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ALERT

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What Awaits in the First Year of Medicare Drug Price Negotiations? CMS Issues Guidance and Solicits Comment on the 2026 Inflation Reduction Act Part D Negotiation Process

I. Introduction

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On March 15, 2023, the Centers for Medicare & Medicaid Services ("CMS") issued an initial guidance memorandum ("Memorandum")[1] describing how it proposes to implement the Inflation Reduction Act Medicare Drug Price Negotiation Program ("Negotiation Program") for the Initial Price Applicability Year of 2026 (the "Initial Year"). In the Memorandum, CMS provides further guidance regarding (i) how it intends to select the Medicare Part D drugs and biologics for which it will negotiate a maximum fair price ("MFP") for the Initial Year (the "Selected Drugs"), (ii) the data and evidence that manufacturers will be required to submit that will inform CMS's initial price proposals, (iii) the structure of the negotiation process, and (iv) implementation and enforcement of the MFP.

Note that the Memorandum only addresses the Negotiation Program for Part D drugs subject to negotiation in the Initial Year. CMS issued the Memorandum as sub-regulatory guidance, without undertaking formal notice and comment rulemaking. While CMS is soliciting comments on certain elements of the proposal, the agency has said that its guidance pertaining to the choice of the Selected Drugs is final.[2] For those sections where CMS has solicited comments, CMS said it will consider any comments received by April 14, 2023 and will issue revised guidance for the Initial Year in response by summer 2023.[3]

This Alert provides an overview of the currently contemplated process through which CMS will identify and negotiate an MFP for the Part D Selected Drugs in 2026, and flags key considerations for manufacturers. While the Memorandum does not address CMS's contemplated process for future years of drug price negotiations or for Medicare Part B drugs, certain agency decisions with respect to Part D drugs in 2026 may be probative of its future intended approach for Part D and Part B products.

II. The Proposed Process to Identify and Negotiate MFPs for the Selected Drugs

1. Identification of "Negotiation Eligible Drugs."

CMS will identify "Negotiation Eligible Drugs" from a larger pool of "Qualifying Single Source Drugs," subject to certain enumerated exclusions and exemptions.

Qualifying Single Source Drugs include (i) drugs that have been approved and marketed under the Food Drug and Cosmetics Act ("FDCA") for at least seven years and are not the listed drug for any drug approved or marketed under an Abbreviated New Drug Application, and (ii) biological products that have been licensed and marketed under the Public Health Service Act ("PHS") for at least 11 years and are not the reference product for a biological product licensed or marketed under section 351(k) of the PHS. A potential Qualifying Single Source Drug will be identified by aggregating all dosage forms and strengths of a drug or biological product with the same active moiety or ingredient and the same holder of the New Drug Application ("NDA") or Biologics License Application ("BLA"), respectively. Additionally, a potential Qualifying Single Source Drug will include all dosage forms and strengths of the drug with the same active moiety or active ingredient that are marketed pursuant to the same NDA(s) or BLA(s) and are (i) repackaged and relabeled products, (ii) authorized generic drugs that are marketed, and (iii) multimarket approval products imported under section 801(d)(1)(B) of the FDCA.[4]

The following categories of Qualifying Single Source Drugs will not be considered Negotiation Eligible:

- **Orphan Drugs:** CMS will exclude any drug or biological product that is designated as a drug for only one rare disease or condition under Section 526 of the FDCA and that is approved for only one or more indication(s) for such disease or condition. CMS will defer to the FDA in several regards in making this determination; notably, CMS said that all dosage forms, strengths, and formulations of the drug must be considered orphan drugs for the drug to qualify for an exclusion from price negotiations. CMS said it is considering additional avenues the agency can take in implementing the Inflation Reduction Act to support orphan drug development.[5]

- **Low-spend Medicare drugs:** CMS also will exclude any Qualifying Single Source Drug with less than $200,000,000 in combined annual Part B and Part D expenditures. For the Initial Year, CMS will review Part D Prescription Drug Event ("PDE") data and Part B claims data for the 12-month period beginning June 1, 2022 and ending May 31, 2023 to make this determination.[6]

- **Plasma-derived products:** CMS will exclude any licensed biological product that is derived from human whole blood or plasma, as indicated on the FDA-approved product labeling.[7]

In addition to these excluded categories, for the Initial Year through 2028, under the statute, CMS will exempt "small biotech drugs," which the Memorandum defines as Qualifying Single Source Drugs with total 2021 Part B or Part D expenditures that constitute (i) no more than 1% of the total 2021 expenditures for all drugs of all manufacturers and (ii) at least 80% of total 2021 expenditures for all drugs of a given manufacturer, subject to certain exceptions. Manufacturers of Part D drugs that seek a small biotech exception for 2026 will be required to submit an exception request by a CMS-specified deadline (likely in June 2023).

2. Election of Selected Drugs.

In determining which Negotiation Eligible Drugs will be subject to price negotiations for the Initial Year, CMS will first identify the 50 Negotiation Eligible Drugs with the highest Part D Total Expenditures.[9] The agency has defined "Total Expenditures" as "total gross covered prescription drug costs," to be derived from Part D Prescription Drug Event ("PDE") data—data that Part D sponsors submit to CMS based on pharmacy reimbursement at the point-of-dispense (i.e., the pharmacy counter), generally before taking into account later-in-time rebates and various other forms of price concessions.[10] CMS will rank the top 50 drugs based on Total Expenditures, removing drugs subject to statutory exceptions and those Negotiation Eligible Drugs that are biological products and have a high likelihood of biosimilar market entry (as substantiated by the manufacturer in an agency request).[11] By September 1, 2023, CMS will publish the top ten Part D drugs, which will serve as the Selected Drugs for the Initial Year.[12]

3. Data Collection from Manufacturers.

The holder of the NDA or BLA (the "Primary Manufacturer") will be required to enter into a Medicare Drug Price Negotiation Agreement within 30 days of CMS's publication of its product's selection—i.e., by October 1, 2023.[13] By October 2, 2023, the Primary Manufacturer will be required to submit to CMS, to inform negotiations, specified data on behalf of itself and, in some cases, Secondary Manufacturers.[14] A "Secondary Manufacturer" either (i) is listed as a manufacturer in the NDA or BLA for the Selected Drug or (ii) markets the Selected Drug pursuant to an agreement with the Primary Manufacturer.[15] The Primary Manufacturer must submit on behalf of itself and any Secondary Manufacturer(s) (i) non-Federal Average Manufacturer Price ("non-FAMP") data from 2021 or the first full calendar year after a drug's market date, (ii) current unit costs of production and distribution, and (iii) market data and revenue and sales volume data.[16] Additionally, the Primary Manufacturer must submit (i) its research and development costs, (ii) information on prior federal financial support, and (iii) data on patents, exclusivities, and applications and approvals under the FDCA or PHS.[17]

CMS will implement a two-way confidentiality policy to protect from disclosure non-FAMP data and any other information that is not publicly available.[18] Manufacturers will likewise be required to keep confidential any information disclosed to them by CMS during the negotiation process, including the initial offer, any subsequent offer, the MFP ceiling price, and any information contained in the agency's justification for an offer.

4. CMS Determination of Ceiling Price and Initial Offer.

a. MFP Ceiling Price. CMS intends to calculate a single MFP across all dosage forms and strengths of each Selected Drug, based on a 30-day supply. The agency will then convert that price to a per-unit MFP. The MFP cannot exceed the lower of:

- **The Sum of "Plan Specific Enrollment Weighted Amounts"**—i.e., a weighted average of the Part D negotiated price (net of point-of-sale and direct and indirect remuneration ("DIR") price concession amounts) adjusted for plan enrollment size,[19] **or**

- **A Specified Percentage of Average Non-FAMP**—i.e., a specified percentage of the average non-FAMP across the four quarters of calendar year 2021 (or across the first full calendar year after market entry, as applicable), subject to an inflationary adjustment. The specified percentage will vary based on the duration of the Selected Drug's monopoly. For the Initial Year, the specified percentage for "short monopoly drugs" (defined as drugs approved after September 1, 2007) is 75%, and for "long monopoly drugs" (defined as drugs approved on or before September 1, 2007) is 40%.[20]

b. Initial Offer. CMS intends to use the Part D net price and/or Part B Average Sales Price for therapeutic alternatives as the "starting point" for developing an initial offer.[21] If there is no therapeutic alternative available at or below the ceiling price, CMS will use the Federal Supply Schedule or Big Four Agency price as the starting point.[22] Therapeutic alternatives will be selected based on review of (i) data submitted by the Primary Manufacturer and the public, (ii) FDA-approved indications, (iii) indications in CMS-approved Part D compendia, (iv) peer-reviewed studies, (v) "widely accepted" clinical guidelines, and, when a therapeutic alternative has not yet been incorporated into "widely accepted" clinical guidelines, (vi) literature searches.[23] Any member of the public can submit evidence regarding therapeutic alternatives. CMS also will prioritize research and real-world evidence specifically relating to Medicare populations.[24]

CMS also will take into account, for purposes of the initial offer, Primary Manufacturer-submitted information regarding research and development costs, unit costs of products, the existence of federal financial support in drug development, market-based revenue and sales data, and relevant patents or exclusivities.

5. Negotiation of MFP.

By February 1, 2024, CMS must provide the Primary Manufacturer with the initial offer and a concise, written justification. After receiving the initial offer, the Primary Manufacturer has 30 days to respond in writing, either accepting the offer or proposing a counteroffer. The counteroffer must be supported by a written explanation considering the factors evaluated by CMS and noting why available data does not support the initial offer. Within 30 days of receipt of the counteroffer, CMS will either accept the counteroffer or invite the Primary Manufacturer to participate in up to three in-person or virtual negotiations. For the Initial Year of the Negotiation Program, CMS must issue its final offer no later than July 15, 2024. All negotiations must conclude, and the manufacturer must reach agreement with CMS, by July 31, 2024.[25]

6. Publication and Implementation of MFP.

By September 1, 2024, CMS will publish the agreed-upon MFP and an explanation of its basis (without reference to confidential information) for each Selected Drug. In the event that CMS and a manufacturer are unable to agree upon an MFP, CMS will so indicate on its website.[26]

Beginning in the Initial Year, manufacturers of Selected Drugs with an agreed-upon MFP will be expected to ensure access to the MFP for Medicare Part D beneficiaries. CMS will require that the Primary Manufacturer ensure that the MFP is made available to pharmacies, mail order services, and other dispensers for units of the Selected Drug for which there is a Secondary Manufacturer. CMS also will require that the Primary Manufacturer reimburse all pharmacies, mail order services, wholesalers and other similar entities for the full amount of any difference between acquisition cost and the MFP within 14 days.[27]

CMS will let the Primary Manufacturer elect whether to provide access to the MFP through upfront discounts or retrospective rebates, but the Primary Manufacturer must submit to CMS a plan explaining its approach. For the Initial Year, such plans will be due to CMS by December 2, 2025. Additionally, Primary Manufacturers must notify CMS of any changes to the plan at least 30 days before such changes are implemented.[28]

III. Key Considerations

- **Competitive market impacts:** The Negotiation Program is likely to alter the competitive landscape for the Selected Drugs and perhaps competitive products, although the specific impacts are difficult to fully predict. In particular, the publication of the MFP more than a year before its effective date may result in spillover pricing impacts in the commercial marketplace. Other competitive market impacts are likely to exist, including on account of guaranteed formulary placement for Part D drugs subject to negotiation.

- **Criteria for reviewing Medicaid expenditures:** The criteria CMS will use to identify the Selected Drugs may be different from those that manufacturers have anticipated. Notable are CMS's intent to (i) rely on PDE data (rather than pricing data adjusted for DIR), in determining Total Expenditures and (ii) aggregate Total Expenditures across all variants of a product with the same active moiety (including products marketed under different NDAs by the same NDA holder).[29]

- **Relevance of NDA/BLA approvals:**

    - Products subject to distinct NDA or BLA approvals will not necessarily be treated as distinct for purposes of negotiation. CMS will treat all drugs with the same active moiety or active ingredient and same holder of an NDA/BLA as a single drug, even where the drugs are marketed pursuant to different NDAs/BLAs.

    - Subject to limited exceptions, CMS also intends to apply the MFP to new NDAs/BLAs for products of the same Primary Manufacturer with the same active moiety/ingredient. Similarly, CMS also intends to apply the MFP to any new drug, biological product, or National Drug Code that the Primary Manufacturer markets pursuant to an existing NDA/BLA for a Selected Drug.

    - Note that, in the case of a fixed combination drug consisting of two or more active ingredients/moieties, CMS will only consider two products as the same single source drug where the products contain all of the same active ingredients/moieties.[30]

- **CMS will consider a wide range of data in determining its initial offer:** Pursuant to this Memorandum, CMS reserves broad discretion regarding the evidence it considers in setting the MFP. Notable are (i) CMS's intent to consider a range of evidence pertaining to therapeutic alternatives from a range of stakeholders, including evidence submitted by the public and certain data that may be more subjective (e.g., real-world evidence and patient-reported data) and (ii) the possibility that CMS will penalize a manufacturer by reducing the MFP where the manufacturer received previous federal financial support in developing the drug or enjoys future price protections via patents.

- **CMS appears to envision a quick negotiation, with potentially limited manufacturer leverage:** As set forth in the Memorandum, negotiations will proceed on a tight timeframe with seemingly limited opportunities for manufacturers to submit and negotiate counteroffers. Moreover, while CMS indicates an intent to respond to counteroffers, it is not clear whether CMS views itself as bound to accept "reasonable" counteroffers by a manufacturer.

- **Burdens on Primary Manufacturers and risks for Secondary Manufacturers:** The Primary Manufacturer is solely responsible for (i) signing the Medicare Drug Price Negotiation Program Agreement with CMS, (ii) collecting and reporting required data, (iii) conducting price negotiations, and (iv) ensuring access to agreed-upon MFPs. While Secondary Manufacturers have no formal obligations, they nonetheless may confront burdens under the Negotiation Program. For example, Primary Manufacturers may ask Secondary Manufacturers to share proprietary data to satisfy the Primary Manufacturer's reporting obligations, which likely will necessitate negotiating agreements regarding information-sharing, confidentiality, and relevant related protections.

- **CMS intends robust enforcement, with severe penalties for non-compliance:** As set forth in the Memorandum, CMS intends to create a mechanism by which pharmacies and beneficiaries will be able to report manufacturers' failure to honor an agreed-upon MFP.[31] In addition, manufacturers are subject to significant civil monetary penalties for non-compliance. Failure to honor the MFP, for example, will result in a penalty equal to ten times the difference between the actual price charged and the MFP. In addition, manufacturers who fail to honor the terms of the Medicare Drug Negotiation Program Agreement (e.g., by failing to timely submit required data) are subject to penalties as high as $1 million per day of violation, and manufacturers who knowingly submit false information are subject to penalties as high as $100 million per violation.[32]

1. See CMS, Memorandum to Interested Parties: "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (March 15, 2023). Unless otherwise indicated, all citations herein are to the Memorandum.
2. Section 10.
3. See CMS, Memorandum to Interested Parties: Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026 (January 11, 2023).
4. Section 30.1.
5. Section 30.1.1.
6. Section 30.1.2.
7. Section 30.1.3.
8. Section 30.2.1.
9. Section 30.2.
10. See Footnote 3 to the Memorandum.
11. Sections 30.3-30.3.1.
12. Section 30.4.
13. Section 40.1.
14. Section 40.2, Appendix C.
15. Section 40.
16. Section 50.1.1.
17. Section 50.1.
18. Section 40.2.1.
19. Section 60.2.2.
20. Section 60.2.3.
21. Section 60.3.
22. Section 60.3.2.
23. Section 60.3.1.
24. Section 50.2.
25. Section 60.4.3.
26. Section 60.6.
27. Section 40.4.
28. *Id.*
29. Section 30.1.
30. Section 60.5.1.
31. Section 90.
32. Section 100.