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CENTER FOR MEDICARE

DATE: December 14, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1860D-14B of the Social Security Act

This memorandum provides interested parties with the revised Medicare Part D Drug Inflation Rebate guidance for 2022, 2023, and 2024. This memorandum includes four sections:

A. An introduction, which begins on page 1.
B. A summary of changes and clarifications to the initial memorandum, the Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum (hereinafter referred to as the "initial memorandum"), released on February 9, 2023, which begins on page 2.
C. A summary of the public comments received in response to the initial memorandum, and the Centers for Medicare & Medicaid Services' (CMS') responses, which begins on page 7.
D. Revised guidance that establishes final policies for the Medicare Part D Drug Inflation Rebate Program, which begins on page 31, and for which a table of contents appears on page 32.

CMS may supplement this guidance with further program instruction or engage in rulemaking to explain how these policies will be implemented.

A. Introduction

Section 11102(a) of the Inflation Reduction Act (IRA), P.L. 117-169, added a new section 1860D-14B(h) to the Social Security Act (the Act), directing the Secretary of the Department of Health and Human Services (HHS) to implement the Part D drug inflation rebate provisions for 2022, 2023, and 2024 by program instruction or other forms of program guidance. In accordance with the law, on February 9, 2023, CMS issued an initial memorandum for implementation of the Part D drug inflation rebate provisions for 2022, 2023, and 2024 and voluntarily solicited comments on a number of key topics in the initial memorandum. The 30-day comment period for the initial memorandum began on February 9, 2023, and concluded on March 11, 2023. CMS received 54 timely comment letters in response to the initial memorandum, representing a wide range of views from academic experts and other thought leaders, consumer and patient

organizations, data vendors/software technology entities, health plans, health care providers, health systems, individuals, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers (PBMs), and trade associations.

CMS will post copies of the timely comment letters that CMS received on the IRA website at https://www.cms.gov/inflation-reduction-act-and-medicare by December 15, 2023. Comment letters from individuals not representing organizations will have the name, address, and contact information of the individual removed for privacy purposes. Additionally, substantively duplicative letters (e.g., submitted as part of a coordinated advocacy campaign) will be combined into a single document.

After consideration of the comments received, CMS is making certain changes to the policies described in the initial memorandum in this revised guidance for 2022, 2023, and 2024. These comments also may be considered in development of rulemaking for future implementation of the Part D Drug Inflation Rebate Program. The public will have an opportunity to submit comments as part of that rulemaking process.

CMS is providing a summary of significant comments that it received in response to the initial memorandum, as well as the agency's response to those significant comments, which begins on page 7. CMS is not responding in this document to all comments it received, but instead is addressing those significant comments that have prompted a revision or a clarification of its policies for implementing the Part D Drug Inflation Rebate Program, or that otherwise raised a significant issue warranting a response explaining to the public CMS' resolution of that question.

B. Summary of Changes and Clarifications in Medicare Part D Drug Inflation Rebate Program Revised Guidance

CMS received many constructive, thoughtful, and helpful comments from consumer and patient groups, manufacturers, pharmacies, and other interested parties on the initial memorandum that was released on February 9, 2023. This section provides a summary of the key changes and clarifications made to the policies described in the initial memorandum based on these comments and other feedback. CMS provides responses to the comments received in section C of this revised guidance and has made corresponding changes and clarifications to the policies described in the initial memorandum, as summarized below.

Section 30—Identification of Part D Rebatable Drugs and Exclusions

- Identification of Part D Rebatable Drugs[1]: CMS has revised section 30 to acknowledge that, although generic drugs may be subject to the Part D drug inflation rebates if they meet certain criteria, such drugs may cease to meet the definition of a Part D rebatable drug during an applicable period.[2] Additionally, CMS has added language to section 30 and added section 40.2.8 of this revised guidance to describe how CMS will handle the identification of generic

[1] For purposes of this revised guidance, CMS uses the term "Part D rebatable drug" to refer to the dosage form and strength with respect to such drug for which Part D drug inflation rebates are calculated.

[2] Section 1860D-14B(g)(7) of the Act defines an applicable period as a 12-month period beginning with October 1 of a year (beginning with October 1, 2022). In accordance with section 1860D-14B(b) of the Act, CMS will calculate rebate amounts for a Part D rebatable drug for each applicable period.

Part D rebatable drugs and exclude from the rebate calculation any units dispensed on or after the date that a generic drug no longer meets the definition of a Part D rebatable drug.

- Exclusion of Certain Part D Rebatable Drugs from Inflation Rebates: In section 30.1 of this revised guidance, CMS has reaffirmed that Part D rebatable drugs for which the manufacturers do not have a Medicaid Drug Rebate Program (MDRP) agreement in effect with the HHS Secretary under section 1927 of the Act as well as Part D rebatable drugs that do not meet the definition of a covered outpatient drug (COD) will be excluded from Part D drug inflation rebate calculations at this time.
- Exclusion of Drugs Where the Average Annual Total Cost Under Part D Is Less Than $100 per Individual per Year Adjusted by Changes in the Consumer Price Index for All Urban Consumers (CPI-U): CMS has revised section 30.2 of this revised guidance to state that for the applicable period beginning October 1, 2023, the $100 per individual per year threshold amount will be increased by the percentage increase in the CPI-U to October 2024 from the CPI-U for October 2023, consistent with the statute.

Section 40—Calculation of the Medicare Part D Drug Inflation Rebate Amount

- Applicable Period for Subsequently Approved Drugs: CMS has revised sections 40.2.2 and 40.3 of this revised guidance to state that the first applicable period for a subsequently approved drug begins on October 1 of the year immediately following the payment amount benchmark period. This revised approach establishes the applicable period as a 12-month period beginning with October 1 of a year, consistent with the statute, and eliminates overlap between the payment amount benchmark period and the first applicable period for subsequently approved drugs.
- Payment Amount Benchmark Period for Drugs First Approved or Licensed On or Before October 1, 2021 But Not Marketed Until After that Date: CMS has revised the guidance to address situations in which a Part D rebatable drug first approved or licensed by the U.S. Food and Drug Administration (FDA) on or before October 1, 2021 is not marketed until after that date and thus would not have an average manufacturer price (AMP)[3] or AMP units to report for the January 1, 2021 through September, 30, 2021 payment amount benchmark period. As described in sections 40.1.2 of this revised guidance, CMS will treat such drugs in the same manner in which it will treat subsequently approved drugs for the purposes of determining the payment amount benchmark period, benchmark period CPI-U, first applicable period, and applicable period CPI-U. CMS intends to address this policy in future rulemaking and will solicit comments on this policy at that time.
- Situations in Which Manufacturers Do Not Report Units: CMS has revised section 40.1.2 of this revised guidance to clarify the policies it will apply in scenarios when one or more quarter(s) of a payment amount benchmark period or applicable period has an AMP value(s) but no associated units reported to the Medicaid Drug Programs system.
- Use of Prescription Drug Event (PDE) Data to Determine Total Units: As described in the initial memorandum and this revised guidance, CMS will use Part D PDE data to determine

[3] Section 1860D-14(g)(6) of the Act defines AMP to have the meaning, with respect to a Part D rebatable drug of a manufacturer, given in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. Pursuant to section 1927(k)(1) of the Act, AMP means, with respect to a covered outpatient drug of a manufacturer for a rebate period (calendar quarter), the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer.

the total number of units of the Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during each 12-month applicable period for the inflation rebate calculation. CMS has revised section 40.2.5 of this revised guidance to reflect that, to identify the billing unit for each National Drug Code (NDC) for determining the total number of units for each Part D rebatable drug, CMS will crosswalk the information from the PDE record to a database (such as FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Element File (NSDE) or Medi-Span) that includes the unit type, matching on the NDC of the Part D rebatable drug.

- Identification of 340B Units: CMS has affirmed in section 40.2.7 of this revised guidance that it continues to evaluate different options for identifying 340B units and will finalize a policy for excluding 340B units by plan year 2026 in accordance with the statute.
- Treatment of New Formulations: As described in the initial memorandum and this revised guidance, in calculating line extension alternative rebate amounts, there may be instances where a Part D rebatable line extension drug has multiple potential initial drugs during an applicable period, and CMS will use the initial drug identified by the manufacturer in the last quarter of the applicable period. CMS has clarified in section 40.4 of this revised guidance that if an initial drug was not identified in the last quarter for a drug that is a line extension, CMS will use the initial drug identified most recently in that applicable period to identify the initial drug for the line extension drug alternative rebate calculation.
- Reducing the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on a U.S. FDA Shortage List: CMS has revised section 40.5.1 of this revised guidance to state that for a Part D rebatable drug that is described as "currently in shortage"[4] on an FDA shortage list at any point during the applicable period, CMS will calculate the reduction in the rebate amount by determining the number of days such drug is described as "currently in shortage" on an FDA shortage list during the applicable period, divide by the number of days in the applicable period, and then multiply that amount by a percentage that is decreased over time. CMS will provide a greater reduction for sole source generic Part D rebatable drugs and plasma-derived products. For a Part D rebatable drug that is not a sole source generic Part D rebatable drug or plasma-derived product, the reduction will be 25 percent for the first applicable period that such drug is "currently in shortage" on an FDA shortage list, 10 percent for the second applicable period, and 2 percent for all applicable periods thereafter. For a sole source generic Part D rebatable drug or plasma-derived product, the reduction will be 75 percent for the first applicable period, 50 percent for the second applicable period, and 25 percent for each subsequent applicable period.
- Reducing the Rebate Amount for a Generic Part D Rebatable Drug or Biosimilar When There is a Severe Supply Chain Disruption: CMS has revised section 40.5.2 to state that CMS will provide a time-limited standard reduction of 75 percent in the rebate amount for a sole source generic Part D rebatable drug or biosimilar when there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event. CMS has further revised section 40.5.2 to modify the definition of a severe supply chain disruption. CMS also revised section 40.5.2 to state that pursuant to the Paperwork Reduction Act of 1995 (the PRA), CMS will issue a proposed collection of information addressing information that must be submitted to CMS by a manufacturer of a

[4] For the purposes of this revised guidance, CMS uses the term "currently in shortage" to refer to Part D rebatable drugs that are in the status of "currently in shortage" on the CDER shortage list, as well as biological products listed on CBER's current shortages list.

generic Part D rebatable drug or biosimilar in order to receive consideration for a rebate reduction under this policy. If CMS determines the request warrants a reduction, CMS will provide a reduction in the rebate amount as described in section 40.5.2. The manufacturer may submit a request for an extension of the reduction in the rebate amount one time such that the reduction would apply for a second applicable period for a maximum of two consecutive applicable periods. CMS has clarified in section 40.5.2 of this revised guidance that if CMS grants a manufacturer's severe supply chain disruption rebate reduction request for an NDC-11, CMS will apply the rebate reduction to the entire generic Part D rebatable drug or biosimilar at the NDC-9 level.

- Reducing the Rebate Amount for a Generic Part D Rebatable Drug Likely to be in Shortage in a Subsequent Applicable Period: CMS has revised section 40.5.3 to state that CMS will provide a time-limited standard reduction of 75 percent in the rebate amount for a sole source generic Part D rebatable drug if CMS determines that the generic drug is likely to be in shortage in a subsequent applicable period without such reduction. CMS also revised section 40.5.3 to state that CMS will issue a proposed collection of information addressing information that must be submitted to CMS by the manufacturer of a generic Part D rebatable drug in order to receive consideration for a rebate reduction under this policy. If CMS determines the request warrants a reduction, CMS will reduce the rebate amount for the applicable period in which the reduction request is submitted or the next applicable period in which the drug is likely to be in shortage, depending on when the request is submitted. The manufacturer may submit a request for an extension of the reduction in the rebate amount one time such that the reduction would apply for a second applicable period for a maximum of two consecutive applicable periods. CMS has clarified in section 40.5.3 of this revised guidance that if CMS grants a manufacturer's rebate reduction request for an NDC-11, CMS will apply the rebate reduction to the entire generic Part D rebatable drug at the NDC-9 level.

Section 50—Ensuring Integrity of the Medicare Part D Drug Inflation Rebates

- Overview of the Reporting Processes: CMS has clarified in section 50 the process CMS will use to report the rebate amount to the manufacturer of a Part D rebatable drug. CMS has clarified that CMS has determined to issue its process for restatements at a later point in time. Consistent with section 1860D-14B(b)(6) of the Act, CMS will establish a method and process to determine adjustments to the rebate amount for a Part D rebatable drug for an applicable period in the case of a Part D plan sponsor submitting revisions to the number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors and to reconcile any overpayments or underpayments in the rebate amount paid. In connection with development of this restatement process, CMS is also considering options for establishing a standardized method and process at regular intervals to determine any appropriate adjustment to the rebate amount for a Part D rebatable drug for an applicable period to account for a broader set of circumstances involving revised information.
- Process for Rebate Reports and Suggestion of Calculation Error: CMS has revised section 50.1 to clarify that CMS will provide a Preliminary Report, followed by a period of 10 calendar days for a manufacturer of a Part D rebatable drug to review the Preliminary Rebate Report and submit a Suggestion of Calculation Error to CMS, if necessary. CMS will provide technical instruction on how to submit a Suggestion of Calculation Error in a separate communication. Following the Preliminary Rebate Report and Suggestion of Calculation Error period, CMS will provide the Rebate Report to manufacturers of Part D rebatable drugs.

- Rebate Reports for the Applicable Period Beginning October 1, 2022, and the Applicable Period Beginning October 1, 2023: CMS has revised section 50.2 to provide information on the Rebate Reports for the first applicable period (beginning October 1, 2022) and the Rebate Report for the second applicable period (beginning October 1, 2023). According to section 1860D-14B(a)(3) of the Act, the reporting of information and rebate amounts may be delayed until no later than December 31, 2025. CMS will provide a period of 30 calendar days for a manufacturer of a Part D rebatable drug to review their Preliminary Rebate Report and submit a Suggestion of Calculation Error to CMS, if applicable, for these applicable periods.

Section 60—Enforcement of Rebate Amount Payments by Manufacturers

- Payment Obligations and Civil Monetary Penalties (CMPs): CMS has reaffirmed in section 60 that manufacturers that do not pay the Part D drug inflation rebate amount owed for an applicable period for a Part D rebatable drug within 30 calendar days of receiving the Rebate Report may be subject to a CMP equal to 125 percent of the rebate amount, in addition to the rebate amount due under section 1860D-14B(b) of the Act, for such drug for such applicable period. CMS has added that the agency will issue a reminder notice regarding the due date of rebate payments. CMS affirmed that it is exploring all available options to encourage manufacturers' timely compliance with their payment obligations and may use future rulemaking as an opportunity to address its enforcement approach.
- CMP Notice and Appeal Procedures: CMS has clarified in section 60.1 the notice and appeals procedures for CMPs.

Section 70—Formulas

- Example Calculations: CMS has revised section 70 to add example data and calculations to illustrate how CMS will calculate the Part D drug inflation rebate amount. CMS has also revised section 70 to add a formula and example to illustrate rebate reductions when a Part D rebatable drug is no longer described as "currently in shortage" on an FDA shortage list.
- Annual Manufacturer Price (AnMP) and Benchmark Period Manufacturer Price: CMS has clarified in section 70 of this revised guidance that the total units used for each quarter to calculate components for the AnMP and benchmark period manufacturer price will be the sum of the monthly units for the drug reported by the manufacturer.

C. Summary of Public Comments on the Initial Medicare Part D Drug Inflation Rebates Memorandum and CMS' Responses[5]

General Comments

Comment: A few commenters expressed support for the Part D Drug Inflation Rebate Program, with a couple of these commenters noting the program's potential to reduce health disparities, while a few commenters voiced their opposition to the program. A few commenters expressed the importance of transparency and asked that CMS respond to the comments received commensurate with rulemaking and to publish the comments submitted in response to the initial memorandum. A couple of commenters recommended that the Secretary commission the HHS Office of Inspector General (OIG) to review potential implementation options for Part D drug inflation rebates. One commenter stated that CMS should identify for manufacturers a single point of contact for questions regarding the Part D Drug Inflation Rebate Program, similar to how manufacturers are provided with a dedicated contact person and email address for questions related to the MDRP, and also urged CMS to administer the Part D Drug Inflation Rebate Program directly as opposed to contracting with a third party to administer the program to ensure that the Part D Drug Inflation Rebate Program is implemented as intended under section 1860D-14B of the Act and avoid inconsistent procedures or interpretations by third parties.

Response: CMS thanks commenters for expressing their support for the Part D Drug Inflation Rebate Program and appreciates commenters sharing their concerns and recommendations regarding program implementation. Section 1860D-14B(h) of the Act states that the Secretary "shall implement" section 1860D-14B of the Act for 2022, 2023, and 2024 by program instruction or other forms of program guidance. Thus, the initial memorandum is not subject to the notice-and-comment requirements of the Administrative Procedure Act (APA) or the Medicare statute. The terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than rulemaking. The statutory directive in section 1860D-14B(h) of the Act thus specifies that CMS shall follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under the APA or the Medicare statute.

CMS agrees with commenters about the importance of transparency and will post copies of the timely comment letters that CMS received on the IRA website at https://www.cms.gov/inflation-reduction-act-and-medicare by December 15, 2023. CMS is also providing a summary of significant comments that it received in response to the initial memorandum, as well as the agency's response to those significant comments, beginning on page 7 of this revised guidance. At this time, CMS does not intend to request a specific study from the HHS OIG on the Part D Drug Inflation Rebate Program; however, CMS may consult with OIG for technical assistance as needed on implementation. Manufacturers with questions about the Part D Drug Inflation Rebate Program should email CMS at IRARebateandNegotiation@cms.hhs.gov with the subject line "Part D Drug Inflation Rebate Program."

Comment: One commenter requested that CMS consider issuing guidance on the treatment of

[5] CMS did not receive comments on sections 10, 20, 40.2.3, and 40.2.4 of the initial memorandum that are not otherwise addressed elsewhere.

drugs that straddle the Part B and Part D benefits. For example, Medicare Advantage (MA) plans that offer Part D coverage may cover a drug under one or both Part B and Part D depending on how the drug is prescribed and dispensed. This commenter also stated that a Part D plan may cover a drug that is later determined to have been erroneously covered under Part D and should have been covered under Part B and asked what reporting obligations the Part D plan would have to reflect this revision for the purpose of Part D drug inflation rebates.

Response: The rebate amount will be calculated separately under the Part B Drug Inflation Rebate Program and the Part D Drug Inflation Rebate Program. CMS refers this commenter to section 50 of this revised guidance, which describes the statutory obligation to set forth a reconciliation process for Part D rebatable drug unit changes. Please refer to *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act* for information on the Part B Drug Inflation Rebate Program. CMS is not instituting any new reporting requirements on Part D plans through this guidance.

Identification of Part D Rebatable Drugs and Exclusions (Section 30)

Comment: A couple of commenters expressed concern that FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book) and NDC Directory may not be reliable sources for identifying generic Part D rebatable drugs for various reasons (e.g., because they are based on manufacturer-reported data or may be out-of-date). These commenters recommended that CMS work directly with FDA to identify generic drugs that meet the statutory definition of a Part D rebatable drug, and that CMS identify a specific date on which the agency will make its determinations while also using an approach that identifies a change in the status of a generic drug from sole source to multi-source and prorates the inflation rebate amount accordingly. One commenter recommended that CMS provide manufacturers an opportunity to share confirmatory or contradictory details on the status of their products.

Response: CMS appreciates commenters' feedback and has revised section 30 of this guidance to describe how CMS will determine whether a generic drug meets the definition of a Part D rebatable drug. CMS also added section 40.2.8 to the revised guidance to describe how CMS will calculate the rebate amount for a generic drug that meets the definition of a Part D rebatable drug on the first day of the applicable period but ceases to meet that definition during the applicable period if, for example, FDA approves another therapeutically equivalent generic drug under an Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the Federal Food, Drug and Cosmetic Act (FD&C Act) and that generic drug is marketed during the applicable period. As described in sections 30 and 40.2.8 of this revised guidance, CMS will use FDA's Orange Book and NDC Directory to determine whether a generic drug meets the definition of a Part D rebatable drug for the duration of the applicable period. For example, in accordance with section 1860D-14B(g)(1)(C)(ii)(II) of the Act, CMS will use FDA's Orange Book to identify whether FDA has approved an ANDA for a drug that is rated as therapeutically equivalent to the generic drug. CMS will then use the NDC Directory to determine the marketing status of such therapeutically equivalent drug and to determine whether, during the applicable period, the therapeutically equivalent drug was marketed. CMS will exclude from the rebate calculation any units dispensed on or after the date that a generic drug no longer meets the definition of a Part D rebatable drug.

CMS thanks commenters for sharing their concerns regarding the reliability of the Orange Book and NDC Directory to identify generic drugs that meet the definition of a Part D rebatable drug. Sections 1860D-14B(g)(1)(C)(ii)(I)-(II) of the Act instruct CMS to use FDA's Orange Book and NDC Directory to determine whether there is any approved therapeutically equivalent drug for a generic Part D rebatable drug that is being marketed and to use the NDC Directory to determine whether the reference listed drug for the generic Part D rebatable drug or an authorized generic of the reference listed drug is not being marketed. As described in section 30 of this revised guidance, CMS may also consult with FDA for technical assistance regarding information listed in the Orange Book and NDC Directory.

Exclusion of Application of Inflation Rebates to Part D Rebatable Drugs Marketed by Manufacturers Without a Section 1927 Agreement in Effect with the Secretary of HHS and that Do Not Meet the Definition of Covered Outpatient Drug (Section 30.1)

Comment: One commenter expressed support for the approach outlined in the initial memorandum for excluding from Part D drug inflation rebate calculations manufacturers without an MDRP agreement in effect under section 1927 of the Act and drugs that do not meet the definition of a COD, such as vaccines. Another commenter noted appreciation that CMS will monitor how these exclusions from Part D drug inflation rebates may impact manufacturers' behavior and recommended that CMS work with manufacturers to establish an alternative approach to collect information needed for the purposes of calculating the inflation rebate for drugs (in addition to vaccines) that may not be considered CODs and ensure that prices for these drugs, to the extent possible, are not increasing faster than the rate of inflation. A couple commenters stated that the statute limits the sources of data that CMS may use for rebate calculations and if CMS intends to use other sources of data, CMS should undertake rulemaking. One commenter recommended that CMS should use other sources of data such as the Manufacturer Coverage Gap Discount Program to obtain information to calculate Part D drug inflation rebates for drugs that do not meet the COD definition and for manufacturers without section 1927 agreements in effect. This commenter also stated that the Part D drug inflation rebate statute imposes on manufacturers an obligation to pay rebates for Part D rebatable drugs with price increases faster than the rate of inflation, irrespective of whether manufacturers sign an agreement to do so.

Response: CMS appreciates commenters' support and recommendations for alternative approaches that would allow CMS to calculate inflation rebates for Part D rebatable drugs that do not meet the definition of a COD or whose manufacturers do not have an MDRP agreement in effect. CMS has reaffirmed in this revised guidance that Part D rebatable drugs whose manufacturers do not have an MDRP agreement in effect with the HHS Secretary under section 1927 of the Act and Part D rebatable drugs that do not meet the definition of COD will be excluded from Part D drug inflation rebate calculations at this time. CMS will continue to evaluate alternative approaches and will carefully monitor how these exclusions from Part D drug inflation rebate calculations may impact manufacturer behavior.

Exclusion of Drugs Where Average Annual Total Cost Under Part D Is Less Than $100 per Individual Using Such Drug per Year Adjusted by Changes in the CPI-U (Section 30.2)

Comment: One commenter expressed concern that implementation of the Part D drug inflation rebates could impose new administrative or financial burdens on community pharmacies. This commenter requested that CMS confirm community pharmacies will not be required to report additional information for purposes of calculating the $100 per individual per year threshold.

Response: CMS thanks the commenter for sharing these concerns and affirms that section 30.2 of this revised guidance does not impose additional reporting requirements on pharmacies related to the exclusion of drugs where the average annual total cost under Part D is less than $100 per individual per year. CMS will calculate and determine which Part D rebatable drugs fall below, meet, or exceed the $100 per individual per year threshold based on PDE data.

Comment: One commenter stated that calculating average annual total costs using total gross covered prescription drug costs as proposed in the initial memorandum does not align with the actual behavior of manufacturers because it reflects how much a pharmacy may have been reimbursed for a drug rather than the price for which a manufacturer sold the drug. This commenter recommended that CMS consider an alternative methodology that either (1) calculates average annual total cost using AMP or (2) after CMS calculates gross covered prescription drug costs, compares the average cost per script to the AMP for products that are close to the $100 per individual per year threshold and excludes products within 10-15 percent of that threshold.

Response: CMS thanks the commenter for this feedback. Section 1860D-14B(g)(1)(B) excludes from the definition of a Part D rebatable drug a drug or biological if the average annual total cost of the drug under Part D is less than $100 per individual using such drug. CMS believes defining "average annual total cost" under Part D to mean the total costs incurred under a Part D plan for the Part D drug (i.e., the total gross covered prescription drug costs) aligns with the statutory language, which does not direct CMS to consider average annual total cost in relation to AMP.

Calculation of the Medicare Part D Drug Inflation Rebate Amount (Section 40)

Comment: A couple of commenters identified locations in the initial memorandum where CMS incorrectly used the term "marketed" rather than "approved or licensed" when referencing Part D rebatable drugs approved or licensed on or before October 1, 2021.

Response: CMS corrected these inconsistencies throughout this revised guidance and affirms that, in alignment with sections 1860D-14B(g)(3) and (4) of the Act, for Part D rebatable drugs first approved or licensed on or before October 1, 2021, the payment amount benchmark period is January 1, 2021 through September 30, 2021 and the benchmark period CPI-U is the CPI-U for January 2021. In alignment with section 1860D-14B(b)(5)(A) of the Act, for Part D rebatable drugs first approved or licensed after October 1, 2021, the payment amount benchmark period is the first calendar year beginning after the day on which the drug was first marketed, and the benchmark period CPI-U is the CPI-U for January of the first year beginning after the date on which the drug was first marketed. As described in section 40.1.2 of this revised guidance, for a Part D rebatable drug first approved or licensed on or before October 1, 2021 but not marketed

until after this date, the payment amount benchmark period is the first calendar year beginning after the day on which the drug was first marketed, and the benchmark period CPI-U is the CPI-U for January of the first year beginning after the date on which the drug was first marketed.

Units Used for Determination of AnMP and Benchmark Period Manufacturer Price (Section 40.1.1)

Comment: One commenter disagreed that manufacturer-reported monthly units under 1927(b)(3)(A)(iv) of the Act are the appropriate units to use in the calculation of the AnMP and the benchmark period manufacturer price. This commenter stated that the accurate calculation of the weighted average AnMP and benchmark period manufacturer price is possible only if both actual sales and units are used in the calculation, and they recommended that CMS require manufacturers to calculate and submit in the Medicaid Drug Programs system the AnMP based on actual transactions, or alternatively, require manufacturers to submit AMP value and units "as calculated."

Response: CMS appreciates this commenter's input. Sections 1860D-14B(b)(2) and (4) of the Act specify that CMS shall use AMP data and units reported under section 1927 of the Act for the purpose of calculating the AnMP and benchmark period manufacturer price, respectively. Section 1860D-14B(d)(1) of the Act also requires that CMS use information submitted by manufacturers under section 1927(b)(3) of the Act. CMS recognizes that there may be certain circumstances in which the monthly AMP units reported by manufacturers to the Medicaid Drug Programs system may not align to the units that manufacturers use to calculate quarterly AMP. However, because the statute directs CMS to rely on certain information sources specified in the Act, and the "as calculated" data suggested for inclusion by the commenter is not currently required to be reported under these information sources, CMS would not have access to the information that the commenter requested CMS use. CMS believes that manufacturer-reported monthly units under section 1927(b)(3)(A)(iv) of the Act are the best available units to use in the calculation of the AnMP and the benchmark period manufacturer price.

Situations in Which Manufacturers Do Not Report Units (Section 40.1.2)

Comment: A few commenters requested clarification on how CMS will calculate the benchmark period manufacturer price or AnMP for drugs that lack sales during the payment amount benchmark period or applicable period, respectively. Specifically, these commenters asked how CMS will calculate the benchmark period manufacturer price and the AnMP when manufacturers use reasonable assumptions in reporting AMP data to the Medicaid Drug Programs system when there are no sales for a calendar quarter, since the reported AMP values would not have units associated with them. A couple of commenters asserted that AMP units for at least one calendar quarter during the payment amount benchmark period and applicable period are required to calculate the benchmark period manufacturer price and AnMP, respectively. To ensure the accuracy of the benchmark period manufacturer price or AnMP when there are missing units, one commenter recommended that CMS require that manufacturers submit in the Medicaid Drug Programs system AMP data and units based on actual transactions. Alternatively, CMS could require manufacturers to submit AMP data and units "as calculated." Another commenter recommended that if there are no AMP units but there are reported AMPs based on reasonable

assumptions during a payment amount benchmark period or applicable period, the AMPs could be averaged with equal weighting.

One commenter noted that the initial memorandum details how reasonable assumptions will be used to calculate the benchmark period manufacturer price if there are no sales for the entire payment amount benchmark period, but it does not detail how reasonable assumptions will be used to calculate the AnMP if there are no sales for the entire applicable period. Another commenter asked CMS to confirm that the policies on reasonable assumptions described in section 40.1.2 of the initial memorandum apply to both subsequently approved drugs and drugs approved or licensed on or before October 1, 2021.

Response: CMS appreciates these commenters' requests for clarification, as well as their recommendations. CMS has revised section 40.1.2 of this revised guidance to clarify the policies it will apply in scenarios where a manufacturer with an MDRP agreement in effect does not report units to the Medicaid Drug Programs system for one or more quarter(s) of a payment amount benchmark period or applicable period for a COD that is a Part D rebatable drug but does report AMP value(s) for these quarter(s). If there is one or more quarter(s) in the payment amount benchmark period or applicable period that has an AMP value and no associated units, but at least one quarter has both an AMP value and units, CMS will calculate the benchmark period manufacturer price or AnMP, respectively, using data only from quarter(s) with units. That is, quarter(s) without units will be excluded from the calculation because the benchmark period manufacturer price and the AnMP are weighted average prices based on the reported AMP and units, the latter of which would not be available for quarters without units. If there are no units reported for any quarters of the payment amount benchmark period or applicable period, but there are reported AMP values, CMS will take a simple average of the AMP values over the calendar quarters of the payment amount benchmark period or applicable period to calculate the benchmark period manufacturer price or AnMP, respectively. These policies will apply to all Part D rebatable drugs, including Part D rebatable drugs that are treated as subsequently approved drugs.

Comment: One commenter requested clarification on how terminated or expired drugs would be treated under the program. The commenter asked whether the manufacturer would still owe Part D drug inflation rebates for any period after the drug's termination date if the drug has expired, and if CMS would continue to calculate the Part D drug inflation rebate per unit past the drug's termination date.

Response: CMS appreciates this commenter's question, which CMS understands as pertaining to terminated drugs. A terminated drug is a drug for which the termination date has passed, where the termination date is defined as (1) the expiration date of the last batch of a discontinued drug sold by the manufacturer or (2) the date that the drug is withdrawn from the market for health and safety reasons.[6] In the PDE data that CMS will use to determine the total number of units of the Part D rebatable drug, CMS does not expect to see units of terminated drugs that are considered to be terminated due to the expiration date of the last batch of a discontinued drug sold by the manufacturer having passed. This is because it is CMS' policy to reject PDE submissions if the Marketing End Date (defined as the expiration date of the last lot distributed for a product that is

[6] See: https://oig.hhs.gov/oas/reports/region7/70903130.pdf.

no longer manufactured)[7] in FDA's NSDE file for the NDC is prior to the date of service on the PDE.[8] CMS also does not expect to see in this PDE data units of terminated drugs that are considered to be terminated due to the drug being withdrawn from the market for health and safety reasons. Although not expected, if a terminated drug meets the definition for a Part D rebatable drug and is dispensed under Part D and covered by Part D plan sponsors, Part D rebates would apply to these units. As detailed in section 40.2.6 of the initial memorandum and this revised guidance, the total rebate amount to be paid by manufacturers is equal to the product of (1) the total number of units of the Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during the applicable period determined under section 40.2.5 of this revised guidance; and (2) the per unit Part D drug inflation rebate amount determined under section 40.2.4 of this revised guidance.

Comment: A few commenters noted that the initial memorandum did not address how CMS would calculate the benchmark period manufacturer price for drugs that were approved or licensed by FDA on or before October 1, 2021, but were not marketed until after this date. Commenters noted that section 1860D-14B(g)(3) of the Act provides that the payment amount benchmark period for these drugs is January 1, 2021 through September 30, 2021. However, this period would lack data to calculate the benchmark period manufacturer price for these drugs because there would not be AMP data or reasonable assumptions reported to the Medicaid Drug Programs system, given that manufacturers do not begin reporting AMP data (including AMP data based on reasonable assumptions) for a drug until that drug has been marketed. A couple of commenters recommended that CMS use a payment amount benchmark period for these drugs that allows for sufficient data to calculate a benchmark period manufacturer price. Another commenter recommended that CMS create a mechanism for a manufacturer to report a reasonable assumption-based AMP to CMS before a drug is marketed.

Response: CMS thanks commenters for raising this issue and for their recommendations. CMS agrees with commenters that, while section 1860D-14B(g)(3) of the Act contemplates that drugs approved or licensed on or before October 1, 2021 would have a payment amount benchmark period of January 1, 2021 through September 30, 2021, the statute does not address circumstances in which such drugs are not marketed until after October 1, 2021 and thus lack data from January 1, 2021 through September 30, 2021 to calculate the benchmark period manufacturer price. Section 1860D-14B(b)(5)(A) of the Act specifies that the payment amount benchmark period for drugs first approved or licensed after October 1, 2021 ("subsequently approved drugs") shall be the first calendar year beginning after the day on which the drug was first marketed. Because this provision defines the payment amount benchmark period for subsequently approved drugs in relation to when a drug was first marketed, it thereby ensures that there are data available in the payment amount benchmark period to calculate the benchmark period manufacturer price. Given that drugs first approved or licensed on or before October 1, 2021, but not marketed until after that date, would lack data from January 1, 2021 through September 30, 2021 to calculate the benchmark period manufacturer price, CMS believes that it is appropriate to treat such drugs in the same manner in which it will treat subsequently approved drugs to identify the payment amount benchmark period based on the first calendar year beginning after the day on which the

[7] See: https://www.fda.gov/industry/structured-product-labeling-resources/nsde.
[8] Implementation starting September 1, 2012 of PDE Editing using the FDA Online Label Repository (May 14, 2012). https://fda.gov/media/85597/download.

drug was first marketed. CMS has revised section 40.1.2 of this revised guidance to specify this policy. CMS intends to address this policy in future rulemaking and will solicit comments on this policy at that time.

Steps to Calculate the Medicare Part D Drug Inflation Rebate (Section 40.2)

Comment: One commenter noted that the Part D drug inflation rebate is based on AMP, a pricing metric that manufacturers calculate and report to the MDRP. The commenter stated that CMS regulations and guidance do not always address how a manufacturer should treat a particular type of sale in calculating AMP, and that in these circumstances, CMS permits the manufacturer to rely on reasonable assumptions that are consistent with the requirements and intent of federal laws and regulations. Because the Part D Drug Inflation Rebate Program uses AMP data, these reasonable assumptions will have a more significant impact than they have had in the past. The commenter therefore recommended that CMS be responsive to manufacturer requests for technical assistance on price reporting questions that arise.

Response: It is the responsibility of the manufacturers to calculate and report their MDRP information according to law, regulations, and guidance. As noted by the commenter, in the absence of guidance, manufacturers may make reasonable assumptions when determining AMP. CMS also communicates regularly with manufacturers and publishes guidance when it identifies issues or questions that manufacturers may have regarding a specific MDRP topic, including calculation of AMP. CMS publishes these guidance documents at https://www.medicaid.gov/medicaid/prescription-drugs/program-releases/index.html.

Calculation of AnMP (Section 40.2.1)

Comment: A few commenters asserted that AMP can fluctuate for reasons that are outside the control of the manufacturer and that a manufacturer could therefore be charged a rebate even when the drug's list price has not changed. Commenters detailed several reasons why AMP may fluctuate for reasons outside the manufacturer's control: (1) "As reported" AMP data is not always equal to "as calculated" AMP based on actual transactions. For example, the MDRP recommends that manufacturers report the most recent month's positive AMP if a calculated monthly AMP is zero or negative;[9] (2) Lagged price concessions and changes in eligible sales and units could result in an increase in AMP even when the manufacturer has not changed the list price; (3) The AMP calculation methodology for a 5i drug could switch between the 5i AMP and standard AMP methodologies if the drug is not generally dispensed through a retail community pharmacy (RCP)[10] in the payment amount benchmark period but is in the applicable period, or vice versa; (4) A major payer or provider could terminate its contract with the manufacturer; (5) Manufacturing conditions can lead a manufacturer to raise the price of a drug in order to maintain positive margins; and (6) Value-based arrangements can result in fluctuations in the price paid

[9] CMCS Manufacturer Release No. 80, January 5, 2010. https://www.medicaid.gov/sites/default/files/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-080.pdf.

[10] 5i drugs are CODs that are inhaled, infused, instilled, implanted, or injected. Manufacturers are instructed to calculate the AMP for 5i drugs that are not generally dispensed through an RCP using the methodology described at 42 C.F.R. §§ 447.504(d) and (e). 42 C.F.R. § 447.507(b)(1) provides that a 5i drug is not generally dispensed through an RCP if 70 percent or more of the sales (based on units at the NDC-9 level) of the 5i drug, were to entities other than RCPs or wholesalers for drugs distributed to RCPs.

over time for a drug without any manufacturer action. One commenter raised the concern that AMP fluctuations are particularly common for drugs used to treat rare conditions because changes in patients or payers will have a greater impact in a smaller patient population. This commenter also noted that payers often subject drugs that FDA has approved through the accelerated approval pathway to discounts. When the product receives traditional approval because confirmatory studies demonstrate clinical benefit, the payer may no longer apply these discounts. The commenter stated that imposing an inflation rebate in this scenario would be counterintuitive because increased payment for the drug would be reflective of the drug's clinical benefit.

To address these instances of AMP fluctuations (i.e., those cases detailed above), one commenter recommended that CMS not apply a rebate if the AMP increase from the payment amount benchmark period to an applicable period is not in alignment with the list price increase between these periods. They also recommended that CMS require manufacturers to submit the two key components that were used to generate the "as calculated" AMP (eligible dollars and eligible units), thereby allowing CMS to calculate the AnMP using accurate data when "as calculated" and "as reported" AMP values are not the same. This commenter also recommended that CMS apply a "normalization process" when there is a change between the payment amount benchmark period and applicable period in whether a 5i drug is not generally dispensed through an RCP. Another commenter recommended that CMS monitor AMP fluctuations, while one commenter recommended that CMS calculate Part D drug inflation rebates based on wholesale acquisition cost (WAC).

Response: CMS thanks the commenters for expressing their concerns that AMP fluctuations are not always within the control of the manufacturer. Sections 1860D-14B(b)(2) and (4) of the Act specify that CMS shall use AMP data and units reported under section 1927 of the Act for the purpose of calculating the AnMP and benchmark period manufacturer price, respectively. Section 1860D-14B(d)(1) of the Act also requires that CMS use information submitted by manufacturers under section 1927(b)(3) of the Act. CMS is implementing these statutory criteria. In response to the commenter who requested that CMS use "as calculated" data to resolve differences between "as calculated" and "as reported" AMP, CMS notes that because the statute directs CMS to rely on certain information sources specified in the Act, and the "as calculated" data suggested for inclusion by the commenter is not currently required to be reported under these information sources, CMS would not have access to the information that the commenter requested CMS use.

CMS recognizes that there are certain circumstances in which AMP can fluctuate for reasons that may be, at least to some degree, outside of the control of a manufacturer. CMS will implement the Part D Drug Inflation Rebate Program consistent with the statute and will not exclude units of Part D rebatable drugs, including in the event of potential fluctuations for 5i drugs, drugs subject to value-based arrangements, or drugs originally approved by FDA via the accelerated approval pathway. CMS will monitor feedback on the Part D Drug Inflation Rebate Program's implementation related to these drugs and other considerations for potential fluctuations in AMP reporting. CMS also notes that a manufacturer may use a smoothing process for 5i drugs, which may be beneficial to manufacturers who experience fluctuations in sales throughout the year.[11] In

[11] See 81 Fed. Reg. 5,170, 5,240 (February 1, 2016). CMS allows for a smoothing process wherein manufacturers may use data from a current, yet longer, period of time to determine whether a 5i drug meets the threshold to be considered not generally dispensed through an RCP.

response to the commenter who cited manufacturing conditions as a reason for AMP fluctuations beyond a manufacturer's control, CMS directs readers to section 40.5 of this revised guidance, which details how CMS will reduce the rebate amount for Part D rebatable drugs in shortage or likely to be in shortage and in cases of severe supply chain disruptions.

Calculation of Benchmark Period Manufacturer Price (Section 40.2.2)

Comment: One commenter noted that the payment amount benchmark period for Part D rebatable drugs first approved or licensed on or before October 1, 2021 is based on the FDA approval or licensure date for that drug. Because FDA approval or licensure is for a New Drug Application (NDA) or Biologics License Application (BLA), respectively, the commenter asked whether the same approval or licensure date would be applicable for all products and package sizes approved or licensed under the same NDA/BLA for the purpose of determining the drug's payment amount benchmark period.

Response: Section 1860D-14B(g)(3) of the Act provides that the payment amount benchmark period for a Part D rebatable drug first approved or licensed on or before October 1, 2021 is January 1, 2021 through September 30, 2021, whereas section 1860D-14B(b)(5)(A) of the Act provides that the payment amount benchmark period for a Part D rebatable drug first approved or licensed after October 1, 2021 is the first calendar year beginning after the day on which the drug was first marketed. CMS has clarified in section 40.3 of this revised guidance that the date that CMS will use to determine whether a drug was first approved or licensed on or before October 1, 2021 versus after October 1, 2021 is the FDA Approval Date that the manufacturer reports pursuant to section 1927(b)(3)(A)(v) of the Act.

Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units (Section 40.2.5)

Comment: A few commenters supported CMS' consideration of an option to add a field to the PDE file layout to collect how the amount reported in the PDE "Quantity Dispensed" field is measured. A few of these commenters stated that this new field would improve accuracy in determining the total units used to calculate the total rebate amount owed. One of the commenters believed that there is ample time for implementation, and another recommended that CMS enforce use of the new field. Another of these commenters recommended that CMS implement the new field using a standardized process in collaboration with the National Council for Prescription Drug Programs (NCPDP), while another argued that adding the new field would be particularly important for non-oral solid dosage forms, for which pharmacists may enter the number of syringes that were dispensed instead of the number of milliliters of the drug that were dispensed. One commenter stated their support for adding a field to the PDE, while also noting that they often see reporting errors in Medicaid and Medicare, particularly in determining total quantity units, and urged CMS to enact safeguards to prevent these errors from affecting the Part D Drug Inflation Rebate Program.

On the other hand, a few commenters did not support adding a new field to the PDE file layout. One commenter was concerned that requiring this field would not ensure improved accuracy and could cause unnecessary hardship to beneficiaries if the claim is rejected if data in the field are

missing. They stated that adding the field would create burden for pharmacies and claims processors. The processors would need to retain the claim unit of measurement and report it on the PDE. This reporting could increase burden for claims processors because pharmacies may not all submit the unit of measurement identically because pharmacies use various software systems that use data from different sources, and claims processors may be required to check if the unit of measurement was submitted accurately by the pharmacy. This commenter also had concerns that if this unit of measure is required to be included on the PDE and it was inaccurate at the point-of-sale, it would be inaccurately reported on the PDE. One commenter emphasized that additions to the PDE are time-intensive and require extensive file testing by Part D plan sponsors. They urged that, if CMS proceeds with adding a new field to the PDE, CMS should align this change with the timeline outlined in the HPMS memo entitled "New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback" that was published on November 1, 2022.

A couple of commenters presented alternative options for identifying dispensed units. CMS could request NCPDP billing units and applicable conversion factors from manufacturers, potentially via manufacturers' Discount Program Agreement (DPA) reports. Alternatively, CMS could ask FDA to work with NCPDP to address any discrepancies in unit measurements. One commenter did not support or oppose the addition of a PDE field but requested that CMS clarify that reporting of PDE data for the purposes of calculating inflation rebates would not require additional reporting or changes to claim submissions by community pharmacies.

Response: CMS appreciates the numerous perspectives shared by commenters. CMS agrees with commenters' concerns that the addition of this field could increase pharmacy burden or could cause unnecessary hardship to beneficiaries if the claim is rejected because the field is missing. CMS further agrees with commenters' concerns that the unit type information would be inaccurately reported on the PDE if it was inaccurate at point-of-sale, and CMS disagrees with the commenters who suggested that unit inaccuracies could be fully alleviated with the addition of a PDE field to indicate how the amount reported in the PDE "Quantity Dispensed" field is measured. Furthermore, even if CMS were to pursue such a policy, the agency would be unable to align the addition of a "Quantity Dispensed" field with the timeline and extensive testing required by pharmacies before the 2025 PDE File Layouts take effect.

Given that CMS does not believe the inclusion of a units field on the PDE record will improve accuracy and the concerns expressed by interested parties that adding a field would result in substantial pharmacy burden without guaranteeing improved accuracy, CMS has revised section 40.2.5 of this revised guidance to affirm that it will not pursue adding a field to the PDE file layout to collect how the amount reported in the PDE "Quantity Dispensed" field is measured. CMS has also revised section 40.2.5 to reflect that CMS will cross walk the information from the PDE record to a database (such as FDA's NSDE file or Medi-Span) that includes the unit type to identify the NCPCP billing unit. CMS believes that this process is sufficient to identify the NCPDP billing unit. CMS will monitor the approach detailed in 40.2.5 and will continue to consider whether additional instruction or the addition of a PDE field is appropriate in the future.

Calculation of Total Rebate Amount to be Paid by Manufacturers (Section 40.2.6)

Comment: One commenter requested that CMS clarify how it will treat scenarios where a Part D rebatable drug has been divested. The commenter asked whether a rebate calculated using PDE units prior to the divestiture would be the responsibility of the old manufacturer, whereas the PDE units post-divestiture would be the responsibility of the new manufacturer.

Response: CMS appreciates this commenter's request for clarification. Section 1860D-14B(d)(1) of the Act requires that CMS use information submitted by manufacturers under section 1927(b)(3) of the Act for the purpose of carrying out the Part D Drug Inflation Rebate Program. CMS will use the same approach used by the MDRP to identify the manufacturer that is responsible for a Part D drug inflation rebate amount owed. Specifically, the labeler code on an NDC-9 (the level at which Part D drug inflation rebate amounts are calculated) identifies for CMS the manufacturer responsible for a rebate in the MDRP, and in this revised guidance CMS is adopting this same approach for the Part D Drug Inflation Rebate Program.

Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements (Section 40.2.7)

Comment: Many commenters expressed support for CMS' proposal to require an indicator on PDE records to identify 340B units. Some commenters recommended that CMS require an indicator to identify both 340B and non-340B units at the point-of-sale and ensure that Part D plans consistently and accurately reflect the 340B status of all utilization in PDE files. A few commenters recommended that CMS clarify that any requirement to include a 340B claims modifier preempts any state or local law prohibiting the use of modifiers. A few commenters encouraged CMS to begin implementing the necessary predicates for exclusion sooner than 2026. A few commenters expressed concern that the initial memorandum does not provide an adequate process for resolving duplicate discount issues and that a 340B indicator alone is not sufficient.

Many commenters disagreed that the PDE record is the most accurate way to identify 340B discounts for Part D drugs. A few commenters highlighted the operational challenges, administrative burden, and potential for increased dispensing fees and reimbursement issues with both point-of-sale modifiers and retrospective 340B identifiers.

Commenters had varying recommendations as to which entity should be responsible for identifying the 340B units. For example, a few commenters recommended that CMS look to 340B covered entities or manufacturers to appropriately identify and exclude 340B units from the Part D drug inflation rebate calculation. A couple of commenters were concerned about Part D plan sponsors having a role in determining or verifying 340B status. Many commenters suggested additional approaches for identifying 340B units, including that CMS implement a "clearinghouse" model to identify 340B transactions or have third-party administrators provide 340B data to CMS. One commenter agreed that 340B units must be identified retrospectively but stated that it did not have an industry consensus-based recommendation.

Response: CMS thanks commenters for their input and recommendations for how CMS can reliably identify Part D claims filled with 340B units, so these associated units can be excluded

from the determination of units of Part D rebatable drugs beginning in January 2026. CMS is continuing to evaluate different options and will finalize a policy for excluding 340B units beginning with plan year 2026 in accordance with the statute.

Treatment of Subsequently Approved Part D Rebatable Drugs (Section 40.3)

Comment: A few commenters opposed CMS' proposed approach for calculating the AnMP for subsequently approved drugs whereby CMS would have used AMP and AMP units from the nine-month period running from January through September immediately following the end of the payment amount benchmark period. These commenters stated that section 1860D-14B(g)(7) of the Act defines the applicable period as "a 12-month period beginning with October 1 of a year" and therefore asserted that CMS' proposal did not fully align with the language of the statute. These commenters recommended that the first applicable period for a subsequently approved drug begin October 1 of the year following the payment amount benchmark period.

Response: CMS thanks these commenters for their input. In sections 40.2.2 and 40.3 of this revised guidance, CMS has revised its policy so that the applicable period for a subsequently approved drug begins on October 1 of the year immediately following the payment amount benchmark period. This revised approach establishes the applicable period as a 12-month period beginning with October 1 of a year in a manner that is consistent with the statute and avoids the potential for overlap between the payment amount benchmark period and the first applicable period.

Treatment of New Formulations of Part D Rebatable Drugs (Section 40.4)

Comment: One commenter supported CMS' proposed methodology for calculating Part D drug inflation rebates for a line extension of a Part D rebatable drug that is an oral solid dosage form, citing the policy's consistency with the MDRP. This commenter stated that this policy is important in preventing line extensions from "resetting the clock" for the inflation rebate calculation and expressed support for expanding the definition of a "line extension" drug to all types of drugs, not just drugs originally launched in oral solid dosage forms. Another commenter opposed CMS' proposal in the initial memorandum to use the regulatory definitions of "line extension" and "new formulation" found at 42 C.F.R. § 447.502 for the purpose of identifying new formulations of Part D rebatable drugs.[12] They asserted that these definitions are inconsistent with section 1927(c)(2)(C) of the Act and that Congress intended the line extension provision to apply only to drugs involving slight alterations to the original formulation. This commenter also argued that section 1927(c)(2)(C) of the Act makes clear that the alternative rebate calculation for line extension drugs applies only to a line extension that is itself an oral solid dosage form; however, 42 C.F.R. § 447.509 specifies that, for purposes of MDRP, CMS will treat any subsequent form of a product as a line extension so long as the initial formulation was an oral

[12] 42 C.F.R. § 447.502 states that a line extension "means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary). 42 C.F.R. § 447.502 further states that a new formulation "means, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients." See: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.502.

solid dosage form.[13] Due to these concerns, the commenter disagreed with the initial memorandum's proposal to apply these definitions to the Part D Drug Inflation Rebate Program for the purpose of implementing section 1860D-14B(b)(5)(B) of the Act.

Response: CMS appreciates the commenters' perspectives. As detailed in section 40.4 of the initial memorandum and this revised guidance, section 1860D-14B(b)(5)(B)(ii) of the Act defines the term "line extension" as "a new formulation of the drug, such as extended-release formulation, but does not include abuse-deterrent formulations of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended-release formulation." Because section 1927(c)(2)(C) of the Act uses identical language to define the term "line extension" for purposes of MDRP, CMS believes that, for the purposes of identifying new formulations of Part D rebatable drugs in the Part D Drug Inflation Rebate Program, it is appropriate to use the regulatory definitions of "line extension" and "new formulation" that were adopted through rulemaking[14] for the MDRP, which can be found at 42 C.F.R. § 447.502.

Comment: One commenter asked CMS to clarify when the first applicable period begins for newly launched line extensions, asserting that the first applicable period could start earlier than for other types of newly launched Part D rebatable drugs because a benchmark period manufacturer price for the line extension drug is not needed to calculate the rebate amount.

Response: CMS appreciates this commenter's input but disagrees with their assertion. Because CMS is required to establish a formula for calculating Part D drug inflation rebates for a Part D rebatable line extension drug that is consistent with the formulas applied under section 1927(c)(2)(C) of the Act, CMS will take the greater of two rebate amounts to determine the per unit rebate amount for the Part D rebatable line extension drug: (1) the *inflation rebate amount* for the applicable period for the Part D rebatable drug calculated under section 1860D-14B(b) for the Part D rebatable line extension drug; or, (2) the *alternative inflation rebate amount* calculated under the alternative rebate formula consistent with section 1927(c)(2)(C) of the Act. A benchmark period manufacturer price for the Part D rebatable line extension drug is therefore required to calculate the inflation rebate amount. CMS affirms that the first applicable period for a newly launched Part D rebatable drug that is a line extension will begin on October 1 of the year immediately following the payment amount benchmark period, consistent with the timing of the first applicable period for Part D rebatable drugs first approved or licensed after October 1, 2021.

Comment: One commenter expressed support for CMS' decision to exclude combination products from the definition of a "new formulation" at 42 C.F.R. § 447.502 for the purpose of the MDRP.[15] The commenter urged CMS to define "line extension" and "new formulation" for the

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[13] 42 C.F.R. § 447.509(a)(4)(iii) specifies that, for the rebate periods beginning on and after January 1, 2022, the rebate calculation for new formulations applies to "a drug that is a line extension of a single source drug or an innovator multiple source drug, provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form." See: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.509.

[14] Medicaid Program Final Rule (0938-AU96), 85 Fed. Reg. 87,000, 87,039 (Dec. 31, 2020): https://www.govinfo.gov/content/pkg/FR-2020-12-31/pdf/2020-28567.pdf.

[15] In its June 2020 Proposed Rule, CMS proposed to include "combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device" in the definition of "new formulation" at

purpose of the Part D Drug Inflation Rebate Program to also exclude combination products.

Response: As stated above and in section 40.4 of the initial memorandum and this revised guidance, CMS will use the regulatory definitions of "line extension" and "new formulation" that were adopted through rulemaking for the MDRP, which can be found at 42 C.F.R. § 447.502, for the purposes of identifying new formulations of Part D rebatable drugs, including with respect to combination products.

Reducing the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on a U.S. FDA Shortage List (Section 40.5.1)

Comment: One commenter expressed support for the general approach described in the initial memorandum regarding rebate reductions or waivers. A few commenters expressed concern about manufacturers' potential to benefit from a shortage and recommended CMS establish a process that minimizes incentives for manufacturers to maintain a drug on the shortage list to avoid paying inflation rebates on Part D rebatable drugs. A couple of commenters recommended that CMS require that drug manufacturers provide extensive documentation to prove a shortage exists and demonstrate that the manufacturer is taking steps to mitigate or end the shortage. A few commenters disagreed with the assertion that rebate waivers or reductions would incentivize manufacturers to intentionally maintain a drug in shortage and stated that safeguards are unnecessary to prevent such behavior.

A few commenters recommended that for Part D rebatable drugs on an FDA shortage list, CMS provide a limited standard reduction in the rebate amount and allow manufacturers to request a longer or higher reduction or waiver for certain types of drugs or causes of shortages. A few commenters recommended that CMS waive or reduce the rebate amount differently for specific types of Part D rebatable drugs (e.g., rare disease treatments, low- versus high-margin drugs, low- versus high-priced drugs), as well as specific types of shortages (e.g., shortages resulting from quality issues versus shortages due to exogenous circumstances). One commenter suggested CMS coordinate with FDA, which has knowledge of the relevant drug markets and conducts assessments of medical necessity and drug substitutes. One commenter recommended that CMS consider the repeating nature of drug shortages when administering rebate reductions.

Response: CMS thanks commenters for their support and appreciates commenters' input regarding how this policy should be structured. As described in section 40.5.1 of this revised guidance, CMS will provide a variable reduction in the rebate amount based on the length of time a Part D rebatable drug is in the status of "currently in shortage" on an FDA shortage list during an applicable period, with the reduction decreasing over time. To calculate the reduction in the rebate amount for a Part D rebatable drug, CMS will determine the number of days such drug is described as "currently in shortage" on an FDA shortage list in an applicable period, divide by the number of days in the applicable period, and then multiply that amount by a percentage that is

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42 C.F.R. § 447.502. In 85 Fed. Reg. 87,000, 87,039 (Dec. 31, 2020), CMS stated that it "decided not to include a new combination of drugs, and a drug/device combination as a new formulation." See: Medicaid Program Proposed Rule (0938-AT82), 85 Fed. Reg. 37,286, 37,319 (June 19, 2020): https://www.govinfo.gov/content/pkg/FR-2020-06-19/pdf/2020-12970.pdf. See also: Medicaid Program Final Rule (0938-AU96), 85 Fed. Reg. 87,000, 87,039 (Dec. 31, 2020): https://www.govinfo.gov/content/pkg/FR-2020-12-31/pdf/2020-28567.pdf. For 42 C.F.R. § 447.502 see: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.502.

decreased over time.

CMS will provide the same reduction in the rebate amount for Part D rebatable drugs that are currently in shortage on an FDA shortage list regardless of the cause of the shortage. CMS will not provide a full waiver of the rebate amount for drugs currently in shortage on an FDA shortage list, as providing a full waiver of the rebate amount could further incentivize manufacturers to delay taking appropriate steps that may resolve a shortage more expeditiously simply to maintain having the drug listed on FDA's drug shortage list to avoid an obligation to pay rebates for an extended period. Further, in a report analyzing the root causes of drug shortages between 2013 and 2017, FDA found that more than 60 percent of drug shortages were the result of manufacturing or product quality issues, and providing a full waiver of the rebate amount in situations that may be within a manufacturer's control could be perceived as rewarding manufacturers for poor quality management.[16]

CMS understands that some drugs may face supply chain disruptions due to exogenous factors such as a natural disaster or other unique or unexpected events, and manufacturers of such drugs may temporarily increase the price of such drugs to account for increased costs associated with resolving a severe supply chain disruption. As described in section 40.5.2 of this revised guidance, to provide financial relief to manufacturers in such situations, CMS will provide a standard time-limited reduction of 75 percent in the rebate amount for a generic Part D rebatable drug or biosimilar when there is a severe supply chain disruption during an applicable period.

CMS agrees with commenters that CMS should consider manufacturing complexity when assessing whether a manufacturer should have inflation rebates significantly reduced and understands that plasma-derived products have heightened shortage risks as a result of their complex manufacturing and unique reliance on donations of blood plasma, which can impact downstream production and the ability to promptly resolve a shortage. As such, as described in section 40.5.1 of this revised guidance, CMS will provide a higher reduction for plasma-derived Part D rebatable drugs described as "currently in shortage" on an FDA shortage list compared to non-plasma-derived Part D rebatable drugs.

CMS will also provide a greater reduction for generic Part D rebatable drugs, which are often low-margin products whose prices are tied to the marginal cost of production and thus are more vulnerable to shortages and potential market exit when input costs increase.[17] CMS notes that the Part D Drug Inflation Rebate Program does not apply to multi-source generic drugs, which are the drugs most likely to be in shortage.[18] It applies to brand-name drugs and biologicals (including biosimilars) and to sole source generic drugs.

CMS will not require manufacturers to submit a request and justification for rebate reductions for drugs described as "currently in shortage" on an FDA shortage list. However, CMS is exploring what additional information and operational changes would be necessary to implement a policy whereby a reduction in the rebate amount would differ depending on the cause of the shortage and

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[16] See: https://www.fda.gov/media/131130/download?attachment#page=33.
[17] See: https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.
[18] See: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023 and https://www.fda.gov/media/131130/download.

may revise the policy set forth in this revised guidance in the future. Consistent with section 1860D-14B(b)(1)(C)(i) of the Act and as described in section 40.5.1 of this revised guidance, CMS will reduce the rebate amount for each applicable period that a Part D rebatable drug appears in the status of "currently in shortage" at any point during the applicable period. CMS will require manufacturers to submit to CMS a request and justification for a rebate reduction for a generic Part D rebatable drug or biosimilar when there is a severe supply chain disruption, as described in section 40.5.2 of this revised guidance, as well as for a generic Part D rebatable drug that is likely to be in shortage in a subsequent applicable period, as described in section 40.5.3 of this revised guidance. CMS will issue a proposed collection of information addressing information that must be submitted to CMS by a manufacturer of a generic Part D rebatable drug or biosimilar in order to receive consideration for a rebate reduction under the severe supply chain disruption and likely to be in shortage policies. CMS may, as appropriate, consult with FDA for technical assistance.

Comment: A few commenters recommended that CMS provide a full waiver of the rebate amount for a drug described as "currently in shortage" on an FDA shortage list to avoid further exacerbating a shortage and allow a manufacturer to direct resources toward resolving a shortage rather than toward inflation rebate obligations. A couple of commenters recommended that CMS waive the rebate amount regardless of whether all NDCs for a Part D rebatable drug are in shortage, as a shortage for one NDC-11 can affect the availability of other NDC-11s. A couple of commenters recommended that CMS limit the waiver to the portion of the rebate attributable to NDC-11s described as "currently in shortage" on an FDA shortage list.

Response: CMS thanks these commenters for their input. CMS will not provide a full waiver of the rebate amount for any Part D rebatable drugs that are described as "currently in shortage" on an FDA shortage list, as providing a full waiver of the rebate amount could incentivize manufacturers to delay taking appropriate steps to resolve a shortage simply to maintain having the drug listed on an FDA shortage list to avoid an obligation to pay rebates for an extended period. CMS believes the rebate reduction should be proportional to the time the drug is described as "currently in shortage" and decrease over time. Given that drugs and biological products on the FDA shortage lists are maintained at the NDC-10 level, and Part D rebatable drug inflation rebates are calculated at the NDC-9 level, if any NDC-10 for a Part D rebatable drug is described as "currently in shortage" on an FDA shortage list, CMS will apply a reduction in the rebate amount to the entire Part D rebatable drug at the NDC-9 level. CMS acknowledges commenters' concerns about such broad application of the rebate reduction, but agrees with commenters that a shortage of one NDC can affect the availability of other NDCs. CMS will closely monitor market data for the Part D rebatable drugs whose rebates are reduced to ensure the integrity of the application of the rebate reduction policy by the manufacturer.

Reducing the Rebate Amount for a Generic Part D Rebatable Drug or Biosimilar When There Is a Severe Supply Chain Disruption (Section 40.5.2)

Comment: One commenter suggested modifications to CMS' definitions, for example, by adding cyberattacks to the "other unique or unexpected event" definition. One commenter expressed support for CMS' proposed definition of "other unique or unexpected event." Another commenter recommended that CMS coordinate with FDA to create consistent reporting requirements and

definitions. One commenter asked that CMS interpret the severe supply chain disruption provision broadly to allow manufacturers to account for certain cost increases such as those that occurred during the COVID-19 pandemic (e.g., increases in the costs of active ingredients, supplies, and shipping). Another commenter expressed concern that supply chain disruptions can cause swings in AMP that are beyond a manufacturer's control and inflation rebates should not be assessed in these situations.

Response: CMS thanks these commenters for their input. CMS believes that for the purposes of the Part D Drug Inflation Rebate Program, the definitions of the statutory terms "natural disaster" and "other unique or unexpected event" in the initial memorandum are sufficiently broad to capture the range of exogenous and unexpected events that may result in a severe supply chain disruption and thus is maintaining these definitions in the revised guidance. To clarify that CMS considers a severe supply chain disruption to be distinct from a drug shortage for purposes of providing a rebate reduction, CMS has revised the definition of severe supply chain disruption to mean "a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a generic Part D rebatable drug or biosimilar by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product in the United States for at least 90 days." This revision also more closely aligns the definition of a severe supply chain disruption with the definition of "meaningful disruption" in section 506C(h)(3) of the FD&C Act. CMS may consult with FDA for technical assistance in implementing the severe supply chain disruption provision, as needed. CMS understands the concerns regarding the effect of supply chain disruptions on AMP and consistent with the statute, will provide a reduction in the rebate amount (if any) when CMS determines there is a severe supply chain disruption during an applicable period. CMS may consider additional modifications to the severe supply chain disruption policy in the future.

Comment: A couple of commenters recommended that CMS waive the full rebate amount and exercise flexibility in the duration of the waiver and consider the severity of the event that caused the severe supply chain disruption.

Response: CMS thanks commenters for their input. CMS will provide a standard reduction in the rebate amount of 75 percent for a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event. CMS will apply this reduction as described in section 40.5.2 of this revised guidance. CMS appreciates commenters' suggestion that it should exercise flexibility and consider the severity of the supply chain disruption. As described in section 40.5.2 of this revised guidance, the manufacturer of a generic Part D rebatable drug or biosimilar may request a reduction in the rebate amount for a second applicable period when there is a severe supply chain disruption, and the manufacturer submits justification to CMS to support a rebate reduction in a subsequent applicable period. To receive consideration for a rebate reduction for a second applicable period, the manufacturer would have to submit to CMS a request for an extension as described in section 40.5.2 of this revised guidance.

Comment: One commenter asked that CMS lengthen the time period for manufacturers to submit a request for a rebate reduction due to a severe supply chain disruption from 60 days to 90 or 120 days because a manufacturer may not know at 60 days whether a disruption will last at least 90

days.

Response: CMS thanks the commenter for their input. CMS believes that requiring a manufacturer to submit a request for a rebate reduction within 60 days of the first day of a natural disaster or other unique or unexpected event provides the manufacturer sufficient time to evaluate whether such natural disaster or other unique or unexpected event occurred would significantly affect the ability of the manufacturer to fill orders or meet expected demand for its product in the United States for at least 90 days. Furthermore, in developing the policy for reducing rebates when there is a severe supply chain disruption, CMS has tried to ensure consistency across the Part B and Part D Drug Inflation Rebate Programs where feasible, including with respect to the timing of submission of rebate reduction requests. To meet the statutory deadlines for invoicing manufacturers for Part B and Part D rebates owed, six months after the end of each calendar quarter and nine months after the end of each applicable period, respectively, CMS believes it is not feasible to extend the timeframe for the submission of requests for rebate reductions due to severe supply chain disruptions beyond 60 days. However, as described in section 40.5.2 of this revised guidance, for severe supply chain disruptions caused by a natural disaster or other unique or unexpected event that occurred on or after October 1, 2022 but before August 2, 2024, CMS intends to announce a specific deadline for manufacturers to submit a request for a rebate reduction.

Reducing the Rebate Amount for a Generic Part D Rebatable Drug Where Without Such Reduction, the Generic Part D Rebatable Drug is Likely to be Described as in Shortage on Such Shortage List During a Subsequent Applicable Period (Section 40.5.3)

Comment: One commenter stated that the initial memorandum is inconsistent with the statute because while section 1860D-14B(b)(1)(C)(iii) of the Act requires CMS to reduce or waive the rebate amount in the case of a generic Part D rebatable drug if, without such waiver or reduction, the drug is likely to be in shortage during "a subsequent applicable period," the memorandum states that for such drug to receive a waiver or reduction, the generic Part D rebatable drug must be likely to be in shortage during the "next applicable period."

Response: CMS appreciates this feedback. CMS disagrees that the approach that it described in the initial memorandum on how a rebate would be reduced or waived for a generic Part D rebatable drug that is likely to be shortage is inconsistent with section 1860D-14B(b)(1)(C)(iii) of the Act. This provision instructs CMS to reduce or waive the rebate amount in the case of a generic Part D rebatable drug if CMS determines that without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period. The best statutory interpretation is to interpret the term "subsequent applicable period" as the next applicable period. CMS is applying an interpretation of the statute that will give effect to the statutory policy that a generic Part D rebatable drug is likely to be in the status of "currently in shortage" on the FDA shortage list in the next applicable period but for a reduction to the rebate amount. As described in section 40.5.3 of this revised guidance, in determining whether to grant a rebate reduction under this provision, CMS will consider whether the generic Part D rebatable drug is likely to be in shortage in a subsequent applicable period. Additionally, as needed, CMS may consult with FDA for technical assistance. CMS may consider additional modifications to the generic Part D rebatable drugs that are likely to be in shortage policy in the future.

Comment: One commenter stated that CMS should consider approaches to prevent shortage recurrence which acknowledge the unpredictable nature of the generic drug market by, for example, treating generic drugs exiting a shortage as being at risk of shortage, and providing a transitional period of a gradually declining rebate reduction.

Response: CMS thanks the commenter for their input. CMS recognizes that generic drugs are often low-margin products vulnerable to potential market exit and shortages. Most generic drugs – i.e., those with multiple manufacturers – are not subject to the Part D Drug Inflation Rebate Program. In addition, for the limited number of generic drugs that are sole source drugs, CMS is providing a higher rebate reduction for such generic Part D rebatable drugs on FDA's shortage list compared to brand name drugs. For example, for a generic Part D rebatable drug, CMS will reduce the rebate amount by 75 percent for the first applicable period in which such drug is described as "currently in shortage" on an FDA shortage list, 50 percent for the second applicable period, and 25 percent for each subsequent applicable period. In contrast, for a brand name drug, CMS will reduce the rebate amount by 25 percent for the first applicable period in which such drug is described as "currently in shortage" on an FDA shortage list, 10 percent for the second applicable period, and 2 percent for each subsequent applicable period. In addition, CMS will provide a time-limited standard reduction of 75 percent in the rebate amount to assist the manufacturer of a generic Part D rebatable drug that is likely to be in shortage to take steps to avert a shortage. The reduction applies to one applicable period, and the manufacturer may request an extension of the reduction for a second applicable period for a maximum of two consecutive applicable periods. If CMS grants a request for a reduction in the rebate amount for a generic Part D rebatable drug that is likely to be in shortage, and the drug appears in the status of "currently in shortage" on an FDA shortage list during the same applicable period as the one for which the likely to be in shortage reduction request was granted, CMS will apply the 75 percent standard reduction to the entire applicable period for which the likely to be in shortage request was granted. For any subsequent applicable periods that the generic Part D rebatable drug appears in the status of "currently in shortage" on an FDA shortage list, CMS will apply a variable reduction in the rebate amount under the shortages policy described in section 40.5.1 of this revised guidance.

Ensuring Integrity of the Medicare Part D Drug Inflation Rebates (Section 50)

Comment: Many commenters requested additional claims-level or NDC-11-level data and calculation information be included on Rebate Reports. Examples of additional data requests included beneficiary identification information, prescription identification numbers, days supply, quantity dispensed, AnMP data, CPI-U used, fill dates, number of 340B units excluded, claim status (whether the claim was paid or reversed), and the calculated benchmark period manufacturer price. One commenter encouraged CMS not to provide claims-level data to manufacturers and to limit the information provided to manufacturers to only that which is necessary to implement the Part D Drug Inflation Rebate Program. One commenter suggested that CMS work with Part D plans to check the "Quantity Dispensed" field in PDE data to ensure accuracy. Another commenter requested that CMS share the crosswalk that CMS will use to determine the NCPDP billing unit, as well as applicable PDE unit to AMP unit conversions, with manufacturers for verification.

Response: CMS appreciates commenters' requests for additional information. CMS seeks to facilitate manufacturers' understanding of their Rebate Reports, and CMS will consider including additional information regarding calculation inputs in these reports as feasible and necessary. CMS will perform checks to assess the integrity of this information and has outlined a process by which a manufacturer may suggest a calculation error in CMS' determination of the rebate amount in section 50.1 of the revised guidance. This Suggestion of Calculation Error process is intended to allow the manufacturer to submit information that the manufacturer may identify as potential errors in CMS' calculation of the rebate amount. CMS may consider these suggestions at its discretion.

Comment: Many commenters provided suggestions on the proposed true-up process contemplated in the initial memorandum. A few commenters suggested that rebate true-up occur after three years rather than one year to align with the AMP restatement period under MDRP. One commenter requested that manufacturers have the opportunity to reopen Rebate Reports. One commenter requested that CMS clarify when rebate true-up would occur, noting variation in the language used in the initial memorandum. A couple of commenters suggested CMS should limit the time during which CMS can identify and correct Rebate Report errors. Additionally, one commenter suggested rolling a true-up amount due into the next rebate invoice for the next applicable period if CMS expects the rebatable drug to have a rebate amount due for the subsequent applicable period.

Response: CMS appreciates commenters' feedback and has determined to issue its process for restatements at a later point in time. Consistent with section 1860D-14B(b)(6) of the Act, CMS will establish a method and process to determine adjustments to the rebate amount for a Part D rebatable drug for an applicable period in the case of a Part D plan sponsor submitting revisions to the number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors and to reconcile any overpayments or underpayments in the rebate amount paid. In connection with development of this reconciliation process, CMS is also considering options for establishing a standardized method and process at regular intervals to determine any appropriate adjustment to the rebate amount for a Part D rebatable drug for an applicable period to account for a broader set of circumstances involving revised information. CMS continues to assess options for implementing this process and intends to establish this process ahead of issuing Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, which must be issued no later than December 31, 2025.

Comment: One commenter suggested that CMS notify manufacturers if a Part D rebatable drug would have its inflation rebate amount reduced or waived due to shortage or a severe supply chain disruption, or if CMS has determined that a drug is not subject to the inflation rebate obligation for an applicable period due to the exclusion of drugs where the average annual total cost under Part D is less than $100 per individual per year. One commenter suggested that when a manufacturer's rebate amount is impacted by a reduction or waiver, CMS should share the details of the calculations for the original rebate as well as the reduction amount with the manufacturer.

Response: CMS will notify manufacturers when requests are granted for a rebate reduction due to a severe supply chain disruption or the likelihood that a generic Part D rebatable drug will face a

shortage in a subsequent applicable period. As described in section 40.5.1 of this revised guidance, CMS will automatically apply a reduction to rebatable drugs that are listed as "currently in shortage" on an FDA shortage list. Rebate reductions will be applied in the Rebate Reports issued to manufacturers with Part D rebatable drugs; all Rebate Reports will contain, at a minimum, the information described in section 50 of this revised guidance.

CMS does not intend to send notice to manufacturers with drugs that are not considered rebatable. Drugs will not be considered rebatable if they meet the exclusion for drugs whose average annual total cost under Part D is less than $100 per individual per year. Manufacturers of these drugs therefore will not receive any Rebate Reports for these drugs for that applicable period (see section 30 of this revised guidance).

Comment: One commenter recommended that CMS create a computer readable file format for Rebate Reports, such as ASCII delimited or fixed file format.

Response: CMS appreciates these commenters' suggestions and plans to assess feasibility of these file formats before CMS issues Rebate Reports.

Process for Rebate Reports and Suggestion of Calculation Error (Section 50.1)

Comment: A few commenters requested that CMS publish a schedule or anticipated release dates for Rebate Reports. One of these commenters also requested that CMS provide advance notification to generic manufacturers that they have a rebatable drug(s) and the rebate amount that will be due because of the high volume of generic drugs that a single manufacturer may need to track.

Response: Section 1860D-14B(a)(3) of the Act specifies that CMS may issue the Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, no later than December 31, 2025, and sections 50 and 50.2 of this revised guidance include timing and other information regarding CMS' policies for issuing these Rebate Reports. CMS also notes in section 50 of this revised guidance that it intends to publish a regular release schedule or calendar of release dates in the future. Starting with the applicable period beginning October 1, 2024, Rebate Reports will follow the cadence described in section 50.1 of this revised guidance.

CMS will not provide advanced notice to manufacturers of Part D rebatable drugs. However, CMS will provide a Preliminary Rebate report to all manufacturers with a Part D rebatable drug and a review period during which a manufacturer may review the Preliminary Rebate Report and suggest a mathematical error prior to CMS posting the Rebate Report for an applicable period (see section 50.1 of this revised guidance for additional information).

Comment: A couple of commenters requested that any information in the Preliminary Rebate Report be included in the scope of the Suggestion of Calculation Error review. A few commenters requested an additional review or dispute resolution process for Rebate Reports beyond the Suggestion of Calculation Error process.

Response: If a manufacturer of a Part D rebatable drug that owes a Part D inflation rebate

believes in good faith that CMS has made a mathematical error in the rebate calculation, the manufacturer may submit a suggestion of a calculation error to CMS as described in sections 50.1 and 50.2 of this revised guidance. However, we note that section 1860D-14B(f) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part D rebatable drug, and the calculation of the rebate amount. CMS recognizes that manufacturers, at times, may disagree with CMS regarding the rebate calculation.

Comment: Many commenters stated that 10 calendar days for the Suggestion of Calculation Error period does not provide sufficient time for manufacturers to review the Preliminary Rebate Report. Some commenters indicated this timeframe did not align with the time allotted for manufacturer calculations in MDRP or the industry standard of 30 days. Some commenters indicated the 10-day timeframe was insufficient for manufacturers that might have many products subject to rebates. Many commenters suggested CMS provide at least 30 days for manufacturers to review and submit a Suggestion of Calculation Error, while two commenters requested 45 days. One commenter stated that a review window of 10 calendar days was too short, and that CMS should provide a transition period and additional flexibility during the beginning of the Part D Drug Inflation Rebate Program.

Response: CMS thanks commenters for their feedback. In setting the review period of 10 calendar days, CMS considered the volume of the data to be provided to manufacturers, the narrow set of items that may be identified as a Suggestion of Calculation Error, and the operational time period necessary for CMS to complete the process to publish a Rebate Report. Given these factors, CMS believes that a review period of 10 calendar days is sufficient. CMS appreciates the suggestion for additional flexibility during the beginning of the Part D Drug Inflation Rebate Program. CMS has added information in section 50.2 of this revised guidance to provide additional information on Rebate Reports for the first two applicable periods, including providing an extended Suggestion of Calculation Error period of 30 calendar days for these two invoicing cycles. The extended Suggestion of Calculation Error period will provide manufacturers with additional time to become accustomed to the invoicing process and Rebate Reports.

Enforcement of Rebate Amount Payments by Manufacturers (Section 60)

Comment: A couple of commenters requested that CMS issue CMPs only on the rebate amount in the Rebate Report without regard to restatements. One of these commenters stated CMS does not have the authority under section 1860D-14B(e) of the Act to impose CMPs on anything but the manufacturer's failure to pay the initial invoice and that reconciliation described in section 1860(D)-14B(b)(6) does not specifically state that CMPs can be assessed on manufacturers for the "true-up" or similar invoices.

Response: CMS appreciates commenters' feedback and has determined to address restatement processes and related enforcement considerations in future rulemaking.

Comment: A few commenters requested that CMS issue Part D CMP regulations before issuing CMPs. One commenter requested CMS state that it would employ enforcement discretion and not issue CMPs to manufacturers that fail to pay a Part D rebate if the manufacturer made a good faith mistake, has a "bona fide disagreement" with CMS calculations, notes "a payment

discrepancy resulting from unclear guidance on a manufacturer- or drug-specific issue," or fails to pay the rebate due when the manufacturer did not knowingly or intentionally perform the violation. A couple of commenters requested clear procedures for notice, procedures, and timeframes for responding to a CMP notice; one of these commenters also requested a process for corrective action prior to issuance of a CMP notice, using other CMS programs as a model for such procedures.

Response: CMS thanks commenters for their feedback. Section 1860D-14B(e) of the Act provides that "[i]f a manufacturer of a Part D rebatable drug has failed to comply with the requirement under subsection [1860D-14B(a)(2)] with respect to such drug for an applicable period, the manufacturer shall be subject to a civil money penalty in an amount equal to 125 percent of the amount specified in subsection [1860D-14B(b)] for such drug for such period." Section 1860D-14B(h) of the Act directs the Secretary to implement the Part D Drug Inflation Rebate Program for 2022, 2023, and 2024 using program instruction or other forms of program guidance. Section 60.1 of this revised guidance has been added to provide additional details on CMP notice and appeals procedures. CMS will continue to evaluate its policy options to promote manufacturers' compliance with their payment obligations under the Part D Drug Inflation Rebate Program. CMS intends to conduct rulemaking for the Part D Drug Inflation Rebate Program in the future and may consider additional CMP process requirements in such rulemaking.

Formulas (Section 70)

Comment: One commenter recommended that CMS revise the formula for calculating the total rebate amount owed by the manufacturer of a Part D rebatable drug to clarify that "Total Rebates Owed" are based on converted PDE units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors for an applicable period.

Response: CMS thanks the commenter for their feedback but disagrees with this recommendation. Consistent with the statute, to calculate the total rebate owed by a manufacturer for a Part D rebatable drug, CMS will use the total number of units of the Part D rebatable drug dispensed under Part D and covered by Plan D plan sponsors during the applicable period. As described in section 40.2.5 of the revised guidance, the unit type used to determine the quantity dispensed for each NDC is not reported on the PDE record, but this information is available in drug databases such as FDA's NSDE file or Medi-Span. As such, CMS will crosswalk the information from the PDE record to a database that includes the unit type, matching on the NDC of the Part D rebatable drug. CMS understands that in limited instances, the unit type obtained from such drug databases may not match the AMP unit type reported by manufacturers to the Medicaid Drug Programs system, and in these cases, CMS will convert the total units reported on the PDE to the AMP units reported. Because CMS expects these conversions to occur in limited circumstances, CMS is maintaining the language in the initial memorandum in the revised guidance.

D. Revised Guidance on Medicare Part D Drug Inflation Rebate Program

10. Introduction

The purpose of this revised guidance is to provide information to pharmaceutical manufacturers as well as Medicare Part D Prescription Drug Plans (PDPs) and Medicare Advantage – Prescription Drug (MA-PD) plans (hereinafter referred to as Part D plan sponsors) and other interested parties regarding the payment by manufacturers of inflation rebates for the total units of Part D rebatable drugs that are dispensed under Part D and covered by Part D plan sponsors for each 12-month applicable period starting with the applicable period beginning October 1, 2022. An applicable period means a 12-month period beginning with October 1 of a year.

Pharmaceutical manufacturers that increase the price for a Part D rebatable drug faster than the rate of inflation (as measured by changes in the Consumer Price Index for all Urban Consumers, CPI-U), as described in section 1860D-14B of the Act, are required to pay Part D drug inflation rebates to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for Part D rebatable drugs for each 12-month applicable period no later than 30 days after receiving an invoice from CMS.[19] The invoice will be sent no later than nine months after the end of each applicable period, except that CMS has the authority under section 1860D-14B(a)(3) of the Act to delay the timeframe for reporting the information and invoicing rebate amounts to manufacturers for the Part D drug inflation rebates until not later than December 31, 2025, for the first two applicable periods, which began on October 1, 2022 and October 1, 2023. At this time, CMS is not requiring manufacturers to enter into agreements with the Secretary of Health and Human Services (HHS) for the implementation of this program. Pursuant to section 1860D-14B(f) of the Act, there is no administrative or judicial review of determinations of units, the determination of whether a drug is a Part D rebatable drug, and the calculation of the rebate amount.

Section 1860D-14B(h) of the Act directs the Secretary to implement this program for 2022, 2023, and 2024 using program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this revised guidance for implementation of Part D drug inflation rebates for 2022, 2023, and 2024.

In this revised guidance, CMS has clarified and revised policies described in the initial memorandum in response to comments and based on CMS' further consideration of the relevant issues, including policies on which CMS did not expressly solicit comment. This revised guidance describes how CMS will implement the Part D drug inflation rebate provisions and specifies the requirements that will be applicable to manufacturers of Part D rebatable drugs.

If any provision in this revised guidance is held to be invalid or unenforceable, it shall be severable from the remainder of this revised guidance, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances.

[19] "Days" means calendar days unless otherwise specified in this revised guidance.

The table of contents for this revised guidance is as follows:

20. Overview

For each applicable period, manufacturers of Part D rebatable drugs are responsible for paying inflation rebates for each Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during the applicable period, as applicable, no later than 30 days after receiving an invoice for these rebates from CMS. Section 1860D-14B(d) of the Act requires that CMS use information submitted by certain entities in carrying out this section of the IRA. Specifically, the statute requires CMS to use information submitted by manufacturers under section 1927(b)(3) of the Act, by states under section 1927(b)(2)(A) of the Act, and by Part D plan sponsors.

Identification of Part D Rebatable Drugs and Exclusions (see section 30): The statute defines a "Part D rebatable drug" to mean, with respect to an applicable period, a drug or biological that is a covered Part D drug as defined at section 1860D-2(e) of the Act,[20] and that, as of the first day of the applicable period, is a drug approved under section 505(c) of the Federal Food, Drug and Cosmetic Act (FD&C Act), is a biological licensed under section 351 of the Public Health Service Act (PHS Act), or is a generic drug approved under section 505(j) of the FD&C Act that meets certain statutory criteria. A generic drug is only subject to the Part D drug inflation rebate if it is a

[20] The term "covered Part D drug" is also defined at 42 C.F.R. § 423.100.

sole source generic, as further described in section 30. CMS notes that multi-source generic drugs are not subject to the Part D Drug Inflation Rebate Program.

The statute excludes from the definition of a "Part D rebatable drug" a drug or biological if the average annual total cost under Part D per individual that uses the drug is less than $100 for the applicable period beginning October 1, 2022. The $100 amount is increased by percentage increases in the applicable period CPI-U for subsequent applicable periods, as described below.[21]

Components of the Part D Drug Inflation Rebate Calculation (see section 40.1): To calculate the Part D drug inflation rebate amount for Part D rebatable drugs, CMS will use the average manufacturer price (AMP)[22] data reported by manufacturers under sections 1927(b)(3)(A)(i) and (ii) of the Act, units data that are reported by manufacturers each month under section 1927(b)(3)(A)(iv) of the Act, and Prescription Drug Event (PDE) data for the total units of the drug dispensed under Part D and covered by Part D plan sponsors during the applicable period, as reported to CMS by Part D plan sponsors.

Steps to Calculate the Part D Drug Inflation Rebate Amount (see section 40.2): CMS will calculate the rebate amount to be paid by the manufacturer for each Part D rebatable drug for an applicable period as the estimated amount equal to the product of two factors.[23] One factor in this rebate calculation is the amount by which the drug's "annual manufacturer price" (AnMP) for the applicable period (defined at section 1860D-14B(b)(2) of the Act and described in section 40.1 of this revised guidance) *exceeds* the "inflation-adjusted payment amount" for the drug (defined at section 1860D-14B(b)(3) of the Act and described in section 40.1 of this revised guidance). The second factor in the rebate calculation is the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during the applicable period.

The AnMP is a multiple calendar quarter-weighted calculation based on the AMP for the Part D rebatable drug and the units of the drug sold in those calendar quarters as reported by manufacturers under section 1927(b)(3) of the Act. The AnMP is the applicable period's weighted average price paid to a manufacturer by wholesalers for sales of the drug to retail community pharmacies, as well as such pharmacies that purchase drugs directly from manufacturers, consistent with the definition of AMP in section 1927(k)(1) of the Act.

The "inflation-adjusted payment amount" for a Part D rebatable drug for an applicable period is the "benchmark period manufacturer price" of the drug increased by the percentage by which the

[21] The "CPI-U" means the consumer price index for all urban consumers (United States city average) as published by the Bureau of Labor Statistics (https://www.bls.gov/). See section 1860D-14B(g)(5).

[22] Section 1860D-14(g)(6) of the Act defines AMP to have the meaning, with respect to a Part D rebatable drug of a manufacturer, given in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. Pursuant to section 1927(k)(1) of the Act, AMP means, with respect to a covered outpatient drug of a manufacturer for a rebate period (calendar quarter), the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer.

[23] This calculation is subject to the statutory provisions addressing actual and likely shortages and severe supply chain disruptions, special treatment for new formulations, and reconciliation in the case of revised information. See sections 1860D-14B(b)(1)(A), (b)(1)(C), (b)(5)(B), and (b)(6) of the Act.

applicable period CPI-U *exceeds* the benchmark period CPI-U.[24] The benchmark period manufacturer price for a Part D rebatable drug is also a multiple calendar quarter weighted average calculation, based on the AMP for the drug and the units sold of the drug in those calendar quarters. For Part D rebatable drugs first approved or licensed by the Food and Drug Administration (FDA) on or before October 1, 2021, the time period for establishing the benchmark period manufacturer price is the first three calendar quarters of 2021 (i.e., January through September 2021).

CMS will determine the total number of units based on information reported to CMS by Part D plan sponsors on the Part D PDE records for the 12-month applicable period. Beginning in 2026, the statute requires that Part D units that are subject to discounts under section 340B of the PHS Act, also known as the 340B Drug Pricing Program, be excluded from the total Part D units considered for purposes of calculating the Part D drug inflation rebates. The statute does not require the exclusion of such 340B units from Part D rebatable drug units before this time, that is, in advance of 2026.

Treatment of Subsequently Approved Part D Rebatable Drugs (see section 40.3): For Part D rebatable drugs that are first approved or licensed by FDA after October 1, 2021, the statute under section 1860D-14B(b)(5)(A) provides for the establishment of a different payment amount benchmark period and benchmark period CPI-U than for Part D rebatable drugs first approved or licensed on or before October 1, 2021.

Treatment of New Formulations of Part D Rebatable Drugs (see section 40.4): Under section 1860D-14B(b)(5)(B), in the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, CMS is required to establish a formula to determine the rebate amount and the inflation-adjusted payment amount with respect to each such Part D rebatable drug and an applicable period consistent with the formula applied under section 1927(c)(2)(C) of the Act for a rebate period.[25]

Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage, in Cases of Severe Supply Chain Disruptions, and Where Without Such Reduction a Generic Part D Rebatable Drug is Likely to be in Shortage in a Subsequent Applicable Period (see section 40.5): The statute requires CMS to reduce or waive the rebate amount with respect to a Part D rebatable drug for an applicable period in three cases: (1) for a Part D rebatable drug that is described as currently in shortage on an FDA drug shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; (2) for a generic Part D rebatable drug or biosimilar when CMS

[24] "Benchmark Period CPI-U" means the consumer price index for all urban consumers for January 2021. See section 1860D-14(g)(4).

[25] "Line Extension" is defined in statute at section 1860D-14B(b)(5)(B)(ii) of the Act to mean, "with respect to a Part D rebatable drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation." The same statutory term and definition of "line extension" are in section 1927(c)(2)(C) of the Act and further defined in [Medicaid] regulation at 42 C.F.R. § 447.502, to mean, "for a drug, a new formulation of the drug, but does not include an abuse deterrent formulation of the drug (as determined by the Secretary)." "New formulation" is also defined at 42 C.F.R. § 447.502, to mean, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event; and (3) for a generic Part D rebatable drug when CMS determines that without such a reduction or waiver in the rebate, the drug is likely to be described as in shortage on the FDA drug shortage list during a subsequent applicable period. CMS notes that multi-source generic drugs are not subject to the inflation rebate program.

Process for Rebate Reports and Suggestion of Calculation Error (see section 50.1): Under section 1860D-14B(a) of Act, no later than nine months after the end of each applicable period, CMS must report to each manufacturer of a Part D rebatable drug the following information for an applicable period: (1) the amount, if any, of the excess of the AnMP for the Part D rebatable drug for the applicable period; and, (2) the rebate amount for the Part D rebatable drug for the applicable period. CMS will first issue a Preliminary Rebate Report with the information reported to the manufacturer, followed by a Rebate Report (which serves as the invoice to manufacturers for the rebate amount due). Manufacturers of Part D rebatable drugs may provide CMS with a Suggestion of Calculation Error identified by the manufacturer in CMS' Preliminary Rebate Report if the manufacturer believes in good faith that there is a mathematical calculation error to be corrected before the Rebate Report is finalized. Manufacturers should notify CMS, share the Suggestion of Calculation Error, and provide supporting documentation (if applicable) within 10 calendar days of receiving a Preliminary Rebate Report. CMS reserves discretion to consider these suggestions as appropriate.

Rebate Reports for the Applicable Period Beginning October 1, 2022, and the Applicable Period Beginning October 1, 2023 (see section 50.2): The statute provides CMS a transition period for invoicing manufacturers for each Part D rebatable drug for the first two applicable periods (October 1, 2022 through September 30, 2023, and October 1, 2023 through September 30, 2024) until not later than December 31, 2025. The Rebate Reports for these applicable periods will be issued no later than December 31, 2025, and will include an extended Suggestion of Calculation Error period of 30 calendar days. Beginning with the applicable period beginning on October 1, 2024, the Rebate Report invoicing cycle as described in section 50 of this revised guidance will apply.

Enforcement of Rebate Amount Payments by Manufacturers (see section 60): Manufacturers that do not pay the Medicare Part D inflation rebate amount owed for an applicable period for a Part D rebatable drug may be subject to a Civil Monetary Penalty (CMP) equal to 125 percent of the rebate amount, in addition to the rebate amount due under section 1860D-14B(b) of the Act, for such drug for such applicable period.

Formulas (see section 70): Formulas and example calculations are set forth to illustrate the Part D drug inflation rebate calculations for various sections of this revised guidance.

To allow for public input, CMS solicited comments on the various topics addressed in the initial memorandum, including:

- Options to bill manufacturers in the future for Part D drug inflation rebates for Part D rebatable drugs of manufacturers that do not have an agreement in effect with the

Secretary under the Medicaid Drug Rebate Program (MDRP), as well as Part D rebatable drugs that are not covered outpatient drugs (CODs) under the MDRP (section 30.1);
- Options to identify the Part D rebatable drug billing units on the prescription claim and PDE file to assure that manufacturers are being accurately billed for Part D drug inflation rebates (section 40.2.5);
- Options for methods to identify 340B units to exclude them from Part D rebatable drug units beginning in 2026 (section 40.2.7);
- Processes to address reduction or waiver in rebates for drug shortages and severe supply chain disruptions (section 40.5);
- Mechanisms to ensure integrity of the Part D drug inflation rebate invoicing process, including the use of Preliminary Rebate Reports and Preliminary True-Up Reports (section 50); and
- Process to impose CMPs on manufacturers that fail to pay rebates (section 60).

30. Identification of Part D Rebatable Drugs and Exclusions

Section 1860D-14B(g)(1)(A) of the Act defines a "Part D rebatable drug," in part, as a drug or biological described at section 1860D-14B(g)(1)(C) that is a "covered Part D drug" as that term is defined in section 1860D-2(e) of the Act. A drug or biological described in section 1860D-14B(g)(1)(C) means a drug or biological that, as of the first day of the applicable period involved is: (1) a drug approved under a New Drug Application (NDA) under section 505(c) of the FD&C Act; (2) a drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act that meets the criteria in section 1860D-14B(g)(1)(C)(ii), as described below; or (3) a biological licensed under section 351 of the PHS Act.

In general, the statute excludes multi-source generic drugs from the definition of a Part D rebatable drug. Specifically, section 1860D-14B(g)(1)(C)(ii) of the Act narrows the scope of Part D rebatable drugs approved under a 505(j) ANDA (i.e., generic Part D rebatable drugs) that may be subject to a Part D drug inflation rebate to certain cases where: (1) the reference listed drug approved under section 505(c) of the FD&C Act, including any "authorized generic drug" (as that term is defined in section 505(t)(3) of the FD&C Act), is not being marketed, as identified in FDA's National Drug Code (NDC) Directory; (2) there is no other drug approved under section 505(j) of the FD&C Act that is rated as therapeutically equivalent (in FDA's Orange Book) and that is being marketed, as identified in FDA's NDC Directory; (3) the manufacturer is not a "first applicant" during the "180-day exclusivity period," as those terms are defined in section 505(j)(5)(B)(iv) of the FD&C Act; and (4) the manufacturer is not a "first approved applicant" for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v) of the FD&C Act. Generic drugs that meet these four criteria in section 1860D-14B(g)(1)(C)(ii) of the Act are referred to as sole source generic drugs throughout this revised guidance.

In order to evaluate whether a drug approved under a section 505(j) application would meet all of these criteria, CMS will use FDA's NDC Directory, FDA's Orange Book, and other sources to obtain the necessary information.[26] For example, with respect to identifying whether the reference

[26] NDC Directory: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory. FDA Orange Book: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

listed drug or an authorized generic of the reference listed drug is being marketed, CMS will rely on information included in FDA's NDC Directory, in accordance with section 1860D-14B(g)(1)(C)(ii)(I). CMS will also rely upon information included in the NDC Directory, as well as the Orange Book, to determine whether another drug has been approved under a 505(j) ANDA that is therapeutically equivalent to the generic Part D rebatable drug and is being marketed, in accordance with section 1860D-14B(g)(1)(C)(ii)(II). To determine whether the manufacturer of the generic drug is a first applicant during the 180-day exclusivity period, or whether the manufacturer of the generic drug is a first approved applicant for a competitive generic drug therapy, CMS will refer to FDA website resources such as the Orange Book and may consult with FDA for technical assistance as needed. CMS will determine whether a generic drug that is a covered Part D drug meets the definition of a Part D rebatable drug based on the status of the drug on the first day of the applicable period.

CMS understands that a generic drug that meets the definition of a Part D rebatable drug in section 1860D-14B(g)(1)(C)(ii) on the first day of an applicable period could become non-rebatable during that applicable period if, for example, FDA approves another therapeutically equivalent generic drug under a 505(j) ANDA and that generic drug is marketed during that applicable period. CMS will use FDA's Orange Book and NDC Directory to determine whether a generic drug that met the definition of a Part D rebatable drug on the first day of the applicable period continued to meet that definition for the duration of the applicable period. Section 40.2.8 of this revised guidance discusses how CMS will calculate Part D drug inflation rebates for a generic drug that meets the definition of a Part D rebatable drug under section 1860D-14B(g)(1)(C)(ii) of the Act on the first day of the applicable period but ceases to meet the definition during that same applicable period.

30.1 Exclusion of Application of Inflation Rebates to Part D Rebatable Drugs Marketed by Manufacturers Without a Section 1927 Agreement in Effect with the Secretary of HHS and that Do Not Meet the Definition of Covered Outpatient Drug (COD)

Section 1860D–14B(d)(1) specifies sources of information CMS shall use in carrying out the statutory section for Part D drug inflation rebates. One identified source of information that CMS must use is information submitted by manufacturers under section 1927(b)(3) of the Act. Manufacturers are required to submit price and drug product information under section 1927 of the Act and their effectuated agreements with the Secretary of HHS to participate in the MDRP.[27] The Part D drug inflation rebate calculation will use data that manufacturers report under the MDRP, including the AMP data reported under section 1927 of the Act for a drug, and the total number of units of the drug that are reported each month and used to calculate the monthly AMP. Manufacturers report these data to CMS for each COD, as defined in section 1927(k)(2)-(4) of the Act, dispensed and paid for under the state plan.

[27] Under the Medicaid Program, states may provide coverage of outpatient drugs as part of the medical assistance furnished to eligible individuals as an optional benefit as described in sections 1902(a)(10) and (a)(54) and 1905(a)(12) of Act. Section 1903(a) provides for federal financial participation (FFP) in state expenditures for these drugs. In general, for Medicaid or Medicare Part B payment to be made available for a COD, a manufacturer must enter into, and have in effect, a Medicaid National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services (HHS) as set forth in section 1927(a) of the Act. Additionally, in order to

Not every drug that may satisfy the definition of a Part D rebatable drug is marketed by a manufacturer that has an MDRP agreement in effect with the Secretary. As a result, information may not be reported under section 1927 of the Act for all Part D rebatable drugs, and thus may not be available to CMS for purposes of calculating Part D drug inflation rebates under section 1860D-14B. Said differently, in cases where a Part D rebatable drug is marketed by a manufacturer that does not have an obligation to report pricing and drug product data under section 1927(b)(3) of the Act because it does not have an MDRP agreement currently in effect, the manufacturer does not currently report information needed for CMS to be able to calculate Part D drug inflation rebates. Therefore, due to this operational issue, at this time, CMS intends that the Part D rebatable drugs of a manufacturer that does not have an agreement in effect with the Secretary under the MDRP would not be subject to Part D drug inflation rebates. CMS is continuing to assess other means to collect the needed information to subject the Part D rebatable drugs of such manufacturers to the required Part D drug inflation rebates.

In addition, certain drugs and biologicals are specifically excluded from the definition of COD under sections 1927(k)(2)(B) and (k)(3) of the Act.[28] For example, vaccines are expressly excluded from the COD definition, and manufacturers with effectuated agreements participating in the MDRP are not required to report pricing and drug product information for such products. As a result, such products will be excluded from Part D drug inflation rebate calculations at this time.

Under either situation described above, because reporting of manufacturer data does not currently occur, and thus the information required to calculate Part D drug inflation rebates is not available, no rebate amounts will be calculated for these Part D rebatable drugs and no rebates will be collected for the applicable period at this time. CMS will monitor how these exclusions from Part D drug inflation rebates may impact manufacturer behavior and may revisit this exclusion in the future.

30.2. Exclusion of Drugs Where Average Annual Total Cost Under Part D Is Less than $100 per Individual Using Such Drug per Year Adjusted by Changes in the CPI-U

The statute at section 1860D-14B(g)(1)(B) of the Act requires that the definition of a Part D rebatable drug not include a drug or biological if the "average annual total cost" under Part D for such period per individual who uses such a drug or biological, as determined by the Secretary, is less than $100 per year, as determined by the Secretary using the most recent data available, or, if data are not available, as estimated by the Secretary. The statute provides that the $100 annual amount for the applicable period beginning October 1, 2022 is to be increased by percentage changes in the CPI-U for subsequent applicable periods, as described below.

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meet the requirement for a rebate agreement in section 1927(a), manufacturers must also meet the requirements of section 1927(a)(5), which require a manufacturer to enter into an agreement that meets the requirements of section 340B of the PHS Act, as well as section 1927(a)(6) of the Act, which requires a manufacturer to enter into a master agreement with the Secretary of Veterans Affairs in compliance with 38 U.S.C. 8126 (see section 1927(a)(1)).

[28] The definition of COD does not include, based on the limiting definition at section 1927(k)(3) of the Act, a covered outpatient drug in situations where the COD is provided as part of, or as incident to and in the same setting, and for which payment may be made under title XIX, as part of payment for certain services, and not as direct reimbursement for the drug. Additionally, if a COD is not used for a medically accepted indication, it is not a COD.

For purposes of this exclusion, the calculation of the statutory threshold will be calculated as follows:

- For the applicable period beginning October 1, 2022, the statutory threshold is $100;
- For the applicable period beginning October 1, 2023, the statutory threshold is the 2022 threshold amount (*i.e.*, $100) increased by the percentage increase in CPI-U for the 12-month period beginning October 1, 2023, in accordance with section 1860D-14B(g)(1)(B)(ii)(I). That is, the $100 amount will be increased by the percentage increase in CPI-U to October 2024 from the CPI-U for October 2023. If the resulting amount is not a multiple of $10, CMS will round that amount to the nearest multiple of $10 as set forth at section 1860D-14B(g)(1)(B) to determine the 2023 threshold amount, as required by the statute.[29]
- For subsequent applicable periods, the statutory threshold is the inflation-adjusted threshold for the prior year (that is, the amount before CMS applied rounding, if applicable) increased by the percentage increase in the CPI-U for the 12-month period beginning with October of the previous period, in accordance with section 1860D-14B(g)(1)(B)(ii)(II). If the resulting amount is not a multiple of $10, CMS would round that amount to the nearest multiple of $10 as set forth at section 1860D-14B(g)(1)(B) to determine the applicable threshold for that subsequent year.

Formulas of these calculations are below, and an example calculation is provided in section 70.1 of this revised guidance:

> Threshold for applicable period beginning October 1, 2022 = $100
>
> Threshold for applicable period beginning October 1, 2023 = $100 (October 1, 2022 statutory threshold) *multiplied by* (October 2024 CPI-U/October 2023 CPI-U) (apply rounding to the nearest multiple of $10)
>
> Threshold for applicable period beginning October 1, 2024 = Unrounded October 1, 2023 calculated threshold *multiplied by* (October 2024 CPI-U/October 2023 CPI-U) (apply rounding to the nearest multiple of $10)
>
> Threshold for applicable period beginning October 1, 2025 = Unrounded October 1, 2024 calculated threshold *multiplied by* (October 2025 CPI-U/October 2024 CPI-U) (apply rounding to the nearest multiple of $10)

CMS is defining "individual who uses such a drug or biological" as each unique Medicare Part D beneficiary who was dispensed the Part D rebatable drug that was covered by a Part D plan sponsor during the applicable period. CMS will use PDE data with total gross covered drug costs greater than zero to identify all such Part D Medicare beneficiaries and determine the number of individuals who used such drug or biological during the applicable period.

CMS will calculate the average annual total cost based on total gross covered drug costs for the

[29] CMS will round any amount less than $5 over a multiple of $10 down to that multiple of $10, and any amount $5 or more over a multiple of $10 up to the next multiple of $10.

Part D rebatable drug at the NDC-9 level. CMS will divide the total gross covered drug costs for the drug by the number of unique Part D beneficiaries as described above that were dispensed the drug in that applicable period. For this calculation, CMS will use PDE data with total gross covered drug costs greater than zero that are available for the drug with dates of service during that applicable period. Drugs that are determined to have average annual total costs under Part D of less than $100 per individual using such drug per year, adjusted by changes in the CPI-U, will be excluded from Part D drug inflation rebate calculations for the applicable period in question.

40. Calculation of the Medicare Part D Drug Inflation Rebate Amount

The Part D drug inflation rebate amount, as specified under section 1860D-14B(b) of the Act, for each Part D rebatable drug and applicable period is the estimated amount that is equal to the product of: (1) the total number of units of the Part D rebatable drug dispensed under Part D and covered and paid by Part D plan sponsors during the applicable period; and, (2) the amount, if any, by which the AnMP for such Part D rebatable drug for the applicable period *exceeds* the inflation-adjusted payment amount for the Part D rebatable drug for the applicable period, subject to certain considerations.[30] The formulas and calculations for determining Part D drug inflation rebate amounts are further described in the following sections, and section 70 of this revised guidance provides examples of these calculations.[31]

The AnMP is the applicable period's weighted average price paid to a manufacturer by wholesalers for sales of the drug to retail community pharmacies, as well as such pharmacies that purchase drugs directly from manufacturers, consistent with the definition of AMP in section 1927(k)(1) of the Act, and is calculated based on the statutory formula that defines AnMP as the sum of the products of: (1) the AMP for the Part D rebatable drug for each quarter of an applicable period; and (2) the total number of units of such drug reported by the manufacturer under section 1927(b)(3)(A)(iv) of the Act for each such calendar quarter of such period *divided* by the total number of units of such drug reported under section 1927(b)(3)(A)(iv) of the Act with respect to the four calendar quarters in such applicable period.

The inflation-adjusted payment amount for a Part D rebatable drug for an applicable period is determined by increasing the benchmark period manufacturer price by the percentage by which the applicable period CPI-U, which is the CPI-U for the October month of the applicable period, exceeds the benchmark period CPI-U, which for drugs first approved or licensed on or before October 1, 2021, is the CPI-U for January 2021, and for drugs first approved or licensed after October 1, 2021, is the January CPI-U of the first calendar year beginning after the drug is first marketed. The statute defines the applicable period CPI-U at section 1860D-14B(g)(5) to mean, with respect to an applicable period, the consumer price index for all urban consumers for the first month of such applicable period.

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[30] As noted elsewhere, this calculation is subject to the statutory provisions addressing shortages and severe supply chain disruptions, special treatment for new formulations, and reconciliation in the case of revised information. See sections 1860D- 14B(b)(1)(A), (b)(1)(C), (b)(5)(B), and (b)(6). "Rebate Amount" is expressly defined in section 1860D-14B(b) and is the estimated amount due to CMS from a manufacturer for the Part D rebatable drug(s) for an applicable period, as applicable.

[31] CMS will not round values as part of the calculation steps described in section 40. The invoice amount due (describe in section 50) will be rounded to the nearest cent.

The benchmark period manufacturer price for a Part D rebatable drug is also a weighted average price calculated for a specific period in time, using a methodology similar to that used to calculate the AnMP for the Part D rebatable drug. The benchmark period manufacturer price is determined using the AMP for the drug and the units sold of the drug reported by the manufacturer under section 1927(b)(3)(A)(iv) of the Act for the relevant calendar quarters in the benchmark period.

40.1 Components of the Medicare Part D Drug Inflation Rebate Amount Calculation

Section 1860D-14B(a)(1) of the Act requires that CMS report to each manufacturer for each Part D rebatable drug and applicable period the following information, not later than nine months after the end of each applicable period: (1) the amount, if any, by which the AnMP of a Part D rebatable drug exceeded the inflation-adjusted payment amount; and (2) the rebate amount for each Part D rebatable drug for the applicable period.

To determine the amount by which the AnMP for a Part D rebatable drug exceeds the inflation-adjusted payment amount, CMS will increase the benchmark period manufacturer price by the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U, as illustrated below.

The primary data elements that will be used to calculate the Part D drug inflation rebates are AMP data reported under sections 1927(b)(3)(A)(i) and (ii) of the Act by manufacturers for the Part D rebatable drug, units data that are reported by manufacturers each month under section 1927(b)(3)(A)(iv) of the Act for the drug, and PDE data for the total units of the drug dispensed under Part D and covered by Part D plan sponsors during the applicable period, as reported to CMS by Part D plan sponsors. Section 70 of this revised guidance further describes how each factor in the rebate amount calculation will be determined.

40.1.1 Units Used for Determination of the AnMP and Benchmark Period Manufacturer Price

Under section 1927(b)(3)(A)(iv) of the Act, manufacturers report the total number of units used to calculate a COD's monthly AMP. The total units used for each quarter to calculate components of the AnMP and benchmark period manufacturer price will be the sum of the three months of units for the drug reported by the manufacturer. These manufacturer-reported AMP units represent the total units of a drug sold by the manufacturer each month to retail community pharmacy and wholesaler purchasers as described under section 1927(k)(1)(A) of the Act. Manufacturers may include under certain circumstances non-retail community pharmacy sales units in the calculation of their AMPs for 5i drugs.[32] The quarterly units would be calculated as:

[32] 5i drugs are CODs that are inhaled, infused, instilled, implanted, or injected. Manufacturers are instructed to calculate the AMP for 5i drugs that are not generally dispensed through an RCP using the methodology described at 42 C.F.R. §§ 447.504(d) and (e). 42 C.F.R. § 447.507(b)(1) provides that a 5i drug is not generally dispensed through an RCP if 70 percent or more of the sales (based on units at the NDC-9 level) of the 5i drug, were to entities other than RCPs or wholesalers for drugs distributed to RCPs.

Q1 quarterly units = month 1 units + month 2 units + month 3 units
Q2 quarterly units = month 4 units + month 5 units + month 6 units
Q3 quarterly units = month 7 units + month 8 units + month 9 units
Q4 quarterly units = month 10 units + month 11 units + month 12 units

See section 70.3 for an example of the calculation of quarterly units.

CMS believes that the manufacturer-reported monthly AMP units under section 1927(b)(3)(A)(iv) are the appropriate units to use in the calculation of the AnMP and the benchmark period manufacturer price for the Part D drug inflation rebates because using the total units sold by the manufacturer for the Part D rebatable drug as reported will allow for the accurate calculation of both the AnMP, as well as a benchmark period manufacturer price, as prescribed by the statute. CMS will not use the Medicaid units reported by states under section 1927(b)(2)(A) because these Medicaid units reported by the state only reflect units of the COD dispensed for which payment was made under the Medicaid state plan during the applicable calendar quarter, and not the total units of the drug sold by manufacturers to retail community pharmacy and wholesaler purchasers, which the manufacturer uses to calculate the AMP that is reported to CMS.

40.1.2 Situations in Which Manufacturers Do Not Report Units

It is possible that a manufacturer may not have sales or monthly units of a COD to report to the Medicaid Drug Programs system for a calendar quarter. This may occur because there may be a temporary interruption in sales of the COD, or there may be no sales immediately after the drug is first approved or licensed by FDA. In cases where there is a temporary interruption in sales because of a supply chain disruption or manufacturing issue, and the manufacturer has not been terminated from the MDRP such that the drug is no longer in the MDRP, under MDRP guidance, the manufacturer can report the prior quarter's AMP using reasonable assumptions. When there may not yet be any sales for a quarter following a drug's approval or licensure, MDRP guidance also allows a manufacturer to make reasonable assumptions for the quarter with respect to reporting AMP for the drug.[33] However, no monthly units would be reported for such quarters. Additionally, if a manufacturer enters a termination date on a COD in the MDRP, the Medicaid Drug Programs system automatically populates the next four quarters with the last AMP reported by the manufacturer for the drug, meaning that the manufacturer may not have units to report for quarters following termination. For these reasons, one or more quarter(s) of a payment amount benchmark period or applicable period may have an AMP value(s), but no associated units reported to the Medicaid Drug Programs system.

[33] As noted in CMCS Manufacturer Release No. 78, dated June 26, 2007, and in regulation preamble (see Medicaid Program; Covered Outpatient Drugs Final Rule with Comment Period, 81 Fed. Reg. 5170 (CMS 2345-FC), February 1, 2016), in the absence of specific guidance, a manufacturer may make "reasonable assumptions" when reporting drug pricing and drug product data to CMS, provided that those assumptions are consistent with the requirements and intent of the Medicaid statute, federal regulations, the Medicaid National Drug Rebate Agreement (NDRA), and any relevant guidance issued by CMS. As noted in that Manufacturer Release, CMS requests that manufacturers not submit their reasonable assumptions to CMS, and should a manufacturer disregard those instructions and submit their assumptions, they will not be reviewed, and neither their receipt nor any subsequent inaction by CMS constitutes acquiescence by CMS to the submitted assumptions. Manufacturers must retain a record (written or electronic) outlining reasonable assumptions used in required reporting under the program as provided in the recordkeeping requirements at 42 C.F.R. § 447.510(f).

In these instances, when one or more quarter(s) of a payment amount benchmark period or applicable period has an AMP value(s) but no associated units reported to the Medicaid Drug Programs system, CMS will use the following policies to calculate the benchmark period manufacturer price or AnMP, as applicable:

- If there is one or more quarter(s) in the payment amount benchmark period or applicable period that has an AMP value(s) and no associated units, but at least one quarter has both an AMP value and units, CMS will calculate the benchmark period manufacturer price or AnMP, respectively, using data only from quarter(s) with units. That is, quarter(s) without units will be excluded from the calculation.
- If there are no units reported for any quarters of the payment amount benchmark period or applicable period, but there are reported AMP values, CMS will average the AMP values over the calendar quarters of the payment amount benchmark period or applicable period to calculate the benchmark period manufacturer price or AnMP, respectively.

These policies will apply to all Part D rebatable drugs, including Part D rebatable drugs treated as subsequently approved drugs.

In the case of a Part D rebatable drug approved or licensed on or before October 1, 2021 that is not marketed until after that date and thus does not have AMP or AMP units reported for any calendar quarters from January 1, 2021 through September 30, 2021, CMS will treat such drugs in the same manner as it will treat subsequently approved drugs for the purposes of establishing the payment amount benchmark period, benchmark period CPI-U, first applicable period, and applicable period CPI-U (see section 40.2.2 of this revised guidance). For example, for a drug approved in August 2021 that is not marketed until November 2021, the payment amount benchmark period will be the entire next calendar year, 2022, and the benchmark period manufacturer price will be determined using the AMP data reported for that payment amount benchmark period.

40.2 Steps to Calculate the Medicare Part D Drug Inflation Rebate Amount

The rebate amount for which a manufacturer will be invoiced with respect to each Part D rebatable drug will be determined based on the factors and steps described below.

40.2.1 Calculation of AnMP

In accordance with section 1860D-14B(b)(2) of the Act, CMS will calculate the AnMP for a Part D rebatable drug for an applicable period as the sum of the products of: (1) the AMP for the drug, as calculated by the manufacturer for a unit of such drug and reported to CMS by the manufacturer to the Medicaid Drug Programs system, for each calendar quarter of the applicable period; and, (2) the ratio of the total units reported by the manufacturer under section 1927(b)(3)(A)(iv) of the Act for the drug for each calendar quarter of the applicable period to the total number of units of the drug for all four calendar quarters in the applicable period.

The formula for the calculation of the AnMP for a Part D rebatable drug is as follows (see formula example in section 70.4 of this revised guidance):

(AMP for calendar quarter beginning October) *multiplied by* (sum of monthly units for October calendar quarter/total units for 12-month applicable period) +
(AMP for calendar quarter beginning January) *multiplied by* (sum of monthly units for January calendar quarter/total units for 12-month applicable period) +
(AMP for calendar quarter beginning April) *multiplied by* (sum of monthly units for April calendar quarter/total units for 12-month applicable period) +
(AMP for calendar quarter beginning July) *multiplied by* (sum of monthly units for July calendar quarter/total units for 12-month applicable period)

40.2.2 Calculation of Benchmark Period Manufacturer Price

CMS will determine the benchmark period manufacturer price for each Part D rebatable drug in accordance with section 1860D-14B(b)(4) of the Act, subject to the considerations set forth in section 1860D-14B(b)(5) of the Act and in this revised guidance. The benchmark period manufacturer price is the price that will be increased by the percentage change in the applicable period CPI-U compared to the benchmark period CPI-U to determine the inflation-adjusted payment amount as described at section 1860D-14B(b)(3) of the Act.

The benchmark period manufacturer price for a Part D rebatable drug will be calculated as the sum of the products of: (1) the AMP of the drug, as calculated for a unit of such drug for each of the calendar quarters of the payment amount benchmark period, and (2) the ratio of the total units reported by the manufacturer under section 1927(b)(3)(A)(iv) of the Act for the drug for each calendar quarter of the payment amount benchmark period to units of the drug for all quarters in the payment amount benchmark period. To the extent that a new NDC-9 of an existing Part D rebatable drug enters the market, CMS will use the benchmark period manufacturer price of the earliest NDC-9 of the Part D rebatable drug consistent with the information the manufacturer reports for the NDC-9 under section 1927(b)(3) of the Act. CMS will use different formulas to determine the benchmark period manufacturer price for Part D rebatable drugs that are first approved or licensed by FDA on or before October 1, 2021, and for Part D rebatable drugs first approved or licensed by FDA after October 1, 2021.[34] (See sections 70.5 and 70.6 of this revised guidance for formulas and examples.)

- Benchmark Period Manufacturer Price for Part D Rebatable Drugs First Approved or Licensed On or Before October 1, 2021: As described above, the benchmark period manufacturer price would be calculated as the sum of the products of: (1) the AMP for the drug for each of the three quarters of 2021 (i.e., January through September) reported by the manufacturer; and (2) the total AMP units reported under section 1927(b)(3)(A)(iv) of the Act for each of the quarters divided by the total units reported for the three quarters. To illustrate, the benchmark period manufacturer price for a Part D rebatable drug first approved or licensed on or before October 1, 2021 would be calculated as follows:

[34] As described in section 40.1.2 of this guidance, in the case of a Part D rebatable drug approved or licensed on or before October 1, 2021 that is not marketed until after that date and thus does not have AMP or AMP units reported for any calendar quarters in the payment amount benchmark period, CMS will treat such drugs in the same manner as it will treat subsequently approved drugs for the purposes of establishing the payment amount benchmark period, benchmark period CPI-U, first applicable period, and applicable period CPI-U.

(AMP for calendar quarter beginning January 2021) *multiplied by* (sum of monthly units for January 2021 calendar quarter/total units for 9-month period of January to September 2021) +
(AMP for calendar quarter beginning April 2021) *multiplied by* (sum of monthly units for April calendar quarter/total units for 9-month period of January to September 2021) +
(AMP for calendar quarter beginning July 2021) *multiplied by* (sum of monthly units for July calendar quarter/total units for 9-month period of January to September 2021)

- Benchmark Period Manufacturer Price for Part D Rebatable Drugs First Approved or Licensed After October 1, 2021: For Part D rebatable drugs first approved or licensed after October 1, 2021, the benchmark period manufacturer price will require a different calculation. (See further discussion in section 40.3 of this revised guidance regarding Treatment of Subsequently Approved Drugs.) CMS will use the four calendar quarters for the entire calendar year (January 1 to December 31) after the drug was first marketed,[35] using the same methods of calculations specified above. That is, the sum of the products of: (1) the AMP for the drug for each calendar quarter in the payment amount benchmark period for the subsequently approved drug; and, (2) the total AMP units reported by the manufacturer under section 1927(b)(3)(A)(iv) of the Act for each of the corresponding quarters in the payment amount benchmark period divided by the total units reported for the four quarters. To illustrate, the benchmark period manufacturer price for a Part D rebatable drug first approved or licensed after October 1, 2021, would be calculated as follows, with each calendar quarter referring to the calendar quarter of the calendar year that begins after the drug's first market date:

  (AMP for calendar quarter beginning January) *multiplied by* (sum of monthly units for January calendar quarter/total units for 12-month period of January to December) +
  (AMP for calendar quarter beginning April) *multiplied by* (sum of monthly units for April calendar quarter/total units for 12-month period of January to December) +
  (AMP for calendar quarter beginning July) *multiplied by* (sum of monthly units for July calendar quarter/total units for 12-month period of January to December) +
  (AMP for calendar quarter beginning October) *multiplied by* (sum of monthly units for October calendar quarter/total units for 12-month period of January to December)

The first applicable period following the payment amount benchmark period for these subsequently approved drugs will begin on October 1 of the year immediately following the payment amount benchmark period and will end on September 30 of the subsequent year, as described in section 40.3 of this revised guidance.

Section 1860D-14B(b)(5)(C) of the Act specifies a different payment amount benchmark period and benchmark period CPI-U for a Part D rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period will be reset as the last year that begins during such price applicability period for such

[35] Note that the date that the drug is first marketed will be the date that the manufacturer reports for the drug as its "market date" to the Medicaid Drug Programs system. See section 40.3 of this revised guidance.

drug, and the benchmark period CPI-U will be the January of the last year beginning during such price applicability period.[36]

40.2.3 Calculation of Inflation-Adjusted Payment Amount

The inflation-adjusted payment amount for a Part D rebatable drug for an applicable period would be the benchmark period manufacturer price determined in section 40.2.2 of this revised guidance for the Part D rebatable drug for an applicable period *increased* by the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U. (See section 70.7 of this revised guidance for a numerical example.)

- Determination of Applicable Period CPI-U: The statute requires that CMS use the CPI-U of the first month of the applicable period; that is, the CPI-U as of October of the applicable period, as the applicable period CPI-U.

- Determination of Benchmark Period CPI-U: The statute requires that CMS use the CPI-U value as of January 2021 as the benchmark period CPI-U except that for drugs first approved or licensed after October 1, 2021, CMS must use as the benchmark period CPI-U the January CPI-U of the calendar year beginning after the day on which the drug is first marketed.[37]

- Calculation of Inflation-Adjusted Payment Amount for Drugs First Approved or Licensed on or Before October 1, 2021: The statute specifies that the inflation-adjusted payment amount for a drug first approved or licensed on or before October 1, 2021 is the benchmark period manufacturer price increased by the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U (i.e., Benchmark Period Manufacturer Price *multiplied by* (CPI-U October applicable period/CPI-U January 2021)).

- Calculation of Inflation-Adjusted Payment Amount for Drugs First Approved or Licensed After October 1, 2021: The statute specifies that the inflation-adjusted payment amount for a drug first approved or licensed after October 1, 2021 is the benchmark period manufacturer price increased by the percentage by which the applicable period CPI-U exceeds the CPI-U for January of the calendar year beginning after the day on which the drug is first marketed (i.e., Benchmark Period Manufacturer Price *multiplied by* (CPI-U October applicable period/CPI-U January of year after drug is first marketed)).

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[36] See also: Section 120 of CMS' June 30, 2023 memorandum titled, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[37] As described in section 40.1.2 of this guidance, for Part D rebatable drugs approved on or before October 1, 2021 but not marketed until after that date, CMS will use the January CPI-U of the calendar year beginning after the day on which the drug is first marketed.

40.2.4 Calculation of the per Unit Part D Drug Inflation Rebate Amount

The statutory formula at section 1860D-14B(b) for the Part D drug inflation rebate amount indicates, in part, that the per unit rebate amount is the amount, if any, by which the AnMP for a Part D rebatable drug for the applicable period *exceeds* the inflation-adjusted payment amount for the Part D rebatable drug for the period.

In this regard, the actual per unit rebate amount for a Part D rebatable drug is the amount, if any, by which the AnMP for such Part D rebatable drug for the applicable period calculated under section 40.2.1 of this revised guidance *exceeds* the inflation-adjusted payment amount for the Part D rebatable drug calculated under section 40.2.3 of this revised guidance. (See section 70.7 of this revised guidance for a numerical example.)

40.2.5 Use of PDE Data to Determine Total Units Subject to Rebate and Crosswalk to AMP Units

Section 1860D-14B(g)(2) of the Act defines "unit" as the lowest dispensable amount (such as tablet or capsule, milligram of molecules, or grams) of a Part D rebatable drug, as reported under section 1927(b)(3) of the Act. Part D PDE data with total gross covered prescription drug costs greater than zero will be used to determine the total number of units of the Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during each 12-month applicable period for the inflation rebate calculation.

From the PDE data, CMS will obtain the total number of units from the field "Quantity Dispensed" for each Part D rebatable drug, and the NDC of the drug from the field "Product Service ID" for each 12-month applicable period. Units reported in the Quantity Dispensed field on the PDE record are industry standard National Council for Prescription Drug Programs (NCPDP) defined values of each, milliliter, and grams. The unit type used to determine Quantity Dispensed for each NDC is not reported on the PDE record, but this information is available in drug databases such as FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Element File (NSDE) file and Medi-Span. To identify the NCPDP billing unit for each NDC, CMS will crosswalk the information from the PDE record to a database (such as FDA's NSDE file or Medi-Span) that includes the unit type, matching on the NDC of the Part D rebatable drug.

In contrast to how units are reported on the PDE by Part D plans and MA-PD plans, manufacturers can report the AMP for their drugs in the Medicaid Drug Programs system with 10 different unit types (i.e., each, capsule, tablet, suppository, transdermal patch, injectable anti-hemophilic factor, millicurie, microcurie, gram, and milliliter). Given the difference in how units are reported between the two programs, to determine units for purposes of calculating Part D drug inflation rebates, CMS will compare the Part D rebatable drug units reported for the drug in the PDE record to the units reported for the drug in the Medicaid Drug Programs system for the monthly AMP. Based on CMS' initial analyses comparing NCPDP billing units in the PDE data to the AMP units reported to the Medicaid Drug Programs system, CMS expects that in most cases, units of the Part D rebatable drug reported in the PDE record will match the AMP units reported in the Medicaid Drug Programs system.

However, in the limited instances where the units do not match, CMS will convert the total units

reported in the PDE to the AMP units that are reported by the manufacturer for the drug under section 1927 of the Act. For example, if an NDC is reported as a unit of "each" in the PDE record, and as a unit of "grams" to the Medicaid Drug Programs system, CMS will multiply the unit of "each" times the total "grams" for each unit to convert the PDE units to AMP units. To illustrate, if the product is dispensed in a 10-gram tube and the PDE record has this recorded as a unit of "1" for "each," this will be converted to "10" for purposes of calculating Part D drug inflation rebates to conform to the Medicaid units of "grams" for this product.

At this time, CMS will not add a field to the PDE file layout to collect how the amount reported in the PDE "Quantity Dispensed" field is measured (e.g., each, milliliter, gram). CMS believes that crosswalking the information from the PDE record to a database (such as FDA's NSDE file or Medi-Span) that includes the unit type will provide sufficient information to identify the NCPDP billing unit. CMS will monitor this approach and may implement additional reporting requirements in the future, as needed, to ensure that the unit used to calculate Part D inflation rebates is accurate.

40.2.6 Calculation of Total Rebate Amount to be Paid by Manufacturers

The rebate amount, as specified under section 1860D-14B(b), for a Part D rebatable drug and applicable period, is the estimated amount that is equal to the product of: (1) the total number of units of the Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during the applicable period, as described in section 40.2.5 of this revised guidance; and, (2) the amount, if any, by which the AnMP for such Part D rebatable drug for the applicable period *exceeds* the inflation-adjusted payment amount for the Part D rebatable drug for the period determined under section 40.2.4 of this revised guidance.

The calculation would be: Total Rebates Owed = Total PDE Units of a Part D Rebatable Drug dispensed under Part D and covered by Part D sponsors for an applicable period ***multiplied by*** the Per Unit Rebate Amount. (See section 70.9 for a numerical example).

40.2.7 Exclusion of 340B Acquired Units from Part D Rebatable Drug Requirements

Section 1860D-14B(b)(1)(B) requires that beginning with plan year 2026, CMS must exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Drug Pricing Program. Because this requirement starts after the first quarter of the applicable period that begins in October 2025, CMS will exclude the 340B units starting on January 1, 2026.

The current NCPDP Telecommunications Standard Version D.0 for pharmacy claims does not require a pharmacy to identify which dispensed drugs were purchased at a discount under the 340B program. Although the standard does include a field where a 340B indicator could be provided in a "B1" transaction,[38] it is optional for pharmacies to use, based on agreements with

[38] A pharmacy would use the value of "20" in the Submission Clarification Code (420-DK) field to indicate use of a 340B drug at the time of the adjudication or dispensing of the claim. See: National Council on Prescription Drug Program (NCPDP) 340B Information Exchange Reference Guide Version 2.0, June 2019, https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.

trading partners (e.g., health plans, manufacturers, and state Medicaid agencies). In addition, the standard specifies that the indicator in the "B1" transaction can only be used prospectively, so a pharmacy that makes the retrospective determination that the drug was purchased at or below the 340B ceiling price cannot apply this modifier retrospectively to the claim. The NCPDP does allow use of an "N1" transaction[39] to retrospectively identify drugs purchased under the 340B program, but CMS understands that few pharmacies use this transaction. Consequently, CMS does not currently require or even accept a 340B indicator on the PDE record.

CMS is continuing to evaluate the most reliable way to identify drugs that were purchased at a discount under the 340B program and dispensed by a pharmacy and covered by a Medicare Part D plan. In the initial memorandum, CMS solicited comments on alternative approaches for excluding 340B units and is considering different options prior to finalizing a policy to exclude such units from Part D Rebate Reports by 2026, in accordance with the statute.

40.2.8 Removal of Units When a Generic Drug is No Longer a Part D Rebatable Drug

In general, multi-source generic drugs are not subject to the Part D Drug Inflation Rebate Program, but sole source generic drugs may qualify as a Part D rebatable drug. As described in section 30 of this revised guidance, the statute specifies that generic drugs approved under section 505(j) of the FD&C Act are subject to inflation rebates if they meet the criteria in section 1860D-14B(g)(1)(C)(ii) of the Act as of the first day of the applicable period involved. However, a generic drug that meets the definition of a Part D rebatable drug on the first day of an applicable period could cease to meet the definition during that applicable period if, for example, FDA approves another therapeutically equivalent generic drug under a 505(j) ANDA and that drug is marketed during the applicable period. A generic drug that meets the definition of a Part D rebatable drug on the first day of an applicable period may also cease to meet that definition during that applicable period if the reference listed drug or an authorized generic of the reference listed drug for the generic Part D rebatable drug was previously discontinued and the manufacturer resumes marketing of such drug during the applicable period.

To determine whether a generic drug meets the criteria for rebatability during an applicable period, CMS will use FDA's Orange Book to identify whether FDA has approved a 505(j) ANDA for a drug that is rated as therapeutically equivalent to the generic Part D rebatable drug. If CMS determines that FDA has approved such a therapeutically equivalent generic drug, CMS will then use the NDC Directory to determine the marketing status of such therapeutically equivalent drug and to determine whether, during the applicable period, the therapeutically equivalent drug was marketed. Similarly, CMS will use the NDC Directory to identify whether the reference listed drug, or an authorized generic of the reference listed drug was marketed during the applicable period. CMS will exclude from the rebate calculation any units dispensed on or after the date that a generic drug no longer meets the definition of a Part D rebatable drug.

[39] If it is determined that a 340B drug was dispensed after the claim has been adjudicated, then an N1 transaction can be submitted with the 420-DK submission.

40.3 Treatment of Subsequently Approved Part D Rebatable Drugs

Section 1860D-14B(b)(5)(A) of the Act prescribes a different payment amount benchmark period and benchmark period CPI-U for Part D rebatable drugs first approved or licensed by FDA after October 1, 2021. The date that CMS will use to determine when a drug is first approved or licensed is the FDA Approval Date that the manufacturer reports pursuant to section 1927(b)(3)(A)(v) of the Act. As specified in section 1860D–14B(b)(5)(A), the payment amount benchmark period for drugs first approved or licensed after October 1, 2021 is "the first calendar year beginning after the day on which the drug was first marketed" and the benchmark CPI-U period is "January of the first year beginning after the date on which the drug was first marketed."

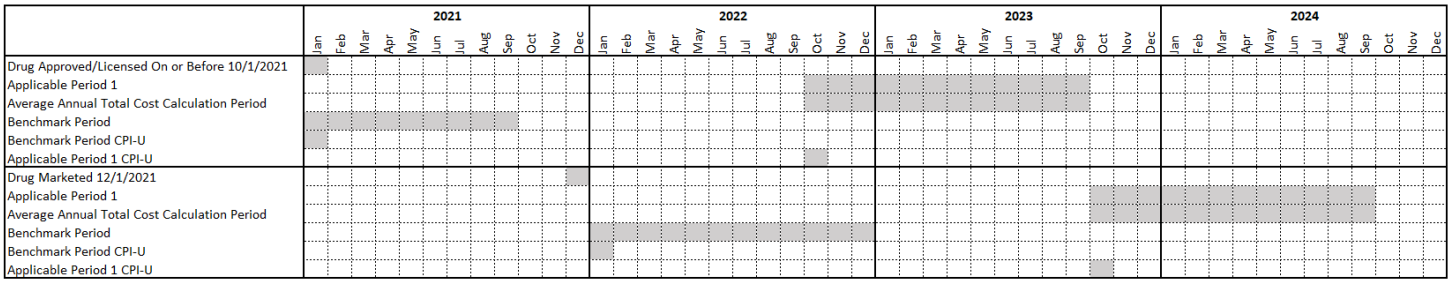
To identify the "first marketed" date, CMS will use the market date that the manufacturer is required to report under section 1927(b)(3)(A)(v) of the Act.[40]

The first applicable period for a subsequently approved drug will begin on October 1 of the year following the payment amount benchmark period. For example, if a manufacturer reports that the market date for a subsequently approved Part D rebatable drug is a date in the month of September 2023, the statute establishes the payment amount benchmark period as the first calendar year beginning after the day the drug is first marketed. The benchmark period manufacturer price for this drug would be established based on the data reported for the payment amount benchmark period, calendar year 2024. The first applicable period would then begin on October 1, 2025. In this example, the AnMP for the Part D rebatable drug for the applicable period would be calculated using the AMP and units reported by the manufacturer under section 1927(b)(3) of the Act for the four quarters of the applicable period: October 1, 2025 through September 30, 2026.

Figure 1 below provides a summary of data timelines for Part D drug inflation rebate calculations. This figure compares the data timeline for a Part D rebatable drug that is first approved or licensed on or before October 1, 2021 (the threshold for whether a drug is considered a subsequently approved drug), and a Part D rebatable drug first approved or licensed after October 1, 2021 and marketed on December 1, 2021.

[40] CMS acknowledges that the agency has proposed to define "market date" at 42 C.F.R. § 447.502 based on the first sale of the drug, rather than the date the drug was first available for sale (see 88 Fed. Reg. 34,238, 34,256 (May 26, 2023)). For the purpose of the Part D Drug Inflation Rebate Program, CMS will use the market date that the manufacturer is required to report under section 1927(b)(3)(A)(v) of the Act, including any changes to this reporting requirement such as if the proposed regulatory definition of "market date" is finalized. CMS acknowledges that this approach may apply a different definition of the first marketing date than would apply with respect to Part B rebatable drugs under section 1847A(i) of the Act but consistent with section 1860D-14B of the Act, it is appropriate to rely on the reporting systems that are already in place under section 1927 of the Act.

Figure 1: Summary of Data Timelines for Part D Drug Inflation Rebate Provisions



Note: An enlarged version of this figure appears in the Appendix.

40.4 Treatment of New Formulations of Part D Rebatable Drugs

The statute at section 1860D-14B(b)(5)(B)(i) requires CMS to determine a formula for both the rebate amount and the inflation-adjusted payment amount for a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form for an applicable period that is consistent with the formula applied in the MDRP at section 1927(c)(2)(C) of the Act for determining a rebate obligation for a rebate period.

Section 1927(c)(2)(C) of the Act provides for an alternative rebate calculation for line extension drugs under the MDRP, and CMS issued guidance on how this calculation is performed for these purposes.[41] Section 1860D-14B(b)(5)(B)(ii) further states that for a Part D rebatable drug, "the term line extension means a new formulation of the drug, such as extended release formulation, but does not include abuse-deterrent formulations of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation." This language is identical to the definition of "line extension" in section 1927(c)(2)(C). Regulatory definitions of "line extension" and "new formulation" were adopted through rulemaking[42] for the MDRP and can be found at 42 C.F.R. § 447.502. CMS will use these definitions for the purposes of identifying new formulations of Part D rebatable drugs.

For purposes of the MDRP, section 1927(c)(2)(C) of the Act sets out an alternative rebate calculation for line extensions of CODs, and to determine whether the alternative rebate calculation applies to a COD, the manufacturer is responsible for determining whether there is one or more CODs that can potentially be the initial COD on which to base the alternative rebate calculation. The manufacturer is required to consider all potential initial CODs for a line extension reported to the MDRP each calendar quarter, and identify in the Medicaid Drug Programs system the single initial COD for the calendar quarter that had the highest additional rebate ratio, which is calculated as the quotient of the inflation rebate amount for the initial drug as a percentage of the initial drug's AMP for the calendar quarter. This rebate ratio is then multiplied by the AMP of the line extension drug.[43] The total rebate amount calculated under

[41] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/unit-rebate-amount-calculation-for-line-extension-drugs-with-example/index.html.
[42] See 85 Fed. Reg. 87,000, 87,101 (December 31, 2020).
[43] In Medicaid, the alternative rebate calculation also includes the basic rebate for a COD, as defined in section 1927(c)(1). No such basic rebate is calculated for Medicare Part D drug inflation rebates.

section 1927(c)(2)(C)(ii) of the Act is compared to the total rebate amount calculated under section 1927(c)(2)(C)(iii) and the higher amount is the applicable rebate for the line extension drug under Medicaid.

To implement this provision for Part D drug inflation rebate purposes for a Part D rebatable line extension drug, consistent with the formulas applied under section 1927(c)(2)(C) of the Act, CMS will use information from the Medicaid Drug Programs system and identify line extensions based on manufacturer reporting of drugs as line extensions and related pricing and product data in that system. The first step in the calculation is to determine the inflation rebate amount for the Part D rebatable line extension drug per the requirements under section 1860D-14B(b).

In the second step, an alternative inflation rebate amount for the Part D rebatable line extension drug will be calculated consistent with the formula applied under section 1927(c)(2)(C) of the Act for line extension drugs under Medicaid. That is, CMS will determine an inflation rebate amount ratio for the initial drug identified by the manufacturer in the last quarter of the Part D inflation rebate applicable period (explained further below) by dividing the inflation rebate amount for that initial drug for the applicable period by the AnMP for that initial drug for the applicable period, as calculated under section 1860D-14B(b). The ratio will then be multiplied by the AnMP of the Part D rebatable line extension drug for the applicable period. (See section 70.10 for an example of the calculation.)

The greater of the two rebate amounts, (1) the *inflation rebate amount* for the applicable period for the Part D rebatable drug calculated under section 1860D-14B(b) for the Part D rebatable line extension drug; or, (2) the *alternative inflation rebate amount* calculated under the alternative rebate formula consistent with section 1927(c)(2)(C), will be used as the per unit rebate amount for the Part D rebatable line extension drug. That amount will then be used to calculate the total rebate amount owed by the manufacturer for each Part D rebatable line extension drug for the applicable period by multiplying the applicable rebate amount by the total units of the Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during the applicable period.

Note that Medicaid rebates are calculated quarterly, and a different initial drug may be identified in different quarters by the manufacturer for a particular line extension drug. Part D drug inflation rebates are calculated based on a 12-month applicable period, meaning there may be instances where a Part D rebatable line extension drug has multiple potential initial drugs during the applicable period that could be used for the alternative inflation rebate amount calculation. In such situations, for consistency, CMS will use the initial drug identified by the manufacturer in the last quarter of the Part D inflation rebate applicable period to identify the initial drug for the line extension drug alternative inflation rebate calculation. If an initial drug was not identified in the last quarter for a drug that is a line extension, CMS will use the initial drug identified most recently in that applicable period to identify the initial drug for the line extension drug alternative inflation rebate calculation.

40.5 Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage, in Cases of Severe Supply Chain Disruptions, and Where Without Such Reduction a Generic Part D Rebatable Drug is Likely to be in Shortage in a Subsequent Applicable Period

The calculation of the estimated rebate amount for a Part D rebatable drug and an applicable period is subject to section 1860D-14B(b)(1)(C) of the Act, which requires CMS to reduce or waive the rebate amount for a Part D rebatable drug with respect to an applicable period in three distinct cases: (1) when a Part D rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; (2) when CMS determines there is a severe supply chain disruption during the applicable period for a generic Part D rebatable drug[44] or biosimilar, such as a disruption caused by a natural disaster or other unique or unexpected event; and (3) when CMS determines that without such a reduction or waiver, a generic Part D rebatable drug is likely to be described as in shortage on such shortage list during a subsequent applicable period. See Table 1 below for a summary of how CMS will reduce the rebate amount in each of these three cases.

As described in section 30 of this revised guidance, multi-source generic drugs are not Part D rebatable drugs.

Table 1: Determination of Rebate Reduction Amount for Part D Rebatable Drugs

	Drug Shortage		**Severe Supply Chain Disruption**	**Likely to be in Shortage**
Duration of Reduction	Indefinite for as long as drug is "currently in shortage" on an FDA shortage list		One year; manufacturer may request an extension of the reduction for an additional year for up to two consecutive years total	
Percent Reduction	Part D rebatable drug other than a plasma-derived product or generic Part D rebatable drug	Part D rebatable plasma-derived product or generic Part D rebatable drug	Part D rebatable biosimilar or generic Part D rebatable drug	Generic Part D rebatable drug
First year	25%	75%	75%	75%
Second year	10%	50%	75%	75%
Subsequent years	2%	25%	Not applicable	Not applicable

Note: The scope of generic drugs subject to Part D drug inflation rebates is limited to sole source generic drugs. Multi-source generic drugs are not Part D rebatable drugs.

As described in section 40.5.1, for a Part D rebatable drug that is described as "currently in shortage" on an FDA shortage list at any point during the applicable period, CMS will apply a variable reduction in the rebate amount based on the length of time the drug is in shortage and will decrease the amount of the reduction over time. CMS will provide a greater reduction for generic Part D rebatable drugs, which are often low-margin products whose prices are tied to the marginal cost of production and thus are more vulnerable to potential market exit and shortage

[44] A generic Part D rebatable drug (described in section 1860D-14B(g)(1)(C)(ii) of the Act) is a drug approved under section 505(j) of the FD&C Act (i.e., a generic drug) that meets certain criteria outlined in subsections (g)(1)(C)(ii)(I)-(IV).

when input costs increase.[45] CMS will also provide a greater reduction for plasma-derived products than non-plasma derived products because the former rely on a variable supply of donated blood plasma that can impact downstream production and therefore hamper the ability to promptly resolve a shortage.

CMS will provide a standard reduction of 75 percent in the rebate amount for a generic Part D rebatable drug or biosimilar when CMS determines that there is a severe supply chain disruption during the applicable period or when CMS determines that a generic Part D rebatable drug is likely to be in shortage in a subsequent applicable period without a rebate reduction. CMS is limiting the maximum rebate reduction under the severe supply chain disruption and generics likely to be in shortage policies to two consecutive applicable periods total. CMS believes providing a standard, time-limited reduction in these two cases could mitigate the likelihood of shortage while avoiding creating incentives for manufacturers to delay resolving a severe supply chain disruption or other potential shortage situation for the purpose of avoiding an obligation to pay a rebate.

Rebate reductions are not additive, and CMS will not apply multiple reductions for the same Part D rebatable drug and applicable period. Thus, if a generic Part D rebatable drug or biosimilar that is described as "currently in shortage" on an FDA shortage list during an applicable period experiences a severe supply chain disruption during that same applicable period, the manufacturer may receive a rebate reduction under either the severe supply chain disruption policy or the shortage policy, but not both. Section 40.5.2 describes how CMS will apply rebate reductions if a generic Part D rebatable drug or biosimilar that is "currently in shortage" on an FDA shortage list experiences a severe supply chain disruption or if a generic Part D rebatable drug or biosimilar is granted a severe supply chain disruption rebate reduction request and that drug subsequently appears as "currently in shortage" on an FDA shortage list during the same applicable period as the severe supply chain disruption rebate reduction was granted. Similarly, if a manufacturer believes its generic Part D rebatable drug is likely to be in shortage in a subsequent applicable period because there was a severe supply chain disruption caused by a natural disaster, the manufacturer may receive a rebate reduction under either the severe supply chain disruption policy or the generics likely to be in shortage policy, but not both.

CMS believes these rebate reduction policies balance providing appropriate financial relief for manufacturers in certain circumstances, including when there is a severe supply disruption resulting from exogenous circumstances outside of a manufacturer's control, while not incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption, or maintain a situation in which a generic would be at risk of shortage to avoid an obligation to pay rebates. CMS will continue to evaluate these policies and may update them in future years. CMS underscores that most shortages involve multi-source generic drugs,[46] which are not Part D rebatable drugs and thus are not subject to Part D drug inflation rebates.

CMS will not provide a full waiver of the rebate amount for any Part D rebatable drug in shortage, for any generic Part D rebatable drug or biosimilar when there is a severe supply chain

[45] See: https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.
[46] See: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023.

disruption, or for any generic Part D rebatable drug that is likely to be in shortage in a subsequent applicable period without a reduction. CMS believes a full waiver of the rebate amount could create incentives for manufacturers to delay resolving a severe supply chain disruption or actual or likely drug shortage for the purpose of avoiding an obligation to pay a rebate.

40.5.1 Reducing the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on a U.S. FDA Shortage List

Section 1860D-14B(b)(1)(C)(i) of the Act requires CMS to reduce or waive the rebate amount for a Part D rebatable drug described as currently in shortage on the shortage list in effect under section 506E of the FD&C Act at any point during the applicable period. To determine whether a Part D rebatable drug is described as currently in shortage on a shortage list under section 506E of the FD&C Act at any point during the applicable period, CMS will use the FDA drug and biological product shortage lists under section 506E of the FD&C Act. Both the FDA Center for Drug Evaluation and Research (CDER) and the FDA Center for Biologics Evaluation and Research (CBER) maintain shortage lists (hereinafter referred to as an "FDA shortage list" or "shortage list") via web pages for drugs and biologicals within their respective jurisdictions.[47] To be eligible for a reduction of the rebate amount for an applicable period, which is calculated at the NDC-9 level, at least one NDC-10 for the Part D rebatable drug must have its shortage status described as "currently in shortage" on an FDA shortage list at any point during the applicable period.[48] A Part D rebatable drug in the status of "discontinued," "to be discontinued," or "resolved" will not be considered "currently in shortage." CMS will monitor the status of a Part D rebatable drug on an FDA shortage list. Manufacturers do not need to submit any information to CMS to be eligible for a reduction of the rebate amount for a Part D rebatable drug described as "currently in shortage" on an FDA shortage list during an applicable period.

To calculate the reduction in the rebate amount for a Part D rebatable drug described as "currently in shortage" on an FDA shortage list during an applicable period, CMS will calculate the number of days such drug is described as "currently in shortage" on an FDA shortage list in an applicable period, divide by the number of days in the applicable period, and then multiply that amount by a percentage that is decreased over time. For a Part D rebatable drug (including a biosimilar) that is not a generic Part D rebatable drug or a plasma-derived product, CMS will apply a 25 percent reduction for the first applicable period such Part D rebatable drug is described as "currently in shortage," 10 percent reduction for the second applicable period, and 2 percent reduction for each subsequent applicable period. For a Part D rebatable drug that is a generic Part D rebatable drug or a plasma-derived product, CMS will apply a 75 percent reduction for the first applicable period such Part D rebatable drug is described as "currently in shortage," 50 percent reduction for the second applicable period, and 25 percent reduction for each subsequent applicable period. See Table 1 above.

For a Part D rebatable drug for which the status changes from "currently in shortage" to

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[47] See: CDER shortage list: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; CBER shortage list: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-shortages-and-discontinuations.

[48] For the purposes of this revised guidance, CMS uses the term "currently in shortage" to refer to Part D rebatable drugs that are in the status of "currently in shortage" on the CDER shortage list, as well as biological products listed on CBER's current shortages list.

"resolved" during an applicable period, CMS will count the number of days that such drug was described as "currently in shortage" during that applicable period for the calculation of the rebate reduction. When the status of a Part D rebatable drug changes from "currently in shortage" to "resolved" and either remains in the status of "resolved" or is removed from the list, and then appears on the list in the status of "currently in shortage" in the next applicable period, CMS will apply the shortage policy as if there was a continuous shortage and move to the percent reduction applicable for the second applicable period. (In this scenario, CMS would apply a 50 percent reduction for the second applicable period for a generic Part D rebatable drug or plasma-derived product and a 10 percent reduction for a Part D rebatable drug that is not a generic or plasma-derived product.) When the status of a Part D rebatable drug changes from "currently in shortage" to "resolved" and either remains in the status of "resolved" or is removed from the list for at least one applicable period, and then subsequently reemerges on a shortage list, CMS will treat the subsequent shortage as a new shortage and will apply the percent reduction applicable for the first applicable period (i.e., 75 percent reduction for a generic Part D rebatable drug or plasma-derived product and a 50 percent reduction for a Part D rebatable drug that is not a generic or plasma-derived product). The formula for the calculation of the reduced applicable period rebate amount is below, and an example calculation is found in section 70.11 of this revised guidance:

Reduced Applicable Period Rebate Amount = applicable period rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was listed as currently in shortage during applicable period) + applicable period rebate amount *multiplied by* (1 *minus* percentage time drug was listed as currently in shortage during applicable period)

Because drugs and biologicals on the FDA shortage lists are maintained at the NDC-10 level, and Part D drug inflation rebates are calculated at the NDC-9 level, if any NDC-10 under the NDC-9 appears on the FDA drug shortage list, CMS will apply the rebate reduction to the entire Part D rebatable drug at the NDC-9 level. CMS will closely monitor market data for the Part D rebatable drugs for which the rebate is reduced to ensure the integrity of the application of the rebate reduction policy by the manufacturer.

40.5.2 Reducing the Rebate Amount for a Generic Part D Rebatable Drug or Biosimilar When There Is a Severe Supply Chain Disruption

Section 1860D-14B(b)(1)(C)(ii) of the Act requires CMS to reduce or waive the rebate amount for an applicable period in the case of a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during the applicable period, such as a severe supply chain disruption caused by a natural disaster or other unique or unexpected event. (As above, CMS underscores that multi-source generic drugs are not Part D rebatable drugs and are not subject to Part D drug inflation rebates.) CMS is defining a severe supply chain disruption to mean a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a generic Part D rebatable drug or biosimilar by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

The statute provides examples of potential causes for a severe supply chain disruption, such as a natural disaster or other unique or unexpected event. CMS is defining a "natural disaster" to mean any natural catastrophe, including, but not limited to, any of the following: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or regardless of cause, any fire, flood, or explosion. CMS is defining "other unique or unexpected event" to mean any exogenous, unpredictable event outside of a manufacturer's control, including, but not limited to, a geopolitical disruption, pandemic, or act of terror.

To receive a reduction in the rebate amount when there is a severe supply chain disruption during the applicable period, the manufacturer of a generic Part D rebatable drug or biosimilar must demonstrate in writing to CMS that: (1) a severe supply chain disruption has occurred during the applicable period, (2) the disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the generic Part D rebatable drug or biosimilar, and (3) the severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

To receive consideration for a rebate reduction when there is a severe supply chain disruption during an applicable period, such as that caused by a natural disaster or other unique or unexpected event, a manufacturer will be required to submit a request to CMS that includes information and supporting documentation to substantiate these three criteria. CMS expects that such information and supporting documentation may include:

a. Evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses to make or distribute the generic Part D rebatable drug(s) or biosimilar(s), such as a change in the production or distribution of the generic Part D rebatable drug(s) or biosimilar(s) that is reasonably likely to lead to a significant reduction in the U.S. supply of product and significantly affects the manufacturer's ability to fill orders or meet expected demand for the generic Part D rebatable drug(s) or biosimilar(s) for at least 90 days, with information about when the manufacturer expects supply of the generic Part D rebatable drug(s) or biosimilar(s) to meet expected demand;
b. Evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the duration (expected or actual) of the severe supply chain disruption; and,
c. Evidence of the manufacturer's physical presence related to manufacturing the generic Part D rebatable drug(s) or biosimilar(s) in a geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that affects the manufacturer's generic Part D rebatable drug(s) or biosimilar(s), evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the generic Part D rebatable drug or biosimilar, on a supplier of an ingredient or packaging, or method of shipping or distribution that the manufacturer uses.

CMS may consider additional criteria in the future to evaluate requests submitted under this section. A manufacturer that seeks a severe supply chain disruption rebate reduction will be required to submit a request to CMS. In accordance with the Paperwork Reduction Act (PRA), CMS intends to propose a collection of information addressing information that must be submitted to CMS by a manufacturer of a generic Part D rebatable drug or biosimilar in order to receive consideration for a rebate reduction under this policy, including the process steps for that submission. Upon completion of the PRA process for the information collection, CMS intends to announce the deadline for manufacturers to submit their requests for a rebate reduction due to a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that occurred on or after October 1, 2022, but before August 2, 2024. CMS intends to require manufacturers to submit requests, along with all supporting documentation, by that deadline to receive consideration for a rebate reduction for a severe supply chain disruption during that time period. If the manufacturer makes a timely request that includes all the supporting documentation, and CMS determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, then CMS will reduce the rebate amount by 75 percent for that manufacturer's generic Part D rebatable drug or biosimilar for the applicable period in which the event that caused the severe supply chain disruption occurred. For a severe supply chain disruption caused by a natural disaster or other unique or unexpected event occurring on or after August 2, 2024, CMS intends to require the request for a reduction of the rebate amount to be made within 60 days of the first day that a natural disaster or other unique or unexpected event that caused the severe supply chain disruption occurred or began.

If the manufacturer submits a timely request and all supporting documentation less than 60 days before the end of an applicable period, CMS will apply the rebate reduction to the next applicable period. For example, if there is a hurricane on September 1, 2024, that causes a severe supply chain disruption, and the manufacturer submits a rebate reduction request with appropriate supporting documentation on September 29, 2024, which CMS grants, CMS would reduce the rebate amount for the applicable period beginning on October 1, 2024.

If the manufacturer's request is incomplete or untimely, CMS will deny the request. CMS may consult with FDA for technical assistance, as needed.

If a severe supply chain disruption continues into a second applicable period after the start of the natural disaster or other unique or unexpected event, the manufacturer may request a reduction of the rebate amount for that second applicable period by submitting a request to CMS. To receive consideration for a rebate reduction extension, the manufacturer must submit to CMS a request along with any new supporting documentation. CMS expects that such information and supporting documentation may include new or updated information on why the generic Part D rebatable drug(s) or biosimilar(s) continues to be affected by the severe supply chain disruption during the second applicable period. In accordance with the PRA, CMS intends to propose a collection of information addressing information that must be submitted to CMS by the manufacturer of a generic Part D rebatable drug or biosimilar in order to receive consideration for an extension of the rebate reduction, including the process steps for that submission. CMS may also consider other available evidence, such as market sales data, to inform its determination regarding the availability of the manufacturer's generic Part D rebatable drug or biosimilar in the marketplace and whether availability has returned to normal during an applicable period. If the

manufacturer submits a complete and timely extension request, and CMS determines that the information submitted warrants an extension of the rebate reduction, then CMS will reduce the rebate by 75 percent for a second consecutive applicable period for that manufacturer's generic Part D rebatable drug or biosimilar. If the manufacturer's request is incomplete or untimely, CMS will deny the request.

A rebate reduction extension request and any new supporting documentation must be submitted at least 60 days before the start of the second applicable period, except for when the initial request is made less than 60 days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period rather than the applicable period in which the event occurred. In these cases, the rebate reduction extension request must be submitted at least 60 days prior to the end of that next applicable period. As in the example above, if there is a hurricane on September 1, 2024 that causes a severe supply chain disruption and the manufacturer submits a rebate reduction request on September 29, 2024, which applies to the applicable period beginning October 1, 2024, a manufacturer must submit a rebate reduction extension request at least 60 days before the end of that applicable period (i.e., by August 1, 2025) to receive consideration for a reduction for the second consecutive applicable period starting October 1, 2025. Upon completion of the PRA process for the information collection, CMS intends to announce the deadline for manufacturers to submit their extension requests for a rebate reduction due to a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that occurred on or after October 1, 2022, but before August 2, 2024. CMS intends to require manufacturers to submit extension requests, along with all supporting documentation, by that deadline to receive consideration for a rebate reduction extension for a severe supply chain disruption during that time period.

If CMS grants a manufacturer's severe supply chain disruption rebate reduction request for an NDC-11, CMS will apply the rebate reduction to the entire generic Part D rebatable drug or biosimilar at the NDC-9 level. CMS will closely monitor market data for generic Part D rebatable drugs and biosimilars for which the rebate is reduced to ensure the integrity of the application of the severe supply chain disruption rebate reduction policy by the manufacturer.

CMS is limiting the rebate reduction under the severe supply chain disruption policy to two consecutive applicable periods total per drug per CMS determination of a severe supply chain disruption. If there are multiple events causing severe supply chain disruptions during the same applicable period for the same generic Part D rebatable drug or biosimilar as for which a rebate reduction request was granted, the manufacturer will receive only one rebate reduction for that product for the applicable period. For example, if the manufacturer of a generic Part D rebatable drug or biosimilar is granted a severe supply chain disruption rebate reduction request for its product due to a natural disaster that occurred in January 2024 and then experiences a second severe supply chain disruption caused by a second, distinct natural disaster in July 2024, CMS would not grant the second rebate reduction request. That is, the manufacturer would receive the 75 percent reduction for one applicable period for the severe supply chain disruption caused by the first natural disaster but would not receive a rebate reduction for the second natural disaster. However, if the second natural disaster exacerbated the severe supply chain disruption caused by the first natural disaster, the manufacturer may reflect such circumstances in its request for an extension of the rebate reduction for a second applicable period.

Beginning with the applicable period that begins on October 1, 2024, CMS will review rebate reduction requests within 60 calendar days of receipt of all documentation, if feasible. CMS' decisions to deny a request are final and will not be subject to an appeals process.

If CMS grants a severe supply chain disruption rebate reduction request for a generic Part D rebatable drug or biosimilar, and the drug or biosimilar appears in the status of "currently in shortage" on an FDA shortage list during the same applicable period as the one for which the severe supply chain disruption reduction request was granted, CMS will apply the 75 percent reduction to the entire applicable period for which the severe supply disruption request was granted and will not grant any additional reduction for the "currently in shortage" status during that applicable period. For any subsequent applicable periods that the generic Part D rebatable drug or biosimilar appears in the status of "currently in shortage" on an FDA shortage list, CMS will apply a variable reduction in the rebate amount consistent with the shortages policy described in section 40.5.1 of this revised guidance. For example, if CMS grants a severe supply chain disruption rebate reduction request for a generic Part D rebatable drug or biosimilar that was submitted on November 15, 2024 and that generic Part D rebatable drug or biosimilar appears as "currently in shortage" on an FDA shortage list from September 15, 2025 until May 15, 2026, CMS will apply a 75 percent reduction in the rebate amount for the duration of the applicable period for which the severe supply chain disruption rebate reduction request was granted (i.e., October 1, 2024 to September 30, 2025), and then will apply the variable reduction, as described in section 40.5.1, beginning with a 75 percent reduction for a generic Part D rebatable drug and a 25 percent reduction for a Part D rebatable biosimilar for the applicable period beginning October 1, 2025.

If a generic Part D rebatable drug or biosimilar that is described as "currently in shortage" on an FDA shortage list experiences a severe supply chain disruption, the manufacturer may submit a severe supply chain disruption rebate reduction request. If granted, CMS will apply a 75 percent reduction in the rebate amount for the duration of the applicable period in which the event that caused the severe supply chain disruption occurred rather than the reduction under the policy for a Part D rebatable drug described as "currently in shortage." If CMS receives the request and all supporting documentation less than 60 days before the end of an applicable period, CMS will apply the 75 percent rebate reduction to the next applicable period. For example, if a generic Part D rebatable drug or biosimilar that is described as "currently in shortage" on an FDA shortage list in the applicable period beginning October 1, 2023 is granted a severe supply chain disruption rebate reduction request as a result of a natural disaster that occurs on April 5, 2024, CMS will apply a 75 percent reduction in the rebate amount for the duration of the applicable period in which the natural disaster occurred (i.e., October 1, 2023 to September 30, 2024). In this same example, if the natural disaster instead occurs on September 5, 2024, CMS will apply the reduction under the policy for a Part D rebatable drug described as "currently in shortage" for the duration of the applicable period beginning October 1, 2023 (i.e., October 1, 2023 to September 30, 2024), and then a 75 percent reduction under the severe supply chain disruption policy to the next applicable period beginning October 1, 2024 (i.e., October 1, 2024 to September 30, 2025).

CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. CMS is clarifying in this revised guidance that

information provided as part of a request for a rebate reduction when there is a severe supply chain disruption that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA).[49] In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. § 1905 requires executive branch employees to protect such information. CMS will protect confidential and proprietary information as required by applicable law.

40.5.3 Reducing the Rebate Amount for a Generic Part D Rebatable Drug Where Without Such Reduction, the Generic Part D Rebatable Drug is Likely to be Described as in Shortage on Such Shortage List During a Subsequent Applicable Period

Section 1860D-14B(b)(1)(C)(iii) of the Act requires CMS to reduce or waive the rebate amount for a generic Part D rebatable drug for an applicable period if CMS determines that without such reduction or waiver, the generic Part D rebatable drug is likely to be described as in shortage on the shortage list authorized under section 506E of the FD&C Act during a subsequent applicable period. This statutory provision does not apply to biosimilars.[50] (As above, CMS underscores that multi-source generic drugs are not Part D rebatable drugs and are not subject to Part D drug inflation rebates.)

The statute does not provide examples of reasons that a generic Part D rebatable drug may be likely to be in shortage in a subsequent applicable period, and CMS believes that many causes of likely shortage would be covered under the severe supply chain disruption reduction policy described in section 40.5.2. Thus, CMS expects this section to apply to a limited number of generic Part D rebatable drugs that are likely to be in shortage for reasons that are distinct from those under the severe supply chain disruption policy. CMS anticipates that a generic Part D rebatable drug may qualify for a reduction in the rebate amount under this section if the manufacturer of a generic Part D rebatable drug experiences a significant increase in the demand of the drug because, for example, other manufacturers of the drug recently discontinued production of the drug, leaving the manufacturer of the generic Part D rebatable drug as the sole manufacturer or because of an expansion of the approved or accepted indications of the drug in nationally recognized, evidence-based guidelines and CMS-approved Part D compendia.

To receive consideration for a rebate reduction when a generic Part D rebatable drug is likely to be in shortage, a manufacturer will be required to submit a request to CMS that includes certain information and supporting documentation. CMS expects that such information and supporting documentation may include:

a. Evidence that supports a likely future shortage, including anticipated cause(s) of the shortage and information about why the manufacturer believes the generic Part D rebatable drug is likely to be described as in shortage on the shortage list in a subsequent applicable period, such as evidence indicating the manufacturer is experiencing issues acquiring active pharmaceutical ingredients (API) or raw materials necessary to

[49] 5 U.S.C. § 552(b)(3), (4).

[50] Section 1860D-14B(b)(1)(C)(iii) applies to generic Part D rebatable drugs (as so described), which are described more fully in section 1860D-14B(g)(1)(C)(ii) of the Act.

manufacture the drug, or evidence that other manufacturers recently discontinued production of a generic Part D rebatable drug such that the remaining manufacturer has experienced a significant increase in demand of the drug.

b. Evidence of the anticipated start date and duration of the potential shortage, the actions the manufacturer is taking to avoid the potential drug shortage, and how the reduction of the rebate amount would reduce the likelihood of the drug ending up on the FDA shortage list.

CMS may consider additional criteria in the future to evaluate requests submitted under this section. A manufacturer that seeks a rebate reduction under this section will be required to submit a request to CMS. In accordance with the PRA, CMS intends to propose a collection of information addressing information that must be submitted to CMS by a manufacturer of a generic Part D rebatable drug in order to receive consideration for a rebate reduction under this policy, including the process steps for that submission. Upon completion of the PRA process for the information collection, CMS intends to announce the deadline for manufacturers to submit their requests for a rebate reduction due to a likely shortage. CMS intends to require manufacturers to submit requests, along with all supporting documentation, by that deadline to receive consideration for a rebate reduction.

CMS intends to require the request for a reduction of the rebate amount to be submitted to CMS at least 60 days before the start of the next applicable period in which the generic Part D rebatable drug is likely to be in shortage to qualify for the reduction in the applicable period that the request is submitted. CMS will review the submitted information, along with any available market data, to determine if the generic Part D rebatable drug is likely to be described as "currently in shortage" on an FDA shortage list in a subsequent applicable period. CMS may also consult with FDA for technical assistance, as needed, to determine whether the generic Part D rebatable drug is likely to be described as "currently in shortage" on an FDA shortage list in the next applicable period. If the manufacturer makes a timely request that includes all the supporting documentation, and CMS determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, then CMS will reduce the rebate amount by 75 percent for the generic Part D rebatable drug for the applicable period during which the request was submitted in an effort to assist the manufacturer in preventing or averting the inclusion of the generic Part D rebatable drug on the shortage list in the next applicable period. For complete requests and documentation submitted with less than 60 days remaining in the applicable period, CMS will apply any reduction of the rebate amount to the next applicable period in which the generic Part D rebatable drug is likely to be in shortage.

To receive consideration for a rebate reduction, the request must be submitted to CMS before the start of the next applicable period in which the generic Part D rebatable drug is likely to be in shortage. If the manufacturer's request is incomplete or untimely, CMS will deny the request.

If the likelihood of shortage continues for a second applicable period, the manufacturer may request a reduction of the rebate amount for that second applicable period by submitting a request to CMS. To receive consideration for a rebate reduction extension, the manufacturer must submit to CMS a request along with any new supporting documentation, if applicable. CMS expects that such information and supporting documentation may include new or updated information on why the generic Part D rebatable drug is likely to be in shortage during the second applicable period.

In accordance with the PRA, CMS intends to propose a collection of information addressing information that must be submitted to CMS by the manufacturer of a generic Part D rebatable drug in order to receive consideration for an extension of the rebate reduction, including the process steps for that submission. CMS intends to consider rebate reduction extension requests submitted at least 60 days before the start of the second applicable period, except for when the initial request is made less than 60 days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period. In these cases, CMS intends to consider extension requests submitted at least 60 days prior to the end of that next applicable period.

Upon completion of the PRA process for the information collection, CMS intends to announce the deadline for manufacturers to submit their extension requests for a rebate reduction for a generic Part D rebatable drug due to a likely shortage in the applicable period beginning on October 1, 2024. CMS intends to require manufacturers to submit extension requests, along with all supporting documentation, by that deadline to receive consideration for a rebate reduction extension.

If CMS grants a manufacturer's likely to be in shortage rebate reduction request for an NDC-11, CMS will apply the rebate reduction to the entire generic Part D rebatable drug at the NDC-9 level. CMS will closely monitor market data for the generic Part D rebatable drugs for which the rebate is reduced to ensure the integrity of the application of the rebate reduction policy by the manufacturer.

Beginning with the applicable period that begins on October 1, 2024, CMS will review rebate reduction requests within 60 calendar days of receipt of all documentation, if feasible. CMS' decisions to deny a request are final and will not be subject to an appeals process. CMS is limiting the rebate reduction under the likely to be in shortage provision to two consecutive applicable periods total per generic Part D rebatable drug per CMS determination of likelihood of shortage.

If CMS grants a request for a reduction in the rebate amount for a generic Part D rebatable drug that is likely to be in shortage in a subsequent applicable period without such reduction, and the drug appears in the status of "currently in shortage" on an FDA shortage list during the same applicable period as the one for which the likely to be in shortage reduction request was granted, CMS will apply the 75 percent standard reduction to the entire applicable period for which the likely to be in shortage request was granted. For any subsequent applicable periods that the generic Part D rebatable drug appears in the status of "currently in shortage" on an FDA shortage list, CMS will apply a variable reduction in the rebate amount under the shortages policy described in section 40.5.1 of this revised guidance. For example, if a generic Part D rebatable drug is granted a likely to be in shortage request that was submitted on August 15, 2024 and appears as "currently in shortage" on an FDA shortage list from September 15, 2025 until May 15, 2026, CMS intends to apply a 75 percent reduction in the rebate amount to the entire applicable period for which the likely to be in shortage request was granted (i.e., October 1, 2024 to September 30, 2025). CMS then intends to apply the variable reduction, as described in section 40.5.1, beginning with a 75 percent reduction for a generic Part D rebatable drug for the applicable period beginning October 1, 2025.

CMS will keep confidential, to the extent allowable under law, any requests for a rebate

reduction, including supporting documentation. CMS is clarifying in this revised guidance that information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of FOIA. In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. § 1905 requires executive branch employees to protect such information. CMS will protect confidential and proprietary information as required by applicable law.

50. Ensuring Integrity of the Medicare Part D Drug Inflation Rebates

Under section 1860D-14B(a) of Act, no later than nine months after the end of each applicable period, CMS must report to each manufacturer[51] of a Part D rebatable drug the following information for the applicable period: (1) the amount, if any, in excess of the amount of the AnMP for the Part D rebatable drug; and (2) the rebate amount for the Part D rebatable drug.

CMS is adopting the process described below to help ensure the integrity of the information reported by CMS under section 1860D-14B(a) of the Act. Through Rebate Reports, CMS will provide the information identified above as specified in section 1860D-14B(a) of the Act for an applicable period, and CMS intends to also provide the NDC(s) for the Part D rebatable drug and the total number of units for the Part D rebatable drug for the applicable period used in the calculation of the rebate amount. CMS will consider including additional information used in the rebate calculation in these reports to the extent feasible and necessary.

Manufacturers will first receive a Preliminary Rebate Report and will have the opportunity to provide a Suggestion of Calculation Error to CMS, which CMS may consider at its discretion. Manufacturers will then receive the Rebate Report, including the rebate amount due to CMS, no later than nine months after the end of the applicable period. This process is described in section 50.1 of this revised guidance. A rebate amount due must be paid to CMS within 30 calendar days after receipt of a Rebate Report.

CMS intends to post Preliminary Rebate Reports and Rebate Reports to a secure, online portal that is facilitated by a CMS-contracted Third-Party Administrator (TPA). The portal will also include a process for manufacturers to provide a Suggestion of Calculation Error and to make rebate payments to CMS. CMS will provide instructions on how manufacturers of Part D rebatable drugs can sign up and gain access to this portal to receive their Preliminary Rebate Report and Rebate Report prior to the issuance of the first Rebate Report. Manufacturers of Part D rebatable drugs who are signed up for the portal will receive an automated email notifying them when a report is available to view electronically in the portal.

In accordance with section 1860D-14B(a)(3) of the Act, CMS may delay reporting of rebate information for the first two applicable periods (October 1, 2022, through September 30, 2023, and October 1, 2023, through September 30, 2024) until no later than December 31, 2025 (see section 50.2 of this revised guidance). Beginning with the applicable period beginning on October

[51] CMS will use the same approach used by the MDRP to identify the manufacturer that is responsible for a Part D drug inflation rebate amount owed. See section 1927(k)(5).

1, 2024, Rebate Reports will be sent to manufacturers no later than nine months after the end of the applicable period. CMS intends to provide a regular release schedule or calendar of release dates for Rebate Reports in future applicable periods. A summary of the full timeline for reports and deadlines is illustrated below.

Consistent with section 1860D-14B(b)(6) of the Act, CMS will establish a method and process to determine adjustments to the rebate amount for a Part D rebatable drug for an applicable period in the case of a Part D plan sponsor submitting revisions to the number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors and to reconcile any overpayments or underpayments in the rebate amount paid. CMS continues to assess options for implementing this process and intends to establish this process ahead of issuing Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, which must be issued no later than December 31, 2025.

In connection with development of this reconciliation process, CMS is also considering options for establishing a standardized method and process at regular intervals to determine any appropriate adjustment to the rebate amount for a Part D rebatable drug for an applicable period to account for a broader set of circumstances involving revised information. CMS considerations include what timing for recalculation may be appropriate to capture relevant changes to data inputs and whether the timing should align with restatements of Part B rebatable drug rebate amounts. Additionally, CMS is also considering circumstances where a recalculation may be appropriate for a particular manufacturer's rebate amount for an applicable period after issuing the Rebate Report for the applicable period based on CMS identifying a calculation error or determining manufacturer pricing or product data under section 1927(b)(3) of the Act was misreported. CMS is also considering potential time limits for revisions and whether certain circumstances, such as instances of fraud, should be exempt from such time limits.

Summary of Part D Drug Inflation Rebate Amount Reports and Deadlines

Milestone	Timing/Deadline
Part D Rebate – CMS must invoice manufacturers not later than 9 months after the end of applicable period	
Preliminary Rebate Report sent to Manufacturers	No later than 6 months after the end of the applicable period
Manufacturer Reviews	Manufacturer Suggestion of Calculation Error should be submitted to CMS no later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 9 months after the end of the applicable period
Manufacturer Rebate Payment Due (if applicable)	No later than 30 calendar days after receipt of the Rebate Report

50.1 Process for Rebate Reports and Suggestion of Calculation Error

CMS will provide all manufacturers with at least one Part D rebatable drug, including when the rebate amount is $0 (i.e., no rebate is owed), with a Preliminary Rebate Report within 6 months of the end of each applicable period via the TPA's online portal.

Within 10 calendar days from the date of the receipt of the Preliminary Rebate Report, manufacturers of Part D rebatable drugs may provide CMS, for its discretionary consideration, with a Suggestion of Calculation Error in the manufacturer's Preliminary Rebate Report for Part D drug inflation rebate amounts owed if the manufacturer believes in good faith that there is a calculation error to be corrected before the Rebate Report is finalized.

Through a method and process determined by CMS, manufacturers should notify CMS via the TPA's online portal to share a Suggestion of Calculation Error, including supporting documentation (if applicable), within 10 calendar days after receiving the Preliminary Rebate Report. CMS will provide technical instruction on the method and process to submit a Suggestion of Calculation Error in separate program communications.

CMS will consider each Suggestion of Calculation Error at its discretion and calculate the rebate amount (see section 40 of this revised guidance) for the Rebate Report. Manufacturers will receive the Rebate Report no later than nine months after the end of the applicable period except for Rebate Reports issued during the transition period (see section 50.2 of this revised guidance). The Rebate Report will include the same data elements as the Preliminary Rebate Report. The Rebate Report will serve as the invoice for the rebate amount due, if any, for each NDC of the Part D rebatable drug for the applicable period.

Manufacturers will have 30 calendar days from the date of receipt of the Rebate Report to pay the rebate amount owed. The date of receipt is defined as the calendar day following the day in which the Rebate Report was posted via the TPA's online portal. For example, if the Rebate Report is posted to the portal on June 30, 2026, then July 1, 2026, will be the date of receipt and therefore day one of the thirty-calendar-day payment period.

Failure to pay the rebate amount timely and in full as indicated on the Rebate Report may result in future administrative measures, including the initiation of the CMP process (see section 60 of this revised guidance). Additional information on how to submit a payment for a rebate amount due will be provided in separate program communications.

Section 1860D-14B(f) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part D rebatable drug, and the calculation of the rebate amount. Because of this limitation on administrative and judicial review, CMS is not providing an administrative dispute resolution process.

50.2 Rebate Reports for the Applicable Period Beginning October 1, 2022, and the Applicable Period Beginning October 1, 2023

As permitted under section 1860D-14B(a)(3), CMS is delaying Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, until no later than December 31, 2025.

The delayed issuance of the Rebate Reports and modifications during this transition simplifies payment procedures for manufacturers with rebatable Part D drugs.

CMS intends to issue a Preliminary Rebate Report for the applicable period beginning October 1, 2022, and the applicable period beginning October 1, 2023, in summer 2025. CMS will provide manufacturers an extended Suggestion of Calculation Error period of 30 calendar days. Then, CMS will issue the Rebate Report for these applicable periods no later than December 31, 2025. Rebate Reports will include will contain the same information described in section 50.1 of this revised guidance. Payment will be due 30 calendar days after receipt. Failure to pay a rebate amount due timely and in full may result in an enforcement action (see section 60 of this revised guidance). Additional information on how to submit a payment for a rebate amount due will be provided in separate program communications.

60. Enforcement of Rebate Amount Payments by Manufacturers

In accordance with section 1860D-14B(a)(2) of the Act, the manufacturer of a Part D rebatable drug is required to provide a rebate equal to the rebate amount specified in section 1860D-14B(b) for the rebatable drug for the applicable period within 30 calendar days of receipt of the rebate amount from CMS.

CMS is evaluating all available options to ensure manufacturers' timely compliance with their rebate payment obligations, including, without limitation, potential recovery approaches and enforcement actions, such as imposing CMPs in accordance with the authority in section 1860D-14B(e) of the Act. For example, CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation. CMS intends to conduct rulemaking for the Part D Drug Inflation Rebate Program in the future and may use that opportunity to address its enforcement approach.

In accordance with section 1860D-14B(e) of the Act, manufacturers that do not pay the Part D drug inflation rebate amount owed for an applicable period for a Part D rebatable drug may be subject to a CMP equal to 125 percent of the rebate amount, in addition to the rebate amount due under section 1860D-14B(b) of the Act, for such drug for such applicable period. CMS will include information in the Rebate Report described in section 50 of this revised guidance to remind manufacturers that late or unpaid rebate payments may result in a CMP. CMS will also issue reminder notices regarding the due date of rebate payments.

In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil monetary penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and/or civil monetary penalties owed by the manufacturer.

60.1 CMP Notice and Appeals Procedures

Section 1860D-14B(e) of the Act sets forth the formula for determining the CMP amount, which equals 125 percent of the rebate amount calculated in addition to the rebate amount due under section 1860D-14B(b) for the Part D rebatable drug for an applicable period. Where CMS makes a determination to impose a CMP, CMS will provide a written notice of the CMP, including information regarding the opportunity to request a hearing as outlined in section 1128A of the Act. As required by section 1128A of the Act, the CMP notice will include the following:

- The basis for the CMP;
- The CMP amount due;
- The deadline for the manufacturer to respond with a hearing request or submit CMP payment;
- The method to submit CMP payment(s); and
- Information on the right to request a hearing.

The manufacturer will have 60 calendar days from the date of receipt of the CMP Notice to submit a written request for a hearing or pay the CMP. The date of receipt is defined as the calendar day following the day in which the CMP notice is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act and operationalized by 42 C.F.R. § 423 Subpart T will apply. As noted above, CMS intends to conduct rulemaking for the Part D Drug Inflation Rebate Program in the future and may use that opportunity to address its enforcement approach, including with regard to CMPs.

70. Formulas

70.1 Calculation for Exclusion of Drugs Where Average Annual Total Cost Under Part D Is Less than $100 per Individual Using Such Drug per Year Adjusted by Changes in the CPI-U

Formula

Threshold for applicable period beginning October 1, 2023 = $100 (October 1, 2022 statutory threshold) *multiplied by* (October 2024 CPI-U/October 2023 CPI-U) (apply rounding to the nearest multiple of $10)

Threshold for applicable period beginning October 1, 2024 = Unrounded October 1, 2023 calculated threshold *multiplied by* (October 2024 CPI-U/October 2023 CPI-U) (apply rounding to the nearest multiple of $10)

Threshold for applicable period beginning October 1, 2025 = Unrounded October 1, 2024 calculated threshold *multiplied by* (October 2025 CPI-U/October 2024 CPI-U) (apply rounding to the nearest multiple of $10)

Example

The CPI-Us used in the following example (both actual and illustrative) [52] are as follows:

- CPI-U October 2023 = 307.671
- CPI-U October 2024 = 317.528
- CPI-U October 2025 = 333.836

The thresholds are shown below:

October 1, 2022 threshold = **$100** (per section 1860D-14B(g)(1)(B) of the Act)

October 1, 2023 threshold:
100 * (317.528/307.671) = 103.203747 (which rounds down to $100 after applying CMS rounding) so October 1, 2023 threshold = **$100**

October 1, 2024 threshold:
103.203747 * (317.528/307.671) = 106.510134 (which rounds up to $110 after applying CMS rounding) so October 1, 2024 threshold = **$110**

October 1, 2025 threshold:
106.510134 * (333.836/317.528) = 111.980414 (which rounds down to $110 after applying CMS rounding) so October 1, 2025 threshold = **$110**

70.2 Example Data

The following tables contain example data to be used in subsequent examples throughout sections 70.3-70.10 of this revised guidance.

Illustrative Example Data

1) Quarterly AMP data reported by manufacturers under sections 1927(b)(3)(A)(i) and (ii) of the Act
Benchmark Period:

NDC-9	Q1 AMP	Q2 AMP	Q3 AMP	Q4 AMP
00000-0000	$99	$98	$102	$101

Applicable Period:

NDC-9	Q4 AMP	Q1 AMP	Q2 AMP	Q3 AMP
00000-0000	$120	$121	$119	$120

[52] Historical CPI-Us were retrieved from the CPI for All Urban Consumers (CPI-U) table on BLS.gov on November 30, 2023. Future CPI-Us are illustrative.

2) Monthly AMP units data reported by manufacturers under section 1927(b)(3)(A)(iv)
Benchmark Period:

NDC9	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
00000-0000	1000	0	0	998	1002	995	1005	990	1010	1000	970	1030

Applicable Period:

NDC9	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
00000-0000	2000	1998	2002	1980	2020	1990	2010	2000	1800	2200	1850	2150

3) PDE data for the total Part D units of the drug dispensed under Part D and covered by Part D plan sponsors during the applicable period that are reported to CMS by Part D plan sponsors:

NDC9	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
00000-0000	110	120	130	140	150	160	170	180	190	200	210	220

70.3 Quarterly Units

The quarterly AMP units using the values provided for the Benchmark Period in section 70.2 would be calculated as:
Q1 quarterly units = Jan units + Feb units + Mar units = 1,000 + 0 + 0 = 1,000
Q2 quarterly units = Apr units + May units + Jun units = 998 + 1,002 + 995 = 2,995
Q3 quarterly units = Jul units + Aug units + Sep units = 1,005 + 990 + 1,010 = 3,005
Q4 quarterly units = Oct units + Nov units + Dec units = 1,000 + 970 + 1,030 = 3,000

The quarterly AMP units using the values provided for the Applicable Period in section 70.2 would be calculated as:
Q4 quarterly units = Oct units + Nov units + Dec units = 2,000 + 1,998 + 2,002 = 6,000
Q1 quarterly units = Jan units + Feb units + Mar units = 1,980 + 2,020 + 1,990 = 5,990
Q2 quarterly units = Apr units + May units + Jun units = 2,010 + 2,000 + 1,800 = 5,810
Q3 quarterly units = Jul units + Aug units + Sep units = 2,200 + 1,850 + 2,150 = 6,200

70.4 Calculation of the AnMP for a Part D Rebatable Drug

Formula

(AMP for calendar quarter beginning October) *multiplied by* (sum of monthly AMP units for October calendar quarter/total AMP units for 12-month applicable period) +
(AMP for calendar quarter beginning January) *multiplied by* (sum of monthly AMP units for January calendar quarter/total AMP units for 12-month applicable period) +
(AMP for calendar quarter beginning April) *multiplied by* (sum of monthly AMP units for April calendar quarter/total AMP units for 12-month applicable period) +
(AMP for calendar quarter beginning July) *multiplied by* (sum of monthly AMP units for July calendar quarter/total AMP units for 12-month applicable period)

All dates referenced in this subsection are with respect to the applicable period in section 70.2.

Example

Using the example values for the Applicable Period provided in section 70.2, the AnMP for the Part D Rebatable Drug would be equal to the following:

$120 * (6,000/24,000) +

$121 * (5,990/24,000) +

$119 * (5,810/24,000) +

$120 * (6,200/24,000)
=
$120.01

70.5 Calculation of the Benchmark Period Manufacturer Price for Part D Rebatable Drugs First Approved or Licensed on or Before October 1, 2021

Formula

(AMP for calendar quarter beginning January 2021) *multiplied by* (sum of monthly AMP units for January 2021 calendar quarter/total AMP units for 9-month period of January to September 2021)
+
(AMP for calendar quarter beginning April 2021) *multiplied by* (sum of monthly AMP units for April 2021 calendar quarter/total AMP units for 9-month period of January to September 2021) +
(AMP for calendar quarter beginning July 2021) *multiplied by* (sum of monthly AMP units for July 2021 calendar quarter/total AMP units for 9-month period of January to September 2021)

Example

Using the example values provided in section 70.2, the benchmark period manufacturer price would be equal to the following:
$99 * (1,000/7,000) +
$98 * (2,995/7,000) +
$102 * (3,005/7,000)
=
$99.86

70.6 Calculation of Benchmark Period Manufacturer Price for Part D Rebatable Drugs First Approved or Licensed After October 1, 2021- the First Full Calendar Year After the Drug Was First Marketed

The calendar quarters referred to below are the calendar quarters of the calendar year that begins after the drug's first market date.

Formula

(AMP for calendar quarter beginning January) *multiplied by* (sum of monthly AMP units for

January calendar quarter/total AMP units for 12-month period of January to December) +
(AMP for calendar quarter beginning April) *multiplied by* (sum of monthly AMP units for April calendar quarter/total AMP units for 12-month period of January to December) +
(AMP for calendar quarter beginning July) *multiplied by* (sum of monthly AMP units for July calendar quarter/total AMP units for 12-month period of January to December) +
(AMP for calendar quarter beginning October) *multiplied by* (sum of monthly AMP units for October calendar quarter/total AMP units for 12-month period of January to December)

Example

Using the example values provided in section 70.2, the benchmark period manufacturer price would be equal to the following:
$99 * (1,000/10,000) +
$98 * (2,995/10,000) +
$102 * (3,005/10,000) +
$101 * (3,000/10,000)
=
$100.20

70.7 Calculation of Inflation-Adjusted Payment Amount

Examples

Using the applicable and benchmark periods illustrated in Figure 1 in section 40.3 of this revised guidance, the example values in section 70.2 of this revised guidance, and the CPI-U values below, the following are example calculations of the inflation-adjusted payment amount:

CPI-U January 2021: 261.582

CPI-U October 2022: 298.012
CPI-U January 2022: 281.148
CPI-U October 2023: 307.671

Example 1

For Part D rebatable drugs first approved or licensed on or before October 1, 2021: Benchmark Period Manufacturer Price *multiplied by* (CPI-U October applicable period/CPI-U January 2021)

$99.86 * (298.012/261.582) = $113.77

Example 2

For Part D rebatable drugs first approved or licensed after October 1, 2021 and marketed before January 1, 2022: Benchmark Period Manufacturer Price *multiplied by* (CPI-U October applicable period/CPI-U January of calendar year after drug is first marketed)

$100.20 * (307.671/281.148) = $109.65

70.8 Calculation of per Unit Rebate Amount

Formula

The per unit rebate amount for a Part D rebatable drug is equal to:

The amount by which the AnMP for the Part D Rebatable Drug *exceeds* the Inflation-Adjusted Payment Amount.

Example

Using the example data in section 70.2, the per unit rebate amount for a Part D rebatable drug licensed or approved on or before October 1, 2021 would be:

AnMP for the Part D Rebatable Drug *minus* Inflation-Adjusted Payment Amount =

$120.01 – $113.77= $6.24

70.9 Calculation of Total Rebate Amount Owed by Manufacturer per Part D Rebatable Drug

Formula

Total Rebates Owed = Total PDE Units of a Part D Rebatable Drug dispensed under Part D and covered by Part D sponsors for an applicable period *multiplied by* the Per Unit Rebate Amount

Example

Using the example data in section 70.2 of this guidance (and, for this example, assuming that no unit type conversion is required between AMP units and PDE units), the total rebate amount owed by a manufacturer for a Part D rebatable drug licensed or approved on or before October 1, 2021 is as follows:

Total Rebates Owed =

(Oct Units + Nov Units + Dec Units + Jan Units + … + Sep Units) * Per Unit Rebate Amount =

1,980 * $6.24 = $12,355.20

70.10 Calculation of the Part D Rebatable Line Extension Drug Inflation Rebate

Formula

The per unit rebate amount for a Part D rebatable line extension drug is the amount that is the greater of:

- Rebate amount for the Part D rebatable line extension drug determined under section 1860D-14B(b); or
- Alternative inflation rebate amount: (Per unit rebate amount for the initial drug for the applicable period *divided by* the AnMP for the initial drug for the applicable period) *multiplied by* the AnMP for the line extension drug for the applicable period
    - Note: the initial drug used will be the initial drug identified by the manufacturer in the last quarter of the applicable period. If an initial drug was not identified in the fourth quarter for a drug that is a line extension, CMS will use the initial drug identified most recently in that applicable period.

Example

Using the following illustrative values:

- Per unit rebate amount for line extension drug determined under section 1860D-14B(b) = $0.50
- Line extension drug applicable period AnMP = $3.00
- Initial drug per unit rebate amount = $1.50
- Initial drug applicable period AnMP = $4.00

The per unit rebate amount for the line extension drug determined under section 1860D-14B(b) is $0.50.

The per unit rebate amount for the line extension drug using the alternative inflation rebate calculation is:
($1.50/$4.00) * $3.00 = $1.13.

Because $1.13 > $0.50, the per unit rebate amount for the line extension drug is $1.13.

70.11 Reducing the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on an FDA Shortage List – Determination of Rebate Reduction for Part D Rebatable Drugs Changing Shortage Status

Formula

Reduced Applicable Period Rebate Amount = applicable period rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was listed as currently in shortage during applicable period) + applicable period rebate amount *multiplied by* (1 *minus* percentage time drug was listed as currently in shortage during applicable period)

Example

Using the following illustrative values for a Part D rebatable drug that is not a generic drug or plasma-derived product, that was first approved or licensed and marketed on or before October 1, 2021, and for which a rebate amount is owed:

- Applicable Period Rebate Amount: $1,000
- First Applicable Period = October 1, 2022 – September 30, 2023 (365 days)
- Second Applicable Period = October 1, 2023 – September 30, 2024 (366 days)
- Percent Reduction for First Applicable Period = 25%
- Percent Reduction for Second Applicable Period = 10%
- Listed as currently in shortage on an FDA shortage list from October 1, 2022 – January 31, 2023
- Changed to resolved February 1, 2023 – May 31, 2023
- Reverted back to currently in shortage for June 1, 2023 – December 31, 2023
- Changed to resolved January – September 2024:

The drug was listed as currently in shortage on an FDA shortage list from October 1, 2022 – January 31, 2023 (123 days) and June 1, 2023 – September 30, 2023 (122 days) for a total of 245 days of the 365-day first applicable period, or about **67%** of the first applicable period.[53]

The drug was listed as currently in shortage on an FDA shortage list from October 1, 2023 – December 31, 2023 (92 days) of the 366-day second applicable period or about **25%** of the second applicable period.

Reduced First Applicable Period Rebate Amount = $1,000 *multiplied by* (1 *minus* 0.25) *multiplied by* **0.67** + $1,000 *multiplied by* (1 *minus* **0.67**)

Reduced First Applicable Period Rebate Amount = $832.50

Reduced Second Applicable Period Rebate Amount = $1,000 *multiplied by* (1 *minus* 0.10) *multiplied by* **0.25** + $1,000 *multiplied by* (1 *minus* **0.25**)

Reduced Second Applicable Period Rebate Amount = $975.00

[53] The amounts in this example are rounded for the purposes of illustrating how CMS will calculate the reduced applicable period rebate amount for Part D rebatable drugs that are "currently in shortage" on an FDA shortage list. CMS will not round the amounts in interim calculations but will round to the nearest cent for the final rebate amount.

Table 1: Examples of Rebate Reductions for Part D Rebatable Drugs Changing Shortage Status

Shortage Timeline	Applicable Period 1	Applicable Period 2	Applicable Period 3	Applicable Period 4
Drug A	Status changes from no shortage to "Currently in Shortage"	Status changes from "Currently in Shortage" to "Resolved"	"Resolved"	"Resolved"
Percent Reduction for Drug A	25% * (days in shortage / days in applicable period)	10% * (days in shortage / days in applicable period)	0%	0%
Drug B	"Currently in Shortage"	"Currently in Shortage"	"Currently in Shortage"	Status changes from "Currently in Shortage" to "Resolved"
Percent Reduction for Drug B	25%	10%	2%	2% * (days in shortage / days in applicable period)
Drug C	"Currently in Shortage"	Status changes from "Currently in Shortage" to "Resolved"	"Resolved"	Status changes from "Resolved" to "Currently in Shortage"
Percent Reduction for Drug C	25%	10% (days in shortage / days in applicable period)	0%	25% * (days in shortage / days in applicable period)

This example applies to Part D rebatable drugs that are not generic drugs or plasma-derived products.

Appendix: Summary of Data Timelines for Part D Drug Inflation Rebate Provisions