

*Summary***Medicare Drug Price Negotiation Program Initial Guidance****Overview**

On March 15, 2023, the Centers for Medicare & Medicaid Services (CMS) issued an initial guidance regarding the Medicare Drug Price Negotiation Program (“Negotiation Program”) established by the Inflation Reduction Act of 2022 (IRA). This initial guidance describes how CMS intends to implement the Negotiation Program for initial price applicability year (IPAY) 2026 (January 1, 2026 to December 31, 2026), and specifies the requirements that will be applicable to manufacturers of Medicare Part D drugs that are selected for negotiation and the procedures that may be applicable to manufacturers of Medicare Part D drugs, Medicare Part D plans (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs)), and providers and suppliers (including retail pharmacies) that furnish Medicare Part D drugs. Notably IRA provisions not applicable in IPAY2026, including the selection and negotiation of Part B drugs, are not addressed in this guidance.

We have provided a detailed summary of the substantive provisions of the guidance, below. Key elements of the guidance include:

- **Definition of Qualifying Single Source Drug:** CMS is defining the term “qualifying single source drug” (QSSD) very broadly to include all dosage forms and strengths of the drug with the same active moiety (or, for biologics, active ingredient) and the same holder of a New Drug Application (NDA) (or, for biologics, a Biologics License Application (BLA))—inclusive of products that are marketed pursuant to different NDAs/BLAs. In addition, for purposes of counting the 7/11 years that must elapse, CMS will use the earliest date of approval of the initial FDA application number assigned to the NDA/BLA holder for the active moiety/active ingredient. By defining the term QSSD so broadly, CMS may have increased the number of products that may be eligible for negotiation earlier than had been anticipated. However, the emergence of a biosimilar/generic for any dosage form or strength will result in a product losing its status as a QSSD or, if applicable, selected drug, also potentially removing products from the Negotiation Program earlier than expected.
- **Orphan Drug Exclusion:** CMS confirmed that an orphan drug can have multiple indications and still benefit from the exclusion, but all such indications must be for a single disease or condition. However, CMS is “considering whether there are additional actions the agency can take in its implementation of the Negotiation Program to best support orphan drug development.”
- **Small Biotech Exception:** A determination by CMS that a given QSSD qualifies for the Small Biotech Exception for IPAY2026 does not mean that the drug will continue to qualify for the exception for future price applicability years, meaning that the manufacturer must continue to submit applications for all three years of the exclusion’s applicability (2026-2028).
- **Biosimilar Delay Request:** A biosimilar manufacturer may submit a request, prior to the selected drug publication date, for CMS’s consideration to delay the inclusion of a negotiation-eligible reference product for the biosimilar on the selected drug list. The biosimilar manufacturer eligible to submit the request must be the holder of the BLA for the biosimilar, or if the biosimilar is not yet licensed, the sponsor of the BLA submitted for review by the FDA. CMS spells out a detailed process for the request in the guidance.

- **Removal of Selected Drugs.** A selected drug will cease to be a selected drug and will no longer be subject to the Negotiation Program if 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 the FDA has licensed a biosimilar biological product 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 biological product, as applicable, is marketed pursuant to such approval or licensure. The effect and timing of losing selected drug status will depend on when CMS makes these determinations. The approval (or, if applicable, licensure) and marketing of an authorized generic drug would not qualify as meeting the statutory requirement that a generic drug or biosimilar has been marketed. CMS will also monitor the market for “robust and meaningful” competition; one example of this is assessing whether the generic drug or biosimilar is regularly and consistently available for purchase through the drug supply chain.
- **Manufacturer Agreement.** CMS intends to enter into an Agreement (a “Medicare Drug Price Negotiation Program Agreement”) with the Primary Manufacturer of each selected drug, while still imposing several requirements pertaining to Secondary Manufacturers on the Primary Manufacturer. CMS intends to designate the entity that *holds* the NDA/BLA for the selected drug to be the Primary Manufacturer subject to an Agreement. The guidance describes how CMS intends to implement the various Agreement requirements set forth in the statute. For example, the Primary Manufacturer is responsible for ensuring access to the MFP, even as CMS acknowledges that each component of the drug supply chain may have a role in making the MFP available to MFP-eligible individuals. CMS intends to require that Primary Manufacturers provide access to the MFP to dispensers (e.g., pharmacies) in one of two ways: (1) by ensuring the price paid is no greater than MFP; or (2) by providing retrospective reimbursement for the difference between the dispensing entity’s acquisition cost and the MFP. Primary Manufacturers that select the latter option must ensure that dispensers (as well as intermediary entities such as wholesalers) are reimbursed the difference between their acquisition cost and the MFP within 14 days. CMS also reserves the right to impose requirements determined by CMS to be necessary for purposes of administering the Negotiation Program on the Primary Manufacturer, as permitted by statute, but does not specify what those requirements might be.
- **Data Use Limitations.** CMS seeks to impose strict limitations on the Primary Manufacturer related to the submission of data and the use, disclosure, and destruction of data and other information received during the negotiation process. With respect to data reported by manufacturers, on the other hand, CMS only intends to treat information on non-FAMP and *certain* data elements as proprietary information, protected from disclosure under Exemption 4 of FOIA and only available for use by CMS and the Comptroller General; however, CMS does not propose to impose these restrictions on data that is available to the public.
- **Data Regarding Therapeutic Alternatives.** For purposes of negotiating a maximum fair price (MFP), CMS intends to consider evidence about therapeutic alternatives described in section 1192(e)(2) of the Social Security Act (the “Act”) submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties. CMS intends to release a Negotiation Data Elements ICR, which will describe how CMS intends to collect these data. CMS also intends to conduct its own literature review along these lines, prioritizing research that is methodologically rigorous.
- **Use of QALYs.** As required by section 1194(e)(2) of the Act, CMS will not use information in the negotiation process that treats extending the life of individuals in certain populations as of lower value. CMS specifically cites to “certain uses of quality-adjusted life-years (QALYs)” as falling within this prohibited category. CMS is soliciting comment on other metrics, in addition to QALYs,

that should similarly be excluded from consideration on the grounds it treats extending the lives of these populations of lesser value.

- **Single MFP.** CMS intends to identify a single MFP at each step of the negotiation process, even for a selected drug with multiple dosage forms and strengths. CMS intends to determine the single MFP to be included in an initial offer as the cost of 30-day equivalent supply for the selected drug. CMS will then develop a methodology for translating the finalized MFP back into per-unit prices at the dosage form and strength level. To maintain transparency, the methodology will be shared with the Primary Manufacturer of the selected drug during the negotiation process.
- **Ceiling Price.** CMS will not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling price. The ceiling price will be based on the lower amount of two calculations: (1) The sum of the plan-specific enrollment weighted amounts; and (2) An amount equal to the applicable percent of the average non-FAMP. Both amounts are calculated per a 30-day equivalent supply across the NDC-11s for each specific dosage form and strength of the selected drug.
- **Developing initial offer and counteroffer.** To determine an initial offer and counteroffer for the selected drug, CMS intends to use the following process: (1) identify indications for the selected drug and therapeutic alternative(s); (2) use as a starting point the Part D net price for Part D drug therapeutic alternative(s) and/or Part B average sales price for Part B therapeutic alternative(s); (3) evaluate clinical benefits of the selected drug to adjust the starting point; (4) further adjust the preliminary price through consideration of manufacturer-specific data (e.g., R&D costs; current unit costs of production and distribution) to determine the initial offer price.
- **Manufacturer Compliance and Oversight.** CMS will monitor Primary Manufacturers' compliance with the terms of Medicare Drug Negotiation Agreements ("Agreements") and will establish a mechanism to notify the Primary Manufacturer of violations of Agreement terms. Primary Manufacturers that fail to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Process can be subject to an excise tax or Civil Monetary Penalties (CMPs).
- **340B.** A manufacturer participating in the 340B program is not required to provide a 340B covered entity with access to the MFP of a selected drug (with respect to an MFP-eligible individual receiving the drug from a covered entity) if the 340B ceiling price is lower than the drug's MFP. However, a manufacturer must provide a 340B covered entity with access to a drug's MFP if the MFP is lower than the 340B ceiling price. Should it be subsequently determined that 340B ceiling price is lower than the MFP for a selected drug, then the manufacturer (participating in the 340B program) would have to provide the 340B covered entity the difference between the MFP and 340B ceiling price.
- **Impact of Negotiation on Inflation Rebate Provisions:** CMS confirmed that selected drug status does not exempt drug from inflation rebate provisions.

Comment Solicitation

In the initial guidance, CMS is voluntarily soliciting comment almost all topics, including:

- Terms and conditions contained in the Agreement, including the Primary Manufacturer's and CMS' responsibilities;
- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments;
- Process for the offer and counteroffer exchange between CMS and manufacturers;
- Content of an explanation for the MFP;
- Method for applying the MFP across different dosage forms and strengths of a selected drug;

- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198; and
- Processes for compliance monitoring and imposition of CMPs for violations.

Comments are due to CMS at the [IRA mailbox](#) by April 14, 2023. CMS is not, however, seeking comment regarding section 30 (“Identification of Selected Drugs for IPAY2026”) or section 90.3 (which states that the Treasury Department and IRS anticipate issuing separate guidance on the administration of the excise tax). CMS also directs the public to comment on the [Small Biotech Exception Information Collection Request \(ICR\)](#) using the process described in that ICR, rather than in response to the guidance.¹ Once CMS has had the opportunity to consider the comments submitted, the agency will issue revised guidance for IPAY2026. **In the revised guidance, CMS may make changes to any policies, including any policies on which CMS has not expressly solicited comment.**

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¹ Note that comments are due in response to the ICR by March 27, 2023. The public will have an additional opportunity to submit comments for 30 days following issuance of the 30-day *Federal Register* notice on this ICR.

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SECTION 30: IDENTIFICATION OF SELECTED DRUGS FOR IPAY2026 (NOT OPEN FOR COMMENT)

- Under the IRA, the selection of drugs under the Negotiation Program is a three-step process, under which CMS sequentially identifies the following three categories of products, subject to certain exemptions: (1) QSSDs; (2) negotiation-eligible drugs; and (3) selected drugs. Under the IRA, there are three categories of drugs that are excluded from the QSSD definition: (1) certain orphan drugs; (2) low-spend Medicare drugs; and (3) plasma-derived products.
- As noted above, CMS is issuing the guidance in this section 30 as final, without comment solicitation.

Section 30.1: Identification of QSSDs for IPAY2026

- **In the guidance, CMS is defining the term “qualifying single source drug” very broadly to include all dosage forms and strengths of the drug with the same active moiety (or for biologics, active ingredient) and the same holder of an NDA (or, for biologics, a BLA)—inclusive of products that are marketed pursuant to different NDAs/BLAs.**
 - CMS further clarifies that a given QSSD will also include authorized generics/authorized biologics, as well as repackaged and relabeled products and multi-market approval (MMA) products imported under section 801(d)(1)(B) of the FD&C Act with the same active moiety/active ingredient that are marketed pursuant to such NDA(s)/BLA(s).
 - Note, however, that if a drug is a ***fixed combination drug*** (as defined in 21 CFR § 300.50) with two active moieties/active ingredients, the distinct combination of active moieties/active ingredients will be considered as one active moiety/active ingredient for purposes of identifying QSSDs. So, a product containing only one (but not both) of the active moieties/active ingredients will be considered a unique QSSD.
- **For purposes of counting the 7/11 years that must elapse, CMS will use the earliest date of approval of the initial FDA application number assigned to the NDA/BLA holder for the active moiety/active ingredient.**
 - As such, separate NDA approvals do not “reset” the clock.
 - For IPAY2026, this initial approval must have occurred on or before September 1, 2016.
- **CMS will use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar biological product has been approved for any dosage form or strength.** Notably, CMS would make this determination for “any of the strengths or dosage forms of the potential QSSDs for IPAY2026.”
 - If CMS identifies that there exists generic/biosimilar “bona fide” competition for “any strength or dosage form of a potential QSSD,” the entire drug is disqualified from negotiation.
 - For purposes of IPAY2026, CMS will review PDE data for a given generic drug or biosimilar during the 12-month period between August 16, 2022 – August 15, 2023 to determine whether the manufacturer of a generic/biosimilar engaged in “bona fide marketing” of the product.

Section 30.1.1: Orphan Drug Exclusion

- **To be considered for the orphan drug exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition under section 526 of the FD&C**

Act and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition.

- To qualify for the orphan drug exclusion, *all dosage forms and strengths and different formulations* of the QSSD described in section 30.1 of this memorandum must meet the criteria for exclusion.
- CMS will use the FDA Orphan Drug Product designation database and approvals on the FDA website to determine whether a drug qualifies for the orphan drug exclusion.
- CMS is considering whether there are additional actions the agency can take in its implementation of the Negotiation Program to best support orphan drug development.

Section 30.1.2: Low-Spend Medicare Exclusion

- **CMS will exclude from the final list of QSSDs for IPAY2026 any drugs for which the sum of Total Expenditures under Part D and total allowed charges, inclusive of beneficiary cost sharing, under Part B are less than \$200 million.**
 - CMS will use Part D PDE data and Part B claims data for the period of June 1, 2022 through May 31, 2023, and that are submitted no later than June 30, 2023, to identify low-spend Medicare drugs with less than \$200 million in combined expenditures for purposes of IPAY2026.

Section 30.1.3: Plasma-Derived Therapies

- **CMS will exclude plasma-derived products when identifying QSSDs**
 - For purposes of this exclusion, CMS is defining a plasma-derived product as a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling.
 - CMS will refer to product information available on the FDA Approved Blood Products website to identify approved blood products regulated as biological products and the FDA Online Label Repository to verify if the product is derived from human whole blood or plasma. CMS will also consult with FDA as needed.

Section 30.2: Identification of Negotiation-Eligible Drugs for IPAY2026

- CMS will employ the following process to identify negotiation-eligible drugs, which for IPAY2026, will be 50 drugs in total:

"Negotiation-Eligible Drug" Identification Process	
Process	Details
Step 1 – Identify QSSDs	Identify all QSSDs as described above
Step 2 – Identify Part D PDE Data for QSSDs	Pull PDE data from the period from June 1, 2022 through May 31, 2023, that are submitted by June 30, 2023.
Step 3 – Calculate Part D Total Expenditures	Use PDE data to calculate Total Expenditures under Part D for each such QSSD.
Step 4 – Apply small biotech exception	CMS will (1) remove drugs that are subject to the small biotech drug exception
Step 5 – Rank remaining drugs by Part D Total Expenditures	Rank remaining QSSDs by Total Expenditures under Part D during the relevant 12-month period

Step 6 – Identify 50 drugs with highest Part D Total Expenditures	Identify the 50 QSSDs with the highest Part D Total Expenditures during the relevant 12-month period – these are the negotiation-eligible drugs for IPAY2026
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Section 30.2.1: Exception for Small Biotech Drugs

- **To identify small biotech drugs subject to the exclusion, CMS will consider whether, for dates of service in calendar year 2021, the Part D Total Expenditures for the QSSD were: (1) equal to or less than one percent of the Part D Total Expenditures for all covered Part D drugs; and (2) were equal to at least 80 percent of the Part D Total Expenditures for all covered Part D drugs for which the manufacturer had a Coverage Gap Discount Program (CGDP) agreement in effect during 2021.**
 - Subject to the aggregation rule (described below), the Total Expenditures used in this calculation will not include expenditures for products of repackers and relabelers who had CGDP agreements for the QSSD during 2021.
 - The aggregation rule requires CMS to treat as a single manufacturer all entities that, as of December 31, 2021, were treated as a single employer under the Internal Revenue Code (IRC) of 1986 with the entity that had the CGDP agreement for the QSSD on that date. Because CMS does not have the information necessary to make the determination as to whether this aggregation rule applies, CMS will require a manufacturer seeking the small biotech exception to submit an application to the company, using the form described in the Small Biotech Exception ICR (which remains open for public comment through March 27, 2023).
 - This application must be submitted by the deadline established by CMS, which is expected to be in June 2023.
- CMS will employ the following process to identify whether a given drug qualifies for the small biotech exception based on the information submitted on the Small Biotech Exception ICR Form:

"Selected Drug" Identification Process	
Process	Details
Step 1 – Identify 2021 Manufacturer	Identify the manufacturer that had a CDGP agreement for the drug in effect as of December 2021 (“2021 Manufacturer”)
Step 2 – Identify All NDC-11s for the Manufacturer’s controlled group	Identify the complete set of 11-digit National Drug Codes (NDC-11s) for which any member of the 2021 Manufacturer’s “controlled group” ² had a CGDP agreement in effect as of December 31, 2021
Step 3 – Identify Part D PDE Data	Identify Part D PDE data for the period from January 1, 2021 through December 31, 2021 for all such NDC-11s.
Step 4 – Perform necessary calculations	Using such PDE data, determine whether: (1) the Part D Total Expenditures for the QSSD were equal

² Defined as all corporations or partnerships, proprietorships, and other entities treated as a single employer under section 52(a) or (b) of the Internal Revenue Code.

	to or less than one percent of the Part D Total Expenditures for all covered Part D drugs; and (2) the Part D Total expenditures for the QSSD were equal to at least 80 percent of the Part D Total Expenditures for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect during 2021.
Step 5 – Rank remaining drugs by Part D Total Expenditures	Rank remaining QSSDs by Total Expenditures under Part D during the relevant 12-month period
Step 6 – Identify 50 drugs with highest Part D Total Expenditures	Identify the 50 QSSDs with the highest Part D Total Expenditures during the relevant 12-month period – these are the negotiation-eligible drugs for IPAY2026

- **A determination by CMS that a given QSSD qualifies for the Small Biotech Exception for IPAY2026 does not mean that the drug will continue to qualify for the exception for future price applicability years.**
 - The manufacturer will be required to resubmit a request for the drug to be considered for the small biotech exception again for 2027 and 2028;³ the process for submitting these subsequent requests will be described in later guidance.

Section 30.3: Selection of Drugs for Negotiation for IPAY2026

CMS will employ the following process to select drugs for negotiation, which for 2026, will be 10 drugs in total:

"Selected Drug" Identification Process	
Process	Details
Step 1 – Rank Negotiation Eligible Drugs	Rank 50 negotiation-eligible Part D drugs in descending order with highest-spend drugs first
Step 2 – Apply Any Biosimilar Delays	Remove any biological products that qualify for a biosimilar delay
Step 3 – Select Top 10 Drugs	Select the top 10 ranked drugs (or all if less than 10)
Step 4 (if applicable) – Apply Tie Breakers	If two or more negotiation-eligible drugs are ranked 10 th based on total expenditures, CMS will rank those negotiation-eligible drugs based on which drug has the earliest approval/licensure date

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

- A biosimilar manufacturer may submit a request, prior to the selected drug publication date, for CMS's consideration to delay the inclusion of a negotiation-eligible reference product for the biosimilar on the selected drug list.

³ The small biotech exception applies only between 2026-2028.

- The biosimilar manufacturer eligible to submit the request must be the holder of the BLA for the biosimilar, or if the biosimilar is not yet licensed, the sponsor of the BLA submitted for review by the FDA.

Section 30.3.1.1 Requirements for Granting an Initial Delay Request for IPAY2026

- **A biosimilar manufacturer who believes that a reference drug for their biosimilar may be a selected drug for IPAY2026 may submit an Initial Delay Request, which CMS will disregard if the reference drug would not, in fact, be a selected drug.**
 - CMS encourages biosimilar manufacturers to consult "publicly available data on expenditures for covered Part D drugs, including data published by CMS," which may allow a biosimilar manufacturer to determine the likelihood that their reference drug may be a selected drug.
- **To be eligible for a delay, the reference drug must be an extended-monopoly drug⁴ for the IPAY absent the biosimilar delay—for 2026, this means that the reference drug must have received its initial BLA between January 1, 2010, and January 1, 2014.**
 - Separately, however, section 1194(c)(4)(B)(ii) of the Act also provides that selected drugs for which a negotiation agreement with the Secretary is in effect during initial price applicability years 2026-2030 are excluded from the definition of extended-monopoly drugs.
 - CMS believes that the two provisions do not overlap because the exception to the "extended-monopoly drug" of section 1194(c)(4)(B)(ii) requires that the reference drug actually be selected and negotiated, while the Initial Delay Request is made before the reference drug is a selected drug and actually negotiated.
 - Thus, an Initial Delay Request will be available for initial price applicability years 2026-2029 notwithstanding the exception to the "extended-monopoly" drug definition.
- **Biosimilar Licensure for Any of Reference Drug's Dosage Form, Strengths, or Indications is Sufficient for Initial Delay Request.**
 - The biosimilar manufacturer's licensure application for review or approval by the FDA must include the reference product for which the Initial Delay Request is sought.
 - The licensure application for the biosimilar does not need to include all dosage forms, strengths, or indications for which the reference drug has received approval in order for CMS to grant the delay request.
- **An Initial Delay Request cannot be granted if more than one year has elapsed since the biosimilar was licensed and marketing of the biosimilar has not commenced.**
 - For IPAY2026, if the biosimilar is licensed and marketed prior to September 1, 2023, then the reference drug is no longer a QSSD. If the biosimilar is licensed prior to September 1, 2022, but is not marketed before September 1, 2023, then an Initial Delay Request is not possible and the reference drug may be selected for negotiation.
- **An Initial Delay Request cannot be granted to a biosimilar manufacturer and reference manufacturer that are treated as being the same manufacturer.** For purposes of this determination, the following entities are considered to be the same manufacturer:

⁴ Section 1194(c)(4)(A) defines an "extended monopoly drug" as a drug "with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable."

- All persons treated as a single employer per section 52(a)-(b) of the Internal Revenue Code.
- All persons in a "partnership", which is defined as a "syndicate, group, pool, joint venture, or other organization through or by means of which any business financial operation, or venture is carried on by the reference manufacturer and the biosimilar manufacturer."
- **Biosimilar manufacturers cannot enter into either of following types of agreement with a reference manufacturer and benefit from the biosimilars delay provisions:**
 - An agreement that requires or incentivizes the biosimilar manufacturer to submit an Initial Delay Request; or
 - An agreement that directly or indirectly restricts the quantity of the biosimilar that may be sold over a specified period of time.
 - For IPAY2026, CMS will consider any such agreement on or after September 1, 2023 as violating this requirement.

Section 30.3.1.2 High Likelihood

- **For an Initial Delay Request to be granted, the biosimilar must be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year.**
 - For 2026, CMS must find a high likelihood that the biosimilar will be licensed and marketed before September 1, 2025 (2 years after September 1, 2023). If CMS does not find that there is a high likelihood that the biosimilar will be licensed and marketed before September 1, 2025, CMS will deny the Initial Delay Request.
- Initial Delay Requests must demonstrate that (1) an application for licensure under section 351(k) of the PHS Act has been accepted for review or approved by the FDA, and (2) there is clear and convincing evidence that the biosimilar will be marketed before September 1, 2025 (i.e., 2 years after September 1, 2023—the selected drug publication date for IPAY2026).

High Likelihood Determination IPAY2026		
(1) Application for Licensure Having Been Accepted or Reviewed by the FDA	(2) Clear and Convincing Evidence of Marketing	
CMS states that for Initial Delay Requests for IPAY2026, the biosimilar manufacturer's licensure application must be approved or accepted for review by the FDA no later than August 15, 2023 to provide enough time for CMS to review prior to publication of the selected drug list. Otherwise, CMS	Biosimilar manufacturer must <i>demonstrate that patents related to the reference drug are unlikely to prevent the biosimilar from being marketed.</i> CMS will consider this requirement met if: (1) there are no non-expired approved patent applications	Biosimilar manufacturer must <i>demonstrate that the biosimilar manufacturer will be operationally ready to market the biosimilar.</i> CMS will assess this by considering the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading

will deny the Initial Delay Request. CMS did not specify what the cut-off date will be for future initial price applicability years.	relating to the reference drug that are applicable to the biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable non-expired patent relating to the reference drug that the patent holder asserted was applicable to the biosimilar; or (3) the biosimilar manufacturer has a signed legal agreement with the reference manufacturer that permits the biosimilar manufacturer to market the biosimilar in one or more dosage form(s), strength(s), and indication(s) before September 1, 2025, without imposing improper constraints on the biosimilar manufacturer; and (4) there is no active litigation (including but not limited to patent litigation) with the reference manufacturer with respect to the reference product.	up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before September 1, 2025, and (2) a manufacturing schedule consistent with the public-facing statements and any revenue expectations.
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- **CMS notes that the biosimilar delay provision is not subject to administrative or judicial review per section 1198(2) of the Act.**

Section 30.3.1.3 Submitting an Initial Delay Request for IPAY2026

- **For IPAY2026, manufacturers may submit Initial Delay Requests via email and Box.**
 - For future years, CMS plans to issue guidance on use of CMS HPMS to receive and process these requests in the future.

Initial Delay Request IPAY2026	
Process	Details
Step 1 – Email Intent to Apply	By 11:59pm PT on May 10, 2023, biosimilar manufacturer should send email to IRArebateandnegotiation@cms.hhs.gov to indicate intention of submitting an Initial delay Request.

Step 2 – Access Application Template	Within 5 business days of receipt, CMS will respond by providing the biosimilar manufacturer with: • (1) a fillable template for the Initial Delay Request form, and • (2) Access to a Box folder specific to the biosimilar manufacturer's Initial Delay Request No parties other than CMS (and its contractors) and the biosimilar manufacturer will have access to this folder.
Step 3 – Submit Completed Application	By 11:59pm PT on May 22, 2023, biosimilar manufacturer should upload a complete Initial Delay Request to the Box folder or an alternative submission approach approved by CMS. CMS will consider an Initial Delay Request complete if it includes: • A complete Initial Delay Request form as provided by CMS; • All agreements related to the Biosimilar filed with the FTC or Assistant Attorney General; • The manufacturing schedule for the biosimilar submitted to the FDA, to the extent available; • SEC disclosures about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product that pertain to the marketing of the biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.

Section 30.3.1.4 Process and Timing After Submission of an Initial Delay Request for IPAY2026

- **CMS may require additional information from the biosimilar manufacturer before adjudicating an Initial Delay Request.**
 - Within 5 business days of the biosimilar manufacturer uploading the required documentation to its Box folder (or alternative submission approach approved by CMS), CMS will send an email confirmation to the biosimilar manufacturer using the same email address used by the biosimilar manufacturer in its initial email to CMS expressing its intent to submit an Initial Delay Request.
 - CMS may request additional information to adjudicate the Initial Delay Request which will be made in writing, for IPAY2026, by June 30, 2023.
 - The deadline for any additional requested information will be no later than July 3, 2023.⁵

⁵ The one exception to this general rule is the August 15, 2023 deadline that CMS will use to determine whether the biosimilar's application for licensure was accepted for review or approved by the FDA as part of its "high likelihood" determination.

CMS Review of Initial Delay Requests IPAY2026⁶	
Process	Details
Step 1 – Review for Completeness	CMS will review each Initial Delay Request to determine whether it includes all of the elements for an Initial Delay Request and was submitted by the applicable deadline.
Step 2 – Review for Statutory Compliance	CMS will review the Initial Delay Request to determine if it meets all of the statutory requirements described in section 30.3.1.1, with the exception of the high likelihood requirement.
Step 3 – Review for High Likelihood Determination	CMS will review the Initial Delay Request to determine whether it demonstrates a high likelihood that the Biosimilar will be licensed and marketed by September 1, 2025, as described in section 30.3.1.2.
NOTE: CMS review will terminate as soon as the Initial Delay Request fails to meet any of these requirements.	

- **If a reference drug that was the subject of an Initial Delay Request does not appear on the selected drug list, then it indicates that the Initial Delay Request was successful (to the extent that the reference drug *would* have been listed).**
- **CMS will also notify each biosimilar manufacturer separately regarding the disposition of their Initial Delay Request on or after September 1, 2023, but no later than September 30, 2023.**
 - If the Initial Delay Request was unsuccessful, CMS will provide a brief written summary of its determination that will include the reasons for its denial, which may include but is not limited to:
 - Failure to submit all elements of the Initial Delay Request by the applicable deadline;
 - Failure to meet another statutory requirement (other than the high likelihood requirement), including notification of whether the reference drug would have been a selected drug absent the Initial Delay Request; or
 - Failure to demonstrate a high likelihood requirement.
 - NOTE: Reference manufacturers named in unsuccessful Initial Delay Requests will not be notified.
 - If the Initial Delay Request was successful, CMS will provide a brief written summary of its determination that will identify the reference drug that would have been a selected drug absent the successful Initial Delay Request.
- **CMS notes that other policies related to the biosimilar delay provision will be included in future guidance, including but not limited to:**
 - the deadline and process for submitting an Initial Delay Request for IPAY2027;
 - the deadline and process for submitting an Additional Delay Request for IPAY2027, in the event an Initial Delay Request for IPAY2026 is granted and CMS determines by mid-2024 that the Biosimilar was not licensed and marketed during the initial delay period;⁷
 - the criteria for adjudicating Additional Delay Requests;
 - the impact of Initial Delay Requests and Additional Delay Requests on the selected drug list for IPAY2027; and
 - the application and calculation of rebates for a Reference Drug for 2026, as applicable.

⁶ All steps will be performed by CMS prior to the selected drug publication date: September 1, 2023.

⁷ CMS will publish a specific date in future guidance.

Section 30.4: Publication of the Selected Drug List

- **CMS will publish the selected drug list no later than September 1, 2023 on CMS's IRA webpage.**
 - The list will include the 10 (or all, if such number is less than 10) drugs selected for negotiation for IPAY2026.

SECTION 40: REQUIREMENTS FOR MANUFACTURERS OF SELECTED DRUGS FOR IPAY2026

- **CMS intends to enter into an Agreement (a “Medicare Drug Price Negotiation Program Agreement”) with the Primary Manufacturer of each selected drug, while still imposing several requirements pertaining to Secondary Manufacturers on the Primary Manufacturer.**
 - CMS intends to designate the entity that *holds* the NDA/BLA for the selected drug to be the Primary Manufacturer subject to an Agreement. An entity that is (a) listed as a manufacturer in an NDA or BLA for the selected drug; or (b) markets the selected drug pursuant to an agreement with the Primary Manufacturer, would be designated as a Secondary Manufacturer (including a manufacturer of any authorized generics and any repacker or relabeler of the selected drug).
 - In the Agreement with the Primary Manufacturer, CMS will include several requirements pertaining to the Secondary Manufacturer, including (a) a requirement to report to CMS a list of any Secondary Manufacturers and the NCD-11s of the selected drugs marketed by them; (b) a duty to report any applicable submission data to inform negotiation held by the Secondary Manufacturer; and (c) a requirement to ensure that any Secondary Manufacturer make the MFP available to MFP-eligible individuals and dispensers.
 - The Primary Manufacturer of a selected drug will be required to:
 - Sign the Agreement with CMS;
 - Collect and report all data required for negotiation;
 - Negotiate an MFP with CMS;
 - Ensure the MFP is made available to all MFP-eligible individuals and dispensers; and
 - Respond to CMS requests within specified timeframes.
- **The negotiation period for the IPAY2026 will begin on the earlier of: (a) the date on which the agreement is executed by both parties; or (b) October 1, 2023.**
 - Within 5 days of the publication of the ten selected drugs (which must be not later than September 1, 2023), a Primary Manufacturer that elects to enter into an Agreement must submit through HPMS relevant contact information for representatives authorized to legally bind the manufacturers to the terms and conditions of the Agreement.
 - At least one authorized representative for the Primary Manufacturer must access the CMS HPMS and sign the Agreement by October 1, 2023.
 - *CMS notes it will make reasonable efforts to make the final text of the Agreement available prior to the publication of the selected drug list.*
- **The Primary Manufacturer of a selected drug must submit data to inform the negotiation process by October 2, 2023**
 - While CMS anticipates Primary Manufacturers will be able to access the data elements to be submitted to inform the negotiation prior to any Agreement being executed, Primary

- Manufacturers will not be able to submit the data elements until the Agreement is fully executed.
- Data elements will include: information on the non-FAMP and any information that CMS requires to carry out negotiation, including the statutory negotiation factors (e.g., R&D costs, prior federal financial support, data on pending and approved patent applications).
 - *CMS seeks comment specifically on a requirement that Primary Manufacturers submit data elements for both themselves and any Secondary Manufacturers.*
 - *CMS also seeks comment on a requirement for Primary Manufacturers to report to CMS any new approved and marketed NDC-11s, or discontinued NCD-11s, of the selected drug for themselves and on behalf of any Secondary Manufacturers.*
 - **CMS intends to treat information on non-FAMP and certain data elements as proprietary information, protected from disclosure under Exemption 4 of FOIA and only available for use by CMS and the Comptroller General**
 - CMS' confidentiality policy would treat data elements submitted as proprietary if the information constitutes commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that cannot be found publicly. CMS would treat R&D costs and recoupment, unit costs of production and distribution, pending patent applications, and market data and revenue and sales volume data to be proprietary, unless the information that is provided to CMS is already publicly available.
 - CMS intends to treat the data on prior Federal funding and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS believes these data are available publicly.
 - In its explanation for the MFP, to be published by March 1, 2025, CMS intends to only make high-level comments about proprietary data, noting it may say, for example, "the manufacturer has recouped its research and development costs."
 - *CMS is seeking comments on which manufacturer data elements require submission of proprietary information and the basis for such conclusion. CMS is also seeking comment about the proper balance between the public's interests in transparency and the protection of business information in this context.*
 - **CMS seeks to impose strict data use provisions and limitations on the Primary Manufacturer related to the submission of data and the use, disclosure, and destruction of data and other information received during the negotiation process.**
 - CMS intends to require that a Primary Manufacturer not disclose to the public any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, or any information contained in any concise justification provided with an offer.
 - CMS also seeks to prohibit the disclosure of any information exchanged verbally during the negotiation period, as well as to prohibit audio/video recording of negotiations.
 - CMS intends to prohibit Primary Manufacturers from using any of the information obtained during the negotiation process for any purposes other than the Medicare Drug Negotiation Program.
 - Primary Manufacturers must submit a Certification of Data Destruction to CMS and destroy all information received during the negotiation period from CMS within 30 days of a determination by CMS that the drug or biological no longer qualifies as a selected drug.

- *CMS is seeking comment on the data use limitations it intends to impose on manufacturers, as well as whether there are possible scenarios where a manufacturer might need to disclose this information.*
 - *CMS is also seeking comment on the data destruction policies and scenarios where a manufacturer might need to retain certain pieces of information, for example to comply with state or federal laws.*
- **CMS intends to use the Agreement to outline the offer and counteroffer process and to use HPMS to share the initial offer and concise justification.**
 - The renegotiation process for a selected drug, which begins in 2028, will be subject to future guidance released by CMS.
- **CMS intends to require that Primary Manufacturers provide access to the MFP to dispensers (e.g., pharmacies) in one of two ways: (1) by ensuring the price paid is no greater than MFP; or (2) by providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP.**
 - Part D sponsors can provide MFP-eligible individuals with access to MFP without additional steps required of the manufacturer by ensuring the negotiated prices used in payment by each Part D plan sponsor not exceed the applicable MFP plus any dispensing fee.
 - However, because the IRA also requires that manufacturers provide access to the MFP for selected drugs to dispensers, CMS intends to allow access to MFP by dispensers either at the point-of-sale or through the provision of retrospective reimbursement for the difference.
 - By December 2, 2025, a Primary Manufacturer must submit to CMS its process for making the MFP available for the selected drug. CMS intends to impose a 10-year record retention requirement on any sales of selected drugs and to regularly audit sales for compliance.
 - Primary Manufacturers must ensure that dispensers (as well as intermediary entities such as wholesalers) are reimbursed the difference between their acquisition cost and the MFP within 14 days.
 - The Primary Manufacturer is responsible for ensuring the MFP is made available, including for units of the selected drug for which there is a Secondary Manufacturer.
- **Primary Manufacturers must provide access to the MFP to a 340B covered entity for an MFP-eligible individual if the MFP is below the 340B ceiling price for the selected drug.**
 - A Primary Manufacturer is *not* required to provide access to the MFP for a selected drug to a 340B covered entity if the 340B ceiling price is lower than the MFP for the selected drug.
 - If the 340B ceiling price is subsequently determined to be lower than the MFP, then the manufacturer would be responsible for providing to the covered entity the difference between the MFP and the 340B ceiling price.
- **The Primary Manufacturer must comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program.**
- **The Agreement will remain in effect, including through renegotiation, until the selected drug is no longer considered a selected drug, or the Agreement is terminated by either party.**
- **Other Provisions in the Agreement.**
 - If the Primary Manufacturer subject to an Agreement transfers the NDAs/BLAs to another entity, CMS will continue to hold the Primary Manufacturer responsible until the Primary Manufacturer transfers the requirements to the new holder.

- CMS intends to continue to hold the Primary Manufacturer responsible for any outstanding negotiation rebate liabilities related to the biosimilar delay provision unless and until such liabilities are transferred to the new holder of the NDA(s)/BLA(s).
- CMS intends to require that if any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if the invalid or unenforceable provision(s) were eliminated, and without any effect on any other provisions.
- CMS intends to define all days as calendar days unless otherwise specified in statute, guidance, or rulemaking.

SECTION 50: NEGOTIATION FACTORS

- **As described above, CMS intends to hold the Primary Manufacturer responsible for reporting information on the manufacturer-specific factors described in section 1194(e)(1) of the Act on behalf of itself and the Secondary Manufacturer(s).**
 - The deadline for reporting this information will be October 2, 2023.
- **CMS intends to consider evidence about therapeutic alternatives described in section 1192(e)(2) of the Act submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties.**
 - CMS also intends to conduct its own literature review along these lines, prioritizing research that is methodologically rigorous.
- **CMS intends to consider research on, and real world evidence relating to Medicare populations (i.e., ESRD, aged, and disabled) as particularly important.**
- **CMS intends to release a Negotiation Data Elements ICR, which will describe how CMS intends to collect the data relevant to the negotiation factors described in sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act.**

Section 50.1: Manufacturer-Specific Factors

- **Consistent with section 1194(e)(1) of the Act, CMS will consider the following manufacturer-specific data, as reported by the Primary Manufacturer:**
 - Research and development 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, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
 - 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 for the Primary Manufacturer and any Secondary Manufacturer(s) (with the exception of costs related to the acquisition of the selected drug, which would be reported only for the Primary Manufacturer).
- **Appendix C of the guidance outlines proposed definitions for the following terms of relevance to the manufacturer-specific factors:**

- R&D costs, including sub-definitions for the following categories of R&D costs: basic, pre-clinical research costs; post-investigational New Drug (IND) application costs; completed FDA-required Phase IV trials; post-marketing trials; abandoned and failed drug costs; and all other R&D costs.
- Recoupment of R&D costs.
- Current unit costs of production and distribution
- Prior federal financial support.
- Patents, exclusivities and approvals
- Market data and revenue and sales volume data

Section 50.1.1: Non-FAMP Data

- **For IPAY2026, CMS will require the Primary Manufacturer to submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar year 2021, or in the case there is no non-FAMP for the selected drug in calendar year 2021, the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of the first full year following market entry of such drug.**
 - Appendix C of the guidance includes proposed definitions for “non-FAMP unit” and “non-FAMP price.”

Section 50.2: Evidence About Therapeutic Alternatives for the Selected Drug

- **Consistent with section 1194(e)(2) of the Act, CMS will consider the following factors related to therapeutic alternatives:**
 - 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, herein referred to as “specific populations”); and
 - The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.
- **As required by section 1194(e)(2), CMS will not use information in the negotiation process that treats extending the life of individuals in certain populations as of lower value.**
 - CMS specifically cites to “certain uses of quality-adjusted life-years (QALYs)” as falling within this prohibited category.
 - *CMS is soliciting comment on other metrics, in addition to QALYs, that should similarly be excluded from consideration on the grounds it treats extending the lives of these populations of lesser value.*
- **In considering impact on specific populations and patients with unmet medical needs, CMS will prioritize research specifically designed to focus on these populations over studies that**

include outcomes for these populations but for which these populations were not the primary focus.

SECTION 60: NEGOTIATION PROCESS

- **CMS outlines the negotiation process as involving:**
 - Development of the written initial offer;
 - The process for making such offer and providing a concise justification to the Primary Manufacturer of a selected drug;
 - The process and requirements for accepting an offer or providing a counteroffer;
 - The potential for one to three meetings between CMS and the Primary Manufacturer;
 - The conclusion of negotiation; and
 - The publication of the MFP.

Section 60.1 Establishment of a Single Proposed MFP for Negotiation Purposes

- **CMS intends to identify a single MFP at each step of the negotiation process, even for a selected drug with multiple dosage forms and strengths.**
 - Each offer and counteroffer would include a single MFP. Then, CMS will apply the determined MFP across different dosage forms and strengths of a selected drug.
 - CMS intends to determine the single MFP to be included in an initial offer as the cost of 30-day equivalent supply for the selected drug.
 - CMS will then develop a methodology for translating the finalized MFP back into per-unit prices at the dosage form and strength level. To maintain transparency, this methodology will be shared with the Primary Manufacturer of the selected drug during the negotiation process.
 - CMS solicits comments on its intended approach to identify a single price for each step of the negotiation process, and on the advantages/disadvantages of converting to a 30-day equivalent supply price. CMS also solicits comments on whether there are other approaches that allow CMS to calculate a single price across dosage forms and strengths and allow for a more direct comparison with therapeutic alternatives, which might have different dosage forms, strengths, and frequency of use than the selected drug.

Section 60.2 Limitations on Offer Amount

- **CMS will not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling price.**

Section 60.2.1 Determination of the Ceiling for the MFP

- **The ceiling price will be based on the lower amount of two calculations:**
 - (1) The sum of the plan-specific enrollment weighted amounts
 - (2) An amount equal to the applicable percent of the average non-FAMP
- **As described in greater detail, below, CMS intends to calculate a single amount per a 30-day equivalent supply across the NCD-11s for all dosage forms and strengths of the selected**

drug for each methodology, and then compare the two amounts to determine the lower ceiling for the MFP.

- The price per 30-day equivalent supply will be used to calculate the two ceiling amounts to allow for aggregation across different dosage forms and strengths.
- CMS will confirm that the MFP, as applied to a given dosage form and strength, does not exceed the ceiling price.

Section 60.2.2 Sum of Plan Specific Enrollment Weighted Amounts

- **Using PDE and DIR data for plan year 2022, CMS plans to employ a 10-step process to calculate a plan specific enrollment weighted amounts for a selected drug.**
 - CMS would include all Part D plans that have PDE data for the selected drug in this calculation. Part D plans with no utilization for the selected drug or without enrollment for 2022 will be excluded.

Calculation of Plan Specific Enrollment Weighted Amounts	
Process	Details
Calculating Sum of Plan Specific Enrollment Weighted Amounts for EACH Dosage Form and Strength of the Selected Drug (Steps 1-7)	
Step 1	For each Part D plan, CMS would identify the PDE data for the selected drug for 2022 (that is, PDE records with dates of service during the period beginning on January 1, 2022 and ending on December 31, 2022).
Step 2	For each Part D plan, CMS would sum the negotiated price amounts (as defined in 42 CFR § 423.100) and the estimated rebate at point of sale amounts (ERPOSA) across the PDE records for each of the NDC-11s of each dosage form and strength. CMS would also calculate the 30-day equivalent supply for each PDE record and sum the 30-day equivalent supply across the PDE records for each of the NDC-11s of each dosage form and strength.
Step 3	For each Part D plan, CMS would sum the total DIR amounts found in the 2022 Detailed DIR Report for all NDC-11s of each dosage form and strength and subtract the total ERPOSA calculated in step 2 to avoid double counting price concessions applied at the point of sale to calculate the total DIR amount for each dosage form and strength of the selected drug.
Step 4	For each Part D plan and each dosage form and strength of the selected drug, CMS would subtract the total DIR amount calculated in step 3 from the sum of the negotiated price amounts calculated in step 2 and then divide by the total 30-day equivalent supply of the dosage form and strength, also determined in step 2. This calculation results in the price per 30-day equivalent supply of the dosage form and strength of the selected drug, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan.
Step 5	Separately, CMS would identify the total number of individuals enrolled in all Part D plans in December 2022, and the total number of individuals enrolled in each Part D plan in that month

Step 6	For each Part D plan, CMS would divide the total number of Part D beneficiaries enrolled in the Part D plan during December 2022 as identified in step 5 by the total number of individuals enrolled in all Part D plans in December 2022 also as identified in step 5, and multiply this quotient by the price for a 30-day equivalent supply, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan, calculated in step 4, to arrive at the plan specific enrollment weighted amount.
Step 7	CMS would then sum the amounts calculated in step 6 across all Part D plans to calculate the sum of the plan specific enrollment weighted amounts for each dosage form and strength of the selected drug.
Calculating Sum of the Plan Specific Enrollment Weighted Amounts for The Selected Drug Across ALL Dosage Forms and Strengths (Steps 8-10)	
Step 8	CMS would use the Part D PDE data for 2022 to calculate the total 30-day equivalent supply for each dosage form and strength of the selected drug across all Part D plans. Also, CMS would use the same data to calculate the total 30-day equivalent supply of the selected drug across all dosage forms and strengths and all Part D plans.
Step 9	For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for the dosage form and strength by the total 30-day equivalent supply across all dosage forms and strengths of the selected drug as identified in step 8, and multiply this quotient by the sum of the plan specific enrollment weighted amounts for the dosage form and strength as calculated in step 7.
Step 10	CMS would then sum amounts calculated in step 9 across all dosage forms and strengths of the selected drug to calculate the sum of the plan specific enrollment weighted amounts for the selected drug.

Section 60.2.3 Average Non-Federal Average Manufacturer Price

- **CMS intends to use the non-FAMP of each NDC-11 and the unit volume data for each quarter for the selected drug as submitted by the Primary Manufacturer.**
 - CMS would use the 2022 Part D PDE data submitted to CMS at the NDC-11 level by Part D plans to determine the 30-day equivalent supply.
- **To ensure comparability between the applicable percent of the average non-FAMP and the sum of the plan-specific enrollment weighted amounts, CMS intends to use the same data sources.**
 - CMS intends to base the average non-FAMP calculations on a 30-day equivalent supply and intends to use the same data source for weighting both the sum of the plan-specific enrollment weighted amounts and the average non-FAMP to determine which amount is lower.

Calculation of Plan Average Non-Federal Average Manufacturer Price	
Process	Details
Calculating The Applicable Percent Of The Average Non-FAMP For EACH Dosage Form And Strength Of The Selected Drug.	
Step 1	In order to calculate an average non-FAMP that is comparable to the sum of plan specific enrollment weighted amounts described in section 60.2.2 of this memorandum, CMS would

	compare the non-FAMP unit type (e.g., tablet) to the PDE units (i.e., each, milliliter, and grams). In instances where the units are different, CMS would convert the non-FAMP unit type to the PDE units so that the two amounts (average non-FAMP and sum of plan specific enrollment weighted amounts) represent the same quantity of the selected drug.
Step 2	CMS would calculate the non-FAMP per unit by dividing the non-FAMP per package by the total number of units per package for that NDC-11.
Step 3	For each NDC-11 of the selected drug and for each quarter during calendar year 2021, CMS would divide the total unit volume (calculated as the product of the total number of packages sold by the number of units per package for that NDC-11) in that quarter by the total unit volume across all four quarters during calendar year 2021, and multiply this quotient by the non-FAMP. Note: In the case that there is not a non-FAMP available for such drug for calendar year 2021, CMS would use the non-FAMP and total unit volumes for the quarters of the first full year following the market entry for such drug.
Step 4	For each NDC-11 of the selected drug, CMS would sum the amounts calculated in step 3 across quarters to calculate the average non-FAMP for that NDC-11 in calendar year 2021. CMS believes steps 3 and 4 are necessary to account for unit volume fluctuations that may occur across quarters for each NDC-11.
Step 5	For each NDC-11 of the selected drug, CMS would divide the total unit volume in calendar year 2021 for that NDC-11 by the total unit volume in calendar year 2021 for all NDC-11s of the same dosage form and strength, and multiply this quotient by the average non-FAMP in calendar year 2021 for that NDC-11 calculated in step 4.
Step 6	For each dosage form and strength of the selected drug, CMS would sum the amounts calculated in step 5 to calculate the average non-FAMP for that dosage form and strength in calendar year 2021. CMS believes steps 5 and 6 are necessary to account for unit volume fluctuations that may occur across NDC-11s of a dosage form and strength.
Step 7	For each dosage form and strength of the selected drug, CMS would then multiply the average non-FAMP in calendar year 2021 calculated in step 6 by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 to September 2022 as specified in section 1194(c)(1)(C)(i) of the Act. Note: In the case that there is not a non-FAMP available for that dosage form and strength of the selected drug for calendar year 2021, CMS would use the percentage increase from December of the first full year following the market entry for that dosage form and strength instead of September 2021, as required under section 1194(c)(1)(C)(i) of the Act.
Step 8	After CMS has calculated the average non-FAMP in calendar year 2021 for each dosage form and strength of the selected drug, adjusted for inflation, CMS would apply the applicable percent specified in section 1194(c)(1)(C) of the Act for the monopoly type determined for the selected drug based on its initial approval date.
Step 9	CMS would then multiply the average non-FAMP for calendar year 2021 for each dosage form and strength of the selected drug, adjusted for inflation and with the applicable percent applied calculated in step 8, by the quotient of the total number of units of that dosage form and strength divided by the total 30-day equivalent supply (i.e., this quotient would represent the average units per 30-day supply equivalent) for that dosage form and strength calculated from Part D PDE data for 2022 to determine the average non-FAMP for a 30-day equivalent supply of that dosage form and strength of the selected drug. As noted above in section 60.2.1 of this memorandum, CMS believes calculating the average non-FAMP for a 30-day

	equivalent supply is necessary to account for potential different units and treatment regimens across dosage forms and strengths.
Calculating The Applicable Percent Of The Average Non-FAMP For ALL Dosage Form And Strength Of The Selected Drug.	
Step 10	For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for the dosage form and strength by the total 30-day equivalent supply across all dosage forms and strength of the selected drug calculated from Part D PDE data for 2022, and multiply this quotient by the average non-FAMP for that dosage form and strength calculated in step 9.
Step 11	CMS would then sum amounts calculated in step 10 across dosage forms and strengths of the selected drug to calculate the applicable percent of the average non-FAMP for the selected drug.

Section 60.2.4. Selection and Application of the Ceiling for the MFP

- **CMS intends to select the lowest of the plan specific enrollment weighted amount (Step 10) and average non-federal average manufacturer price (Step 11) as the ceiling price.**
 - Once the ceiling price is identified, CMS will ensure that the MFP per 30-day equivalent supply for each dosage form and strength of the selected drug is not above the ceiling price.
 - This approach allows for a single ceiling for the MFP and enables CMS to determine if the initial offer and counteroffer (across dosage forms and strengths) is at or below the ceiling price specific to each dosage form and strength of the selected drug

Section 60.3 Methodology for Developing an Initial Offer

- **To determine an initial offer and counteroffer for the selected drug, CMS intends to use the following process:**
 - Identification of indications for the selected drug and therapeutic alternative(s).
 - Use as a starting point the Part D net price for Part D drug therapeutic alternative(s) and/or Part B average sales price (ASP) for Part B therapeutic alternative(s).
 - Evaluation of clinical benefits of the selected drug to adjust the starting point.
 - Further adjustment of the preliminary price through consideration of manufacturer-specific data (e.g., R&D costs; current unit costs of production and distribution) to determine the initial offer price.

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

- **CMS will use FDA labeling information and nationally recognized, evidence-based guidelines and recognized by CMS-approved Part D compendia to identify indications for a selected drug that are not statutorily excluded from Part D coverage, and to identify therapeutic alternatives.**
 - Then, for each indication, CMS intends to identify a pharmaceutical therapeutic alternative(s). CMS will refer to data submitted by the Primary Manufacturer and the

public, FDA-approved indications, indications included in CMS-approved Part D compendia, widely accepted clinical guidelines, and peer-reviewed studies.

- CMS intends to begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes.

Section 60.3.2 Developing a Starting Point for the Initial Offer

- **As a starting point for the initial offer, CMS intends to use the Part D net price(s) and/or ASP(s) of therapeutic alternative(s) for the selected drug, as applicable, subject to the ceiling price of the selected drug.**
 - CMS states that this allows it to focus the initial offer on clinical benefit by adjusting this starting point relative to whether the selected drug offers more, less, or similar clinical benefit compared to its therapeutic alternatives.
 - If there are multiple therapeutic alternatives, CMS considers the range of net prices and/or ASPs as well as the utilization of each therapeutic alternative to determine the starting point.
 - If there are no therapeutic alternative(s), or if therapeutic alternatives have prices above the ceiling price for the selected drug, CMS will use the Federal Supply Schedule (FSS) or "Big Four Agency" price, or in the absence of those references, the statutory ceiling.
 - *CMS is soliciting comments on the advantages and disadvantages of using net prices and/or ASPs as the starting point for the initial offer for selected drugs with at least one therapeutic alternative and the Federal Supply Schedule or Big Four price for selected drugs with no therapeutic alternative or for selected drugs with therapeutic alternatives with net prices and/or ASPs greater than the statutory ceiling.*
 - *CMS is also soliciting comment on other starting points for the initial offer, including but not limited to other domestic reference prices, along with their disadvantages and advantages.*
 - *Lastly, in the event there are multiple therapeutic alternatives for the selected drug, CMS is soliciting comment on how to consider the range of net prices and/or ASPs and utilization of each therapeutic alternative to determine a single starting point for developing the initial offer.*

Section 60.3.3 Adjusting the Starting Point Based on Clinical Benefit

- **To evaluate the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), as applicable, CMS intends to broadly evaluate the body of clinical evidence.**
 - This includes data received from the public and manufacturers, and data identified through a CMS-led literature review.
 - CMS may also analyze Medicare claims or other drug datasets for utilization patterns, clinical data, or other information relevant to the selected drug and its therapeutic alternative(s) and may consult with clinical and academic experts.
- **The starting point adjusted based on evidence of clinical benefit produces the "preliminary price."**

- Once the starting point for the initial offer has been established and evidence on clinical benefit has been considered, CMS intends to adjust the starting point for the initial offer based on the review of the clinical benefit (this adjusted price is referred to herein as the “preliminary price”).
- As noted above, CMS will not use QALYs.
- CMS describes its approach as "qualitative" and involves "adjusting the starting point upward or downward relative to the clinical benefit offered by the selected drug compared to its therapeutic alternatives."

Section 60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

- **CMS intends to assess comparative effectiveness between a selected drug and its therapeutic alternatives by considering factors in two domains: (1) Outcomes; and (2) Safety.**
 - CMS intends to focus the review of clinical benefit on outcomes of particular importance to the condition or disease being treated by the selected drug and will determine such outcomes from the CMS-led literature review and information submitted by manufacturers and the public through the Negotiation Data Elements ICR.
 - CMS will consider whether the selected drug fills an unmet medical need, which CMS intends to define as treating a disease or condition in cases where very limited or no other treatment options exist.
 - CMS intends to determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression).

Indication-Specific Outcomes	Safety Profile
● Health Outcomes ○ (e.g., cure, survival, progression-free survival, improved comorbidity, etc.) ● Intermediate Outcomes ● Surrogate Endpoints ○ (e.g., lower blood pressure reducing the risk of stroke) ● Patient-Reported Outcomes ● Patient Experience	● Risks ● Harms ● Side effects

Section 60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives

- **For selected drugs with no therapeutic alternatives, CMS intends to adjust the starting point for the initial offer based on the extent to which the selected drug fills an unmet medical need.**
 - Unmet medical need will be considered separately for each indication.
 - Unmet need is more likely where limited or no treatment options exist.

Section 60.3.4 Consideration of Manufacturer-Specific Data

- CMS will consider the "manufacturer-specific" data required by statute as follows to arrive at the initial offer price:

Consideration of Manufacturer-Specific Data for Preliminary Price ⁸	
Research & Development Costs	CMS will compare the research and development costs and the global, net revenue reported by the Primary Manufacturer. If Primary Manufacturer has not recouped R&D, CMS <i>may</i> consider adjusting the preliminary price upward, and vice-versa.
Unit Costs of Production and Distribution	CMS intends to consider the relationship between the preliminary price and the unit price of production and distribution. CMS may consider adjusting the preliminary price downward if the unit cost of production and distribution is lower than the preliminary price, and vice-versa.
Prior Federal Financial Support	CMS intends to consider the extent to which the Primary Manufacturer benefited from Federal financial support. Prior Federal financial support could result in a downward adjustment.
Pending and Approved Patent Applications or Exclusivities	CMS intends to consider the length of the available patents and exclusivities before the selected drug may no longer be single source. Patents/exclusivities that will last for a number of years could result in a downward adjustment.
Market Data and Revenue and Sales Volume (U.S.)	CMS intends to consider how the data compare to the CMS preliminary price. If the average commercial net price is lower than the preliminary price, CMS may consider a downward adjustment.

Section 60.4 Negotiation Process

Timeline for the Negotiation Process for MFP of Selected Drug IPAY2026	
Milestone	Timing/Deadline
CMS publishes Drug Price Negotiation Process Information Collection Request	Spring 2023
Negotiation period begins	Earlier of: (a) the date the Primary Manufacturer enters into an Agreement; or (b) October 1, 2023
CMS sends written initial offer to Primary Manufacturer (with the proposed MFP and concise justification)	No later than February 1, 2024
Primary Manufacturer accepts offer or proposes an optional written counteroffer	No later than 30 days after receipt of written initial offer
Process for when Primary Manufacturer chooses to make a written counteroffer:	
CMS accepts counteroffer or holds negotiation meeting with Primary Manufacturer (if CMS rejects the counteroffer)	No later than 30 days after CMS' receipt of written counteroffer
All negotiation meetings end (maximum of 3 negotiation meetings allowed)	No later than June 30, 2024
CMS sends final offer to manufacturer	No later than July 15, 2024

⁸ Appendix C of the guidance has a detailed breakdown of these factors.

Primary Manufacturer accepts or rejects final offer	No later than July 31, 2024
Process after agreements on MFP are reached:	
Negotiation period ends	August 1, 2024
CMS publishes MFP for selected drugs	No later than September 1, 2024
CMS publishes MFP for selected drug a Primary Manufacturer agreed to via written acceptance after the end of negotiation period	No later than 30 days after MFP is determined
CMS publishes public explanation for the agreed-upon MFPs	No later than March 1, 2025
Negotiated MFP effective for selected drugs	January 1, 2026

Section 60.5 Application of the MFP Across Dosage Forms and Strengths

- **The agreed-upon MFP will establish one price for the selected drug per 30-day equivalent supply, which CMS will apply across different dosage forms and strengths.**
 - CMS seeks to scale the MFP per unit based on price differentials across dosage forms and strengths. For this calculation, CMS is considering using the wholesale acquisition cost (WAC) of the selected drug.
 - CMS intends to publish the MFP per unit price for each dosage form and strength, which will be calculated through a 10-step approach.

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

- **CMS intends to apply the MFP to drug or biological products marketed pursuant to the new NDA or BLA (or as a supplement to an existing NDA or BLA) if the Primary Manufacturer for a selected drug receives approval or licensure for a new NDA or BLA for the same active moiety/ingredient after the drug has been selected.**
 - *CMS is soliciting comment on how to compute the MFP for a drug or biological product or NDC that is a selected drug and is marketed for the first time, pursuant to an existing or new NDA or BLA, after the drug is selected and an MFP has been agreed.*

Section 60.6 Publication of the MFP

- **CMS intends to publish on the CMS website the following:**
 - The selected drug, the initial price applicability year, and the MFP file by September 1, 2024.
 - The explanation for the MFP no later than March 1, 2025. CMS will only make high-level comments on the data submitted or discussed during negotiations, without sharing any proprietary information.
 - When a drug is no longer a selected drug (with the reason).
 - When Primary Manufacturer and CMS cannot agree upon an MFP.

Section 60.7 Exclusion from the Negotiation Process

- **CMS will not begin, or will suspend, negotiation for selected drugs that meet the criteria in section 70 (generic/biosimilar competition).**
 - When the negotiation process is not started or is suspended, such selected drug will continue to be a selected drug through the initial price applicability year.

SECTION 70: REMOVAL FROM SELECTED DRUG LIST BEFORE OR DURING NEGOTIATION, OR AFTER MFP IS IN EFFECT

- **A selected drug will cease to be a selected drug and will no longer be subject to the negotiation process if CMS determines:**
 - 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 the FDA has licensed a biosimilar biological product under Section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and
 - The generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure.
- **The approval (or, if applicable, licensure) and marketing of an authorized generic drug would not qualify as meeting the statutory requirement that a generic drug or biosimilar has been marketed.**
 - For purposes of the Negotiation Program, an authorized generic drug approved under Section 505(t)(3) of the FD&C Act (and a biological product that is approved under Section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling or packaging, product code, tradename, or trademark) is treated as the same QSSD as the listed drug.
- **Starting in October 2023, CMS intends to use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar has been approved or licensed for any strength(s) or dosage form(s) of the selected drugs for IPAY2026.**
 - If a generic or biosimilar has been approved or licensed, CMS will review PDE data with dates of service during the most recent 12-month period to determine if the biosimilar manufacturer has engaged in bona fide marketing of that drug or product.
 - CMS will monitor manufacturers of generic drugs or biosimilar biological products to ensure they are engaging in bona fide marketing of the generic or biosimilar biological product. More details are provided in Section 90.4 of the guidance.
- **A selected drug included on the selected drug list will remain a selected drug for an IPAY and each subsequent year beginning before the first year that begins at least 9 months after the date on which CMS determines a generic or biosimilar has been marketed.**
 - However, If CMS makes a determination of generic or biosimilar availability on or after the selected drug publication date, but before or during the negotiation period for the relevant initial price applicability year, the selected drug will not be subject to the negotiation process for the negotiation period, and an MFP will not be established.

Date on which CMS determines that a generic drug or biosimilar biological product is approved and marketed	Result with respect to selected drug for the Negotiation Program
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September 1, 2023 through August 1, 2024 (which includes Negotiation Period for IPAY2026)	Selected drug remains a selected drug for IPAY2026, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2027.
August 2, 2024 through March 31, 2026	Selected drug remains a selected drug and MFP applies for IPAY2026; selected drug ceases to be a selected drug on January 1, 2027.
April 1, 2026 through March 31, 2027	Selected drug remains a selected drug and MFP applies for IPAY2026 and calendar year 2027; selected drug ceases to be a selected drug on January 1, 2028

SECTION 80: MFP ELIGIBLE INDIVIDUALS

- **MFP-eligible individuals may receive a selected drug in two contexts (described below)**
 - **When Dispensed:** When a selected drug is dispensed a selected drug at a pharmacy, by mail order service, or another dispenser, the individual must:
 - be enrolled under a prescription drug plan in Medicare Part D or an MA–PD plan under Medicare Part C (including Employer Group Waiver Plans); and
 - have coverage for such selected drug under their plan.
 - **When Administered or Furnished:** When a selected drug is furnished or administered by a hospital, physician, or other provider of services or supplier:
 - the individual must be enrolled under Medicare Part B (including those enrolled in an MA plan under Medicare Part C); and
 - payment would need to be available under Medicare Part B for such selected drug.

SECTION 90: MANUFACTURER COMPLIANCE AND OVERSIGHT

- CMS will monitor the Primary Manufacturers’ compliance with the terms of the Agreement and will establish a mechanism to notify the Primary Manufacturer of violations of Agreement terms.

Section 90.1: Monitoring of Manufacturer Compliance

- **CMS will monitor Primary Manufacturers’ compliance with the terms of the Agreement and with the Negotiation Program.**
 - CMS will provide information about the negotiation process to each Primary Manufacturer, following publication of selected drugs for each initial price applicability year; this information can include key timelines, procedural requirements, instructions, IRA resources, and contact information.
 - CMS intends to track and monitor progress in each step during the negotiation period, engage in direct communication with Primary Manufacturers, and will issue reminders and warning letters (if applicable) in advance of deadlines.
 - Primary Manufacturers that fail to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Process can be subject to an excise tax or Civil Monetary Penalties (CMPs).

Section 90.2: Monitoring of Access to the MFP

- **During a price applicability period, a Primary Manufacturer must provide eligible individuals with access to the MFP for a selected drug at the pharmacy, mail-order service, or other dispenser at the point-of-sale. Additionally, the Primary Manufacturer must provide the pharmacy, mail-order service, or other dispenser with access to the MFP for the selected drug.**
 - Primary Manufacturers must establish safeguards to ensure that MFP-eligible individuals, pharmacies, mail-order services, and other dispensers can access MFP on units of the selected drug for which there are Secondary Manufacturers.
 - MFP will apply to all sales of the selected drug to MFP-eligible individuals.
 - CMS will establish procedures for reporting violations related to MFP access for MFP-eligible individuals enrolled in PDPs or MA-PDs.
- **The Primary Manufacturer is responsible for ensuring access to the MFP, even as CMS acknowledges that each component of the drug supply chain may have a role in making the MFP available to MFP-eligible individuals.**
 - CMS notes that efforts to support transparency can assist dispensing entities and MFP-eligible individuals determine if they are accessing MFP for a selected drug.
 - MFPs for selected drugs will be published, per the IRA; MFPs for selected drugs for IPAY2026 must be published by September 1, 2024.
 - Additionally, CMS anticipates that pharmaceutical database companies will publish MFPs.
 - *CMS is seeking comments on additional ways that CMS can assist dispensing entities and MFP-eligible individuals identify the MFP for a selected drug and determine whether they can access it.*
 - CMS will leverage existing mechanisms to ensure that dispensing entities can access MFP, and that MFP is only provided to eligible individuals.
 - As an example, each Part D plan must use a unique Part D processor identification number (RxBIN) and Part D processor control number (RxPCN) to identify a Part D payer; according to CMS, this mechanism can ensure that the pharmacy can identify (at the point-of-sale) if an individual is eligible for MFP.
 - As another example, CMS explains how chargeback payments and rebate mechanisms in the private sector allow entities to receive rebates or discounts after purchases are made. According to CMS, the private sector can make modifications to these existing mechanisms to effectuate MFP access, as appropriate.
 - CMS intends to establish a process for beneficiaries, dispensing entities, and providers and suppliers to report instances to CMS in which they should have had access to MFP, but it was not made available.
 - CMS might establish a toll-free phone line and email box; submissions may include the reporting entity's name, information on the incident, the manufacturer's name, and contact information for follow-up.
 - CMS would review the submissions, investigate, and impose CMPs on the Primary Manufacturers, if needed.
 - *CMS is seeking comments on how such a process might operate most effectively, including suggestions on ways that CMS could provide technical assistance to entities to ensure they can provide MFP to eligible individuals, and to ensure*

that MFP-eligible individuals whose cost-sharing was inconsistent with MFP are “made whole.”

- Additionally, CMS expects manufacturers and other stakeholders to report instances in which a dispenser was not passing through the MFP to an eligible individual or extending the MFP to a non-MFP-eligible individual.
- ***CMS is seeking comments on approaches to support Primary Manufacturers in meeting the obligation to ensure that Secondary Manufacturers provide access to the MFP for dispensing entities.***
 - For example, it is possible for an entity to purchase one or more drug or biological products included in the selected drug from a wholesaler, repackaging or relabel such products, and then re-market them pursuant to one or more NDA(s) or BLA(s) included in the selected drug. CMS believes that the MFP should be made available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed units of the selected drug marketed by such manufacturers. CMS is soliciting comment on how it might monitor MFP access for these units of a selected drug, including how to identify the other manufacturers that market these selected drugs, and what mechanisms are available to ensure MFP is available for these units of the selected drug.
- ***According to CMS, it is possible for an entity that meets the statutory definition of a manufacturer, but is not a Primary Manufacturer, to market one or more biological products pursuant to one or more NDAs or BLAs included in the selected drug.***
 - An entity can purchase one or more drugs or biologicals included in the selected drug from a wholesaler, repackaging or relabel them, and remarket pursuant to one or more NDAs or BLAs; CMS believes that MFP should be made available for dispensed units of the selected drugs marketed by such manufacturers.
 - ***CMS therefore seeking comments on how it can monitor MFP access for these units of a selected drug, including how to identify other manufacturers that market these selected drugs, and what mechanisms are available to ensure that MFP is made available for these units.***
- ***Should it be subsequently determined that 340B ceiling price is lower than the MFP for a selected drug, then the manufacturer (participating in the 340B program) would have to provide the 340B covered entity the difference between the MFP and 340B ceiling price.***
 - As noted above, a manufacturer participating in the 340B program is not required to provide a 340B covered entity with access to the MFP of a selected drug (with respect to an MFP-eligible individual receiving the drug from a covered entity) if the 340B ceiling price is lower than the drug’s MFP.
 - However, a manufacturer must provide a 340B covered entity with access to a drug’s MFP if the MFP is lower than the 340B ceiling price.
 - CMS intends to work with HRSA to ensure that 340B covered entities can access MFP, where appropriate.

Section 90.3: 26 USC Section 5000D Excise Tax on Sale of Designated Drugs During Noncompliance Periods **(NOT OPEN FOR COMMENT)**

- The IRS will administer the excise tax. The Treasury Department and IRS intend to issue guidance on this; therefore, CMS is not soliciting comments.

Section 90.4: Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

- As noted above, under the IRA, a selected drug will not be subject to negotiation, and will no longer be a selected drug, if CMS determines that:
 - The FDA approved a generic drug or licensed a biosimilar that lists the selected drug as its reference product, and
 - The generic drug or biosimilar is marketed pursuant to this approval or licensure.
- CMS will monitor the market for “robust and meaningful” competition; one example of this is assessing whether the generic drug or biosimilar is regularly and consistently available for purchase through the drug supply chain.
- *CMS is seeking comments on the most effective ways to monitor whether there is “robust and meaningful” competition in the market after a selected drug is no longer a selected drug.*

SECTION 100: CIVIL MONETARY PENALTIES

- **CMPs will be imposed on Primary Manufacturers that enter into Agreements if the Primary Manufacturers engage in any of the following activities:**
 - Failing to ensure access to a price less than or equal to MFP for MFP-eligible individuals, pharmacies, mail-order services, and other dispensers.
 - Failing to pay the rebate amount for a biologic for which inclusion on the selected drug list was delayed, but the product has since undergone negotiation.
 - Violating certain terms of the Agreement.
- Manufacturers that provide false information related to the aggregation rule under the Small Biotech Exception will also be subject to CMPs (*see Section 100.3*).
- CMS will address failure to pay a rebate for a biological product pursuant to section 1192(f)(4) of the Act in future guidance.

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

- **CMS will impose a CMP on a Primary Manufacturer of a selected drug that entered into an Agreement but did not provide access to a price less than or equal to the MFP for MFP-eligible individuals, pharmacies, mail-order services, other dispensers, hospitals, physicians, or other providers or suppliers.**
 - Under the law, the CMP is 10 times the difference between:
 - The selected drug’s MFP, and
 - The price (of the selected drug) made available for failing to provide the MFP to the eligible recipient.
 - To calculate the CMP, CMS will use the net price to acquire the drug, excluding service fees, as the price made available for the selected drug.

Section 100.2: Violations of the Agreement

- **A Primary Manufacturer of a selected drug that has entered into an Agreement with CMS and fails to comply with CMS’ requirements for the Negotiation Program or fails to provide statutorily required information for negotiation (such as non-Federal Average Manufacturer Price, or FAMP), will be subject to a CMP of \$1,000,000 for each day of the violation.**

- For example, information on each non-FAMP for a selected drug during the applicable period is due to CMS, by October 2, 2023 for IPAY2026.
 - CMS will count the day after the deadline—here, October 3, 2023—as the first day of the violation.
 - The violation period will continue until the Primary Manufacturer provides the required information, the drug is no longer a selected drug, or the Primary Manufacturer terminates the Agreement.
- Additional examples violations include failure to comply with the Agreement’s confidentiality or data use and limitations requirements.
 - CMS will document requests for information required to administer or monitor compliance with the Negotiation Program. CMS will include deadlines for submission of requested information; failure to provide the requested information by the date set forth by CMS will result in a CMP.
 - The first day of violation will be the day after the due date.
 - The violation period will continue until the day the Primary Manufacturer provides the required information to CMS, the drug is no longer a selected drug, or the Primary Manufacturer terminates the agreement.
- A Primary Manufacturer that knowingly submits false information will be out of compliance with the Agreement and will be subject to this CMP.
 - CMS will count the day of submission of the false information as the first day of violation.
 - The violation period will continue until the day the Primary Manufacturer submits accurate information, the drug is no longer a selected drug, or the Primary Manufacturer terminates the Agreement.

Section 100.3: Provision of False Information

- **Providing false information to CMS for the purposes of seeking an exception to the price-negotiation requirements is subject to CMP.**
 - Any manufacturer that knowingly provides false information to apply the Aggregation Rule (in which all persons treated as a single employer under the Internal Revenue Code will be treated as one manufacturer) for the Small Biotech Exception (in which small biotech drugs are ineligible for negotiation) will be subject to a CMP of \$100,000,000 for each item of false information.
 - A biosimilar manufacturer that knowingly submits false information to apply the Aggregation Rule for the Biosimilar Delay (to delay negotiation for that selected drug) will be subject to a CMP of \$100,000,000 for each item of false information.

Section 100.4: Notice and Payment Procedures

- **CMS will provide notice and information about the CMPs to any manufacturers that violate any of the above provisions; manufacturers will have the option to pay the CMP or request a hearing.**
 - The CMP notice will include the basis for the CMP; amount due; deadline for the manufacturer to respond with a hearing request or submit payment; and information on the right to request a hearing.

- Manufacturers will have 60 days from the date of receipt of the CMP notice to request a hearing; the date of receipt is the calendar date after the day on which the CMP notice is issued.
- If a manufacturer does not request a hearing within 60 days, the CMP will be due on day 60, following the date of receipt of the notice.

SECTION 110: PART D FORMULARY INCLUSION OF SELECTED DRUGS

- **CMS intends for Part D plans to include each covered Part D drug that is a selected drug on Part D formularies during Contract Year 2026 and all subsequent years for which the MFP of the selected drug is in effect.**

SECTION 120: APPLICATION OF MEDICARE PART B AND PART D PRESCRIPTION DRUG INFLATION REBATE PROGRAMS TO SELECTED DRUGS

- **Selected drug status does not exempt drug from inflation rebates.**
 - CMS confirms that "whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Part B and Part D inflation rebate programs."
- **Expiration of selected drug status affects benchmark periods.**
 - The statutory formula to determine the Part D drug inflation rebate amount owed by manufacturers for each Part D rebatable drug consists of various components, including the calculation of a benchmark period manufacturer price. Following a selected drug's expiration of its selected drug status, the payment amount benchmark period is reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the January of the last year beginning during such price applicability year.
- **Part B inflation rebates and selected drug status guidance to be issued at a later date.**
 - CMS intends to separately issue guidance regarding the interaction between the Part B inflation rebate program and selected drug status at a later date considering that there will be no Part B selected drugs until IPAY2028.
 - However, CMS does solicit comments on whether guidance is necessary at an earlier date.