MEDICARE DRUG PRICE NEGOTIATION PROGRAM

CENTERS FOR MEDICARE & MEDICAID SERVICES

Frequently Asked Questions: Medicare Prescription Drug Price Negotiation Program for Initial Price Applicability Year 2026

Since publication of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 ("revised guidance"), CMS has received technical questions regarding the methodologies and policies described. This document is intended to provide clarifying responses to those questions. CMS intends to update this list of questions and responses over time to provide information to the public. *(Last Updated: January 4, 2024)*

Questions regarding this document may be directed to IRARebateandNegotiation@cms.hhs.gov.

Methodology for selected drugs for Initial Price Applicability Year 2026

Question: What source(s) did CMS use to identify active ingredient/active moiety?

Response: CMS used the National Library of Medicine's RxNorm database to identify active ingredient(s) for biological products, and a combination of RxNorm and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify active moiety(ies) for small molecule drugs.

Ceiling Calculation and Application of Maximum Fair Price

Question: In section 60.2.2 of the Medicare Drug Price Negotiation Program Revised Guidance, Steps 5 and 6 of the methodology for calculating the sum of plan-specific enrollment weighted amounts ceiling indicate that CMS will include a given plan in the weighting of the NDC-9-unit price across plans if that plan has at least one PDE record for the selected drug in calendar year 2022. Does this mean that CMS will include a plan in that weighting for an NDC-9 if the plan does not have any PDE records (and therefore no net Part D unit price) for that particular NDC-9, but does have one or more PDE records for other NDC-9s associated with the selected drug during 2022?

Response: CMS will not include a plan in the weighting of the NDC-9 unit price across plans if it does not have any PDE records for that NDC-9 in calendar year 2022, even if it has one or more PDE records for other NDC-9s associated with the selected drug in 2022, because CMS would not have the PDE or DIR data necessary to calculate a net Part D price for that NDC-9 for that plan. The plan may be included in the weighting of the NDC-9-unit price for one or more other NDC-9s associated with the selected drug in 2022, if it has at least one PDE record for those NDC-9s.

Question: In section 60.4.1 of the Medicare Drug Price Negotiation Program Revised Guidance, CMS stated that it would provide "information on the calculation of the statutorily-determined ceiling and the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer." What specific details will be included in this information?

Response: The information provided by CMS will include the statutory ceiling calculated by CMS in accordance with section 1194(c) of the Social Security Act (the Act) and section 60.2 of the revised guidance. This information will include, for the selected drug, the amount equal to the applicable percent of the average non-Federal average manufacturer price (non-FAMP) and the amount equal to the sum of the plan-specific enrollment weighted amounts. CMS will provide detailed information on each step of the calculation of the applicable percent of the average non-FAMP. CMS will not provide detailed information on each step of the calculation of the sum of the plan-specific enrollment weighted amounts to avoid potentially revealing proprietary pharmacy and plan information related to the Direct and Indirect Renumeration (DIR) data used in the calculations. Further, in accordance with section 1196(a)(2) of the Act and section 60.5 of the revised guidance, the information provided by CMS will include how any agreed-upon maximum fair price (MFP) would apply across dosage forms and strengths of the selected drug, including detailed information on each step of the calculation.

Revisions to data submitted in response to the Negotiation Data Elements Information Collection Request for Initial Price Applicability Year 2026

Question: The Negotiation Data Elements Information Collection Request (ICR) for IPAY 2026 instructions and Section H (Certification of Submission of Sections A through G for Primary Manufacturers) state that Primary Manufacturers must timely notify CMS if any of the information submitted changes after the initial submission of data. What changes to the submitted data must Primary Manufacturers provide to CMS? When and how should a Primary Manufacturer give this data to CMS?

Response: In accordance with section 40.2 of the revised guidance and Section A (Selected Drug Information) of the Negotiation Data Elements ICR for 2026, a Primary Manufacturer must report to CMS any new NDC-11s of the selected drug at least 30 days prior to their first marketed date for any Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug. The Primary Manufacturer also must report to CMS the delisting of any NDC-11 of the selected drug that is no longer marketed by the Primary Manufacturer or any Secondary Manufacturer(s) within 30 days after its discontinuation. Please timely notify CMS via the IRA Mailbox (IRARebateandNegotiation@cms.hhs.gov) if these NDC-11 changes are applicable to the selected drug.

In addition, the Primary Manufacturer is required to ensure that the data it submitted in response to Sections A through G of the Negotiation Data Elements ICR for IPAY 2026 are complete and accurate. The Primary Manufacturer must submit corrected data to CMS if any previously submitted data are determined to have been incomplete or inaccurate on the date of submission. Primary Manufacturers must timely notify CMS via the IRA Mailbox (IRARebateandNegotiation@cms.hhs.gov) if a data correction may be necessary. CMS will provide the mechanism for sharing any necessary revised information at such time.