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ALERT

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Continued Agency Strides Towards IRA Negotiation Program Implementation: CMS Issues Final Guidance on the 2026 Inflation Reduction Act Medicare Part D Negotiation Process

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I. Introduction

On June 30, 2023, the Centers for Medicare & Medicaid Services ("CMS") issued its final guidance memorandum[1] (the "Final Guidance") on the implementation of the Inflation Reduction Act ("IRA") Medicare Drug Price Negotiation Program for the Initial Price Applicability Year of 2026 (the "Initial Year"). The Final Guidance updates the initial guidance memorandum (the "Initial Guidance") issued on March 15, 2023.[2] This Alert summarizes various key changes and clarifications CMS offered in the Final Guidance pertaining to the process by which CMS proposed to identify and negotiate a Maximum Fair Price ("MFP") for certain Medicare Part D drugs and biologics (the "Selected Drugs") for the Initial Year.

II. Background

On March 15, 2023, CMS issued the Initial Guidance on the Initial Year of the IRA, and solicited comments regarding certain aspects of the contemplated process for identifying the Selected Drugs and negotiating an MFP for each Selected Drug in the Initial Year.[3] CMS received more than 7,500 comments on the Initial Guidance from a diverse array of stakeholders – a number indicating very broad interest in the negotiation program and its implementation. CMS said that it intends to post timely filed comment letters on the Initial Guidance to its IRA website[4] in July 2023. The agency said it may consider such comments when developing program guidance for future years. Notably, CMS also committed to using formal notice-and-comment rulemaking to promulgate guidance pertaining to the negotiation program beginning in 2029.[5]

III. Key Takeaways from the Final Guidance

Overall, in the Final Guidance, CMS showed little deviation in its approach to negotiations from the Initial Guidance. For example, fundamental policy choices such as the aggregation of drugs with the same active moiety/ingredient as a single qualifying drug and the application of the *bona fide* marketing standard remain intact. In the following sections, we summarize certain changes and clarifications that CMS offered in the Final Guidance.

A. Further Clarification Regarding Drugs that Will Be Excluded from the Negotiation Program

1. Orphan Drugs.

CMS affirmed that a drug with FDA designations for more than one rare disease will not qualify for the orphan drug exclusion, even if the drug has not been approved for any indications for the additional rare disease(s) or condition(s). The Final Guidance also clarified that only *active* designations and approvals are relevant to determining eligibility for the exclusion, and that CMS will consider whether drugs that are no longer eligible are qualifying single source drugs based on the date of initial FDA approval, rather than the date that the drugs lost their orphan drug status.[6]

2. Small Biotech Drugs.

Multiple commenters requested that CMS institute a dispute resolution process whereby a manufacturer could challenge CMS's determination of a drug's eligibility for the small biotech exception, including permission to provide supplemental data after the CMS-specified deadline to support their application for the exception. CMS declined to create a small biotech dispute resolution process – without offering any explanation – and indicated that it could not accept supplemental data in light of the "ambitious statutory deadlines" for negotiation in the

Initial Year.[7] CMS said that it will publish the number of drugs that applied for and received the small biotech exception for the Initial Year as part of its publication of Selected Drugs for the Initial Year.[8]

3. Plasma-Derived Products.

CMS confirmed that cell and gene therapies (such as chimeric antigen receptor ("CAR") T cell therapies) are not categorically ineligible for the plasma-derived products exception under the IRA. However, CMS reaffirmed its intention to refer to the FDA Approved Blood Products website[9] in determining whether a product is derived from human whole blood or plasma. (As a practical matter, although some cell and gene therapy products contain genetically modified human blood cells, FDA does not currently list these products as "approved blood products" on this FDA website.) CMS noted that it will consult with FDA as needed to further implement this exclusion.[10]

4. *Bona Fide* Marketing of a Generic or Biosimilar.

CMS clarified that it will review prescription drug event and average manufacturer price data as part of a "totality of the circumstances" assessment of whether a generic or biosimilar is marketed on a *bona fide* basis, which would exempt a particular drug from the negotiation. CMS separately clarified that, while the agency will continue to aggregate products with the same active ingredient or active moiety as a qualifying single source drug,[11] the existence of a generic or biosimilar for one product within a potentially qualifying single source drug will disqualify all products within the potential qualifying single source drug from the negotiation program.[12]

B. Requirements Imposed on Manufacturers

1. Primary and Secondary Manufacturers.

CMS will engage only the primary manufacturer of a Selected Drug in the negotiation program. CMS considers the primary manufacturer to be the entity that holds the New Drug Application(s) ("NDA(s)") or Biologics License Application(s) ("BLA(s)") for the Selected Drug.[13] CMS stated that secondary manufacturers, on the other hand, include entities that are considered manufacturers (as defined in the IRA) and either (i) are listed as a manufacturer in an NDA/BLA for the selected drug or (2) market the selected drug pursuant to an agreement with the primary manufacturer. Secondary manufacturers include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meets these criteria, including those entities that have a marketing agreement with the primary manufacturer.

2. Negotiation Agreement, Including Divestiture and Termination Considerations.[14]

As described in the Initial Guidance, the primary manufacturer of a Selected Drug must enter into a negotiation agreement with CMS. While commenters had requested that CMS afford an opportunity to comment on the terms of the negotiation agreement, in the Final Guidance CMS declined to offer such a comment opportunity, citing the fast-approaching statutory deadline of October 1, 2023 to execute such agreements with manufacturers. Nonetheless, CMS published the text of the negotiation agreement and accompanying instructions through a separate release.[15] Primary manufacturers of Selected Drugs will be able to sign the negotiation agreement for the Initial Year as early as September 1, 2023.[16]

The Final Guidance separately noted that the primary manufacturer will retain responsibility for an existing negotiation agreement unless it transfers all NDAs or BLAs associated with the Selected Drug to a third party.[17]

The Final Guidance separately introduced an expedited process through which a primary manufacturer that does not wish to participate in the negotiation program can terminate the negotiation agreement and avoid excise taxes by simultaneously agreeing to forego Medicaid and Medicare Part D coverage for its products. Any manufacturer that declines to enter an agreement for the negotiation program may avoid incurring excise tax liability by submitting appropriate notice and termination requests 30 days in advance of the date that excise tax liability otherwise would begin to accrue. CMS established a similar process around the termination of existing negotiation program agreements.[18]

3. Confidentiality of Negotiations.

CMS said it does not intend to publicly discuss ongoing negotiations with primary manufacturers, and it intends to treat as proprietary certain data submitted by primary manufacturers in accordance with Sections 1194(e)(1-2) of the Social Security Act. CMS stated, however, that it does intend to publish a narrative explanation of the MFP.

One key change is that, whereas the Initial Guidance would have prohibited primary manufacturers from disclosing information regarding the negotiation process, the Final Guidance included no such restrictions. However, CMS made clear that should a primary manufacturer choose to disclose such information, CMS reserves the right to comment on the specifics of its negotiations with that primary manufacturer. Similarly, should the primary manufacturer choose to disclose any information otherwise deemed by CMS to be proprietary, CMS shall no longer treat the disclosed information as such. CMS also removed the data destruction requirements that were contemplated by the Initial Guidance. CMS further cautioned that discussing MFP negotiations with other primary manufacturers could potentially implicate antitrust laws.[19]

4. Manufacturer Options to Ensure Access to MFP.

CMS will afford primary manufacturers two options to effectuate access to the MFP. Manufacturers may (1) prospectively ensure that the acquisition price paid by the dispensing entity does not exceed the MFP, or (2) retrospectively reimburse the dispensing entity for any difference between the MFP and the acquisition price. With regard to the latter option, CMS is exploring whether it would be sufficient for manufacturers to offer a standard refund (e.g., the difference between the MFP and the wholesale acquisition cost of the Select Drug) and will provide supplemental guidance prior to the Initial Year.

The primary manufacturer also must ensure that the MFP is made available to any dispensing entities of units of the Selected Drug produced or marketed by a secondary manufacturer and must ensure that any refunds be dispersed within 14 days after the manufacturer receives sufficient information to determine whether a unit of the Selected Drug was dispensed to an MFP-eligible individual. To that end, CMS intends to engage a Medicare transaction facilitator to facilitate the necessary exchange of data among pharmaceutical supply chain entities to facilitate access to the MFP.[20]

The Final Guidance provided that, in the Initial Year, CMS will not require manufacturers to ensure access to the MFP for hospitals, physicians, and other providers in the case of an MFP-eligible individual enrolled in Medicare Part B or Medicare Advantage Plans; CMS did not offer a statutory basis for this approach.[21]

5. Negotiation Process.

To inform CMS's initial offer, the agency will identify therapeutic alternative(s) based on clinical appropriateness and consideration of various sources of evidence including clinical guidelines, peer-reviewed literature, drug compendia, and data submitted by manufacturers and the public, but not based on the cost of therapeutic alternative(s). CMS clarified that therapeutic alternative(s) may include generics and biosimilars. CMS also emphasized that it will "take a qualitative perspective when reviewing a selected drug and consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality."[22] In developing the offers, CMS said it will not use comparative clinical effectiveness research in a way that assigns a lower comparative value to extending the life of an elderly, disabled or terminally ill person (as compared to a younger, nondisabled or non-terminally ill person). Likewise, CMS will not use quality-adjusted life years in the negotiation program. However, in cases where some, but not all, of the content of a study is excluded, the agency may still consider allowable content (e.g., clinical effectiveness, risks, harms). The agency will continue to assess whether consideration of cost-effectiveness measures is permitted under the statute.[23]

The Final Guidance also introduced two additional opportunities for stakeholders to provide CMS with input during the MFP negotiation. First, CMS will offer an additional meeting with the primary manufacturer – after the manufacturer submits all required data and before issuance of the initial offer – during which the manufacturer will

be permitted to bring and present up to 50 pages of additional data or other materials, and to present any additional considerations to CMS. Additionally, CMS intends to convene "listening sessions" for patients, beneficiaries, caregivers, and other consumer/patient organizations to provide feedback regarding therapeutic alternatives or other information CMS is considering in developing its initial offer.[24]

6. Monitoring and Enforcement.

The Final Guidance provided further insight regarding the imposition of Civil Monetary Penalties ("CMPs") and associated opportunities for appeal or corrective action under the IRA. CMS will assist manufacturers in submitting fulsome and accurate information – and in avoiding CMPs – by alerting manufacturers to incomplete or potentially inaccurate submissions and transmitting reminders prior to deadlines that could trigger imposition of CMPs if not met. Should CMS request a resubmission to correct incomplete or inaccurate information, manufacturers will have five business days to respond to CMS's request.[25] Failure to timely engage in CMS's request for corrective action could expose manufacturers to CMPs.[26] CMS said it intends to monitor the accuracy of submitted manufacturer data, including through audits as necessary.[27]

With respect to the imposition of CMPs, the Final Guidance clarified that, where imposition of a CMP requires that the manufacturer knowingly acted in violation of the negotiation program agreement, CMS will apply a definition of "knowingly" that aligns with the language used by the Office of Inspector General in the administration of CMPs under 42 C.F.R. § 1002.110 – i.e., "knowingly" means a person "has actual knowledge of any act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required."[28] However, the Final Guidance removed the requirement that a manufacturer "knowingly" submit false information in order to warrant imposition of a CMP.[29] Separately, CMS will establish procedures through which individuals, as well as pharmacies, mail order services, and other dispensing entities, will be able to report instances to CMS in which the manufacturer failed to ensure access to the MFP.[30]

Finally, should a primary manufacturer believe in good faith that CMS has erred in the calculation of the ceiling or computation of the application of the MFP across dosage forms and strengths, CMS will permit the manufacturer to submit a suggestion of error within 30 days – which CMS shall respond to within 30 days of receipt.[31]

7. Part D Formulary Inclusion.

In an effort to mitigate concerns that Medicare Part D plan sponsors will disadvantage Selected Drugs by affording them less favorable formulary placement than non-Selected Drugs (so as to steer patients towards drugs that aren't subject to MFP requirements), CMS said it intends to review Part D plan formularies to identify (i) instances where Part D sponsors place Selected Drugs on non-preferred tiers, (ii) instances where a Selected Drug is placed on a higher tier than non-Selected Drugs in the same class (iii) instances where Part D Plan sponsors require utilization of an alternative brand drug prior to a Selected Drug (i.e., step therapy), or (iv) instances where Part D sponsors impose more restrictive utilization management requirements for a Selected Drug than a non-Selected Drug in the same class.[32]

IV. Next Steps

Additional IRA guidance, including on the revised data collection process, is forthcoming. The deadline for CMS to publicly disclose the list of 10 Selected Drugs for the Initial Year is September 1, 2023, and, thereafter, a manufacturer of a Selected Drug may sign the manufacturer agreement with CMS. As noted above, CMS recently published the manufacturer agreement template and accompanying companion instructions, although these documents are not subject to a public comment opportunity.

Ropes & Gray will continue to monitor for updates on the implementation of the IRA negotiation program.

1. *See* CMS, Final Guidance to Interested Parties: "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026" (June 30, 2023) [hereinafter Final Guidance]. Unless otherwise indicated, all citations herein are to the Final Guidance.
2. *See* CMS, Initial Guidance to Interested Parties: "Medicare Drug Price Negotiation Program: Initial Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" (March 15, 2023).
3. For a summary of the key provisions of the Initial Guidance, please refer to Ropes & Gray's previous alert, available at: https://www.ropesgray.com/en/newsroom/alerts/2023/03/what-awaits-in-the-first-year-of-medicare-drug-price-negotiations.
4. CMS's main IRA website can be accessed at: https://www.cms.gov/inflation-reduction-act-and-medicare.
5. *See* Final Guidance at 1-2.
6. Section 30.1.1.
7. Final Guidance at 19.
8. Section 30.2.1.
9. FDA, *Approved Blood Products* (last updated Jan. 27, 2021), https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
10. Section 30.1.3.
11. Note the exception for fixed combination drugs, which remains in place under the Final Guidance. If a drug is a fixed combination drug with two or more active moieties / ingredients, the distinct combination of active moieties / ingredients will be considered as one active moiety / ingredient for the purpose of identifying qualifying single source drugs. Section 30.1.
12. Section 30.1.
13. Section 40.
14. *Id.*
15. CMS, Medicare Drug Price Negotiation Program Agreement Template, (July 3, 2023), https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf; CMS, Manufacturer Agreement Instructions to Interested Parties: "General Instructions for Completing the Medicare Drug Price Negotiation Program Agreement" (July 3, 2023).
16. Section 40.1
17. Section 40.7.
18. Section 40.1.
19. Section 40.2.2.
20. Section 40.4.
21. Section 80.
22. Section 60.3.
23. Section 50.
24. Section 60.4.
25. Section 40.2.3.
26. *Id.*
27. Section 40.5
28. Final Guidance at 7.
29. *Id.*
30. Section 90.2.
31. Section 40.5.
32. Section 110.