;
- For which, as of the selected drug publication date with respect to a given initial price applicability year, at least 11 years have elapsed since the date of such licensure; and
- That is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act.

The first step in the proposed process would be to identify *potential* qualifying single-source drugs (at proposed §429.125(b)). For drugs, CMS proposes at §429.125(b)(1) to identify a *potential* qualifying single-source drug using all dosage forms and strengths of the drug with the same active moiety and the same holder of an NDA, inclusive of products that are marketed pursuant to different NDAs. For biological products, CMS proposes (at §429.125(b)(2)) to identify a potential qualifying single-source drug using all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a BLA, inclusive of products that are marketed pursuant to different BLAs. Consistent with the policies in Negotiation Program Guidance, CMS proposes to use public sources such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify the active ingredient/active moiety/antigen component of the drug or biological product.

CMS proposes specific policies for certain "fixed combination drugs."[18] In the draft guidance for IPAY 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028, CMS asserted that treating distinct combinations of active ingredients as one active ingredient for the purpose of identifying potential qualifying single-source drugs is generally appropriate. However, CMS in this proposed rule's preamble noted that fixed combination drugs pose a program integrity risk in situations where one or more of the active ingredients in the combination does not result in a clinically meaningful difference in the drug's action. CMS indicates that some manufacturers may avoid having all dosage forms and strengths of a drug, including the new formulation of such drug, with its active moiety(ies)/active ingredient(s)/antigen component(s) included in a qualifying single-source drug in instances in which a new formulation differs from other formulations of the qualifying single-source drug based on the inclusion of an additional active moiety/active ingredient/antigen component that enables an alternative route of administration for the shared active moiety(ies)/active ingredient(s)/antigen component(s). In this scenario, CMS is concerned that application of its general fixed combination drug policy would be in tension with statutory requirements under sections 1192(d)(3)(b) and 1196(a)(2) of the Act because CMS would not aggregate together the original qualifying single-source drug and the new formulation containing the additional active moiety/active ingredient/antigen component, even though these may be appropriately understood as different formulations of the same drug under sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

To address these program integrity risks, CMS here proposes at §429.125(b)(4)(i) a narrow modification to the application of its general fixed combination drug policy:

[18] CMS proposes at §429.20(2)(w) to define "fixed combination drug" as having the meaning set forth in 21 CFR 300.50 (https://www.ecfr.gov/current/title-21/section-300.50).

> [I[f CMS determines that a fixed combination drug with two or more active moiety(ies), active ingredient(s), or, for a vaccine for infectious disease(s), antigen component(s) shares one or more active moiety(ies), active ingredient(s), or antigen component(s) with another drug or biological product(s) with the same NDA/BLA holder, and such products differ in active moiety(ies), active ingredient(s), or antigen component(s) due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), CMS would, for purposes of identifying the potential qualifying single-source drug use all dosage forms and strengths of the drug or biological product with the shared moiety(ies), active ingredient(s), or antigen component(s) and the same NDA/BLA holder. In other words, [CMS] would identify the potential qualifying single source drug as including all dosage forms and strengths with the shared active moiety(ies), active ingredient(s), or antigen component(s) that is offered by the same NDA/BLA holder.

As alternatives to this proposal, CMS considered expressly limiting the proposed modification of the application of the general fixed combination drug policy only to biological products, as currently such biological products licensed in BLAs pose the program integrity risks of which the agency is currently aware. CMS also considered proposing an alternative modification to the general fixed combination drug policy wherein CMS identification of potential qualifying single-source drugs under the fixed combination drug policy would not take into account an active moiety, active ingredient, or antigen component that is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference from other drug or biological products that otherwise have the same active moiety(ies)/active ingredient(s)/antigen component(s). CMS decided not to proceed with these alternatives for reasons discussed in the preamble of this proposed rule. **CMS specifically seeks comment on recommended approaches** to inform CMS identification of active moiety(ies)/active ingredient(s)/antigen component(s) that enable a new route of administration for co-administered active moiety(ies)/active ingredient(s)/antigen component(s), including what types of information or descriptions we should look for within product labeling when identifying such cases. **CMS also seeks comments on the alternatives the agency considered** but is not proposing.

As part of its proposed policies for the identification of qualifying single-source drugs, in accordance with section 1192(e)(1) of the Act and consistent with policies for implementation as described in Negotiation Program Guidance, CMS is proposing at §429.125(c)(1) and (c)(2) that at least 7 years (for drugs) or 11 years (for biological products) must have elapsed between the FDA date of approval or licensure of the potential qualifying single-source drug identified at proposed §429.125(b) and the selected drug publication date with respect to an IPAY. CMS provides illustrative examples of the triggering approval / licensure dates for drugs and biologics for IPAY 2029.

CMS also proposes to define exclusions from qualifying single-source drugs (at proposed §429.125(e)(1) through (3)). CMS proposes to exclude certain orphan drugs pursuant to section

1192(e)(3)(A) of the Act, low-spend Medicare drugs described in section 1192(e)(3)(B) of the Act, and plasma-derived products described in section 1192(e)(3)(C) of the Act.

Still under the broader policy of identifying qualifying single-source drugs, CMS also addresses statutory provisions defining *bona fide* marketing of an approved generic drug or licensed biosimilar, and deselection of a selected drug, as certain provisions of the Negotiation Program statute[19] govern CMS' evaluation of generic and biosimilar competitors to potential qualifying single-source drugs and the agency's further consideration of such products in the deselection of selected drugs.

In accordance with statute, under proposed §429.125(d), CMS would first evaluate whether at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the potential qualifying single-source drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the potential qualifying single-source drug as the reference product. If CMS were to determine there is a generic drug or biosimilar that is approved or licensed, as applicable, for any dosage form or strength of a drug or biological product, and such generic drug or biosimilar is subject to Bona Fide Marketing, then that drug or biological product would not meet the statutory criteria in section 1192(e)(1)(A)(iii) or section 1192(e)(1)(B)(iii) of the Act to be a qualifying single-source drug.

Next, under proposed §429.130, CMS would then "conduct a holistic inquiry based on the totality of the circumstances when evaluating whether the manufacturer(s) of any approved generic drug(s) or licensed biosimilar(s) is or are engaged in Bona Fide Marketing of that generic drug or biosimilar as defined at proposed §429.20." One goal of this "holistic inquiry" is to determine whether meaningful competition exists on an ongoing basis between any dosage form or strength of a potential qualifying single-source drug that includes the listed drug or reference product and any one or more generic drug(s) or biosimilar(s). CMS proposes at §429.130(a)(1)(i) through (iii) to review the following data sources: PDE data, AMP data, and ASP data. If any dosage form or strength of a potential qualifying single source drug is the listed drug or reference product for one or more generic drugs or biosimilars that CMS determines are approved or licensed and subject to Bona Fide Marketing based on the information as described in proposed §429.130(a), the potential qualifying single-source drug would not be considered a qualifying single-source drug for the applicable IPAY. CMS proposes to review the information set forth in proposed §429.130(a) for any potential qualifying single-source drug for initial price

[19] From the proposed rule preamble: "First, section 1192(e)(1)(A)(iii) of the Act states that, to be considered a qualifying single source drug, a drug cannot be the listed drug for any drug approved and marketed under an ANDA under section 505(j) of the FD&C Act. For a biological product, section 1192(e)(1)(B)(iii) of the Act states that the biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act (that is, a biosimilar). Second, section 1192(c)(1) specifies a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines: (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or FDA has licensed a biosimilar under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and (2) the generic drug or biosimilar, as applicable, is marketed pursuant to such approval or licensure."

applicability year 2029 and any IPAY thereafter in January prior to the selected drug publication date.

Pursuant to section 1192(c)(1) of the Act, once the negotiation period concludes, a selected drug would cease to be a selected drug if CMS determines that a generic drug is approved or a biosimilar is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing based on the information considered in proposed §429.130(a). CMS proposes to review the information set forth in proposed §429.130(a), biannually in March and October, starting in October of the calendar year after CMS and the Primary Manufacturer reached an agreement on an MFP for the IPAY for which the drug was selected originally for negotiation and until the agency determines that a selected drug meets the requirements at proposed §429.135(a) to cease being a selected drug.

Consistent with policies described in Negotiation Program Guidance, CMS proposes to maintain monthly reviews of data during this period as proposed at §429.130(c)(4) for drugs selected for negotiation and as proposed at §429.130(c)(5) for drugs selected for renegotiation (if any) for IPAY 2029 and thereafter. However, after the negotiation period ends, the agency believes that less frequent reviews are sufficient and would provide manufacturers, Part D plan sponsors, and other interested parties with notice regarding the specific points in time across a calendar year at which CMS would review the specified data and provide public notice of any selected drugs that are deselected. However, CMS posits that during any review period, one key date includes October to ensure manufacturers and Part D plan sponsors are aware prior to the subsequent June due date for Part D plan sponsors to provide CMS with any required plan bids for the next Medicare plan contract year (as indicated in §423.265(b)(1)) of any selected drugs that may be deselected. Thus, CMS proposes at §429.130(a)(1)(i) through (iv) that the agency would review the last 12 months or the four quarters of data, as applicable, ending with the last full month or quarter of data available to CMS at the time of its review. Specifically, for PDE data, consistent with proposed §429.130(a)(1)(i) and using the example of CMS' review in October, this means that CMS would review PDE data reported from October of the prior calendar year through September of the current calendar year.

CMS proposes that the provisions of this proposed rule, including the policies set forth in §§429.130 and 429.135 with respect to Bona Fide Marketing and deselection of a selected drug, as applicable, would apply starting in 2029 with respect to the drugs selected for IPAY 2026, 2027, or 2028. In accordance with sections 1192(c)(1) and (2) of the Act, CMS proposes at §429.135 to codify provisions related to deselection of a selected drug. Specifically CMS proposes at §429.135(a) that each drug selected for negotiation for an IPAY would remain a selected drug, with respect to such IPAY and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines that at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the selected drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the selected drug as the reference product, and that such generic drug or biosimilar is subject to Bona Fide Marketing. Proposed §429.135(b) clarifies that the circumstances described in §429.135(b) would apply to such selected drug based on the date as of which CMS determines the conditions described in §429.135(a) are met. Table 1 from this section of the proposed rule preamble (reproduced

below) provides illustrative scenarios for the timing of deselection in accordance with proposed §429.135(b) using a drug selected for negotiation for IPAY 2029 as an illustrative example.

TABLE 1: DESELECTION OF A SELECTED DRUG FOLLOWING GENERIC DRUG OR BIOSIMILAR APPROVAL/LICENSURE AND MARKETING

Date on which CMS Determines that a Generic Drug or Biosimilar is Approved/Licensed and Marketed	Result with Respect to Selected Drug for the Negotiation Program
The selected drug publication date for initial price applicability year 2029 through November 1, 2027 (the end of the Negotiation Period for initial price applicability year 2029)	Selected drug remains a selected drug for initial price applicability year 2029, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2030.
November 2, 2027 through March 31, 2029	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029; selected drug ceases to be a selected drug on January 1, 2030.
April 1, 2029 through March 31, 2030	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar year 2030; selected drug ceases to be a selected drug on January 1, 2031.
April 1, 2030 through March 31, 2031	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar years 2030 and 2031; selected drug ceases to be a selected drug on January 1, 2032.
April 1, 2031 through March 31, 2032	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar years 2030, 2031 and 2032; selected drug ceases to be a selected drug on January 1, 2033.

Finally, as proposed at § 429.135(c), if CMS determines a generic drug is approved or biosimilar is licensed for a selected drug, and such generic drug or biosimilar is subject to Bona Fide Marketing prior to the selected drug publication date for the next IPAY (including drugs previously selected for renegotiation), a drug selected for a prior IPAY is not eligible for renegotiation for such next IPAY consistent with section 1194(f)(5) of the Act.

C. Negotiation Program Agreement (§§429.200-429.210)

CMS proposes to codify guidance relating to Negotiation Program Agreements in a new subpart C of part 429. The following key terms and their proposed definitions would apply:

- The term "Medicare Drug Price Negotiation Program Agreement (or Negotiation Program Agreement)" would mean the agreement between a Primary Manufacturer and CMS under §429.200 and section 1193(a) of the Act.
- The term "manufacturer" would be given the meaning set forth in section 1191(c)(1) of the Act.[20]
- The term "Primary Manufacturer" would mean the manufacturer identified by CMS as the NDA holder or the BLA holder for the selected drug.

[20] Section 1191(c)(1) of the Act adopts the definition of "manufacturer" under section 1847A(c)(6)(A) of the Act established for purposes of the average sales price payment methodology for Medicare Part B drugs.

- The term “Secondary Manufacturer” would mean a manufacturer of a drug product included in the selected drug, that is not the Primary Manufacturer for the selected drug, and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on an NDA or BLA of the selected drug. A Secondary Manufacturer would include any manufacturer of any authorized generic drug(s) and any repackager or relabeler of the selected drug that meet either of these criteria.
- The term “Request to Terminate” would mean a written request submitted by a Primary Manufacturer to CMS, that CMS determines meets the conditions under §429.205(b)(1)(A) and (B), to request termination of the Primary Manufacturer’s applicable program agreements in the context of the Primary Manufacturer's decision not to enter into or to terminate a Negotiation Program Agreement.
- The term “applicable program agreement” would mean an agreement under the Medicare Part D Manufacturer Discount Program (under section 1860D-14C of the Act) or a Medicaid drug rebate agreement (under section 1927(b) of the Act).

1. Entrance Into an Agreement With CMS (§429.200)

For IPAY 2029 and subsequent years, proposed §429.200 would establish the Negotiation Program Agreement and the requirements of such which a willing Primary Manufacturer is subject to upon executing a Negotiation Program Agreement with CMS. (The agency would not enter into a Negotiation Program Agreement with any Secondary Manufacturer of a selected drug with respect to that selected drug.)

Deadline. A Primary Manufacturer of a selected drug would have to enter into a Negotiation Program Agreement with respect to its selected drug by 11:59 p.m. PST on February 28 following the selected drug publication date for the IPAY for which the selected drug was selected for negotiation.

Negotiation Period. The negotiation period for a selected drug would begin either (i) February 28 following the selected drug publication date with respect to the IPAY for which the selected drug was selected for negotiation or (ii) the date that the Negotiation Program Agreement is fully executed, whichever occurs first.

Agreement Requirements. The Primary Manufacturer would have to agree to (i) comply with all applicable Negotiation Program requirements, (ii) negotiate (and if applicable renegotiate) an MFP for the selected drug, (iii) provide access to the MFP for the selected drug during its price applicability period, and (iv) provide information to CMS with respect to the selected drug (e.g., NCD-11s, Non-Federal Average Manufacturer Price, research and development costs, unit production and distribution costs, market data and revenue and sales volume data, etc.).

Agreement Term. A Negotiation Program Agreement would take effect on the date an authorized representative of the Primary Manufacturer and CMS sign the agreement and would apply until the agreement is terminated. Once an MFP is negotiated, the MFP would be formalized in an appendix to the Negotiation Program Agreement and signed by both parties.

2. Termination of a Negotiation Program Agreement (§429.205)

A Negotiation Program Agreement would be terminated either when the drug is no longer a selected drug under the Negotiation Program or upon the agency's acceptance of a Primary Manufacturer's Request to Terminate, whichever occurs first.

Request to Terminate. A Primary Manufacturer would be able to submit to CMS a Request to Terminate a Negotiation Program Agreement with respect to a selected drug. That request would also include a request to terminate the manufacturer from its applicable program agreements during the price applicability period for the selected drug. The Primary Manufacturer would also have to attest that through the end of the price applicability period for the selected drug, it would not (i) try to enter into any subsequent applicable program agreement or (ii) seek coverage for **any** of its drugs under the Medicare Part D Manufacturer Discount Program. Receipt of a Request to Terminate would also constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Medicaid Drug Rebate Program. Unless the Primary Manufacturer rescinds its Request to Terminate, the request would take effect on the first date after the receipt of the request that CMS determines none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program.

Election Not To Execute a Negotiation Program Agreement. A Primary Manufacturer that elects not to enter into a Negotiation Program Agreement would be able submit to CMS a written Request to Terminate that meets the requirements described immediately above.

Rescission by Primary Manufacturer of Its Request to Terminate. To rescind a Request to Terminate, a Primary Manufacturer would file a written request for a hearing with CMS. The only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its Request to Terminate before the effective date of termination of the applicable program agreements. Upon receipt of such a request, CMS would hold the hearing "solely on the papers" sufficiently in advance of the effective date of termination of the applicable program agreements.

Effect of Termination. A Primary Manufacturer would be required to make the MFP for the selected drug available before the effective date of termination (i.e., with respect to dispenses, administrations, and furnishings of the selected drug before that date).

Reentry into the Negotiation Program. If a Primary Manufacturer terminates its Negotiation Program Agreement and tries to re-enter any applicable program agreement or get coverage for any of its drugs under the Medicare Part D Manufacturer Discount Program during the selected drug's price applicability period, it would be deemed to have provided an invalid attestation as part of its Request to Terminate. In such a case, the Negotiation Program Agreement would take effect again on the date the manufacturer reentered the applicable program agreement or got coverage for any of it drugs under the Manufacturer Discount Program.

3. Other Provisions of the Negotiation Program Agreement (§429.210)

CMS proposes to codify its ability to amend the Negotiation Program Agreement to reflect changes in law, regulation, or guidance as well as its policy on severability of provisions found invalid or unenforceable by a court of competent jurisdiction.

If a Primary Manufacturer transfers ownership of one or more NDAs or BLAs of the selected drug during a price applicability period to another entity, the Primary Manufacturer would still be responsible for all requirements of the Negotiation Program Agreement associated with the transferred NDA(s) or BLA(s), including the requirement to provide access to the MFP, unless and until the Primary Manufacturer transfers all the NDAs or BLAs of the selected drug that it holds to an entity. That acquiring entity would then assume responsibility as the new Primary Manufacturer.

CMS proposes to add more details for a Primary Manufacturer to successfully transfer responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity. Specifically, all NDA(s) or BLA(s) of the selected drug that it holds would have to be transferred to the acquiring entity and the Primary Manufacturer would have to provide to CMS documentation of the intended transfer of responsibility for all requirements of the Negotiation Program Agreement to the acquiring entity, in the form of a novation, at least 30 calendar days before the intended effective date of any such transfer for CMS review and approval. If the novation agreement is approved and signed by CMS, the acquiring entity would become the successor in interest to the transferring Primary Manufacturer's Negotiation Program Agreement. However, the transferring Primary Manufacturer would still be responsible for any outstanding Negotiation Program rebate liabilities related to the Biosimilar Delay unless those liabilities are transferred to the acquiring entity as the new Primary Manufacturer.

D. Program Administration (§429.300)

CMS proposes to codify its guidance relating to its confidentiality policies. The regulations at §429.300 would state that information that CMS deems to be proprietary will only be used by CMS (or disclosed to and used by GAO) to carry out the Negotiation Program. That information, including trade secrets and confidential commercial or financial information, would be exempt from disclosure if it satisfies certain exemptions under the Freedom of Information Act (5 U.S.C. 552(b)(3) and (4)).

Certain information provided by a Primary Manufacturer with respect to a selected drug would be deemed proprietary (unless it is publicly available). This includes (i) non-FAMP and associated non-FAMP data collection, (ii) research and development costs, (iii) current production and distribution unit costs, (iv) data on pending patent applications, (v) market data and revenue and sales volume in the United States, and (vi) a common Technical File/Drug Master File/“drug dossier” under certain circumstances.

CMS also proposes to redact any information deemed proprietary or covered by the confidentiality policy from any publications related to the Negotiation Program, including the publication of the MFP.

E. Establishment of a Single MFP and Determination of the Ceiling (§§429.400-429.445)

1. Establishment of a Single MFP for Negotiation and Renegotiation Purposes (§429.400)

CMS interprets the statute as requiring negotiation of a single price for a selected drug with respect to its price applicability period. To accomplish that, CMS proposes to:

- Identify a single price to include for each offer and counteroffer in the negotiation process (and renegotiation process, if applicable) for a selected drug, including for a selected drug with multiple dosage forms and strengths; and
- Base the single price on the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths.[21]

2. Collection of Non-FAMP (§429.405)

Per the Negotiation Program Agreement, a Primary Manufacturer of a selected drug would be required to submit to CMS the following information:

- Non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar year 2021 in which the selected drug was sold and non-FAMP data was reported,[22] and
- Non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of the calendar year prior to the selected drug publication date with respect to the IPAY for which the selected drug was selected for negotiation.

The deadline for the submission of this information would be 11:59 p.m. PST on March 1 of the year of the selected drug publication date with respect to the IPAY.

If the non-FAMP is restated because of VA requirements under 38 U.S.C. 8126, then the Primary Manufacturer would be required to update the submission of non-FAMP to CMS for the selected drug.

3. Determination of the Ceiling (§429.410)

Limitations on Offer Amount (Ceiling). For purposes of negotiating the MFP of a selected drug, CMS is statutorily prohibited[23] from making an offer (or agreeing to a counteroffer) for an MFP that exceeds the ceiling, or, if applicable, is less than the Temporary Floor for Small Biotech Drugs.[24]

[21] The guidance states that this methodology was chosen, instead of per unit or per weight-based metric, for a more direct comparison with the therapeutic alternative(s), which might have different dosage forms, strengths, and treatment regimens than the selected drug.
[22] If there is no average non-FAMP available for 2021, then non-FAMP, unit type, and total unit volume must be reported for the four quarters of the first full calendar year following the market entry for such drug.
[23] See section 1194(b)(2)(F) of the Act.
[24] See section 1194(d) of the Act.

Determination of the Ceiling for the MFP. For IPAY 2029 and each subsequent year, the MFP ceiling for a selected drug would be the lower of the amounts determined with respect to the selected drug under the following two methodologies:

Methodology 1:

Selected Drug	Calculation
Covered under Part D but not payable under Part B	Sum of the plan-specific enrollment weighted amounts (under §429.420)
Not covered under Part D but payable under Part B using ASP methodology	ASP payment methodology (under §429.425)
Covered under Part D and paid under Part B using ASP methodology	Combined Part B and Part D amount (under §429.430)
Covered under Part D and paid under Part B but not using ASP methodology	Sum of the plan-specific enrollment weighted amounts (under §429.420)
Not covered under Part D and paid under Part B but not using ASP methodology	N/A

Methodology 2:

The applicable percent,[25] as applicable to the selected drug, of the lower of—

- The average non-FAMP for calendar year 2021, or, as applicable, the first full year after 2021 for which data is available, adjusted by inflation;[26] or
- The average non-FAMP for the year preceding the selected drug publication with respect to the first IPAY of the price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior for which data is available.

4. Calculation of the 30-day Equivalent Supply (§429.415)

To facilitate the determination of a single ceiling price, and the negotiation of a single MFP, across dosage forms and strengths of a selected drug where units and treatment regimens differ, CMS calculates a 30-day equivalent supply for a selected drug and therapeutic alternatives, as applicable. After having considered several alternatives,[27] CMS proposes to codify the methodologies under its most recent guidance.

Part D Selected Drugs. For selected drugs covered under Part D, CMS proposes to codify the use of the methodology under the Part D program that relies on the "days' supply" field in Part D Event (PDE) records to calculate the 30-day equivalent supply for each PDE record associated with the selected drug.

[25] The applicable percent is 75% for short-monopoly drugs, 65% for extended-monopoly drugs, and 40% for long-monopoly drugs.
[26] The average non-FAMP is increased for inflation by the percentage increase in the consumer price index for all urban consumers (all items, United States city average; CPI-U) from September 2021 (or December of the first full year following the market entry), as applicable, to September of the year that is 3 years before the IPAY with respect to which the selected drug was selected for negotiation.
[27] These alternatives included a per-unit approach; a price per course of treatment; consulting with the Primary Manufacturer of each selected drug to determine a methodology; and a flexible methodology to accommodate the clinical disease state and treatment landscape.

Part B Selected Drugs. For selected drugs covered under Part B, CMS also proposes to codify its most recent guidance to calculate a 30-day equivalent supply using an alternative methodology because Part B data does not contain a "days' supply" field. Specifically, CMS would use the "days between service" amount calculated for each Part B claim to calculate the 30-day equivalent supply. For each Part B claim, the number of 30-day equivalent supplies would be equal to the 'days between service' divided by 30. The agency believes the 30-day equivalent supply methodology provides a standardized methodology for the calculation of a price for a standardized treatment duration for all dosage forms and strengths of selected drugs and therapeutic alternatives. It would also permit easier comparison across the selected drug and the respective therapeutic alternative(s). The reader is directed to proposed §429.415(a)(2) for the detailed steps CMS would undertake to develop the 30-day equivalent supply for Part B selected drugs.

Drugs Typically Assigned One Time. For selected drugs typically administered one time (e.g., some vaccines, gene therapies, and cancer therapies), CMS proposes to assign a value of "12" for the 30-day equivalent supply for those selected drugs.

5. Determination of the Sum of the Plan-specific Enrollment Weighted Amounts (§429.420)

Data Used. CMS proposes to use the PDE file data and Direct and Indirect Remuneration (DIR) data reported by Part D plans to CMS each year that meet the inclusion and exclusion criteria[28] for the year. Examples of excluded data would be data from plans that have no utilization for the selected drug or plans that have no enrollment for the year that is 4 years prior to the IPAY of the selected drug. The agency would use the most recent year for which all data is available, which it believes would generally be the year that is 4 years prior to the IPAY with respect to which the selected drug was selected for negotiation.

Determination of the Sum of the Plan-specific Enrollment Weighted Amounts. To determine the sum of the plan-specific enrollment weighted amounts across all NDCs of the selected drug, CMS proposes to codify the 10-step methodology used to generate the sum of the plan-specific enrollment weighted amounts for the selected drug for a 30-day equivalent supply under its most recent guidance. However, under the proposed rule, CMS would use the selected drug's NDC-11 as opposed to the NDC-9 level used under the most recent guidance.

6. Determination of the Payment Amount Under Section 1847A(b)(4) of the Act (§429.425)

For Part B selected drugs payable using the average sales price (ASP) methodology under section 1847A(b)(4) of the Act, CMS proposes to codify its guidance and calculate for such a selected drug an amount equal to the lesser of the ASP payment amount or the wholesale acquisition cost (WAC) payment amount under section 1847A(b)(4) for that selected drug in the year that is 3 years before the IPAY of the selected drug for a 30-day equivalent supply across all dosage forms and strengths of the selected drug. CMS notes the amount is not adjusted to account for sequestration.

[28] See proposed regulation §429.120(a)(2) through (5).

CMS would first calculate the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which NDC-11s of the selected drug are assigned, which the agency would then assign as the payment amount under section 1847A(b)(4) for each NDC-11 of the selected drug within such HCPCS code. It would then allocate HCPCS code-level utilization from Part B data across each NDC-11 assigned to such HCPCS code, so that the NDC-level utilization is used as weights when calculating a single payment amount under section 1847A(b)(4) across all dosage forms and strengths of the selected drug.

CMS proposes to codify the 7-step methodology used to calculate the payment amount under section 1847A(b)(4) for the selected drug for a 30-day equivalent supply under its most recent guidance. However, under the proposed rule, CMS would use the selected drug's NDC-11 as opposed to the NDC-9 level used under the most recent guidance.

7. Determination of the Combined Part B and Part D Amount (§429.430)

CMS believes that section 1194(c)(1)(B) of the Act should be interpreted to require the agency to calculate an amount that captures both the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amounts, where both amounts are available for the selected drug. It does not believe it should only select one of the two payment amounts.

The agency proposes to codify its guidance under which it calculates a weighted average of (i) the payment amount under section 1847A(b)(4) (determined pursuant to proposed §429.425) and (ii) the sum of the plan-specific enrollment weighted amounts (determined pursuant to proposed §429.420). The combined Part B and Part D amount would be for all dosage forms and strengths of a selected drug that are payable under Part B under section 1847A(b)(4) and covered under Part D. For the utilization weighting, CMS proposes to treat the NDC–11s of drugs payable under Part B and covered under Part D as having two distinct versions; it would keep those versions separate in the utilization weighting so that the NDC–11s of drugs payable under Part B and covered under Part D contribute separately to the single amount, based on their applicable proportions to the total.

8. Determination of the Applicable Average Non-FAMP Amounts and Applicable Percent of the Average Non-FAMP (§429.435)

As noted above, CMS must calculate the average non-FAMP for calendar year 2021 (or, as applicable, the first full year after 2021 for which data are available), adjusted by inflation, and the average non-FAMP for the year preceding the selected drug publication with respect to the first IPAY of the price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior for which data is available. CMS proposes to codify the methodology under its guidance to determine the lower of the two applicable non-FAMP amounts and apply the appliable percent and to calculate the average non-FAMP for the calendar year 3 years before the IPAY of the selected drug. (CMS notes that the set of NDCs used to calculate the annual average non-FAMP calculation for each may differ.)

CMS would use the list of NDC–11s of the selected drug to determine which NDC–11s of the selected drug would be included in the ceiling calculation. It also proposes to base the average

non-FAMP calculations on a 30-day equivalent supply. It proposes to calculate the average non-FAMP across all NDC–11s of the selected drug separately for the average non-FAMP in calendar year 2021 (or for the first full year following market entry) and for the calendar year that is 3 years before the IPAY of the selected drug. It would calculate an average non-FAMP comparable to the sum of the plan-specific enrollment weighted amount, the payment amount under section 1847A(b)(4), or the combined Part B and Part D amount, as applicable.

The agency proposes to apply the applicable percent to the average non-FAMP associated with the monopoly type for the selected drug based on the initial approval date of the selected drug and its IPAY.[29] CMS would then compare the amounts calculated for the two separate applicable percent of the average non-FAMP amounts and determine the lower amount.

9. Temporary Floor for Small Biotech Drugs (§429.440)

CMS implemented the Small Biotech Exception (SBE) for IPAY 2028 in guidance. The SBE excludes from the definition of a negotiation eligible drug for IPAYs 2026, 2027, and 2028 a qualifying single source drug that meets either the criteria for small biotech drugs at section 1192(d)(2)(A)(i) or section 1192(d)(2)(A)(ii) of the Act. CMS must evaluate whether a selected drug qualifies for the SBE based on "Total Expenditures" under Part B or Part D, and CMS would make separate determinations for each part.

The following key terms and their proposed definitions would apply:

- The term "Part B 2021 Manufacturer" would mean the NDA holder or the BLA holder for the qualifying single source drug on December 31, 2021.
- The term "Part D 2021 Manufacturer" would mean an entity that either (i) had a Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A of the Act in effect for the qualifying single source drug on December 31, 2021, or (ii) had an arrangement whereby the manufacturer's labeler codes were listed on another manufacturer's Medicare CGDP Agreement in effect on December 31, 2021.
- The term "Part B 2021 Manufacturer and its controlled group" would mean a group comprising all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part B 2021 Manufacturer.
- The term "Part D 2021 Manufacturer and its controlled group" would mean a group comprising all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021.

Limit on CMS Offers/Counteroffers. For qualifying single source drugs that meet the requirements to be a Small Biotech Drug, and with respect to which the first IPAY of the price applicability period with respect to such drug is 2029 or 2030, CMS may not offer or agree to a counteroffer for an MFP that is lower than the Temporary Floor for Small Biotech Drugs. Section 1194(d) of the Act mandates that the Temporary Floor for Small Biotech Drugs shall be equal to 66 percent of the average non-FAMP for such drug for 2021 (or, if there is no average

[29] As noted above, the applicable percent is 75% for short-monopoly drugs, 65% for extended-monopoly drugs, and 40% for long-monopoly drugs.

non-FAMP available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such IPAY.

CMS proposes to establish the Temporary Floor for selected drugs determined to be a Small Biotech Drug based on the criteria used and implemented with respect to the SBE for IPAY 2028. The agency notes that if it determines that a given selected drug is eligible for the Temporary Floor for Small Biotech Drugs for IPAYs 2029 and 2030, that determination is not based on whether CMS previously determined that the qualifying single source drug was eligible or not eligible for the SBE for IPAYs 2026, 2027, or 2028.

Information. Primary Manufacturers seeking an exception as a Small Biotech Drug must submit information so CMS may determine whether the drug meets the applicable requirements, which again would be consistent with eligibility requirements for the SBE for IPAY 2028. For example, Primary Manufacturers would have to provide CMS with information to accurately identify the Part B 2021 Manufacturer[30] and its controlled group[31] (if any).

Eligibility for Part B Track. Generally, to be eligible for the exception under Part B (the "Part B Track"), the total expenditures under Part B during 2021 for the selected drug must be:

- Equal to or less than 1 percent of the total expenditures under Part B for all qualifying single source drugs payable under Part B during 2021; and
- Equal to or greater than 80 percent of the total expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group that are payable under Part B during 2021.

Eligibility for Part D Track. Generally, to be eligible for the exception under Part D (the "Part D Track"), the total expenditures under Part D during 2021 for the selected drug must be:

- Equal to or less than 1 percent of the total expenditures under Part D for all covered Part D drugs during 2021; and
- Equal to or greater than 80 percent of the total expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had an agreement in effect under section 1860D-14A on December 31, 2021.

Limitations. The exception would not apply to a selected drug of a Primary Manufacturer if the manufacturer is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act. A specified manufacturer is a manufacturer that, in 2021, had a Medicare Part D coverage gap discount agreement and that had Medicare associated expenditures for all of its drugs totaling less than 1% of aggregate expenditures for Part D and Part B drugs and biologicals. For the acquisition of a Primary Manufacturer to potentially preclude a selected drug from being considered a Small Biotech Drug, CMS proposes that the transaction must occur after 2021 and must involve the acquisition of the Primary Manufacturer after it held the NDA(s) or BLA(s) for the drug.

[30] This is the entity that is the NDA(s) holder or BLA(s) holder for the selected drug on December 31, 2021.
[31] This would include all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part B 2021 Manufacturer.

Determination of the Adjusted Ceiling for the MFP Exception. CMS believes it is possible that the ceiling calculated under §429.410(b) could be lower than the temporary floor for a Small Biotech Drug. Thus, it proposes a "stepwise approach" to calculate an adjusted ceiling that would apply to the negotiation, or renegotiation, process for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs.

First it would determine the unadjusted ceiling under §429.410(b) and compare it to the temporary floor. If the unadjusted ceiling is greater than the temporary floor, no adjustments would be made. However, if the temporary floor is greater than the unadjusted ceiling, CMS proposes to calculate an adjusted ceiling using only the average non-FAMP for the selected drug for the year prior to the selected drug publication date. It believes removing the average non-FAMP available for such drug in 2021 from the calculation of the lower amount of the applicable percent of the average non-FAMP gives effect to both the Temporary Floor and the ceiling calculations.

If the adjusted ceiling is greater than or equal to the Temporary Floor for Small Biotech Drugs, then that adjusted ceiling would be used as the ceiling for the negotiation. If the adjusted ceiling is below the Temporary Floor, then the ceiling would be raised to equal the Temporary Floor. CMS states that it would not make an offer (or agree to a counteroffer) for an MFP that exceeds the adjusted ceiling.

CMS notes this exception applies only for IPAYs 2029 and 2030, and it would not apply to renegotiations for IPAYs after 2030.

Written Notice. CMS would provide a Primary Manufacturer that submitted a request for the SBE written notice of its decision to grant or deny the request and, if granted, CMS' calculation of the temporary floor.

10. Calculation Information and Suggestion of Error (§429.445)

CMS proposes to provide Primary Manufacturers with both information on its various calculations as well as a process by which Primary Manufacturers may submit Suggestions of Errors in those calculations.

Information. CMS proposes to provide information on (i) its calculation of the ceiling, (ii) the computation of how it will apply a single MFP across dosage forms and strengths of the selected drug, and (iii) its calculation of the Temporary Floor for Small Biotech Drugs and adjusted ceiling, as applicable.

Timing. CMS proposes to provide the information described in clauses (i) through (iii) above after the Primary Manufacturer submits the required data (e.g., under proposed §§429.100(d), 429.100(e), 429.405(a), 429.440(b)(1), 429.505(b)(2), 429.615(b)(1), and 429.700(c)(4)(i)(B)(2)). No specific deadlines for the provision of information are included in the regulation text.

Suggestion of Error. If a Primary Manufacturer that believes in good faith that CMS has made an error in the calculations described above, it may submit a Suggestion of Error regarding those calculations for CMS' consideration. The Suggestion of Error would have to be submitted within 10 days of receiving information from CMS. However, the Suggestion of Error process would negate a Primary Manufacturer's obligation to comply with Negotiation Program requirements and would not change any timelines or requirements of the Negotiation Program.

F. Negotiation Process (§§429.500-429.535)

1. General Rule (§429.500)

Section 1194 of the Act describes the process that CMS must follow when conducting negotiation and renegotiation. This section directs CMS to use a consistent methodology and process for negotiation that aims to achieve the lowest MFP for each selected drug. In addition, this section requires CMS to consider certain factors as the basis for determining offers and counteroffers. CMS proposes to codify these provisions at § 429.500(a). CMS also proposes in §429.500(b) that to formalize an agreed-upon MFP, CMS and the Primary Manufacturer must sign an Addendum to the Negotiation Program Agreement, as described in proposed §429.200(e) and discussed in section II.C.1. of the proposed rule

CMS notes that with respect to IPAYs 2026 through 2028, CMS implemented these requirements through guidance. For IPAY 2029 and subsequent years, CMS is proposing in §§429.500 through 429.535 to codify the negotiation process consistent with the requirements of the IRA and such prior guidance, with proposed revisions noted in these sections (and described in more detail below).

2. Negotiation Factors (§429.505)

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining offers and counteroffers. These factors include: 1) data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act and, 2) evidence about alternative treatments, as specified in section 1194(e)(2) of the Act.

CMS is proposing to codify these requirements, as described in more detail below, for IPAY 2029 and subsequent years.

a. Information Related to Section 1194(e)(1) Factors

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining offers and counteroffers, including data submitted by the Primary Manufacturer as specified in section 1194(e)(1) of the Act.

CMS proposes to codify at §429.505(b) that the Primary Manufacturer of a selected drug is required to submit, among other information, information required to carry out the Negotiation Program. Primary Manufacturer required data includes:

- R&D costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
- Current unit costs of production and distribution of the selected drug;
- Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
- 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
- Market data and revenue and sales volume data for the selected drug in the United States.

In accordance with the requirements of the Negotiation Program Agreement, the Primary Manufacturer must submit the required information in this section to CMS in a form or manner specified by CMS by 11:59 pm PST on March 1 of the year of the selected drug publication date. This is inclusive of the NDC-11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.

CMS states that when it considered what information required to carry out its statutory obligation under this section, CMS considered the operational and financial burden to the Primary Manufacturer alongside the importance of collecting sufficient information to inform determination of offers and counteroffers, including development of the initial offer. CMS concluded that the agency is unable to obtain this information from sources other than the Primary Manufacturer of the selected drug, regardless of whether alternative sources for this information may exist.

CMS also proposes in §429.505(c) that a Primary Manufacturer has an ongoing obligation to report any updates to the information provided in proposed §429.505(b) if the Primary Manufacturer becomes aware that any of such information has changed or is otherwise inaccurate. CMS states it will provide the Primary Manufacturer with a method to report any such updates.

CMS notes, and as discussed further in section II.G.4.a. of the proposed rule, that the agency may consider the Primary Manufacturer's prior data submission(s) under proposed §429.505(b), including any updates to such information, to inform renegotiation eligibility and selection, and may use such information during renegotiation if a drug is selected for renegotiation.

b. Information Related to Section 1194(e)(2) Factors

Section 1194(e)(2) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors on the evidence about the selected drug and therapeutic alternative as the basis for determining its offer. These are described at proposed §429.510 and section II.F.3. of the proposed rule, and produced here for completeness and context:

- The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
- FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
- Comparative effectiveness of the selected drug and its 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 as described in section 1194(e)(2)(C) of the Act); and
- The extent to which the selected drug and the therapeutic alternatives to the selected drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

For section 1194(e)(2) factors, CMS proposes to take a two-pronged approach consistent with policies for implementation for IPAY 2028. In this approach, CMS would evaluate existing literature and real-world evidence, conduct internal analytics, and consult subject matter experts and clinicians, whether within CMS or external to CMS, when considering available evidence about alternative treatments to the selected drug. CMS also intends to provide for a voluntary submission of information related to these factors from manufacturers and the public through the Drug Price Negotiation ICR. CMS states that obtaining input from multiple perspectives, including but not limited to manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties will provide the most comprehensive understanding of the selected drug and its therapeutic alternatives.

Thus, CMS proposes at §429.505(d) to codify that the submission of information related to section 1194(e)(2) of the Act on the evidence about the selected drug and therapeutic alternatives will be open to the public and voluntary. Specifically, at paragraph (d)(1), CMS proposes that any interested party, including the Primary Manufacturer of a selected drug, may submit evidence about the selected drugs and their therapeutic alternatives. Evidence about the selected drug and therapeutic alternatives could include:

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

CMS also proposes that it will review cost-effectiveness measures used in studies relevant to the selected drug and may use that content if the use of this measure is permitted in accordance with this section and other applicable law. At paragraph (d)(2), CMS proposes that interested parties must submit this information by 11:59 PST on March 1 of the year of the selected drug

publication date. The agency states that this allows it to consider all submitted evidence in totality and meet the statutory deadline for the initial offer.

Finally, section 1194(e)(2) of the Act places limits on evidence that may be used by CMS. Accordingly, and consistent with CMS' policies for implementation for IPAY 2028 as described in guidance, CMS proposes to codify at §429.505(e), that the agency will not use evidence from comparative clinical effectiveness research 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.

3. Methodology for Developing the Initial Offer (§429.510)

Section 1194(e) of the Act directs CMS to consider certain factors related to manufacturer-specific data and available evidence about therapeutic alternative(s) as the basis for determining offers and counteroffers in the negotiation process. CMS is also required to provide the manufacturer of a selected drug with a written initial offer and a concise justification. The statute does not specify how and to what degree each factor should be considered, thereby providing CMS with the discretion to determine how each factor is considered.

CMS proposes in §429.510 that for purposes of determining the initial offer, CMS would:

- Identify conditions for which the selected drug is used, as described in proposed §429.510(a);
- Identify the therapeutic alternative(s), if any, for the selected drug, as described in proposed §429.510(b) and (c);
- Determine the starting point for the initial offer based on the price(s) of the therapeutic alternative(s) for the selected drug, if any, or an alternative price if there is no therapeutic alternative, as described in proposed §429.510(d);
- Evaluate the selected drug, including compared to its therapeutic alternative(s), for the purposes of adjusting the starting point using the negotiation factors, as described at proposed §429.510(e); and
- Adjust the preliminary price based on the negotiation factors to determine the initial offer price, as described in proposed §429.510(f).

Each of these provisions is discussed in more detail below. CMS states that it would not make any offers or accept any counteroffers for the MFP that are above the statutorily defined ceiling nor below the temporary floor for small biotech drugs, if applicable.

a. *Identifying Conditions for which the Selected Drug is Used (§429.510(a))*

At proposed §429.510(a), CMS proposes to identify conditions for which the selected drug is used that are covered under Part D, payable under Part B, or both. CMS proposes to:

- Consider the prescribing information approved by the FDA for the selected drug (at proposed §429.510(a)(1));
- Consider off-label use to identify conditions for which the selected drug is used, if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically accepted indication, taking into consideration the major drug compendia,

authoritative medical literature, accepted standards of medical practice, or some combination thereof (at proposed §429.510(a)(2)); and
- Exclude from its analysis for development of the initial offer any FDA-approved indication(s) or off-label uses for which CMS believes that utilization of the selected drug within such indication(s) and for such uses is intended solely for use in a setting in which the selected drug is not payable under Part B and not covered under Part D (at proposed §429.510(a)(3)).

Regarding proposed paragraph (a)(3), CMS states that since the MFP resulting from a negotiation may only be applied for drugs payable under Part B, covered under Part D, or both, it is consistent for CMS to exclude from its analysis these FDA-approved indications or off-label uses. By way of example, CMS states it may not include an FDA-approved indication or off-label use in its analysis for the initial offer if such indication or off-label use is recommended for use in clinical practice guidelines only in inpatient hospital settings. CMS also states that a Primary Manufacturer may suggest in its response to the initial offer that use within an FDA-approved indication or an off-label use is relevant for negotiating an MFP for the selected drug, and thus CMS may include such indication or off-label use in its consideration of any counteroffers or revised offers.

b. Identifying Therapeutic Alternatives for Each Condition (§429.510(b) and (c))

For each condition for which the selected drug is used, CMS states it would use the information identified in proposed §429.510(b) and would follow the steps defined in proposed §429.510(c) to identify a pharmaceutical therapeutic alternative(s), if any, for purposes of developing the initial offer. Specifically, CMS proposes at §429.510(b)(1) to identify the therapeutic alternative(s) for each condition(s) for the selected drug is used, using any combination of the following, as available:
- Information submitted by the Primary Manufacturer and the public;
- Prescribing information approved by the FDA;
- Drug classification systems commonly used in the public and private sector for formulary development;
- Major drug compendia;
- Widely accepted clinical practice guidelines;
- Evidence identified through the CMS-led literature review;
- Published drug or drug class reviews;
- Peer-reviewed studies; or
- Medicare claims or other data sets.

In addition to brand name drugs and biological products, CMS proposes to consider generic drugs and biosimilars, including specific formulations or dosage forms and strengths of a brand name drug, brand name biological product, generic drug, or biosimilar, as applicable, when identifying a potential therapeutic alternative(s) to a selected drug as described in proposed §429.510(b)(2).

At proposed §429.510(c), CMS proposes to codify its process for determining the potential therapeutic alternative(s) for s selected drug. CMS states that it considered evaluating non-

pharmaceutical interventions as potential therapeutic alternatives to the selected drug, but states that considering non-pharmaceutical interventions as a therapeutic alternative poses several challenges, including that, from a clinical perspective, non-pharmaceutical interventions are not exclusively used as alternatives to drugs, or vice versa. CMS states that because of these considerations, it is not proposing to use non-pharmaceutical interventions as a therapeutic alternative for selected drugs in this proposed rule but will continue to evaluate this issue.

Given these challenges, CMS believes that pharmaceutical therapeutic alternatives would be the most analogous alternative to the selected drug. CMS proposes at §429.510(c)(1) that it may consult with FDA, clinicians, patients, or patient organizations, and researchers, or any combination thereof to ensure that appropriate therapeutic alternatives are identified.

CMS proposes in §429.510(c)(2) that when determining therapeutic alternative(s) for a selected drug, CMS would consider:

- Off-label use(s) for potential therapeutic alternatives;
- Potential therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action;
- Potential therapeutic alternatives in a different pharmacologic class than the selected drug; and
- Formulations or dosage forms and strengths of a potential therapeutic alternative.

In proposed §429.510(c)(3), CMS proposes that, in cases where there are many potential therapeutic alternatives for a given condition for which the selected drug is used, CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug for the purpose of developing the initial offer. In §429.510(c)(4), CMS proposes to prioritize clinical appropriateness in the selection of therapeutic alternatives.

c. Developing a Starting Point for the Initial Offer (§429.510(d))

To fulfill the statutory requirement to develop the initial offer CMS proposes at §429.510(d) to determine a numerical starting point that would be adjusted based on the section 1194(e)(2) factors to determine a preliminary price. CMS considered a multitude of options for what price should be used as the starting point for developing the initial offer (summarized in the table below). Under any of these options, the initial offer and final MFP would be capped at the statutory ceiling.

Options CMS Considered as a Starting Point for Developing the Initial Offer	
Part D net price(s)	MFP, if available
ASP/WAC(s) of therapeutic alternative(s) for drugs covered under Part D or payable under Part B, respectively, or both	Starting point between: (a) the Part B ASP/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and D amount discussed previously for the therapeutic alternatives (b) the statutory ceiling
Unit cost of production and distribution for the selected drug	
Ceiling for the selected drug	
Domestic reference price for the selected drug (for example, the Federal Supply Schedule56 (FSS) price)	Starting point between (a) the Part B ASPs/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and Part D amount discussed
"Fair profit" price for the selected drug based on	

whether R&D costs have been recouped and margin on unit cost of production and distribution	previously for therapeutic alternatives and (b) unit cost of production and distribution of the selected drug; or some combination thereof.
Net Part D Plan Payment and Beneficiary Liability for drugs covered under Part D	

After considering these options and based on its experience from implementation of the Negotiation Program for IPAYs 2026 through 2028, CMS proposes at §429.510(d)(1) to use the price of the therapeutic alternative(s) as the starting point for developing the initial offer. The prices determined will be expressed as a 30-day equivalent supply, consistent with the requirements at §429.510(d)(2), unless CMS determined it is appropriate to apply a different methodology.

Price of a therapeutic alternatives covered under Part D: CMS proposes at §429.510(d)(1)(i) that the price of a therapeutic alternative would be the lower of: the Net Part D Plan Payment and Beneficiary Liability, WAC, or the MFP for a selected drug negotiated for a prior IPAY (regardless of whether the agreed-upon MFP for such selected drug has become effective).

Price of a therapeutic alternatives covered under Part B: CMS proposes at §429.510(d)(1)(ii) that the price of a therapeutic alternative would be the lower of: ASP, the MFP for a selected drug negotiated for a prior IPAY (regardless of whether the agreed-upon MFP for such selected drug has become effective), or WAC.

Price of a therapeutic alternative that is both payable under Part B and covered under Part D: CMS proposes at §429.510(d)(1)(iii) that for a therapeutic alternative the price would be equal to a combined amount based on the price of the therapeutic alternative under Part D and the price under Part B (as determined under proposed §429.510(d)(1)(i) and (ii)). The single combined amount would be weighted by the utilization of the drug across Part B and Part D.

For a selected drug with no therapeutic alternative or for a selected drug where the price(s) of the therapeutic alternative(s) determined is below the ceiling, CMS proposes at §429.510(d)(3)(i) to use an alternative price equal to the lower of:

- The pharmaceutical price for the selected drug as included in the FSS as managed by the Department of Veterans Affairs;
- The maximum price a manufacturer can charge for the selected drug under 38 U.S.C. 8126 as most recently submitted by the Primary Manufacture; or
- The ceiling for the selected drug as determined in 429.410(b).

If there are multiple therapeutic alternatives and at least one therapeutic alternative price identified is below the ceiling, CMS proposes at §429.510(d)(3)(ii) to determine a starting point for developing the initial offer within a range based on the lower of the prices of the therapeutic alternatives determined under §429.510(d)(1) and the ceiling. In implementing this proposal, CMS states it may weigh prices used to determine the range based on utilization.

Finally, CMS proposes at §429.510(d)(3)(iii) that if there is one therapeutic alternative for the selected drug with a price that is below the ceiling, the price of such therapeutic alternative is the starting point. In all cases, the starting point would not exceed the statutory ceiling and would be subject to adjustments as described further in proposed §429.510(e) and section II.F.3.d. of this

proposed rule.

d. Adjusting the Starting Point and Preliminary Price Based on the Factors Listed at Section 1194(e) of the Act (§429.510(e) and (f))

Section 1194(e) of the Act directs CMS to consider the factors listed at section 1194(e)(1) and 1194(e)(2) of the Act as the basis for any offers and counteroffers and CMS must develop and use a consistent methodology and process for negotiations to achieve the lowest MFP for each selected drug. For IPAYs 2026 through 2028, CMS implemented these requirements through guidance. For IPAY 2029 and subsequent years, CMS is proposing at §429.510(e) to adjust the starting point determined based on the section 1194(e)(2) factors to determine the preliminary price and then to adjust the preliminary price based on the section 1194(e)(1) factors to determine the initial offer. CMS states that this approach ensures that it considers each factor while also providing a consistent methodology for doing so.

(1) Adjusting the Starting Point Based on Section 1194(e)(2) Factors (§429.510(e)). To evaluate section 1194(e)(2) factors, including the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), CMS proposes at §429.510(e)(1) to use a qualitative approach to broadly evaluate the body of available evidence, including any combination of the following, as available:

- Information submitted by the Primary Manufacturer and the public and provided in public events, as available;
- Evidence identified through a CMS-led literature review;
- Medicare claims or other datasets, potentially including evidence related to health care resource utilization and usage patterns of the selected drug versus its therapeutic alternative(s);
- Clinical data;
- Other information relevant to the selected drug and its therapeutic alternative(s).

CMS also proposes at §429.510(e)(2) that it may consult with clinicians, patients or patient organizations, researchers, and/or FDA.

CMS states that when evaluating the literature from the public and manufacturer submissions as well as literature from CMS' review, CMS intends to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process.

CMS also proposes prioritizing research (including both observational research and research based on randomized samples) that is methodologically rigorous, appropriately powered (that is, has sufficient sample size) to answer the primary question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses. CMS also proposes to consider research and real-world evidence relating to Medicare populations, including

individuals with disabilities, patients with end-stage renal disease, and Medicare-aged populations, as particularly important.

To consider comparative effectiveness of a selected drug and its therapeutic alternative(s), CMS proposes at §429.510(e)(3) to identify outcomes to evaluate for each identified condition for which the selected drug is used. At proposed §429.510(e)(3)(i), the type of outcomes and contextual factors that CMS considers include:

- Clinical outcomes;
- Patient-centered outcomes, patient experience data, and patient-reported outcomes, if available;
- Additional outcomes and contextual factors or patient and caregiver preferences to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternative(s), if any; and
- Caregiver perspective to the extent that such perspective reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.

As described in proposed §429.510(e)(3)(ii), relevant outcomes would be identified using the CMS-led literature review and information submitted by the Primary Manufacturer and the public, including patients and caregivers, as well as in the public events.

CMS believes this approach would provide flexibility to consider a variety of aspects in its evaluation of comparative effectiveness, including patient experiences, disease severity, treatment complexity, and/or other unique considerations related to use of the selected drug or its therapeutic alternative(s) for a given condition.

Once the starting point for the initial offer has been established and evidence on section 1194(e)(2) factors has been considered, CMS would apply an upward adjustment, downward adjustment, or no adjustment to the starting point to determine the preliminary price (as proposed at §429.510(e)(4) and (5)). Consistent with the first three cycles of negotiation, CMS proposes to use a qualitative approach to consider nuanced differences between drugs, for example, interactions with other treatments commonly prescribed simultaneously for a condition or disease, and other factors that might not be captured in a more thoroughly pre-specified quantitative approach.

Analysis for Selected Drugs with Therapeutic Alternative(s). For each condition for which CMS identify a therapeutic alternative, CMS proposes to consider the information regarding the four factors outlined in section 1194(e)(2) of the Act collectively. As described at proposed §429.510(e)(4)(i), the CMS review would include, but is not limited to, examining improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) by considering (1) the costs of the selected drug and its therapeutic alternative(s); and (2) the magnitude of differences in outcomes of interest conferred by the selected drug compared to the selected drug's therapeutic alternative(s) for each condition in which CMS identified a therapeutic alternative.

CMS states it understands that a selected drug can be first in class.[32] However, other drugs may have become available since the selected drug's initial approval and therefore CMS proposes in the definition of "therapeutic advance" at proposed §429.20 to consider the extent to which a selected drug represents a therapeutic advance for a condition at the time the section 1194(e)(2) data is submitted. CMS proposes to review the analyses detailed previously for each identified condition of the selected drug and its therapeutic alternative(s) to determine the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) as described in proposed §429.510(e)(4)(i). For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS proposes to consider the extent to which the drug represents a therapeutic advance based on all available information at the time of consideration.

Further, per section 1194(e)(2)(D) of the Act, for each condition in which CMS has identified a therapeutic alternative, CMS states it would consider the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need for each condition for which the selected drug is used. When considering unmet medical need (as defined at proposed §429.20), CMS proposes to consider the selected drug, its therapeutic alternative(s), if any, and any existing treatment options, which may include pharmacologic or non-pharmacologic treatments.

Analysis for Conditions of Selected Drugs Without Therapeutic Alternatives. For conditions of selected drugs without therapeutic alternatives, CMS states it would consider the information regarding the four factors outlined in section 1194(e)(2) of the Act collectively. CMS proposes, described at §429.510(e)(4)(ii), that if a condition identified does not have a therapeutic alternative, then CMS considers three factors:

- The totality of available information;
- Any existing treatment option(s) to determine the extent to which the selected drug addresses an unmet medical need for each identified condition; and
- The magnitude of differences in outcomes of interest conferred by the selected drug to determine the extent to which the selected drug represents a therapeutic advance.

For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS states it would consider the extent to which the drug represents a therapeutic advance based on all available information at the time of consideration.

Preliminary Price. As noted in section II.F.3.d.(1), CMS proposes to take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug. For each selected drug, CMS proposes to adjust the applicable starting point (as determined in proposed §429.510(d)) upward or downward or to not adjust (as described in proposed §429.510(e)(5)) based on the totality of the relevant information and evidence submitted and gathered through its analysis based on section 1194(e)(2) factors.

After the starting point is adjusted, if applicable, the resulting price is referred to as "the preliminary price" (defined in proposed §429.20). CMS proposes to adjust the preliminary price,

[32] For purposes of this discussion, CMS defines first in class drugs as those that have a new mechanism of action, defined by the National Cancer Institute as "a term used to describe how a drug or other substance produces an effect in the body." See: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action.

as appropriate, based on data submitted by the Primary Manufacturer in accordance with section 1194(e)(1) of the Act.

(2) Adjusting the Preliminary Price Based on Consideration of Section 1194(e)(1) Factors. Section 1194(e)(1) of the Act directs CMS to consider certain factors, which must be reported by each Primary Manufacturer, when determining offers and counteroffers. To fulfill this requirement, CMS proposes at §429.510(f) that it may adjust the preliminary price upward, adjusted downward, or not adjusted to account for these manufacturer-specific data elements. This process would be conducted with the aim of achieving the lowest MFP for each selected drug. The section 1194(e)(1) factors are listed at proposed §429.505(b)(2) and include: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) 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; and (5) market data and revenue and sales volume data for the drug in the United States.

As an example for how CMS may consider the relationship between the preliminary price and the unit costs of production and distribution (the factor listed at section 1194(e)(1)(B) of the Act), CMS may consider adjusting the preliminary price downward if the unit costs of production and distribution are lower than the preliminary price, or upward if the unit costs of production and distribution are greater than the preliminary price. Again, CMS states it may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug as described in proposed §429.505(b) to determine if an adjustment is appropriate.

As proposed in §429.510(f)(3)(i), if the resulting amount is above the ceiling (as determined in proposed §429.410), then the initial offer will be equal to the ceiling, and if the amount is below the temporary floor for small biotech drugs (as determined in proposed §429.440), if applicable, then the initial offer will be equal to the temporary floor.

4. Engagement with Primary Manufacturers and Interested Parties (§429.515)

a. Engagement with Primary Manufacturers

Consistent with policies for implementation, CMS proposes in §429.515(a) to hold up to four, optional meetings in a form and manner specified by CMS with Primary Manufacturers of selected drugs that have submitted the information set forth in proposed §429.505.

First Meeting. Intended to offer Primary Manufacturers the option to provide additional context on their data submission as CMS begins evaluating the data submission and developing an initial offer.

Three Remaining Meetings. Focuses on the section 1194(e)(1) factors and section 1194(e)(2) factors, and other topics aimed at working toward an agreement on an MFP. During these

meetings, discussion of disputes and program policies regarding the negotiation process would be considered out of scope.

Meeting Attendance. As proposed in §429.515(a)(2), CMS specifies that meetings would be attended solely by representatives of the Primary Manufacturer and of CMS. CMS proposes at §429.515(a)(2) to continue to limit the number of meeting attendees as specified by CMS. In past engagements, CMS and the Primary Manufacturer were permitted to bring up to eight meeting attendees and both parties would share their participant lists ahead of each meeting. CMS states that it determined this meeting attendee number after considering the roles from each party that would be critical to the conversation while ensuring that the meeting is sized appropriately to encourage active discussion.

Meeting Materials. As proposed at §429.515(a)(3)(i), Primary Manufacturers may provide the following information to be presented and discussed at each meeting:

- New information on the section 1194(e)(2) factors.
- Materials, including pages, slides, and charts and graphs, to facilitate discussion, which must comply with limits on the amount or format of such materials as specified by CMS.

CMS may request that the Primary Manufacturer provide copies of any presented or discussed materials after the meeting in which they are presented or discussed. CMS states it would specify the limits on the amount and format of materials specific to each IPAY via future communications with the Primary Manufacturer. For example, for IPAY 2028, if a Primary Manufacturer is interested in sharing materials at a negotiation meeting, such materials are limited to 15 pages (or a combination of pages, slides, and/or charts and graphs totaling 15 pages) and no more than 30 citations, to focus the discussion on issues that can reasonably be discussed within the scope of the meeting.

Any information shared during these meetings and materials shared afterwards should only contextualize the Primary Manufacturer's submission of data related to section 1194(e)(1) factors specified in proposed §429.505(b).

Meeting Timing. At §429.515(a)(4), CMS proposes that for the first optional meeting that CMS would offer to Primary Manufacturers to attend would occur, at a time to be specified by CMS, after the data submission deadline and before the provision of CMS' initial offer. CMS would offer up to three additional optional meetings to occur after the provision of CMS' initial offer.

Meeting Rules. At §429.515(a)(5), CMS proposes that a written record of these meetings would be developed and retained by CMS in compliance with applicable Federal laws, including the Federal Managers' Financial Integrity Act and the Federal Records Act, and would be subject to the confidentiality policy. The Primary Manufacturer may also develop and retain its own written record. Audio or video recording of the meetings would not be permitted.

CMS would not publicly discuss ongoing negotiations with a Primary Manufacturer, including details of the negotiation meetings. A Primary Manufacturer may publicly disclose information regarding ongoing negotiations with CMS at their discretion. If a Primary Manufacturer discloses information regarding any aspects of the negotiation process prior to the explanation

for the MFP being released by CMS, CMS states it reserve the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer.

b. Engagement with Interested Parties

At proposed §429.515(b), CMS proposes to hold events in a form and manner and at times to be specified by CMS with interested parties to seek input from patients and other interested parties about selected drugs and therapeutic alternatives. CMS states that these public engagement events allow the agency to hear from patients and other stakeholders close to the patient experience—directly and in their own words—about patients' personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions. This type of information helps inform CMS' understanding of what matters to patients. Public engagement events for each IPAY may include, for example, patient-focused roundtable events that would be open to patients, patient advocacy organizations, and caregivers and would allow for discussion among speakers. These patient-focused roundtable events may focus on one selected drug or group selected drugs by condition when appropriate as determined by CMS.

The public engagement events also may include one town hall meeting for all selected drugs that would be focused on the clinical considerations related to the selected drugs and would be open to practicing clinicians and researchers, as well as other interested parties. This town hall meeting may be divided into multiple sessions and may be held across multiple days.

Lastly, CMS may incorporate drugs selected for renegotiation into the public engagement events for drugs selected for negotiation or CMS may hold separate events specifically for drugs selected for renegotiation.

5. Provision of CMS' Initial Offer and Concise Justification (§429.520)

Section 1194(b)(2)(B) of the Act requires that, not later than June 1 following the selected drug publication date with respect to the IPAY, CMS shall provide the Primary Manufacturer of the selected drug with a written initial offer that contains the proposal for the MFP of the drug and a concise justification based on the factors described in section 1194(e) that were used in developing such offer. CMS proposes to codify this in regulation at §429.520(a).

CMS proposes at §429.520(a)(1) that this written initial offer would be accompanied by an Addendum to the Negotiation Program Agreement populated with the proposal for the MFP for CMS and the Primary Manufacturer to formalize agreement upon the MFP if such agreement is reached at this stage.

Concise Justification. With respect to IPAY 2029 and subsequent years, CMS proposes in §429.520(b) to include a concise justification for the written initial offer based on the data set forth in proposed §429.505. This concise justification:

- Includes a qualitative description of the factors from section 1194(e) of the Act as set forth in §429.505 and a description of the methodology that CMS used to develop the written initial offer.

- Provides the Primary Manufacturer with information on the range of evidence and other information considered in that CMS found compelling during the development of the written initial offer.
- May include information obtained through events with interested parties.

CMS believes the information in the concise justification would provide the Primary Manufacturer with information to build a statutory written counteroffer if the Primary Manufacturer decides to reject the written initial offer. CMS notes that the written initial offer and concise justification would not include information that the agency determines to be third-party proprietary pricing information, information that could lead to the calculation of a third-party's proprietary pricing information, protected health information, other information that is protected from disclosure under other applicable law.

6. Statutory Written Counteroffers (§429.525)

Section 1194(b)(2)(C) of the Act requires that the Primary Manufacturer shall either accept the written initial offer under section 1194(b)(2)(B) of the Act, or propose a counteroffer, within 30 days of receipt of the written initial offer. CMS proposes to codify this requirement at §429.525(a), along with certain required components at §429.525(b).

Required components of a written counteroffer. Any statutory written counteroffer must:

- Provide a proposal for the MFP for the selected drug and a justification for such proposal;
- Respond to the justification provided in CMS' written initial offer; and
- Indicate the reasons the Primary Manufacturer believes that the information submitted supports the statutory written counteroffer or otherwise does not support CMS' written initial offer.

CMS response to statutory written counteroffer. Section 1194(b)(2)(D) of the Act requires that, after receiving a counteroffer under section 1194(b)(2)(C) of the Act, CMS must respond in writing to such counteroffer. CMS proposes to codify this requirement at §429.525(c). CMS notes that although the statute does not specify a timeframe for CMS' response to the Primary Manufacturer's statutory written counteroffer negotiations must end prior to November 1 following the selected drug publication date to avoid potential excise tax liability under 26 U.S.C. 5000D(b)(2).

As proposed in §429.525(c)(1), in the case that CMS' written initial offer is not accepted and the Primary Manufacturer submits a statutory written counteroffer, CMS would consider the statutory written counteroffer and either accept or reject it in writing within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later.

As proposed in §429.525(c)(2), to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement that sets forth the agreed-upon MFP.

7. Additional Price Exchange Opportunities (§429.530)

Consistent with policies for implementation, CMS proposes in §429.530(a) to provide additional price exchange opportunities through which CMS and Primary Manufacturers can initiate additional written offers and counteroffers via the CMS HPMS during the period between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and the parties reaching an agreement on the MFP, or at least 8 business days before CMS issues the final offer, whichever is earlier. CMS believes this functionality would enable both parties to have additional flexibility to extend and consider offers and counteroffers during this period.

CMS proposes the following requirements related to the additional price exchange opportunities:

- The additional price exchange opportunities allow for the optional upload of materials which must comply with limits on the amount or format of such materials as specified by CMS, and include an optional text field to enable the offering or counteroffering party to include additional contextual information for the offer or counteroffer.
- Only one written offer or counteroffer per selected drug may be active at a time.
- An offering or counteroffering party may archive its written offer or counteroffer in the period before the other party accepts or rejects it, but not afterwards.
- Parties do not need to alternate making written offers and counteroffers.
- To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement.

8. Notification of Final Offer and Conclusion of Negotiations (§429.535)

In this section, CMS details the proposed notification of final offer and conclusion of negotiations.

Notification of final offer. At §429.535(a), in the event neither CMS' initial offer nor the Primary Manufacturer's statutory written counteroffer were accepted, and an MFP was not agreed to during the negotiation meetings or via the additional price exchange functionality, CMS would send the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" and an Addendum with the final offer MFP by September 30 following the selected drug publication date defined in §429.20.

CMS proposes at §429.535(a)(1), that if a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by October 31 following the selected drug publication date. As proposed at §429.535(a)(2), to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement.

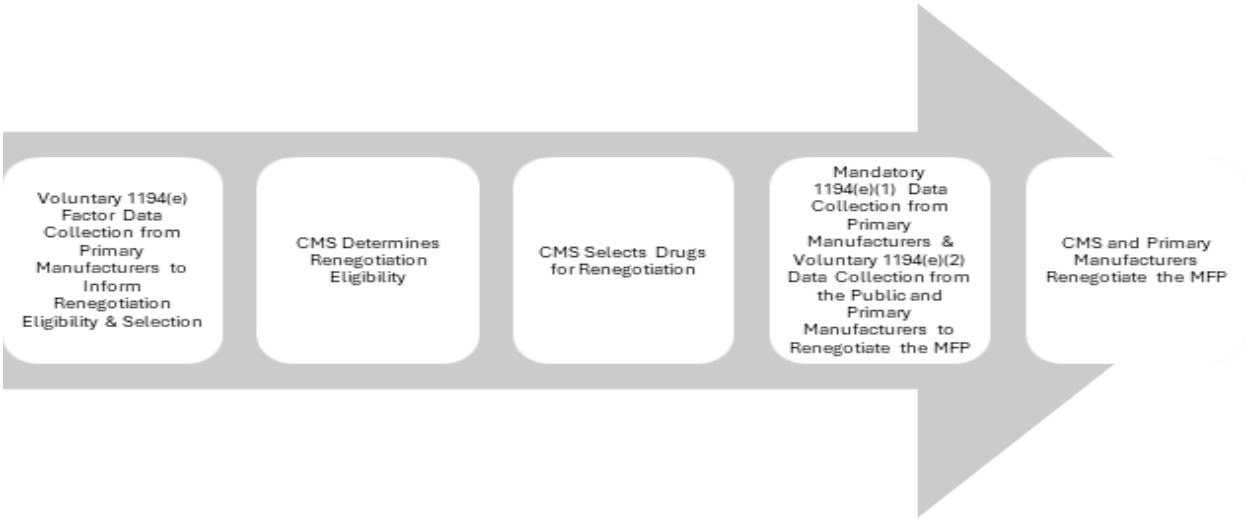
Conclusion of negotiations. Section 1194(b)(2)(E) of the Act requires that all negotiations between CMS and the Primary Manufacturer of the selected drug shall end prior to November 1 following the selected drug publication date, with respect to the IPAY. CMS proposes to codify this at §429.535(b).

G. Renegotiation of an MFP (§§429.600-429.620)

1. General Rule (§429.600)

Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs, the selection of drugs for renegotiation, and the renegotiation process. With respect to IPAY 2028, the first year in which renegotiation could occur per section 1194(f) of the Act, CMS implemented policies for renegotiation in section 130 of the Negotiation Program Guidance. CMS is codifying its policies for renegotiation with respect to IPAY 2029 and subsequent years, consistent with the Negotiation Program Guidance. Figure 2 in the proposed rule and reproduced here describes the renegotiation process steps.

Figure 2: Overview of Renegotiation Process Steps



In brief, the renegotiation process includes the following actions:

- CMS identifies renegotiation-eligible drugs, if any, as described in §429.605.
- CMS selects drugs for renegotiation from among such renegotiation-eligible drugs, if any, as described in §429.610.
- CMS renegotiates the MFP applicable to any such drugs selected for renegotiation in accordance with the process set forth in §429.620.

CMS notes that renegotiation is a component of the Negotiation Program. A Primary Manufacturer that has a Negotiation Program Agreement in effect would be required to adhere to the process and deadlines described throughout the proposed rule. The renegotiation process would conclude with an agreed-upon MFP, unless the Primary Manufacturer chooses not to participate or chooses not to agree upon a new MFP (or CMS determines that a generic drug is approved or a biosimilar is licensed for the selected drug is subject to Bona Fide Marketing during the renegotiation period), in which case it will no longer be subject to the renegotiation process. To meet their MFP effectuation obligations, Primary Manufacturers must make any agreed-upon MFP available.

If the Primary Manufacturer and CMS agree upon an MFP through the renegotiation process, CMS proposes at §429.600(b)(1) that the renegotiated MFP would apply starting January 1 of the IPAY for which the drug was selected for renegotiation. At proposed §429.600(b)(2), the MFP that is agreed upon following renegotiation would apply to all formulations across dosage forms and strengths of the selected drug by applying the methodology set forth at proposed §429.700. CMS also proposes at §429.600(b)(3) that to meet their MFP effectuation obligations, Primary Manufacturers of a selected drug with a renegotiated MFP must provide access to the selected drug's initial agreed-upon MFP in accordance with subpart I for all dispenses, administrations, and furnishings of the selected drug prior to such effective date for the renegotiated MFP. Finally, CMS proposes at §429.600(c) that the agency would publish the list of drugs selected for renegotiation no later than the selected drug publication date (consistent with §429.100(b)(2)).

2. Eligibility of Drugs for Renegotiation (§429.605)

Section 1194(f)(2) of the Act establishes the definition of a "renegotiation-eligible drug" as a selected drug for which (1) a new indication is added to the drug; (2) the drug monopoly status was not that of an extended-monopoly or a long-monopoly drug and changes to that of an extended-monopoly drug; (3) the drug monopoly status was not that of a long-monopoly drug; and changes to that of a long-monopoly drug; or (4) the Secretary determines there has been a material change to any section 1194(e)(1) or (e)(2) factor.

In accordance with section 1194(f)(1) of the Act, CMS proposes to identify renegotiation-eligible drugs from selected drugs negotiated, or renegotiated, if applicable, with respect to prior IPAYs. CMS states that it interprets section 1194(f)(1) of the Act to mean that the Secretary must provide for a process of renegotiation for years during the selected drug's price applicability period. For example, because calendar year 2029 will be a year within the price applicability period for drugs selected for IPAYs 2026, 2027, and 2028, these selected drugs may be eligible for renegotiation with respect to IPAY 2029 (which would involve a renegotiation taking place in calendar year 2027) if these drugs meet any of the eligibility criteria set forth in section 1194(f)(2) of the Act and proposed §429.605.

In its proposed §429.605(a) the scope of selected drugs that would be considered for renegotiation eligibility and selection with respect to IPAYs beginning with IPAY 2029 would include any selected drugs with an agreed-upon MFP from a prior IPAY, which would include a selected drug that has an agreed-upon MFP from a prior renegotiation. Those drugs that would be considered for renegotiation or renegotiation-eligible drugs (defined and discussed in further detail in the subsequent subsections) include:

- Selected drugs for which there is a change in status to an extended-monopoly drug;
- Selected drugs for which there is a change in status to a long-monopoly drug;
- Selected drugs for which a new indication is added; and
- Selected drugs for which there is a material change in a section 1194(e) factor.

CMS notes that a selected drug would not be subject to renegotiation if CMS determines prior to the selected drug publication date for the relevant IPAY that the manufacturer of any generic drug or biosimilar, as applicable, of the selected drug is engaging in Bona Fide Marketing of

such generic drug or biosimilar, based on CMS' consideration of the information set forth at proposed §429.130(a).

CMS notes that selected drugs negotiated in IPAYs 2026 and 2027 were limited to those covered under Part D per section 1192(d)(2)(A) of the Act. In proposed §429.610(a)(2), CMS proposes to consider any selected drugs from IPAYs 2026 and 2027, including those with Part B utilization, for renegotiation eligibility under section 1194(f)(2) of the Act. If such drugs meet the eligibility criteria described in proposed §429.605, they may be selected for renegotiation under section 1194(f)(3) of the Act and as described in proposed §429.610; and may have an agreed-upon MFP after renegotiation.

For such renegotiation-eligible drugs that are selected for renegotiation and for which a renegotiated MFP is agreed upon, the renegotiated MFP would apply to claims payable under Part B and dispenses covered under Part D, as applicable. The MFP that is agreed upon following the renegotiation process would apply to all formulations across dosage forms and strengths of the selected drug, which would include when the selected drug is payable under Part B only, covered under Part D only, and when the drug is payable under Part B and covered under Part D. The Primary Manufacturer of a selected drug with a renegotiated MFP would be required to make the prior agreed-upon MFP available for all dispenses, administrations, and furnishings of the selected drug prior to the effective date of the renegotiated MFP.

a. Selected Drugs for Which There is a Change in Status to an Extended-Monopoly Drug

In accordance with section 1194(f)(2)(C) of the Act, CMS proposes in §429.605(b)(1) that a selected drug that meets the definition of an extended-monopoly drug with respect to initial price applicability years beginning with initial price applicability year 2029, and that did not qualify as an extended-monopoly drug when the drug was selected for negotiation or a prior renegotiation would be determined to be renegotiation-eligible due to a change in status to an extended-monopoly drug.[33]

CMS proposes, in §429.20, defining extended monopoly drug as the meaning set forth in section 1194(c)(4) of the Act. To meet this definition, the initial approval date must be on or before January 1 of the year 12 years prior but no more than 16 years prior under section 505(c) of the FD&C Act or the initial licensure date under section 351(a) of the PHS Act, as applicable, associated with the earliest-approved FDA application containing the active moiety/active ingredient (or in the case of a potential qualifying single source drug identified under §429.125(b)(4), the distinct combination of active moieties/active ingredients).[34]

[33]As CMS proposes to codify in §429.20, section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a Primary Manufacturer has entered into a Negotiation Program Agreement with CMS with respect to an initial price applicability year that is before 2030 from the definition of an "extended-monopoly drug". Therefore, the proposal at §429.605(b)(1) would apply to drugs selected for negotiation in initial price applicability year 2030 or later.

[34] For biological products with approved applications under section 505 of the FD&C Act as of March 23, 2020, that were deemed to be approved BLAs under section 351 of the PHS Act, effective March 23, 2020, under section 7002(e)(4)(A) of BPCI Act, and that are currently licensed and marketed under section 351 of the PHS Act, CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B) of the Act.

b. Selected Drugs for Which There is a Change in Status to a Long-Monopoly Drug

CMS proposes at §429.605(b)(2) that a selected drug that meets the definition of a long-monopoly drug (as proposed in §429.20) and that did not qualify as a long-monopoly drug when the drug was selected for negotiation or a prior renegotiation would be determined to be renegotiation-eligible due to a change in status to a long-monopoly drug.

To meet the definition of a long-monopoly drug, the initial approval date under section 505(c) of the FD&C Act or the initial licensure date under section 351(a) of the PHS Act, as applicable, associated with the earliest-approved FDA application containing the active moiety/active ingredient (or in the case of a potential qualifying single source drug identified under §429.125(b)(4), the distinct combination of active moieties/active ingredients)[35] must be on or before January 1 of the year 16 years prior.

c. Selected Drugs for Which a New Indication is Added

Section 1194(f)(2)(A) of the Act identifies a selected drug for which a new indication is added as a renegotiation-eligible drug. As described in proposed §429.615(a), CMS proposes to collect voluntary information submissions from Primary Manufacturers of selected drugs to inform renegotiation drug eligibility and selection.

To identify whether a new indication has been added to the FDA-approved labeling[36] for a selected drug, CMS proposes at §429.605(c) to review FDA-approved labeling for the selected drug (i.e., using the Drugs@FDA database[37]) and review of voluntary submissions from Primary Manufacturers, if any, are submitted. CMS proposes at §429.605(c)(2)(ii)(A) that it may review off-label use for the purpose of determining whether such off-label use is a new indication for renegotiation eligibility determinations only if voluntarily submitted by the Primary Manufacturer. CMS states that it may consider such off-label use that is for a previously indicated disease or condition as part of the evaluation of section 1194(e) factors for material change for purposes of renegotiation eligibility, as described in proposed §429.605(d).

At §429.605(c)(1), CMS proposes that the agency would determine a drug to be renegotiation-eligible based on the addition of a new indication if the FDA-approved labeling has been updated to include treatment or prevention of a new disease or condition. In the renegotiation context, "new" means not considered in the previous negotiation process or renegotiation process.

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[35] For biological products with approved applications under section 505 of the FD&C Act as of March 23, 2020, that were deemed to be approved BLAs under section 351 of the PHS Act, effective March 23, 2020, under section 7002(e)(4)(A) of BPCI Act, and that are currently licensed and marketed under section 351 of the PHS Act, CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B) of the Act.

[36] Such additions to the FDA approved labeling include new indications approved in both new NDAs/BLAs and supplements to previously approved NDAs.

[37] Available at www.fda.gov/drugsatfda, https://www.fda.gov/vaccines-blood-biologics/cber-regulated-products-supporting-documents.

To ensure the agency has appropriate time to consider applicable data, CMS proposes at §429.610(c)(3) that the new indication must be added to the FDA-approved labeling for the selected drug by the date of the voluntary submission (as proposed at §429.615(b)), on or before March 1 of the year of the selected drug publication date for the IPAY for which the drug would be selected for renegotiation.

The Primary Manufacturer may voluntarily submit data on a new indication, including an indication added to the FDA label or an off-label use, through the due date of the Drug Selection ICR to be specified by CMS upon approval of the Drug Selection ICR by the OMB and prior to the selected drug publication date for which the drug would be selected for renegotiation. If a Primary Manufacturer chooses to submit information on a new indication, CMS states it would update the review of available indications for that selected drug, including incorporating the Primary Manufacturer's submission.[38]

d. Selected Drugs for Which There is a Material Change in a Section 1194(e) Factor

Section 1194(f)(2)(D) of the Act directs CMS to identify a selected drug for which there has been a material change to any factor listed in section 1194(e) as a renegotiation-eligible drug and provides CMS with the discretion to determine what constitutes a "material change."

CMS proposes, at §429.605(d)(1), to consider a change(s) to a section 1194(e) factor for a selected drug to be material if the change(s) to the factor would reasonably be expected to meaningfully alter its consideration of that factor within the context of renegotiation offers and counteroffers, including the initial offer as compared with its consideration of that factor within the context of offers, including the initial offer and, if applicable, counteroffers, during the most recent prior negotiation or renegotiation process for the selected drug.

For purposes of determining whether a selected drug is renegotiation-eligible under section 1194(f)(2)(D) of the Act, CMS would evaluate available information pertaining to section 1194(e) factors (as listed in proposed §429.505(b) and (d) and section II.F.2.b. of the proposed rule) to determine if there is a material change. CMS also proposes to consider voluntary submissions by a Primary Manufacturer of the information discussed in proposed §429.615(a) to inform its determination.

CMS states that this approach complements its review of new indications and it would consider prescribing information as part of this material change evaluation. As part of that inquiry, CMS states it would review the FDA-approved labeling for a material change in prescribing information as described in proposed §429.605(d)(1) and, in doing so, would also capture the impact of labeling updates within a previously indicated disease or condition during such review (for example, expansion of an existing indication to include an additional age group(s)). That is, labeling updates within a previously indicated disease or condition would not be regarded as a "new indication" for renegotiation eligibility under section 1194(f)(2)(A) of the Act but would

[38] CMS expects that there would be a low likelihood of new indications being available for selected drugs whose negotiation or renegotiation period ends on November 1 immediately prior to the Primary Manufacturer submission deadline of November 30.

be considered as part of the review of section 1194(e) factors for material change for purposes of renegotiation eligibility under section 1194(f)(2)(D) of the Act.

To provide sufficient time to consider the applicable information to determine whether a change in a factor listed in section 1194(e) of the Act is material, CMS would consider the applicable information that is available on or before September 30 of the calendar year before the selected drug publication date for which the drug would be selected for renegotiation. CMS further states that its review by September 30 would not be inclusive of information submitted by the Primary Manufacturer through the voluntary submission due November 30. For example, this may include information on any offers or counteroffers made on or before September 30 of the calendar year before the selected drug publication date for which the drug would be selected for renegotiation, including MFPs that were agreed upon for the selected drug or its therapeutic alternatives. Should the Primary Manufacturer choose to submit data through the voluntary submission described in proposed §429.615(a), then CMS may update its review of material change(s) with new applicable information.

Table 2 in the proposed rule (reproduced here) provides a few illustrative examples of this approach to determining a material change(s) to a section 1194(e) factor for the purpose of determining renegotiation eligibility

Table 2: Illustrative Example Scenarios and Potential Result in Determination of Material Change

Example Scenario	Potential Result for Changes in Section 1194(e) Factor
New clinical data is released showing increased clinical value for a greater number or new group of individuals who are prescribed a selected drug.	CMS may determine that in this scenario that this new data would likely meaningfully impact CMS' consideration of section 1194(e)(2)(C) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.
Unit cost of production and distribution increases from $1.00 per unit to $1.50 per unit.	CMS may determine that in this scenario this change would not likely meaningfully impact CMS' consideration of section 1194(e)(1)(B) of the Act in the context of offers and counteroffers. Therefore, this change alone may not be considered a material change.
A therapeutic alternative is now generic, the price for the therapeutic alternative drops significantly, and utilization of the therapeutic alternative increases significantly.	CMS may determine that in this scenario this new data would likely meaningfully impact CMS' consideration of section 1194(e)(2)(A) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.
New clinical data is released showing increased clinical efficacy of the selected drug for one of its indications; a new black box warning indicates additional safety concerns for the selected drug, limiting its use.	CMS may determine that in this scenario the net impact of these changes would not meaningfully impact CMS' consideration of section 1194(e)(2)(C) of the Act in the context of offers and counteroffers. Therefore, these changes alone may not be considered a material change.
An indication for a selected drug was not covered under Part D or payable under Part B at the time the drug was previously negotiated. The indication is now covered under Part D and/or payable under Part B and there are no alternative treatments available for that indication.	CMS may determine that in this scenario the newly covered indication for which there are no alternative treatments to the selected drug would meaningfully impact CMS' consideration of section 1194(e)(2)(D) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.

3. Selection of Drugs for Renegotiation (§429.610)

Section 1194(f)(3) of the Act directs CMS to select drugs for renegotiation from the identified renegotiation-eligible drugs (described in proposed §429.605). Drugs could be eligible for renegotiation due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug or remaining drugs that CMS determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor.

Section 1194(f)(3)(C) of the Act provides CMS with the discretion to make determinations on when a renegotiation is "likely to result in a significant change" in the MFP.

a. Selecting Drugs for Renegotiation Among Renegotiation-Eligible Drugs due to a Change in Monopoly Status

In accordance with section 1194(f)(3)(A) and (B) of the Act and consistent with the existing policies established in the Negotiation Program Guidance, CMS proposes at §429.610(a) to select for renegotiation all drugs that are determined to be renegotiation-eligible due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug as set forth in proposed §429.605(b).

b. Selecting Drugs for Renegotiation Among Renegotiation-Eligible Drugs due to a New Indication or a Material Change in a Section 1194(e) Factor

In accordance with section 1194(f)(3)(C) of the Act and consistent with the existing policies in the Negotiation Program Guidance, CMS proposes to select remaining renegotiation-eligible drugs (that is, selected drugs that are determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor), for renegotiation if CMS expects renegotiation is likely to result in a significant change in the MFP.

CMS proposes to consider two criteria to determine whether renegotiation is likely to result in a significant change in the MFP (discussed in greater detail below) that would be evaluated from a holistic inquiry based on the totality of the information available and the circumstances of the remaining renegotiation-eligible drug(s).

First criterion for significant change (at proposed §429.610(b)(1)(i)). Whether a new indication(s) or material change(s) would be likely to result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP upon engaging in renegotiation with the Primary Manufacturer.

Second criterion for significant change (at proposed §429.610(b)(1)(ii)). Whether such a change in the MFP for the remaining renegotiation-eligible drug(s) would have a significant impact on the Medicare Program.

As proposed at §429.610(b)(2)(ii), CMS would conduct a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug. The scope of the information considered is broader than the scope of information reviewed for renegotiation eligibility. This could include, for example, consultations with FDA, clinicians, patients, patient organizations, and research and a CMS-led review of the information sources.

As proposed at §429.610(b)(1), CMS will only select a drug for renegotiation if that renegotiation-eligible drug meets both criteria. CMS believes that each of these criteria are of

equal importance. CMS interprets section 1194(f)(3)(C) of the Act to require that for a drug that is eligible for renegotiation based on a new indication or material change to a factor listed at section 1194(e) of the Act, CMS must expect that renegotiation would likely result in a change to the MFP, but also that such change must be considered significant, such that the magnitude of change is meaningful and that such change would be significant for CMS.

In establishing the first criterion, CMS reviewed sections 1194(c)(3)(A) through (C) of the Act, which provide the applicable percentage of non-FAMP used to establish a ceiling during negotiation. The applicable percentages are 75 percent for short-monopoly drugs and vaccines, 65 percent for extended-monopoly drugs, and 40 percent for long-monopoly drugs. CMS believes this range of percent change is informative for interpreting what the term "significant change" means in the context of the statute.

CMS calculated the percent change in the applicable percentage for a drug that had a change in monopoly status from a short-monopoly drug (75 percent) to a long-monopoly drug (40 percent), which is approximately 46.7 percent change; this represents the maximum percent change in the applicable percentage that would correspond with a selected drug becoming renegotiation-eligible and selected for renegotiation. Using those data, CMS calculated the percent change in the applicable percentage for a drug that had a change in monopoly status from a short-monopoly drug (75 percent) to an extended-monopoly drug (65 percent), which is approximately 13.3 percent change; this represents the minimum percent change in the applicable percentage that would correspond with a selected drug becoming renegotiation-eligible and selected for renegotiation. CMS rounded these percent changes to the nearest 5 percent, resulting in a range of percent change from 15 to 45 percent that the agency believes represents an informative range for interpreting what a "significant change" means in the context of the statute, as discussed previously.

Using those data, CMS proposes (at §429.610(b)(1)(ii)) that a potential change in the MFP 15 percent or greater following renegotiation would have a significant impact on the Medicare program. CMS considered other options, such as 35 percent which is the difference between the applicable percentage for short-monopoly drugs and vaccines (75 percent) and long-monopoly drugs (40 percent). CMS believes that using the minimum percent change as the applicable percentage that corresponds with a selected drug becoming renegotiation-eligible and selected for renegotiation provides CMS with the best opportunity to both clearly define what constitutes a "significant change to the MFP" and to meet its statutory obligation per section 1194(b)(1) of the Act to establish a process that aims to achieve the lowest MFP for each selected drug. CMS also believes that the use of percent change rather than the difference in the applicable percentages has practical importance in that its language more closely aligns with statute, meaning that a renegotiation would result in a change in the MFP. CMS believes this criterion serves to promote transparency and consistency in the approach to selecting drugs for renegotiation in accordance with section 1194(f)(3)(C) of the Act.

As noted previously, CMS would also examine the complementary criterion of evaluating whether such a change would have a significant impact to the Medicare program. For example, if CMS determines there was a likelihood that the new indication(s) or material change(s) could result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP, it would consider the financial impact to the Medicare program and Medicare beneficiaries by reviewing associated changes in expenditures and beneficiary cost-sharing. In doing so, CMS

seeks to incorporate consideration of whether such change in MFP warrants the time and resource investment by the Primary Manufacturers and CMS in the renegotiation process.

Thus, CMS proposes, at §429.610(b)(2), to consider the totality of other available information to determine whether renegotiation is likely to result in a change in MFP of 15 percent or greater and that such a change would have a significant impact on the Medicare program. This approach would also be consistent with the process for developing the initial offer.

CMS emphasizes that a determination by CMS that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation. Any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in MFP, decrease in MFP, or no change in MFP. Further, the magnitude of the change in MFP could be higher or lower than 15 percent. Similarly, CMS does not presume that the result of a renegotiation will reflect these approximations, for example, with respect to the impact of an agreed upon MFP following the renegotiation process on the Medicare program.

CMS also notes that the relatively short period between the negotiation or renegotiation of an MFP and its subsequent review of such drug for renegotiation may make it less likely that recently negotiated or renegotiated drugs would meet the material change criteria proposed at §429.610(b) and described in section II.G.3.b. of the proposed rule.

Table 3 (reproduced below) provides illustrative examples of how CMS may consider these criteria to determine whether a renegotiation-eligible drug would be selected for renegotiation.

Table 3: Illustrative Example Scenarios and Potential Results for Selection of Renegotiation-Eligible Drugs Due to a New Indicator or Change in a Section 1194(e) Factor

Example Scenario	Potential Result
New comparative clinical effectiveness data has become available that is favorable for the selected drug compared to therapeutic alternatives (for example, studies are published showing the selected drug has a greater positive effect on clinical outcomes relative to therapeutic alternatives), but the ceiling* represents a <15% increase in the MFP.	It is not possible for renegotiation to result in a 15% increase in the MFP (because the ceiling* is less than 15% higher than current MFP), so the selected drug would not be selected for renegotiation.
New comparative clinical effectiveness data has become available that is **unfavorable** for the selected drug compared to its therapeutic alternatives (for example, studies are published showing the therapeutic alternative has a greater positive effect on clinical outcomes relative to the selected drug) and the MFP is much higher than competitors' prices. If such data were used during renegotiation with the Primary Manufacturer, the renegotiated MFP would likely **decrease** by 15% or more compared to the original MFP.	The selected drug would be selected for renegotiation if consideration of the other criterion supports the determination that renegotiation is likely to result in a significant change to the MFP.
New comparative clinical effectiveness data has become available that is **favorable** for the selected drug compared to therapeutic alternatives (for example, studies are published showing the selected drug has a greater positive effect on clinical outcomes relative to the therapeutic alternatives, and the ceiling represents a >15% increase in the MFP.) Upon renegotiating with the Primary Manufacturer, the renegotiated MFP would likely **increase** by 15% or more compared to the original MFP.	

*See proposed §429.620(b) for additional detail on the ceiling that would be used for renegotiation.

4. Data Collection to Inform Renegotiation Eligibility, Selection, and Renegotiation of the MFP for a Selected Drug (§429.615)

Section 1194(f)(1) of the Act directs CMS to provide for a process to renegotiate the MFP for selected drugs that are determined to be renegotiation-eligible under section 1194(f)(2) of the Act and selected in accordance with section 1194(f)(3) of the Act. For IPAY 2028, CMS implemented these requirements through guidance. With respect to IPAY 2029 and subsequent years, CMS proposes two data collections in §429.615 for purposes of informing renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug consistent with the implementation of the program guidance. These two data collections are described at §429.615(a) and §429.615(b), respectively, and are as follows:

- Voluntary Information Submission from Primary Manufacturers to Inform Renegotiation Eligibility and Selection for Selected Drugs; and
- Data Collection from Primary Manufacturers and other Interested Parties for Renegotiation of the MFP.

The first data collection would inform renegotiation eligibility and selection; the second data collection would inform the renegotiation process for drugs selected for renegotiation. CMS issued two ICRs, each for a 60-day public comment period, alongside this proposed rule.[39] The ICRs include more details regarding how manufacturers can submit data, including the format for data submission.

a. Voluntary Information Submission from Primary Manufacturers to Inform Renegotiation Eligibility and Selection for Selected Drugs

Sections 1194(f)(2) and 1194(f)(3) of the Act do not identify any specific source for the information used to inform renegotiation eligibility and selection. CMS believes that the information necessary to determine renegotiation eligibility and selection for drugs with an agreed upon MFP is available without submission by the Primary Manufacturer or other interested parties.

The sources of information CMS intends to use for renegotiation eligibility are listed in proposed §429.605(c)(2), (d)(2), and (d)(3), which includes the following: (1) FDA-approved labeling for the selected drugs; (2) voluntary submissions from the Primary Manufacturer of the selected drug; (3) information pertaining to determine if there has been a material change; and (4) information provided in voluntary submissions.

CMS believes, however, input from the Primary Manufacturer on new indications, including off-label uses, and material changes to any factor listed at section 1194(e) of the Act, if applicable, could provide additional information or further validate- its review. To minimize burden on the Primary Manufacturer, CMS proposes to make this data submission voluntary. CMS states it does not intend to review information submitted by a Primary Manufacturer if its selected drug is renegotiation-eligible due to a change in monopoly status. Statute, sections 1194(f)(3)(A) and (B) of the Act, requires CMS to select all drugs with a change in monopoly status regardless of

[39] CMS-10844 and CMS-10849

whether the drug has a new indication or a material change to a factor; no additional information would be required to make such a determination.

CMS also proposes at §429.605(c)(2)(ii)(A) that the agency would only review off-label uses as a new indication for the purpose of determining renegotiation eligibility if the off-label use meets the definition proposed in §429.20 and is submitted by the Primary Manufacturer in this voluntary submission. CMS believes that the review of off-label use is discretionary and not explicitly mandated in section 1194(f)(2)(A) of the Act. Further, there is no single reliable directory or source of information regarding off-label use of FDA-approved drugs. Therefore, consideration of off-label use would be based on the evidence available for a given selected drug.

Consistent with the Negotiation Program Guidance, CMS proposes at §429.615(a) to provide each Primary Manufacturer of a selected drug the opportunity to submit information on new indications, including new off-label use, and new or updated information on the factors listed in section 1194(e) of the Act to inform renegotiation eligibility. CMS intends to collect this information through the Drug Selection ICR (CMS-10844, OMB 0938-1443) which would include revisions to collect such information to inform renegotiation eligibility and selection. CMS states that it would deem this voluntary submission to be proprietary information from the Primary Manufacturer that is protected from disclosure in accordance with the associated confidentiality policies.

b. Data Collection from Primary Manufacturers and other Interested Parties for Renegotiation

At §429.615(b)(1), CMS proposes to codify several proposals related to data collection from Primary Manufacturers and interested parties for renegotiation.

CMS proposes that the Primary Manufacturer of a drug selected for renegotiation must submit the following information for such drug for the IPAY for which the drug was selected for renegotiation, inclusive of the NDC-11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, to CMS in a form and manner specified by CMS:

- The information specified at §429.505(b)(2)(i) through (v); this includes, for example, R&D costs, current unit costs of production and distribution of the drugs, prior Federal financial support for drug development, and data on pending and approved patient applications, and market data and revenue and sales volume data.
- For drugs selected for renegotiation that were selected originally for negotiation for IPAY 2026 or 2027 and have not previously been selected for renegotiation for IPAY 2028 or thereafter, the information specified below for all NDC-11s of the selected drug payable under Part B, not covered under Part D, and for which the Primary Manufacturer did not include such information with the Primary Manufacturer's data submission for the IPAY for which the selected drug was first selected for negotiation:
    - Non-FAMP, unit type, and total unit volume for each NDC-11, if available, for the same calendar years for which non-FAMP data was reported in the Primary Manufacturer's data submission for the negotiation period in which the selected drug's MFP was negotiated.
    - When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in a calendar year, the non-FAMP submitted for that calendar quarter in paragraphs (b)(1)(ii)(A) and (B) of this

section should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data.

CMS also proposes in accordance with the requirements of its Negotiation Program Agreement a Primary Manufacturer is required to update the information of this section if the Primary Manufacturer becomes aware that any such information has changed or is otherwise inaccurate.

CMS notes that interested parties may submit the data specified in §429.505(d)(3) on the evidence about the selected drug and therapeutic alternatives. In addition, CMS proposes at §429.615(b) that the submission of section 1194(e)(2) information would be due at the same time such information is due for drugs selected for negotiation for the IPAY, that is March 1 of the year of the selected drug publication date for the IPAY for which the drug is selected for renegotiation.

CMS solicits comment on these proposed policies for data collection in the context of renegotiation of the MFP, including whether it may be preferable to more expressly establish CMS' intent to align with data collection in the context of the original negotiation process by replacing the text in proposed §429.615(b) with text that parallels that used in §429.505(a).

5. Renegotiation Process (§429.620)

In accordance with section 1194(f)(4)(B) of the Act, CMS proposes in §429.620 to establish the renegotiation process consistent with the negotiation methodology and process to the extent practicable. This includes the methodology for developing an initial offer; engagement with Primary Manufactures and interested parties; provision of CMS' initial offer and concise justifications; renegotiation written counteroffers; additional price exchange opportunities; notification of final offer and determination that renegotiations have finished; application of the MFP across dosage forms and strengths; publication of the MFP, and establishment of MFPs after the negotiation deadline. CMS proposes certain revisions to the methodology for developing the initial offer for all drugs selected for renegotiation

a. Determining the Ceiling

CMS proposes, at §429.620(b), that the agency will not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling specified in section 1194(b) of the Act. CMS proposes to calculate the ceiling for drugs selected for renegotiation using the process described below.

With respect to selected drugs negotiated for IPAYs 2026 and 2027 and have not been renegotiated in IPAY 2028 or thereafter, CMS incorporates NDC-11s that are payable under Part B, if applicable. Specifically, CMS:

- For a selected drug that is both covered under Part D and payable under Part B, calculates the payment amount under section 1847A(b)(4) of the Act, as set forth in §429.425, for the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation of the previously agreed-upon MFP and the sum of the plan-specific enrollment weighted amounts calculated at the time of the previous negotiation.
- Calculates the average non-FAMP amount(s) used in the calculation set forth in §429.620(b)(2) using the non-FAMP and Part B utilization data for NDC-11s set forth in

§429.615(b)(1)(i) for the same calendar years for which non-FAMP data was reported during the original negotiation and the non-FAMP and Part D utilization data previously used to calculate the average non-FAMP at the time of the previous negotiation.

For the purposes of calculating the ceiling amount under section 1194(c) of the Act, CMS interprets section 1194(f)(4)(B) of the Act as permitting limited updates to the ceiling applied during negotiation when a drug is first selected. CMS interprets the statute that it largely may not recalculate the ceiling amounts determined with respect to the negotiation for which the drug was first selected. CMS states that a contrary interpretation, under which the agency recalculates the ceiling amounts using the most recent data available with respect to the IPAY for which a drug is selected for renegotiation, would likely result in a renegotiation ceiling that, over time, exclusively decreases. Such an interpretation would effectively preclude the possibility of renegotiating a higher MFP for the selected drug, and such a limitation is not set forth in the statute, including in the criteria for renegotiation selection described under section 1194(f)(3)(C) of the Act.

CMS proposes at §429.620(b)(2) to update the applicable percent for purposes of calculating the non-FAMP ceiling for drugs selected for renegotiation due to a change in monopoly status. Consistent with §429.435(a)(4)(vi), the applicable percent would be based on the initial approval date associated with the earliest-approved FDA application belonging to the NDA holder or BLA holder for the selected drug and the IPAY for which the drug is selected for renegotiation.

Finally, CMS proposes to adjust the amounts for the ceiling by an inflationary adjustment for all of the drugs selected for renegotiation. Specifically, CMS proposes at §429.620(b)(3) to adjust the amounts considered for the ceiling by the percent increase in the consumer price index for all urban consumers (CPI-U) from July of the calendar year that is 2 years prior to the IPAY of the most recent agreed upon MFP through July of the calendar year prior to the calendar year in which the drug is selected for renegotiation. This approach is consistent with sections 1194(f)(4) and 1195(b)(1)(A) of the Act and proposed §429.705 under which CMS would publish an updated MFP increased by the annual percentage increase in the CPI-U.

b. Negotiation Factors

Section 1194(f)(4)(B) of the Act requires that the renegotiation process shall be consistent with the methodology and process for negotiation, to the extent practicable. As such, CMS proposes at §429.620(c) to consider the negotiation factors listed at sections 1194(e)(1) and (e)(2) of the Act inclusive of information submitted or shared about the factors listed at sections 1194(e)(1) and (e)(2) of the Act in any prior negotiation or renegotiation(s). This is discussed in II.F.2. of this proposed rule and summary and is consistent with the policies for implementation in the Negotiation Program Guidance.

c. Methodology for Developing an Initial Offer

Consistent with policies for implementation as described in section 130.4.2 of Negotiation Program Guidance, CMS proposes at §429.620(d) that the methodology for developing the initial offer for all drugs selected for renegotiation be the same process and timeline set forth for

development of the initial offer for the negotiation process under proposed §429.510.

As part of this proposed policy, CMS intends to require the Primary Manufacturer to submit the most recent agreed upon MFP as part of the data submission requirement described in proposed §429.615(b)(1) through the Drug Price Negotiation ICR (OMB 0938-1452) discussed in section II.G.4.b. of the proposed rule. CMS believes that considering the MFP during the development of the initial offer would better allow it to incorporate the impact of the offer and counteroffer process from the prior negotiation or renegotiation into the initial offer for the current renegotiation. Submission of the MFP would be a new collection requirement within the existing data submission. All drugs selected for renegotiation will have an agreed upon MFP and adding collection of the MFP as a data point in this submission requirement would be standard for all such selected drugs.

As an alternative to the proposal at §429.620(d), CMS considered applying the policy set forth in the Negotiation Program Guidance. In this option CMS would not include the MFP as a component of the factor listed at section 1194(e)(1)(E) of the Act and therefore the MFP would not be considered within the section 1194(e)(1) adjustment described at §429.510(f). With this alternative, CMS would also not collect the MFP through the Drug Price Negotiation ICR as the data would not be required for offer development or counteroffer consideration. CMS did not propose this option as the agency believes that the MFP is an important data point to consider within the context of renegotiation, as discussed previously.

As another alternative, CMS considered applying a third and separate adjustment based on the prior agreed upon MFP after the adjustment (based on the section 1194(e)(1) factors) is applied to the preliminary price as described at proposed §429.510(f)(2). CMS believes this alternative would also be consistent with the methodology and process for the negotiation process to the extent practicable, but which would incorporate additional adjustments for the renegotiation context to afford distinct weight to the prior negotiation. In this approach, the MFP would be collected through the data submission requirement described at proposed §429.615(b)(1) but considered separately from other information collected related to the section 1194(e)(1) factors. CMS states that under this option CMS would be able to consider negotiation meeting discussions and provide an initial offer that is informed by the prior negotiation or renegotiation process.

d. Engagement with Primary Manufacturers and Interested Parties

CMS propose at §429.620(e) through (l) that the renegotiation process would conform to the same procedures, structure, and timeline set forth for the negotiation process to the extent practicable.

e. Publication of the MFP

For a selected drug for which CMS and a Primary Manufacturer agree upon an MFP through the renegotiation process, CMS proposes at §429.620(k) to publish and update the renegotiated MFP and related information as proposed in §429.705 and as described in section II.H.2. of this rule and summary.

CMS states that it does not intend to include redacted information from any voluntary information submitted by a Primary Manufacturer in response to the Drug Selection ICR in the MFP explanation if the selected drug of the Primary Manufacturer is selected for renegotiation and there is an agreement upon a renegotiated MFP.

If the selected drug is then selected for renegotiation and the Primary Manufacturer submits the same information the Primary Manufacturer provided in response to the Drug Selection ICR also provided in response to the Drug Price Negotiation ICR, CMS may redact and include information provided in response to the Drug Price Negotiation ICR in the MFP explanation of a renegotiated MFP as proposed in section II.H.2. of this rule and summary.

H. Implementation of the MFP (§§429.700-429.710)

1. Application of the MFP Across Dosage Forms and Strengths (§429.700)

Section 1196(a)(2) of the Act requires CMS to establish procedures to compute and apply the MFP across different strengths and dosage forms of a selected drug and not based on the specified formulation or package size or package type of such drug. CMS implemented this requirement through guidance for IPAYs 2026 through 2028.

CMS proposes to codify in regulation at §429.700 the required direction for CMS to establish these procedures. CMS proposes to specify under that section the methodology that it would use to apply the single agreed-upon MFP (which, as discussed in section II.E.4, would be an average price per 30-day equivalent supply for the selected drug across all formulations of the selected drug) across NDC-9s and HCPCs codes, and to calculate an MFP-per billing unit price for each billing unit and payment code associated with the selected drug, as applicable.

CMS proposes, for purposes of computing and applying the MFP across dosage forms and strengths of a selected drug using the WAC of that drug (as reported by the Primary Manufacturer), the following policies:

- To use data from the calendar year occurring 3 years before the IPAY for which the selected drug was selected for negotiation because that year will be the most recent period of available data (referred to here as the most recent data year).
- The MFP would be applied to any NDCs of the selected drug assigned to the Primary Manufacturer or Secondary Manufacturer if such NDCs do not represent sample packages and the Primary Manufacturer reported a non-zero WAC for at least one calendar quarter of that most recent data year.
- For NDCs of Part D selected drugs, PDE records from that most recent data year would be used if the PDE record is associated with a prescription filled during that year and meets the proposed inclusion criteria discussed in section II.B.5.a of the rule.
- For NDCs of Part B selected drugs, Part B data and/or MA encounter data from that most recent data year would be used if the claim and/or record is associated with a service data during that year and meets the proposed inclusion criteria discussed in section II.B.5.b of the rule.

- To calculate the annual WAC per unit, for each selected drug and that most recent data year, CMS would:
    - Calculate the weighted quarterly WAC per unit for each NDC-11 for each calendar quarter of that year by dividing the WAC quarterly units by the total WAC annual units and then multiplying that quotient by the quarterly WAC per unit for that NDC-11; and
    - Sum the resulting weighted quarterly WAC per unit amounts for all NDC-11s for the selected drug.
- Proposed §429.700(b)(2) describes how CMS would convert the annual WAC per unit for each NDC-11 into an amount for a 30-day equivalent supply.
- To calculate the MFP for a 30-day equivalent supply of each NDC-9 of the selected drug, CMS would:
    - Aggregate the WAC per 30-day equivalent supply for each NDC-11 into a WAC per 30-day supply for each NDC-9 of the selected drug.
    - Use the WAC per 30-day equivalent supply for each NDC-9 to calculate a WAC price ratio for each NDC-9 of the drug.
    - Multiply that WAC price ratio for each NDC-9 by the single MFP for the selected drug.
- Proposed §429.700(b)(4) specifies the steps for calculating the NDC-9 MFP per unit and the MFP per billing unit.
- The MFP per billing unit and MFP per NCPDP unit price for each NDC-9 of the selected drug would be included in the publication of MFPs.

In addition, CMS proposes at §429.700(c) the process under which it would apply the MFP to NDCs associated with new NDAs/BLAs, NDCs, or HCPCS codes, including those added during the negotiation period or after agreeing upon an MFP, and to NDCs and HCPCS codes with insufficient PDE, Part B data, or WAC data in that most recent data year. Consistent with the policies described in section 60.5.1 of the Negotiation Program Guidance, CMS would:

- Use available information to determine the 30-day equivalent supply and the WAC ratio.
- Include on the list of NDCs and HCPCS codes of the selected drug:
    - In the case of NDC-11s and HCPCS codes associated with new NDAs or BLAs of the selected drug, the NDCs and HCPCS associated with the NDA or BLA, as appropriate.
    - In the case of new NDC-11s and HCPCS codes for existing NDAs or BLAs of the selected drug, the new NDCs and HCPCS codes, as appropriate.
    - In the case of NDC-11s of the selected drug that have been included on the list of NDCs of the drug lacked sufficient PDE, Part B data, or WAC data for the most recent data year, the NDCs and HCPCS codes, as appropriate.
- Require that the MFP apply to such NDCs and HCPCS codes.

To determine the 30-day equivalent supply and the WAC ratio using available data (as described under the first bullet point above), CMS would determine if a comparable NDC exists with sufficient data for the MFP application calculations to be performed. CMS describes at proposed §429.700(c)(4)(i)(A) the steps for determining the 30-day equivalent supply and WAC ratio if a comparable NDC exists, and at proposed §429.700(c)(4)(i)(B) the steps for determining that supply and ratio if a comparable NDC does not exist.

Further, once CMS accrues sufficient data for NDCs described in §429.700(c)(4)(i)(B), CMS would adjust the MFP application by updating the quotient of total quantity dispensed or administered to a 30-day equivalent supply based on observed PDE data and Part B data for existing NDCs (or NDCs associated with the HCPCS code) that lacked sufficient data to be included in the initial calculation of WAC ratios, and for new NDCs launched after the initial calculation of those ratios. Sufficient data would be considered to have accrued in the following situations:

- It has been one year since the NDCs first appeared in PDE records or the HCPCS codes associated with the NDCs appeared in Part B data; or
- The NDC or HCPCS code accrued the same number of units dispensed/administered as the NDC-11 that had the fewest units dispensed/administered at the time that the WAC ratios were originally calculated.[40]

A Primary Manufacturer would be able to submit a Suggestion of Error if they believe in good faith that CMS made an error in the calculations described above.

2. Publication of the MFP (§429.705)

Section 1195(a)(1) of the Act requires that by not later than November 30 of the year that is 2 years before the IPAY for a selected drug, CMS must publish the MFP for such drug that is negotiated with the manufacturer of such drug. CMS implemented this requirement through guidance for IPAYs 2026 through 2028, including through section 60.6 of the Negotiation Program Guidance for IPAY 2028.

CMS proposes to codify this requirement at §429.705 for IPAY 2029 and subsequent years. For example, for IPAY 2029, CMS would publish the MFP for each selected drug for which CMS and the Primary Manufacturer have reached an agreement on an MFP between November 1, 2027, and November 30, 2027. CMS would publish on the CMS website: (i) the selected drug; (ii) the IPAY; and (iii) the MFP file, which would contain the single MFP for a 30-day equivalent supply of the selected drug, NDC-9 MFP-per-unit price and HCPCS code dosage price and would be updated annually to show the inflation-adjusted MFP for the selected drug. CMS proposes to also publish on the CMS website whether an MFP is not agreed upon, as well as whether a drug is no longer a selected drug and the reason for that change.

According to section 1195(b)(1)(A) of the Act, for each year that is subsequent to the first IPAY of the price applicability period for a selected drug and for which an agreement for such drug is in effect under section 1193 of the Act, not later than November 30 of the year that is 2 years before such subsequent year, CMS must publish the MFP for such drug and year. That MFP (unless renegotiation occurs) is the amount equal to the MFP for the drug for the previous year, increased by the annual percentage increase in the CPI-U for the 12-month period ending with the July immediately preceding that November 30.

[40] Note that there is a third possible condition in section 60.5.1 of the Negotiation Program Guidance that would not be included under the proposal. That third condition is "a year has elapsed since the NDCs first appeared in PDE records or the HCPCS codes associated with the NDCs appeared in Part B data".

CMS proposes to codify in regulation this requirement at §429.705(a)(2). For example, not later than November 30, 2028, CMS would publish on the CMS website updated amounts for any MFPs for IPAY 2029 selected drugs for which a manufacturer agreement is in effect. Those updated MFPs would take effect in 2030 and be equal to the IPAY 2029 MFP for the selected drug increase by the percent increase in the consumer price index for all urban consumers (CPI-U) from July 2027 to July 2028.

In accordance with the requirement under section 1195(b)(2) of the Act, CMS proposes at §429.705(a)(3) that for a selected drug with respect to an IPAY for which the MFP is determined after the MFPs are published for other selected drugs, the MFP for the selected drug would be published not later than 30 days after the date that MFP is determined.

According to section 1195(a)(2) of the Act, CMS must publish the explanation for the MFP of a selected drug with respect to factors under section 1194(e) of the Act, by not later than March 1 of the year before the IPAY for such drug. CMS proposes, beginning for IPAY 2029, to codify in regulation this requirement at §429.705(b). CMS would publish the explanations for MFPs (including narrative explanation, redacted information regarding the negotiation meetings, redacted information submitted by a Primary Manufacturer, and redacted information submitted by interested parties) for each selected drug and drug selected for renegotiation, subject to the proposed treatment of confidential and proprietary information described in section II.D.1 of the rule.

3. Establishment of MFPs After the Negotiation Deadline (§429.710)

Under section 1194(b)(2)(E) of the Act, negotiations between CMS and the manufacturer of a selected drug must end before November 1 following the selected drug publication date for the IPAY for that selected drug. The Primary Manufacturer of the selected drug may be subject to an excise tax under section 5000D of the Internal Revenue Code of 1986 if such negotiations have not ended by such date.

CMS proposes at §429.710 that if actions or delays by the Primary Manufacturer delay the negotiation process such that the MFP may be agreed to after the end of the negotiation period, CMS would continue to engage in the negotiation process under proposed subpart F (discussed in section II.F), would follow timelines consistent with that process and take the time to complete the process as appropriate for the selected drug. If the delay is such that the selected drug has a change in status that is material to CMS' statutory obligations under the negotiation process, when CMS initiates or resumes the negotiation process, it would apply the process based on the status at the time the negotiation process occurs (including for renegotiations, as described in proposed subpart G). If each step of the negotiation process, including issuance of a final offer, is completed and then after the statutory negotiation period the Primary Manufacturer agrees to an MFP, the manufacturer must notify CMS in writing that it accepts the final offer from CMS.

I. Manufacturer Compliance and Oversight (§429.900)

CMS is required under section 1196(b) of the Act to monitor compliance by a manufacturer with the terms of a negotiation agreement (referred to in the Negotiation Program Guidance and the proposed rule as the "Negotiation Program Agreement") and establish a mechanism through which violations of such terms are to be reported. CMS implemented this requirement through guidance for IPAYs 2026 through 2028, including through section 90.1 of the Negotiation Program Guidance for IPAY 2028. CMS proposes, for IPAY 2029 and subsequent years, to codify in regulation at §429.900 policies consistent with that guidance.

Under the proposed §429.900, CMS specifies that Primary Manufacturers must cooperate with the agency's compliance monitoring activities, including providing complete and accurate responses to CMS requests. Failure to provide a timely, accurate, and complete response would be in violation of the Negotiation Program Agreement. Further, if CMS determines the Primary Manufacturer is noncompliant with any requirement of the agreement, the agency would be able to provide a written notice to the manufacturer of the violation, request the manufacturer take specific corrective action (in a form and manner, and by a deadline, specified by CMS), and/or impose a civil monetary penalty on the Primary Manufacturer.

J. Civil Monetary Penalties (§§429.1005-429.1020)

1. Civil Monetary Penalties (CMPs)

Under section 1197 of the Act, a manufacturer of a selected drug is subject to a CMP for any of the following violations:

- As provided under section 1197(a): Failure to provide access to a price that is less than or equal to the MFP for the drug.
- As provided under section 1197(b): Failure to pay the rebate amount for a biological product inclusion of which on the selected drug list was delayed but has since undergone negotiation (as described in section 1192(f)(4) of the Act).
- As provided under section 1197(c): Failing to comply with certain terms of the Negotiation Program Agreement.
- As provided under section 1197(d): Knowingly providing false information pursuant to section 1196(a)(7) of the Act.

CMS implemented these provisions through guidance for IPAYs 2026 through 2028, including through section 100 of the Negotiation Program Guidance, which applies for IPAY 2028. For IPAY 2029 and subsequent years, CMS proposes to codify in proposed subpart K policies (other than regarding its CMP authority pursuant to section 1197(a)) that are consistent with its policies described in that section 100. In Table 4 of the rule CMS provides examples of violations of the Negotiation Program Agreement and other violations that could result in imposition of a CMP addressed in the proposed rule (i.e., violations described in subsections (b), (c), and (d) of section 1197). The agency notes this is not an exhaustive list.

CMS is reserving for future rulemaking codifying, for IPAY 2029 and subsequent years, its policies for CMPs associated with violations described in section 1197(a) (i.e., for failure to provide access to a price less than or equal to the MFP).

Separate from the authority to impose CMPs, under section 5000D of the Internal Revenue Code of 1986, a Primary Manufacturer may be subject to an excise tax for failure to comply with certain Negotiation Program deadlines and other requirements.

2. Violations of the Negotiation Program Agreement (§429.1005)

Under section 1197(c) of the Act, a manufacturer of a selected drug that has entered into a Negotiation Program Agreement that is in violation of a requirement imposed pursuant to section 1193(a)(5) (i.e., a requirement determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the program), including the requirement to submit information pursuant to section 1193(a)(4), is subject to a CMP equal to $1,000,000 for each day of the violation. That dollar amount is updated yearly per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015. CMS states that it intends to use discretion such that the CMPs are reserved for instances of substantive noncompliance.

CMS is proposing to consolidate and clarify its policies for monitoring and enforcement in the context of data reporting. The agency is not proposing to codify its policies under section 40.2.3 of the Negotiation Program Guidance, but instead proposes a consolidated approach consistent with the policies regarding data reporting obligations under sections 90 and 100 of the Negotiation Program Guidance.

CMS states that in cases when it would pursue a CMP, the agency intends to send a written CMP notification that reflects the start and end dates of the penalty accrual and the total amount of the penalty assessed. As an example, the agency states that in the case of a failure to provide required data for negotiation or renegotiation, the end date would be the date the Primary Manufacturer provides the necessary information or otherwise has taken corrective actions determined necessary by CMS to address the violation. If the Primary Manufacturer never provides the information, the daily CMP would accrue until the agreement is terminated as described in proposed §429.205. CMS proposes the same approach in the case of a failure to provide data for a drug selected for renegotiation.

3. Provision of False Information Related to the Biosimilar Delay and Temporary Floor for Small Biotech Drugs (§429.1010)

Section 1197(d) of the Act provides that any manufacturer that knowingly provides false information pursuant to section 1196(a)(7) of the Act is subject to a CMP equal to $100,000,000 for each item of false information. That dollar amount is updated yearly per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.

CMS proposes two circumstances for which the agency may impose a CMP based on the provision of false information:

- On a Biosimilar Manufacturer, for each item of false information the Biosimilar Manufacturer knowingly provides to CMS for use in applying the aggregation rule described at proposed §429.110(b)(1)(iv)(A).
- On a Primary Manufacturer, for each item of false information the Primary Manufacturer knowingly provides to CMS for use in applying the test to determine if a selected drug or drug selected for renegotiation is eligible for the temporary floor for biotech drugs described in proposed §429.440(b)(2).

In the preamble CMS states that it adopts a standard for "knowingly" that has the meaning under 42 CFR 1003.110. Specifically, that a manufacturer satisfies any of the following:

- Has actual knowledge of the information;
- Acts in deliberate ignorance of the truth or falsity of the information; or
- Acts in reckless disregard of the truth or falsity of the information.

4. Failure to Pay a Biosimilar Delay Rebate (§429.1015)

Under section 1197(b) of the Act, if a Reference Manufacturer fails to comply with the rebate requirements under section 1192(f)(4) of the Act, the manufacturer is subject to a CMP equal to 10 times the amount of the rebate that was not paid. CMS proposes to codify this requirement in regulation at §429.1015.

5. Notice and Appeal Procedures (§429.1020)

Under section 1197(e) of the Act, the described CMPs are subject to the provisions of section 1128A of the Act (other than subsections (a) and (b) of that section). Accordingly, CMS proposes that when it makes a determination to impose a CMP, it intends to provide a written CMP notification that would include a description of the basis for the determination, the basis for the penalty, the start and end dates of the penalty, the total amount of the penalty, the due date, the manufacturer's right to a hearing, and information about where to file the request for a hearing. CMPs are due 60 calendar days after receipt of the CMP notification (per section 1128A) unless the manufacturer starts an appeal, in which case the CMP is due 60 calendar days after the appeal decision if there is still a CMP amount owed.

For the appeal process, CMS proposes to adopt the existing procedures under 42 CFR part 423 subpart T that apply to Part D sponsors and manufacturers under the Manufacturer Discount Program.

K. Application of Medicare Part B and Part D Drug Inflation Rebate Programs to Selected Drugs

Under section 1847A(i) of the Act, manufacturers must pay rebates (based on specific requirements) to Medicare for Part B rebatable drugs (e.g., certain single source drugs, biological products, and biosimilars) with prices that increase faster than the rate of inflation. Similarly, under section 1860D-14B of the Act, manufacturers that increase the price for a Part D rebatable drug faster than the rate of inflation are required to pay Medicare rebates (based on specific requirements). CMS reviews the following:

- It does not matter whether a drug is or is not a selected drug for that drug to be subject to the Part B and Part D drug inflation rebates.
- When a selected drug is no longer considered as such, certain components of the applicable rebate amount formula are recalculated.
- In the 2025 Physician Fee Schedule final rule, CMS codified:
    - The identification of the payment amount benchmark quarter and of the benchmark period CPI-U when a Part B rebatable drug is no longer considered to be a selected drug.[41]
    - The identification of the payment amount benchmark period and of the benchmark period CPI-U when a Part D rebatable drug is no longer considered to be a selected drug.[42]

III. Proposed Implementation of IRA Provisions for the Medicare Prescription Drug Benefit Program

A. Part D Formulary Inclusion of Selected Drugs

1. Background

Section 1860D-4(b)(3)(I)(i) of the Act requires, beginning in 2026, that Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP is in effect for that year. A Part D plan sponsor is not prohibited from removing from their formularies such a selected drug if the removal would be permitted under §423.120(b)(5)(iv) or a successor regulation. The statute does not otherwise specify formulary requirements for these selected drugs as far as placement or utilization management.

As discussed in further detail below, in the proposed rule, CMS proposes to codify in regulation at §423.120(b)(2)(vii) and (viii) that requirement and exception. The exception would permit Part D plan sponsors to remove the selected drug if the removal would be permitted under the successor regulations at proposed §423.120(e)(2)(i), (f)(2), (f)(3), and (f)(4).

2. Part D Formulary Inclusion of Selected Drugs (§423.120)

CMS reviews existing statutory and regulatory requirements and restrictions on formulary design as well as the agency's formulary review process, which it believes ensures that Part D plan sponsors comply with such requirements and restrictions. The agency states that, consistent with section 110 of the Negotiation Program Guidance and with its statutory duty to monitor Part D plans' compliance with all applicable formulary requirements, it would continue to use its formulary review process to assess the following:

- Any instances where Part D plan sponsors place selected drugs on non-preferred tiers;
- Any instances where a selected drug is placed on a higher cost-sharing tier than non-selected brand drugs in the same class;

[41] §427.303(c)(5) and (e)(5).
[42] §428.202(c)(5) and (e)(5).

- Any instances where Part D plan sponsors require utilization of an alternative non-selected brand drug prior to a selected drug (i.e., step therapy); or
- Any instances where Part D plan sponsors impose more restrictive utilization management (e.g., step therapy and prior authorization) for a selected drug compared to a non-selected brand drug in the same class.

CMS would expect Part D plan sponsors to provide a reasonable justification during the annual bid review process to support a submitted plan benefit design or formulary design that includes any of the above practices. CMS would approve a Part D plan bid only if the plan benefit design and formulary design complies with applicable statutory and regulatory requirements.

Because a selected drug includes all dosage forms and strengths to which the MFP applies, CMS proposes that Part D plan sponsors would continue to be required to include on their formularies all those dosage forms and strengths of the selected drug that constitute a Part D drug and for which the MFP is in effect.

3. Successor Regulation Exception Permitting Formulary Substitutions of Selected Drugs

Background. Section 1860D-4(b)(3)(I)(ii) of the Act is a rule of construction (referred to in the proposed rule as the "exception") that specifies nothing in section 1860D-4(b)(3)(I)(i) of the Act (i.e., the requirement that Part D plan sponsors must include on their formularies each covered Part D drug that is a selected drug for which an MFP is in effect) is to be construed as prohibiting a Part D plan sponsor from removing a selected drug from a formulary if permitted under §423.120(b)(5)(iv) or any successor regulation. When section 1860D-4(b)(3)(I) was enacted, §423.120(b)(5)(iv) permitted a plan to immediately substitute on the formulary a newly available generic drug for its brand name drug if certain notice and timing requirements were satisfied. The 2025 Parts C/D Final Rule, however, made changes to the regulations which moved (with revisions) the approval requirements for immediate substitutions to §423.120(e)(2)(i) and codified the corresponding notice requirements at §423.120(f)(2), (3), and (4).

Exception Permitting Formulary Substitutions of Selected Drugs. CMS proposes a new §423.120(b)(2)(viii) that would codify in regulation the exception under section 1860D-4(b)(3)(I)(ii) of the Act as well as the agency's identification of §423.120(e)(2)(i), (f)(2), (f)(3), and (f)(4) as the "successor regulation" for the purposes of implementing that exception. This is consistent with section 110.1 of the Negotiation Program Guidance.

Existing §423.120(e)(2)(i) specifies:

> A Part D sponsor may make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval . . . because such drug was not yet available on the market, and the Part D sponsor has

provided advance general notice as specified in paragraph (f)(2) of [section 423.120].

Under §423.120(f)(2), (3), and (4), a Part D plan sponsor that makes an immediate substitution under §423.120(e)(2)(i) must (among other requirements) provide advance general notice and retrospective notice to current and prospective enrollees and other specified entities, and ensure that written notice includes specific content.

Therefore, under the proposed §423.120(b)(2)(viii), nothing in the proposed §423.120(b)(2)(vii) requirement would be construed as prohibiting a Part D plan sponsor from removing from its formulary a selected drug if (in accordance with the successor regulations identified above) the sponsor adds to the formulary on the same or lower cost sharing tier and with the same or less restrictive PA, ST, or QL requirements as a newly available corresponding drug (defined in §423.100) to the selected drug. Under the proposal, Part D plans sponsors would continue to be able to remove a selected drug that is a reference product and replace it with an interchangeable biological product as an immediate substitution, in addition to being able to remove a selected drug that is a brand name drug and replace it with a generic drug as an immediate substitution.

Corresponding Drugs Do Not Include Selected Drugs. CMS discusses how the current definition of "corresponding drug" under §423.100[43] could, if read in isolation, be interpreted as allowing a Part D plan sponsor to remove a selected drug under the exception (described above) if the sponsor adds an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product. Such a removal, though, would not be consistent with the requirement imposed by section 1860D-4(b)(3)(I)(i) of the Act that the sponsor must include on its formulary each covered Part D drug that is a selected drug for which an MFP is in effect. This is because an authorized generic drug (which includes unbranded biological products that are marketed under the BLAs) and the qualifying single source drug that is the listed drug or reference product of that authorized generic drug is treated as the same qualifying single source drug and, thus, the same selected drug.

Since an authorized generic of a brand name drug that is a selected drug or an unbranded biological product marketed under the same BLA as the brand name biological product that is a selected drug is also included as the selected drug, proposed §423.120(b)(2)(vii) would require the Part D plan sponsor to include on its formulary each such authorized generic or unbranded biological product that is a covered Part D drug for which an MFP is in effect. A Part D sponsor would be able to remove, for example, such a brand name biological product and such an unbranded biological product from its formulary when making an immediate substitution under §423.120(e)(2)(i) by adding a single interchangeable biological product to its formulary, and the interchangeable biological product that is the corresponding drug for the selected drug could replace both the reference product and the unbranded biological product, as long as the requirements in the proposed successor regulations at §423.120(e)(2)(i), (f)(2),(f)(3), and (f)(4) are met.

[43] Under current §423.100, the definition states that a corresponding drug "means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product."

In the Final 2026 Part D Redesign Program Instructions, CMS clarified this by amending the definition of "corresponding drug" in section 90 of the program instruction, which was incorporated into section 110.1 of the Negotiation Program Guidance for 2027 and 2028. The revised definition states that a corresponding drug does not include a selected drug, as defined in section 1192(c) of the Act.

CMS is now proposing to codify in regulation at §423.100 that revised definition of corresponding drug from section 110.1 of the Negotiation Program Guidance for IPAY 2029 and subsequent years.

Timing of Immediate Substitutions. CMS discusses how the language of section 1860D-4(b)(3)(I) requires a selected drug to be included on Part D plan sponsors formularies first and that the statutory exception to that requirement is for the subsequent "removal" of that selected drug in accordance with regulations (discussed above). The proposed successor regulations (as discussed above) permit a Part D plan sponsor (if the sponsor meets notice requirements) to remove a selected drug that is a brand name or reference product from its formulary and replace it with a generic of the brand name drug or an interchangeable product of the reference product if the sponsor previously "could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval…because such drug was not yet available on the market".[44] The timing elements, therefore, point to the submission of the initial formulary.

As an example, in the case of a Part D plan sponsor that has a selected drug for IPAY 2029, which was on the plan's 2028 formulary, if a generic or interchangeable biological product of the selected drug becomes available on the market in 2028 *after* the sponsor submitted its initial 2029 formulary for approval, the sponsor could add the generic drug or interchangeable biological product and remove the selected drug from its formulary as an immediate substitution for 2028 and 2029. That is because the Part D plan sponsor could not have included the generic drug or interchangeable biological product on its 2028 or 2029 initial formulary submission, the immediate substitution would allow the sponsor to apply the removal to the current year (i.e., 2028) formulary and the already-submitted formulary for 2029.

Under another example, if a Part D plan sponsor includes a selected drug with an IPAY of 2029 on its initial formulary submission for 2029, the sponsor could remove the selected drug as an immediate substitution before the start of 2029 if a generic drug or interchangeable biological product of the selected drug becomes available on the market in 2028 *after* the initial formulary submission. By contrast, if the generic or interchangeable biological product is available on the market *before* the sponsor's 2029 initial formulary submission, the sponsor would need to include the selected drug on its 2029 formulary submission and would not be permitted to remove the selected drug from the formulary as an immediate substitution.

In addition, consistent with section 110.1 of the Negotiation Program Guidance, CMS proposes that removals under the exception under proposed §423.120(b)(2)(viii) could not be carried over subsequent years within the price applicability period solely on the basis that the selected drug was removed in a preceding year. This means that a removal could apply to more than one plan

[44] Section 423.120(e)(2)(i).

year in a price applicability period *only* if it independently meets the immediate substitution requirements for each of those plan years.

B. Negotiated Price for Selected Drugs

Section 1860D-2(d)(1) of the Act requires Part D sponsors to provide beneficiaries with access to negotiated prices for covered Part D drugs.

The definition of "negotiated price" is codified in regulation at existing §423.100 as meaning the price for a covered Part D drug that:

- The Part D sponsor (or other intermediary contracting organization) and network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement the network entity will receive, in total, for a particular drug;
- Includes all price concessions from network pharmacies and other network providers and any dispensing fees, and excludes additional contingent amounts (e.g., incentive fees) that increase prices; and
- Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D plan sponsor passes through to enrollees at the point of sale.

The IRA added subparagraph (D) to section 1860D-2(d)(1) of the Act, which provides that the negotiated price used for payment for a covered Part D drug that is a selected drug cannot be greater than the MFP plus any dispensing fee.

CMS proposes to codify that statutory change by similarly amending, effective for IPAY 2029 and subsequent years, the definition of negotiated price at 423.100. Specifically, the amendments would make paragraph (2) of the definition subject to a new paragraph (4) which would specify that the negotiated price used for payment for a covered Part D drug that is a selected drug, for each year of a price applicability period for the drug, could not exceed the MFP for the drug plus any applicable dispensing fee.

In addition, to align the definition with the agency's described historical interpretation that "negotiated price" includes sales tax and vaccine administration fees, paragraph (2) of the definition of the term under 423.100 would also be revised to specify the inclusion of sales tax and vaccine administration fees.

IV. Collection of Information Requirements

A. Wage Estimates

To estimate the cost of the information collection requirements, CMS used May 2025 information collected by the Bureau of Labor Statistics (BLS) for the professions listed in Table 5 of the proposed rule. CMS doubled the hourly median wage as a "reasonably accurate estimated method."

B. Information Collection Requirements (ICRs)

To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that federal agencies solicit comment on the following issues:

- The need for information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

CMS is soliciting public comments (see section II. of this proposed rule) on each provision that contains an ICR.

CMS submitted two ICRs to OMB as follows:

1. OMB 0938-1443

Requirement	Respondents	Annual Responses	Time per Response (Hours)	Annual Time (Hours)	Labor Cost ($/hour)	Total Cost ($)
Biosimilar Delay	Biosimilar Manufacturers	10	26.0	260	Varies	69,476
Selection of Renegotiation Eligible Drugs	Primary Manufacturers	36	125	4,500	Varies	513,383
Summary		46	Varies	4,760	Varies	582,,859

2. OMB 0938-1452

Requirement	Respondents	Annual Responses	Time per Response (Hours)	Annual Time (Hours)	Labor Cost ($/hour)	Total Cost ($)
Negotiation Data Elements	Primary Manufacturers	20	1,000	20,000	Varies	2,181,704
Renegotiated Drugs	Primary Manufacturers	36	750	27,000	Varies	3,080,300
Negotiated and Renegotiated Drugs	General Public	325	Varies	5,700	49.02	279,414
Temporary Floor Small Biotech	Primary Manufacturers	10	9.75	97	Varies	24,402
Counteroffer	Primary Manufacturers	56	204.25	11,438	Varies	2,127,987
Summary		447	Varies	64,235	Varies	7,793,808[1]

[1]This figure is presented as 7,793,808 in the proposed rule but adds to $7,693,808 in this table and the one reproduced below.

3. Summary of Annual Burden Estimates for OMB 0938-1443 and OMB 0938-1452

Requirement	Annual Responses	Time per Response (Hours)	Annual Time (Hours)	Labor Cost ($/hour)	Total Cost ($)
0938-1443	46	Varies	4,760	Varies	582,859
0938-1452	447	Varies	64,235	Varies	7,793,808
Total	493	Varies	68,995	Varies	8,276,666

V. Regulatory Impact Analysis

A. Detailed Economic Analysis

1. Existing Policies

The CMS Office of the Actuary estimated the impacts of the drug provisions of the IRA using the 2024 President's Budget as a baseline early in calendar year 2023. Since the majority of these provisions were implemented through program instruction, CMS indicates the estimate should be taken only in its historical context, not as a reflection on the experience since its effectuation. The proposed rule highlights certain components of this estimate where recent experience has diverged from CMS' assumptions.

CMS initially estimated the total effects were to reduce government expenditures for Part B, to increase expenditures for Part D through 2030, and to decrease Part D expenditures beginning in 2031 as shown in Table 18 reproduced below. Part B savings were primarily due to: (i) the substantial lowering of payments, relative to current payment, as a result of MFP; and (ii) small impacts from other provisions. Part D ultimately generated cost savings at the end of the budget window, but many of the gains from MFPs and lower trends were initially spent on increased benefits and the loss of manufacturer rebates.

Table 18: Part B and Part D IRA Impacts (in billions)

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Part B										
Total benefits	$0.1	$0.1	$0.1	−$0.2	−$0.3	−$5.8	−$8.4	−$14.7	−$21.4	−$28.4
Premium	0.0	0.0	0.0	−0.1	−0.1	−1.5	−2.1	−3.7	−5.3	−7.1
Total Federal impact	0.1	0.1	0.1	−0.2	−0.2	−4.4	−6.3	−11.0	−16.1	−21.3
Part D										
Total benefits	0.9	6.5	9.5	11.3	7.5	3.0	0.4	−4.5	−10.4	−12.5
Premium	0.0	−0.3	−0.6	−0.3	0.2	0.7	1.3	0.7	−0.1	−0.3
Inflation rebates	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.3	0.3
State transfer impact	0.0	−0.1	−0.4	−0.6	−1.7	−3.5	−5.1	−6.4	−7.6	−8.6
Total Federal impact[1]	0.4	6.6	10.2	11.9	8.8	5.6	3.9	1.0	−3.0	−3.9

[1]The Federal impact is calculated as the benefit impact less: (i) the premium impact; (ii) the inflation rebate impact; and (iii) the State transfer impact.

Since CMS produced these estimates, Part D drugs per capita costs increased more than 18 percent in 2025 over 2024, driven by higher glucagon-like peptide-1 (GLP-1) and specialty drug

usage. Part B drug costs primarily increased due to skin substitutes payable as a drug or biological.

CMS initially projected a discount on Part D drug prices of 11.3 percent for 2026 and 18.2 percent for 2027 using 2025 experience. The actual negotiated discounts are more than 2 percent greater than the original modeling results. Part B MFPs for IPAY 2028 are not currently available for CMS to quantify the change from its original assumptions.

Even though prices declined more than estimated for Part D drugs, CMS indicates that the effect on expenditures is difficult to determine as the 2026 claims experience will also be impacted by the benefit redesign changes implemented in 2025.

Part D drug inflation rebates were higher than originally assumed from $400 million to $500 million or 0.01 to 0.02 percent of gross drug costs. Part B drug inflation rebases were greater than estimates by $14 million for 2023 and $121 million for 2024.

Table 19 reproduced below shows CMS' revised impact of these and other provisions relative to its initial estimates based on later information including provisions of the Working Families Tax Cuts (WFTC) Act:

TABLE 19: PART B AND PART D WFTC ACT IMPACTS
(in billions)

	2028	2029	2030	2031	2032	2033	2034
Part B							
Total benefits	$2.8	$2.7	$0.2	$0.5	$0.4	$1.3	$1.6
Premium	0.7	0.7	0.1	0.1	0.1	0.3	0.4
Total Federal impact	2.1	2.0	0.2	0.3	0.3	0.9	1.2
Part D							
Total benefits	−0.2	0.0	0.1	0.0	0.4	0.8	1.0
Premium	0.0	0.0	0.0	0.0	0.1	0.1	0.2
Inflation rebates	0.0	0.0	0.0	0.0	0.0	0.0	0.0
State transfer impact	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Federal impact	−0.2	0.0	0.1	0.1	0.4	0.6	0.9

2. New Policies Being Proposed

CMS is proposing a variety of different policy changes but indicates that only the proposed narrow modification to the general fixed combination drug policy would potentially have an impact. The other provisions are technical changes that will not result in any additional cost or savings from the Negotiation Program.

As explained earlier, the Negotiation Program applies to single source drugs in their exclusivity period. CMS is proposing a change when a single source drug (referred to as Product A) has a change in its formulation (Product B). Under the proposal, Product A and Product B would be aggregated into the same qualifying single source drug that would apply the MFP earlier to Product B, resulting in Product B potentially being subject to the MFP for a shorter time until generics are available. CMS construes these effects as being potential loss of savings relative to

the alternative but indicates that any lost savings are outside of the budget window and cannot be reliably estimated.