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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 B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act

This memorandum provides interested parties with the revised Medicare Part B Drug Inflation Rebate Program guidance. 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 B 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 B Drug Inflation Rebate Program, which begins on page 44, and for which a [table of contents](#) appears on page 45.

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

A. Introduction

Section 11101 of the Inflation Reduction Act (IRA), P.L. 117-169, added a new section 1847A(i) to the Social Security Act (the Act) establishing a requirement for manufacturers to pay Medicare Part B rebates for certain single-source drugs and biological products with prices that increase faster than the rate of inflation for a calendar quarter. In accordance with the law, on February 9, 2023, CMS issued an initial memorandum for implementation as authorized by section 1847A(c)(5)(C) of the Act. CMS also voluntarily solicited comments on a number of key aspects of 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 37 timely comment letters in response to the initial memorandum representing a wide range of views; commenters included academic experts and thought leaders, consumer and patient organizations, data vendors/software

technology entities, health plans, health care providers, health systems, individuals, pharmaceutical and biotechnology manufacturers, trade associations, and pharmacies.

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.

After consideration of the comments received, CMS is making certain changes to policies described in the initial memorandum in this revised guidance for 2023 and 2024. These comments also may be considered in development of rulemaking for future implementation of the Part B 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 under the Part B 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 B Drug Inflation Rebate Program Revised Guidance

CMS received many constructive, thoughtful, and helpful comments from consumer and patient groups, manufacturers, pharmacies, individuals, 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 B Rebatable Drugs and Exclusions

- **Identification of Part B Rebatable Drugs:** CMS has clarified that generic drugs (those approved under an Abbreviated New Drug Application (ANDA) submitted under 505(j) of the Food, Drug, & Cosmetic (FD&C) Act) do not meet the definition of “single source drug or biological product,” and thus are not Part B rebatable drugs. CMS has revised section 30.1 of this revised guidance to clarify that single-source drugs or biological products that are within the same billing and payment code as of October 1, 2003, per section 1847A(c)(6)(C)(ii) of the Act, also will be excluded from the definition of a Part B rebatable drug. CMS also has clarified in this section that it is excluding units of separately payable radiopharmaceuticals for the purposes of identifying Part B rebatable drugs at this time. As such, these units of radiopharmaceuticals also will not be subject to the coinsurance adjustment at this time.

- Exclusion of Drugs Where the Average Total Allowed Charges Under Part B is Less Than \$100 per Individual Using Such Drug 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 describe CMS' methodology for identifying drugs where the average total allowed charges is less than \$100 per individual per year in instances when a single-source drug or biological product was initially billed under a grouped Healthcare Common Procedures Coding System (HCPCS) code (e.g., a not otherwise classified (NOC) code) and was later billed under a unique HCPCS code.^{1, 2}

Section 50—Calculation of the Medicare Part B Drug Inflation Rebate Amount

- Overview of the Calculation of the Medicare Part B Inflation Rebate Amount: CMS has clarified in section 50.1 that the calculation of the Part B inflation rebate amount will not be adjusted for sequestration.³ That is, CMS will not apply sequestration to either the inflation adjusted payment amount (benchmark quarter) or the specified payment amount (rebate quarter).
- Identification of the Payment Amount Benchmark Quarter: CMS has revised section 50.3 to address situations in which a Part B rebatable drug approved or licensed by the U.S. Food and Drug Administration (FDA) on or before December 1, 2020 is not marketed until after that date and does not have ASP or WAC data to report for the July 1, 2021 to September 30, 2021 payment amount benchmark quarter. As described in section 50.3 of this revised guidance, CMS will treat such drugs in the same manner in which it will treat subsequently approved drugs. CMS intends to address this policy in future rulemaking and will solicit comments on this policy at that time. CMS also has revised section 50.3 to state that it will use the first date of sale of any National Drug Code (NDC) ever marketed under any New Drug Application (NDA) or Biologics License Application (BLA) associated with the HCPCS code to define first marketing date.
- Identification of the Payment Amount in the Payment Amount Benchmark Quarter: CMS has revised section 50.4 to describe its approach for identifying the payment amount in the payment amount benchmark quarter for Part B rebatable drugs previously billed under a grouped HCPCS code during the benchmark quarter and later billed under unique HCPCS codes.
- Identification of the Benchmark Period CPI-U: CMS has clarified in section 50.5 that the benchmark period CPI-U for Part B rebatable drugs that were previously billed under a grouped, NOC code is the first month of the third full quarter after the drug was assigned a unique HCPCS code.
- Removal of Units with a Rebate Under Section 1927 of the Social Security Act: CMS has revised section 50.8.2 to state that CMS will remove units from claims with dates of service during a month within a rebate quarter when the Medicare beneficiary has Medicaid coverage that may provide cost-sharing assistance. These are Qualified

¹ "HCPCS code" means the Healthcare Common Procedure Coding System code to which a Part B rebatable drug has been assigned.

² Single-source drugs or biological products are typically assigned to their own unique HCPCS codes (i.e., they are the only drug associated with a specific HCPCS code). Drugs for which there are two or more products rated as therapeutically equivalent are multiple-source drugs, and such drugs are typically assigned to the same HCPCS code.

³ Sequestration refers to mandatory, across-the-board spending cuts in certain types of federal spending, including Medicare.

Medicare Beneficiary (QMB) Plus, Specified Low-Income Medicare Beneficiary (SLMB) Plus, QMB-only beneficiaries, and other full dually eligible beneficiaries.

- Removal of Units that Are Packaged into the Payment Amount for an Item or Service and Are Not Separately Payable: CMS has revised section 50.8.3 of this revised guidance to state that because units of biosimilar biological products that are not packaged into the payment amount for an item or services are separately payable, they will be included in the Part B inflation rebate calculation. Such products will be excepted from the Hospital Outpatient Prospective Payment System (OPPS) threshold packaging policy when their reference biological products are separately paid from the set of Part B rebatable drugs.
- Removal of Units Subject to Discarded Drug Refunds: CMS has added section 50.8.6 of this revised guidance to note that CMS may consider a policy to exclude units of discarded amounts of a drug or biological that exceed the applicable percentage (i.e., threshold), and for which manufacturers are required to pay a refund, from the calculation of Part B inflation rebates in future rulemaking. This new section also explains the process CMS may pursue for removing units of discarded drugs from the calculation of rebates. CMS intends to address this policy in future rulemaking and will solicit comments on this policy at that time.
- Reducing the Rebate Amount in the Case of a Part B Rebatable Drug Currently in Shortage on a U.S. FDA Shortage List: CMS has revised section 50.11 to state that for a Part B rebatable drug that is described as “currently in shortage”⁴ on an FDA shortage list at any point during a calendar quarter, 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 in a calendar quarter, divide by the number of days in the calendar quarter, and then multiply that amount by a percentage that is decreased over time. CMS will provide a greater reduction for plasma-derived products. For a Part B rebatable drug that is not a plasma-derived product, the reduction will be 25 percent for the first four calendar quarters such drug is “currently in shortage” on a shortage list, 10 percent for the second four calendar quarters, and 2 percent for all calendar quarters thereafter. For a Part B rebatable drug that is a plasma-derived product, the reduction will be 75 percent for the first four consecutive calendar quarters, 50 percent for the second four consecutive calendar quarters, and 25 percent for all subsequent calendar quarters.
- Reducing the Rebate Amount for a Part B Rebatable Biosimilar Biological Product When There is a Severe Supply Chain Disruption: CMS has revised section 50.12 to state that CMS will provide a time-limited, standard reduction of 75 percent in the rebate amount for a Part B rebatable drug that is a biosimilar biological product (“Part B rebatable biosimilar biological product”) when there is a severe supply chain disruption during a calendar quarter, such as that caused by a natural disaster or other unique or unexpected event. CMS has further revised section 50.12 to modify the definition of a severe supply chain disruption. CMS also revised section 50.12 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 by the manufacturer of a Part B rebatable biosimilar biological product to CMS in order to receive consideration for a rebate reduction under this policy. If CMS determines that a reduction should be granted, CMS

⁴ For the purposes of this revised guidance, CMS uses the term “currently in shortage” to refer to Part B 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.

will provide a reduction in the rebate amount for the calendar quarter in which the severe supply chain disruption occurred and the three subsequent calendar quarters thereafter. 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 the fifth through eighth calendar quarters for a maximum of eight calendar quarters. CMS has clarified in section 50.12 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 Part B rebatable biosimilar biological product at the HCPCS code level.

Section 60—Ensuring Integrity of the Medicare Part B Drug Inflation Rebates

- **Overview of the Reporting Processes:** CMS has clarified in section 60 the process CMS will use to report the rebate amount to the manufacturer of a Part B rebatable drug. CMS is considering options for restatement of the rebate amount to be addressed in future rulemaking to account for revised information, and has removed the proposed true-up process from this guidance. For a potential restatement process for a Part B rebatable drug, CMS is considering what timing for recalculation may be appropriate to capture relevant changes to data inputs and whether timing should align with that in the Part D revised rebate guidance.
- **Process for Rebate Reports and Suggestion of Calculation Error:** CMS has revised section 60.1 to clarify that CMS will provide a Preliminary Report, followed by a period of 10 calendar days for a manufacturer of a Part B 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 B rebatable drugs.
- **Rebate Reports for Calendar Quarters in Calendar Year (CY) 2023 and CY 2024:** CMS has revised section 60.2 to provide information on the Rebate Reports for CY 2023 and CY 2024. CMS will provide Rebate Reports for calendar quarters in CY 2023 and CY 2024 to manufacturers no later than September 30, 2025, per section 1847A(i)(1)(C) of the Act. CMS will issue one Rebate Report for the four quarters in CY 2023 and one Rebate Report for the four quarters in CY 2024. CMS will provide a period of 30 calendar days for a manufacturer of a Part B rebatable drug to review their Preliminary Rebate Report and submit a Suggestion of Calculation Error to CMS, if applicable, for these quarters.

Section 70—Enforcement of Rebate Amount Payments by Manufacturers

- **Payment Obligations and Civil Monetary Penalties:** CMS has reaffirmed in section 70 that manufacturers that do not pay the Medicare Part B inflation rebate amount owed for a calendar quarter for a Part B rebatable drug within 30 calendar days of receiving a rebate invoice (i.e., the Rebate Report) may be subject to a civil monetary penalty (CMP) of at least 125 percent of the rebate amount, as applicable, for such drug for such quarter. The manufacturer will be held responsible for paying the full rebate amount in the Rebate Report and any CMP amount levied for late payment. CMS has added that the agency will issue a reminder notice regarding the due date of rebate payments. CMS has 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.

Section 80—Formulas

- Example Calculations: CMS has added example data and calculations to illustrate how CMS will calculate the Part B inflation rebate amount. CMS has also revised section 80 to add a formula and example to illustrate rebate reductions in the case when a Part B rebatable drug is no longer described as “currently in shortage” on an FDA shortage list.

C. Summary of Public Comments on the Initial Medicare Part B Drug Inflation Rebates Memorandum and CMS' Responses⁵

General Comments

Comment: A couple of commenters expressed concern with CMS issuing portions of the initial memorandum as final without requesting public comment. They stated that by not accepting comments on all sections of the initial memorandum, CMS “shortchanged” interested parties and undermined due process. One of these commenters also noted that the Inflation Reduction Act does not provide sufficient time for CMS to implement processes and procedures necessary to ensure compliance.

Response: Section 1847A(c)(5)(C) of the Act permits the Secretary to implement the Medicare Part B Inflation Rebate Program using program instruction or otherwise. Thus, the initial memorandum is not subject to the notice-and-comment requirements of the Administrative Procedure Act. CMS concluded that there was good cause to issue parts of the initial memorandum as final due to timing constraints to implement the adjustment to beneficiary coinsurance for April 2023. Although sections 30, 40, 50.2 to 50.7, and 50.9 were issued as final, CMS received 16 timely comments on these sections. In this revised guidance, CMS summarizes and responds to those comments, and CMS revised section 30 to help clarify, as needed, policies it will follow to implement the determination of Part B rebatable drugs. CMS will continue to consider comments it received as it develops guidance and rulemaking for future years of the Part B Inflation Rebate Program.

CMS disagrees that interested parties were shortchanged in their opportunity to provide comments on the initial memorandum. CMS engaged with the interested parties through various platforms, including meetings held before and after the initial memorandum was published. After the publication of the initial rebate guidance memorandum, CMS held a one-hour call to discuss the memorandum and take questions from manufacturer participants in February 2023. In Fall of 2022, CMS established an IRA webpage for all IRA program policies and updates and created an IRA mailbox (IRAREbateandNegotiation@cms.hhs.gov) to receive queries from the public related to implementation of the Part B and Part D Inflation Rebate Programs and the Medicare Drug Price Negotiation Program. For example, CMS received queries through the IRA mailbox from interested parties on whether dually eligible enrollees are eligible for the coinsurance adjustment.

Comment: A few commenters recommended CMS include responses to comments and describe how guidance has been revised based on feedback from interested parties. One of these commenters expressed the importance of CMS ensuring transparency by meaningfully considering and responding to feedback from interested parties on its proposals.

Response: CMS appreciates the commenters' suggestions. CMS agrees that it is important to consider and respond to feedback from interested parties on proposals. As such, in this revised guidance, CMS has summarized key changes and clarifications made to the initial memorandum

⁵ CMS did not receive comments on sections 20, 30.2, 50.2, 50.5 – 50.7, and 80 of the initial memorandum that are not otherwise addressed here.

based on comments and feedback from interested parties. CMS also provides summaries of significant comments it received in response to the initial memorandum and the agency's response to those comments.

Identification of Part B Rebatable Drugs and Exclusions ([Section 30](#))

Although section 30 was issued as final in the initial memorandum due to timing constraints for implementation of the adjustment to beneficiary coinsurance, CMS received comments on section 30. In this revised guidance, CMS summarizes and responds to those comments, and CMS revised sections 30.1 and 30.3 to help clarify, as needed, the policies it will follow to implement the Part B Inflation Rebate Program. CMS will continue to consider these comments as it develops guidance and rulemaking for future years of the Part B Inflation Rebate Program.

Identification of Part B Rebatable Drugs ([Section 30.1](#))

Comment: A few commenters recommended that CMS clarify in revised guidance that the exclusion for “multiple-source drugs” applies to all drugs defined under section 1847A(c)(6)(C) of the Act, including single-source drugs that the statute requires CMS to “treat” as multiple-source drugs under clause (ii) of that section. Commenters stated that because the statute requires CMS to treat these drugs as if they are multiple-source drugs, it would not be permissible for CMS to apply Part B inflation rebates to these drugs, as the inflation rebate applies only to single-source drugs.

Response: CMS appreciates the commenters' recommendation. CMS clarified in section 30.1 of this revised guidance that single-source drugs or biological products that were within the same billing and payment code as of October 1, 2003 are treated as multiple-source drugs, per section 1847A(c)(6)(C)(ii) of the Act, and will be excluded from the definition of a Part B rebatable drug. CMS interprets the provisions in section 1847A(c)(6)(C)(ii) of the Act to mean that single-source drugs or biological products are treated as multiple-source drugs if they were within the same HCPCS code as of October 1, 2003. Because section 1847A(i)(2) of the Act defines a Part B rebatable drug as a “single-source or biological (as defined in subparagraph (D) of subsection (c)(6))...,” which requires that a single-source drug not be a multiple source drug, drugs and biological products described in subclause (c)(6)(C)(ii) are excluded from the definition of a Part B rebatable drug and therefore are not subject to Part B inflation rebates. Additionally, CMS clarified in section 30.1 that generic drugs (those approved under an ANDA submitted under 505(j) of the FD&C Act do not meet the definition of “single source drug or biological product,” and thus are not Part B rebatable drugs.

Comment: A couple of commenters requested CMS clarify that skin substitutes will not be subject to Part B inflation rebates for 2023 and in future years and will not be subject to the beneficiary coinsurance adjustment. One commenter additionally expressed concern that the initial memorandum suggests CMS has the authority to consider skin substitutes as Part B rebatable drugs in the future. The commenter noted that skin substitutes are neither single-source drugs, biological products, or biosimilar biological products; therefore, they cannot be Part B rebatable drugs.

Response: CMS thanks these commenters for their input. CMS reiterates in this revised guidance it will exclude HCPCS codes that describe products currently referred to as skin substitutes for the purposes of identifying Part B rebatable drugs at this time. As such, these products will not be subject to the beneficiary coinsurance adjustment, as CMS continues broader policy deliberation regarding Medicare skin substitute payment.

Comment: One commenter supported CMS' intention not to include, for the purposes of identifying as Part B rebatable drugs, units of drugs and biological products billed using a HCPCS code that represents an "unclassified," "unspecified," or NOC drug or biological product or claims for such products when no other HCPCS code is applicable. The commenter also asked CMS to specify in final guidance that new Part B drugs are not subject to inflation rebates until a HCPCS code is assigned.

Response: CMS appreciates the commenter's support. Consistent with this revised guidance, CMS will exclude drugs and biological products that are billed using a HCPCS code that represents an "unclassified," "unspecified," or NOC drug or biological product or claims for such drugs and biological products when no other HCPCS code is assigned. Additionally, CMS clarified in section 50.4 of this revised guidance that in instances when Part B rebatable drugs that were previously billed under a NOC code are later assigned a unique HCPCS code, CMS will use the payment amount in the payment amount benchmark quarter for the third full quarter in which a drug was assigned a unique HCPCS code.

Comment: One commenter requested clarification on how the payment amount for the payment amount benchmark quarter would be calculated for new Part B drugs where a HCPCS payment amount has not yet been set. The commenter recommended that since manufacturers submit NDC-11 level ASPs for these new drugs, CMS use these data for each HCPCS code to calculate the payment amount. The commenter also requested CMS provide manufacturers with the methodology for this calculation. Another commenter expressed concerns that the initial memorandum assumes new drugs will have a dedicated (or unique) HCPCS code during the benchmark quarter, which it states could be problematic because some newly marketed drugs are not assigned dedicated HCPCS codes by the third full quarter after marketing. The commenter noted that if CMS intends to use HCPCS codes in determining the rebate amounts, it should ensure HCPCS codes are available by the payment amount benchmark quarter and establish a plan for handling cases when HCPCS codes are not yet available during this quarter.

Response: CMS appreciates the commenters' input. The comments reference drugs that have not been assigned a HCPCS code and where a payment amount has not been established. In these cases, such drugs would be billed to Part B using a HCPCS code that represents an "unclassified," "unspecified," or NOC drug or biological product. Consistent with both the initial version of this guidance and this revised guidance, CMS will exclude drugs and biological products that are billed using a HCPCS code that represents an "unclassified," "unspecified," or NOC drug or biological product or claims for such drugs and biological products when no other HCPCS code is assigned. CMS notes that the quarterly process for updating HCPCS codes, including establishing new HCPCS codes, provides an existing mechanism for CMS to use to minimize the number of Part B rebatable drugs that would be billed with "unclassified," "unspecified," or NOC codes. Additionally, CMS is undertaking an effort to reduce the use of NOC codes and establish or

revise HCPCS codes to separately identify these products.⁶ CMS publishes current and prior coding decision summaries at <https://www.cms.gov/medicare/coding/medhcpcsgeninfo/prior-years-cms-hcpcs-levelii-coding-decisions-narrative-summary>. Although CMS has a process to determine the allowed payment amount when such HCPCS codes are billed, current Medicare claims data do not allow CMS to determine the average total allowed charges for such drug or biological product for a year per individual that uses such a drug or biological product, or to identify units billed—which are necessary steps to determine if a drug is a Part B rebatable drug. Furthermore, CMS notes the clarification in section 50.4 of this revised guidance that in instances when Part B rebatable drugs that were previously billed under a NOC code and later assigned a unique HCPCS code, CMS will use the payment amount in the payment amount benchmark quarter for the third full quarter in which a drug was assigned a unique HCPCS code. Finally, as described in section 60.2 of this revised guidance, manufacturers may submit a Suggestion of Calculation Error in response to these reports if they believe a mathematical error was made or appropriate exclusions were not applied.

Comment: One commenter noted that errors associated with changes to “single-source” status may be an area where manufacturers seek to correct or amend Part B rebate invoices and requested a forum to resolve discrepancies between CMS’ determination that a drug is no longer “single-source” and a manufacturer’s determination.

Response: CMS appreciates the commenter’s remark. Section 1847A(i)(8) of the Act precludes administrative or judicial review of the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount. Disputes on these topics will not be considered. Manufacturers of Part B rebatable drugs that owe an inflation rebate can submit a Suggestion of Calculation Error if they identify a mathematical error in the calculation by CMS, which CMS may consider at its discretion.

Exclusion for Certain Vaccines ([Section 30.3](#))

Comment: One commenter requested that CMS update section 30.3 of the initial memorandum to clarify that monoclonal antibodies indicated for pre-exposure prophylaxis against COVID-19, which will continue to be covered and paid for under section 1861(s)(10) of the Act after the relevant emergency use authorization declaration is terminated, are also excluded from the Part B inflation rebate, in accordance with their understanding of the 2023 Physician Fee Schedule final rule.

Response: Section 30.3 of this revised guidance clarifies that monoclonal antibodies indicated for pre-exposure prophylaxis against COVID-19 and covered and paid for under section 1861(s)(10) of the Act, as described in the CY 2024 Physician Fee Schedule (PFS) final rule, are excluded from the Part B inflation rebate.

With respect to monoclonal antibodies used as treatment or post-exposure prophylaxis of COVID-19, which are covered and paid for under the under section 1861(s)(10) of the Act through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act for drugs and biological products is terminated, we also clarified in the revised

⁶ See: <https://www.cms.gov/files/document/frequently-asked-questions-single-source-drugs-and-biologicals.pdf>.

Section 30.3 that these products will be excluded from the definition of Part B rebatable drug for applicable calendar quarters.

Computation of Beneficiary Coinsurance and Amounts Paid Under Section 1833(a)(1)(EE) of the Social Security Act ([Section 40](#))

Comment: Some commenters expressed support for the section 40 guidance on Computation of Beneficiary Coinsurance and Amounts Paid Under Section 1833(a)(1)(EE) of the Act. Some commenters stated the implementation of the Part B coinsurance change will effectively protect Medicare beneficiaries from the higher coinsurance that would normally result from drug price increases that exceed inflation and would lower out-of-pocket costs. One commenter stated that CMS’ plan to base coinsurance on the inflation adjusted “list” price will provide meaningful savings to people on Medicare even if manufacturers decide to raise prices beyond inflation. This commenter noted the policy will protect beneficiaries from annual price increases and provide predictability in their drug costs and that reduced prices, improved health, and prevention of hospitalizations will greatly enrich the health and wellbeing of their patient community. One commenter stated the adjusted coinsurance policy is essential because high out-of-pocket costs are a major contributor to medication non-adherence and consequently worse patient health outcomes.

Response: CMS thanks commenters for their support of this policy. Before the beginning of each calendar quarter, CMS posts payment information for separately payable Part B drugs, including the Part B rebatable drugs subject to the coinsurance adjustments, in the Medicare Part B Quarterly Average Sales Price (ASP) public files, which are available on CMS.gov. Each ASP public file also includes the coinsurance adjustments for certain Part B rebatable drugs as required by the IRA. Additionally, CMS publishes a separate “Reduced Coinsurance for Certain Part B Rebatable Drugs under the Medicare Prescription Drug Inflation Rebate Program” document quarterly that lists the HCPCS and drug names of all drugs with an inflation-adjusted coinsurance. As discussed in section 40 of this revised guidance, if the payment limit for the drug for the applicable quarter is subsequently revised, CMS will determine the coinsurance percentage based on the revised payment limit. If corrections or updates to the files are required, CMS will issue restatements.

Comment: In reference to the timing of when ASP files with adjusted beneficiary coinsurance percentages are available, one commenter stated that receiving these files two weeks before the calendar quarter begins is not feasible from a systems perspective for plan sponsors or pharmacy benefit managers (PBMs) to reprogram and be ready to adjudicate claims at the adjusted coinsurance in time. The same commenter also sought clarification on the timing of when ASP files would be available ahead of each quarter. The commenter noted that section 30 of the initial memorandum says, “approximately two months before the start of a calendar quarter, CMS will identify Part B rebatable drugs using available information in order to determine the beneficiary coinsurance percentage that is applicable for the calendar quarter.” The commenter further notes a statement made on the Monthly CMS Part C&D IRA User Call on February 8, 2023, where CMS stated that it could not commit to making the ASP files with adjusted beneficiary coinsurance percentages available more than two weeks in advance of a calendar quarter, and in some cases, it may be less. The commenter requested CMS clarify whether the two-month lead time discussed

in the initial memorandum is the timing CMS will follow to release these files starting with the July 1, 2023 calendar quarter.

Response: CMS thanks the commenter for raising this operational concern when implementing the adjusted beneficiary coinsurance policy. CMS clarified in section 30.1 of this revised guidance that it begins the process to identify Part B rebatable drugs and determine the beneficiary coinsurance percentage two months before the applicable quarter. As CMS requires ASP data from manufacturers to determine which Part B rebatable drugs should have adjusted coinsurance in the applicable quarter, and ASP submissions are not due until two months before the start of the applicable quarter, CMS cannot start the process earlier. In addition to the time required for manufacturers to submit ASP data, CMS also requires time to complete the complex analysis and perform quality checks before issuing the files identifying HCPCS codes with adjusted coinsurance for the upcoming quarter. CMS issues the ASP files and list of drugs with inflation-adjusted coinsurance percentages before the start of each quarter and may issue restatements at any time needed corrections are identified.

Comment: One commenter expressed appreciation to CMS for beginning the process to identify Part B drugs subject to a reduced coinsurance two months before the start of a calendar quarter because Medicare Advantage (MA) plans need sufficient lead time to operationalize the beneficiary coinsurance percentages. The commenter recommended that CMS work with plans during the quarter when the adjusted coinsurance percentages first apply to address any implementation challenges and mitigate any member confusion.

Response: CMS thanks the commenter for this feedback. CMS is committed to promoting transparency and engagement about the Part B Inflation Rebate Program and reduced coinsurance for certain Part B rebatable drugs. Each quarter, CMS posts payment information for separately payable Part B drugs, including the Part B rebatable drugs subject to the coinsurance adjustments, in the Medicare Part B Quarterly ASP public files, which are available on CMS.gov. Each ASP public file also includes the coinsurance adjustments for certain Part B rebatable drugs as required by the IRA. Additionally, CMS established an IRA mailbox (IRAREbateandNegotiation@cms.hhs.gov) to receive queries related to implementation of the Part B and Part D Inflation Rebate Programs and the Negotiation Program. CMS encourages interested parties with questions to submit questions about the Part B Inflation Rebate Program to this mailbox. Questions on the ASP public files or reduced coinsurance for Part B rebatable drugs should be sent to the ASP mailbox (sec303aspdata@cms.hhs.gov).

Comment: One commenter requested guidance on whether the beneficiary coinsurance adjustment for Part B rebatable drugs applies to out-of-network claims.

Response: Please refer to the HPMS memo titled, “Inflation Reduction Act Changes to Cost-Sharing for Part B Drugs for Contract Year 2023, Medicare Advantage and Section 1876 cost plans” issued November 7, 2022, which references requirements at 42 C.F.R., § 422.100(j).⁷

⁷ Available at <https://www.cms.gov/httpseeditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-hpms-memos-archive/hpms-memos-wk-2-november-7-11>.

Comment: A few commenters recommended CMS engage with provider and patient communities to support understanding of the rebates and their impact on beneficiary coinsurance. One commenter recommended that CMS provide model language for member and provider communications describing the adjusted beneficiary coinsurance policy to ensure alignment on communications across health plans.

Response: As part of the implementation of the adjusted beneficiary coinsurance policy, CMS issued various documents to support provider and patient education. These include a fact sheet on the policy and quarterly lists of HCPCS codes subject to adjusted coinsurance.⁸ These materials and other fact sheets related to inflation rebates can be found on the CMS IRA webpage.⁹ For Medicare Advantage, CMS also issued the November 2022 “Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Contract Year 2023 Medicare Advantage and Section 1876 Cost Plans” memorandum and the July 2023 “Frequently Asked Questions: Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Medicare Advantage and Section 1876 Cost Plans” document.^{10, 11} CMS declines to issue model language describing the policy and instead refers interested parties to the previously referenced documents. Additional questions can be sent to the IRAREbateandNegotiation@cms.hhs.gov mailbox.

Calculation of the Medicare Part B Drug Inflation Rebate Amount ([Section 50](#))

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 B 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 B 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.¹² Although not expected, if a terminated drug meets the definition for a Part B rebatable drug and is administered and covered under Medicare Part B, Part B rebates would apply to these units. As detailed in section 50.1 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 B rebatable drug dispensed under and covered by Part B during the rebate quarter determined under section 50.8; and (2) the per unit Part B drug inflation rebate amount determined under section 50.1.

⁸ See: <https://www.cms.gov/files/document/fact-sheet-part-b-rebatable-drug-coinsurance-reduction.pdf> and <https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare>.

⁹ See <https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare>.

¹⁰ Available at <https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-hpms-memos-archive/hpms-memos-wk-2-november-7-11>.

¹¹ See: <https://mabenefitsmailbox.lmi.org/MABenefitsMailbox/S3Browser/GetFile?path=IRA%20Part%20B%20Rebatable%20Drugs%20and%20Insulin%20FAQs.pdf>.

¹² See: <https://oig.hhs.gov/oas/reports/region7/70903130.pdf>.

Overview of the Calculation of the Medicare Part B Inflation Rebate Amount ([Section 50.1](#))

Comment: One commenter recommended that CMS should not calculate inflation rebates for drugs that are in value-based arrangements. Specifically, the commenter noted that drugs used to treat rare and ultra-rare conditions may be disproportionately included in value-based arrangements, stating that such arrangements rely on patient-specific outcomes for determining the price for the treatment. The commenter also stated that fluctuations in ASP from quarter to quarter are particularly common for drugs treating rare and ultra-rare conditions and expressed concern about patient access to drugs being impeded if inflation rebates are imposed on manufacturers for drugs where the list price or contract terms have not changed. Another commenter similarly stated that ASP can fluctuate for reasons outside a manufacturer's control and when pricing changes have not occurred. This commenter recommended CMS monitor fluctuations in ASP and identify flexibilities to ensure inflation rebates do not harm patient access. Similarly, one commenter stated that CMS should consider historical pricing and factors that may justify price increases for a rebatable drug where inflation rebates may apply. The commenter provided an example of unexpected market or manufacturing conditions that may lead a manufacturer to raise the price of a drug to maintain positive margins. The commenter expressed concern that if rebates are applied for situations like these, manufacturers may choose to leave the market and thereby reduce patient access.

Response: CMS thanks the commenters for this feedback. CMS recognizes the price of drugs in value-based arrangements may be affected by patient-specific outcome measures, which may be, at least to some degree, outside the control of the manufacturer. CMS will implement the Part B Drug Inflation Rebate Program consistent with the statute and at this time will not exclude units of drugs in value-based arrangements from rebate calculations. CMS will monitor feedback on the Part B Drug Inflation Rebate Program's implementation related to value-based agreements and other considerations for potential fluctuations in ASP reporting.

As described in section 1847A(i)(3) of the Act and section 50 of this revised guidance, CMS is required to compare the inflation-adjusted payment amount to the specified amount, which is the amount set forth in 1847A(i)(3)(A)(ii)(I) of the Act. CMS is statutorily required to impose an inflation rebate if the specified amount exceeds the inflation-adjusted payment amount. However, beyond value-based arrangements, CMS recognizes that there are certain circumstances in which prices can fluctuate for reasons that may be, at least to some degree, outside of the control of a manufacturer. CMS directs readers to sections 50.10-50.12 of this memorandum, which details how CMS will reduce the rebate amount for Part B rebatable drugs in shortage and in cases of severe supply chain disruptions.

Comment: One commenter suggested CMS eliminate its current ASP reporting system and incorporate ASP reporting into the Medicaid Drug Program (MDP) system. The commenter stated this shift would be more efficient for users and that Medicare Part B unit data could be published for manufacturers in the system.

Response: CMS thanks the commenter for this feedback. CMS will use the existing ASP reporting system to gather the data to calculate ASP prices and inflation rebates. Future changes

to how ASP information is reported to CMS and what system is used are beyond the scope of this revised guidance.

Comment: One commenter suggested that CMS implement recommended guidance from U.S. Department of Health and Human Services (HHS) Office of Inspector General’s (OIG) December 2022 reports, “CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data to Ensure Accurate Part B Drug Payments” and “Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices” before implementing the Part B rebate provisions in the IRA. In these reports OIG recommended CMS: (1) build a strategy to strengthen its internal controls for ensuring the accuracy of Part B drug payments and (2) actively review current guidance related to the areas OIG identified and determine whether additional guidance would ensure more accurate and consistent ASP calculations.¹³ The commenter stated that guidance informed by these reports needs to precede implementation of the inflation rebates as manufacturers may change how they report ASP data in response to guidance. The commenter expressed concern that such changes may result in changes in ASP and be construed as price increases, instead of shifts due to manufacturers following guidance.

Response: CMS thanks the commenter for this feedback. CMS concurred with OIG’s recommendations in both reports. Specifically, CMS stated that it would review current related guidance and determine whether additional guidance and/or rulemaking is needed. CMS also stated that it concurred with OIG’s recommendation to develop a strategy to strengthen internal controls to ensure the accuracy of Part B payments. As required by law, the Part B inflation rebates began for quarters beginning in January 2023, one month after the OIG reports were published. Therefore, CMS could not issue all guidance and/or rulemaking that it deems necessary before the inflation rebate policy went into effect. CMS will remain cognizant of future guidance and/or rulemaking issued related to these reports and address how policies to improve ASP reporting will interact with the inflation rebate policy, if necessary, in the future.

Identification of the Payment Amount Benchmark Quarter ([Section 50.3](#))

Comment: One commenter suggested that CMS consider implementation of a WAC-based inflation rebate rather than the Part B payment amount-based rebate. The commenter stated several reasons for why they prefer a WAC-based inflation rebate, including manufacturer control over WAC, concerns about a rebate program based on payment for a HCPCS code that includes different products (and non-Part B-covered drugs), concerns over guidance and clarity around ASP, and predictability of WAC and WAC changes.

Response: As described in section 1847A(i)(3) of the Act and section 50 of this revised guidance, CMS is required to calculate the rebate amount for Part B drugs by comparing the inflation-adjusted payment amount to the lesser of 106 percent of either ASP or WAC for the calendar quarter for single-source drugs and biological products (the specified amount). For biosimilars, CMS must compare the inflation-adjusted payment amount to 100 percent of the ASP for the biosimilar biological product plus 6 percent (or 8 percent, if a biosimilar qualifies for the temporary add-on payment described in 1847A(b)(8) of the Act) of the lesser of ASP or WAC for the reference biological product for the calendar quarter (the specified amount). CMS cannot

¹³ See <https://oig.hhs.gov/oei/reports/OEI-03-21-00390.pdf> and <https://oig.hhs.gov/oei/reports/OEI-BL-21-00330.pdf>.

implement a solely WAC-based inflation rebate, as statute requires that CMS use the lesser of ASP or WAC for single-source drugs and biological products and ASP plus 6 percent of the reference product's ASP or WAC, whichever is lower, for biosimilars.

Comment: One commenter requested CMS provide clarification on whether the first marketed date for a Part B rebatable drug will apply to all NDCs within a HCPCS code or to a particular NDC. This commenter suggested that CMS clarify if the first marketed date to determine the payment amount benchmark quarter will change if the original NDC is terminated. Another commenter asked, since FDA approval is based on the NDA/BLA, if it was correct to assume that the same approval date would apply to all products and package sizes within the NDA/BLA.

Response: As described in section 50.3 of this revised guidance, the first marketed date of a Part B rebatable drug is evaluated at the level of the product's FDA approval (such as an NDA or BLA). This means that the first marketed date will be based on the earliest date of first sale of any NDC marketed under the same FDA application number (i.e., NDA or BLA) associated with a HCPCS code as of the rebate quarter, regardless of whether the drug was billed under that HCPCS code when those sales began. This first marketed date will apply to all NDCs within a HCPCS code and to all products and package sizes marketed under the same FDA approved application.

If the original NDC on which the first marketed date is based is terminated, the first marketed date will remain the same. Defining the first marketed date at the level of the product's FDA approval allows CMS to retain the same first marketed date even if the NDCs and/or HCPCS codes used to bill for the NDC change over time.

Comment: A few commenters sought clarification on how a payment amount benchmark would be determined for drugs that are approved on or before December 1, 2020, but first marketed after this date, resulting in no sales during the entirety of the payment amount benchmark quarter to calculate ASP. One of these commenters noted that, at a minimum, it would be helpful for CMS to confirm that manufacturers may use reasonable assumptions in such situations.

Response: CMS thanks these commenters for raising this issue. Given that drugs first approved or licensed on or before December 1, 2020, but not marketed until after that date, that lack ASP data from July 1, 2021 through September 30, 2021, would not have ASP or WAC data to calculate the payment amount in the payment amount benchmark quarter, 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 quarter based on the third full calendar quarter after the day on which the drug was first marketed. CMS has revised section 50.3 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. Additionally, with regard to reasonable assumptions, manufacturers are not required to submit any additional ASP information specifically to support the calculation of the payment amount benchmark period or the rebate beyond what is already required for the purposes of Part B and therefore whether a manufacturer would have to use reasonable assumptions in any such submission is moot.

Identification of the Payment Amount in the Payment Amount Benchmark Quarter ([Section 50.4](#))

Comment: One commenter expressed concern that CMS’ proposed approach to calculating the payment amount for the payment amount benchmark quarter could be subject to gaming. The commenter stated that since CMS will use the date of first sale reported by the manufacturer to determine the payment amount benchmark quarter, manufacturers may delay ASP reporting for the first full quarter of sales so that the payment amount for the benchmark quarter is based on WAC instead of ASP.

Response: CMS thanks the commenter for this feedback. When ASP is not available for a new drug, CMS will use WAC to determine the payment amount. CMS notes that section 1927(b)(3)(A)(iii)(I) of the Act requires manufacturers with a Medicaid drug rebate agreement to report ASP data as specified in section 1847A of the Act. Section 1847A(f)(2) of the Act requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs and biological products payable under Part B and described in sections 1842(o)(1)(C), (E), or (G) and 1881(b)(14)(B) of the Act. Additionally, sections 1847A(d)(4)(B) and (C) of the Act apply CMPs for failure to report timely and accurate ASP data for manufacturers without Medicaid drug rebate agreements, consistent with the civil money penalties found at sections 1927(b)(3)(C)(i) and (ii) of the Act for manufacturers with Medicaid drug rebate agreements.¹⁴ If CMS determines that a manufacturer has made a misrepresentation in the reporting of its ASP (including the date of first sale), CMS may refer the issue to HHS’ OIG to determine whether a CMP should be imposed.

Comment: One commenter requested clarification on whether the payment limit for a drug is based on the ASP data submitted by the manufacturer of that drug or if it is based on a volume-weighted ASP of all the drugs in a certain HCPCS code. If the latter, the commenter also requested clarity on whether that same approach would apply to calculating the “specified amount” described in section 50.1 of the initial memorandum.

Response: CMS issues quarterly ASP public files based on ASP data submitted by manufacturers. Generally, the payment limit is set per HCPCS code. Since Part B rebatable drugs are single-source drugs or biological products, they typically will have only one manufacturer. However, it is possible that a Part B rebatable drug may have multiple manufacturers that serve as repackagers/relabelers or sell an authorized generic of the drug. In this case, all NDCs for the drug for all manufacturers would be aggregated under the same HCPCS code(s) and a volume-weighted average of the manufacturers’ ASP would be calculated to determine the payment limit for the applicable HCPCS code. CMS confirms that, if ASP is used, the same approach would apply for calculating the specified amount.

Determination of the Total Number of Units ([Section 50.8](#))

Comment: A couple of commenters requested transparency from CMS on the methodology and calculations used to determine the total number of units subject to inflation rebates. One

¹⁴ See: <https://www.cms.gov/files/document/manufacturers-reporting-requirements-under-consolidations-appropriations-act-caa-2021.pdf>.

commenter requested visibility into the claims-level data so that CMS' determination of included and excluded units could be reviewed and validated. Similarly, commenters expressed concern regarding duplicate discounts across the 340B Program and the Part B Inflation Rebate Program and recommended CMS provide manufacturers with claims-level data to allow manufacturers to validate 340B units that are removed from Part B inflation rebate calculations. One commenter recommended CMS require covered entities to share claims-level data with manufacturers to avoid duplicate 340B discounts. One commenter recommended CMS establish a mechanism for manufacturers to identify 340B units in their Preliminary Rebate Report and Preliminary True-Up Rebate Report.

Response: Section 50.8 of this revised guidance provides details on the methodologies CMS will use to exclude the appropriate units from inflation rebates. CMS declines to provide claims-level data to manufacturers regarding the 340B Program or other statutory exclusions of units from rebate counts as CMS does not believe this is necessary to operate the program due to the Rebate Report policy described in section 60 of this revised guidance. As described in section 60.1 of this revised guidance, CMS will provide a Preliminary Rebate Report for each rebate quarter and has reserved consideration for a true-up process for future rulemaking. 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 60.1 of this revised guidance.

Removal of 340B Units ([Section 50.8.1](#))

Comment: Many commenters supported CMS' approach for excluding units subject to 340B pricing.

Response: CMS thanks these commenters for the support.

Comment: One commenter expressed concerns that 340B covered entities will not agree that CMS' December 2022 subregulatory 340B modifier guidance is legally binding, and will therefore underreport units.

Response: CMS believes the policies included in the initial memorandum and finalized in this revised guidance will help ensure accurate exclusion of 340B units from Part B inflation rebates. CMS is requiring all 340B covered entities to include the "JG" or "TB" modifier, as applicable, on separately payable claim lines for drugs acquired through the 340B Program with dates of service beginning no later than January 1, 2024. CMS will remove from the rebate calculation units in claim lines that were identified as being 340B units by being billed with the "JG" or "TB" modifiers for dates of service on or after January 1, 2024. For claims with dates of service during 2023, CMS will remove units in all institutional claim lines that were billed with the "JG" or "TB" modifiers and all other units in institutional claims submitted by critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments (PBDs).¹⁵

¹⁵ See: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf>.

For professional claims with dates of service during 2023, CMS will remove all units in claims for Medicare suppliers that are listed by the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System (OPAIS) as participating in the 340B Program, by using employer identification numbers (EINs) to identify these suppliers' Medicare Identification Numbers and the claims submitted with such identifiers. CMS believes that this method to identify 340B claims for dates of service during 2023 is the most appropriate method to operationalize excluding 340B claims with the available data.

Additionally, consistent with the CY 2024 OPPTS/Ambulatory Surgical Center (ASC) final rule, CMS will require a single 340B modifier ("TB"), for dates of service on or after January 1, 2025.¹⁶ As such, starting in CY 2025, CMS will identify 340B units in claim lines billed with the "TB" modifier from final action claims and remove these units from the calculation of Part B inflation rebates. CMS issued updated 340B modifier guidance on December 14, 2023 to revise its December 2022 guidance to align with the OPPTS/ASC final rule regarding the use of "TB" as a single 340B modifier for dates of service on or after January 1, 2025.¹⁷ Under section 1847A of the Act, CMS has the authority to implement the Part B drug inflation rebate program using program instruction; thus, the subregulatory guidance is legally binding. CMS expects Medicare providers and suppliers who bill for separately payable Part B drugs and biological products and participate in the 340B Program to comply with updated requirements to submit appropriate modifiers that are detailed not only in subregulatory guidance, but also in the OPPTS/ASC final rule.

Comment: Some commenters stated that creating an enforcement mechanism would ensure 340B covered entities consistently use claims modifiers and would allow for more accurate exclusion of 340B units from Part B inflation rebates. These commenters and some others recommended CMS require the use of a claims modifier to identify non-340B units, in addition to the "JG" or "TB" claims modifier to identify 340B units. Further, commenters recommended CMS specify that accurate use of the "JG" or "TB" claims modifiers or the non-340B claims modifier is necessary for a claim to be considered complete and eligible for reimbursement. A few commenters said this would align with CMS' approach for the Part B discarded drug modifier, where providers and suppliers submitting claims for single-dose container or single-use package drugs under Part B must use modifiers to indicate whether medicine was discarded or provided and document the number of units. One commenter stated that requiring providers to use a non-340B modifier would improve the integrity of the Part B Inflation Rebate Program, as providers would more closely consider the identification of 340B units and apply modifiers accordingly.

Some commenters recommended CMS establish an audit process to ensure adherence to program requirements. A few commenters recommended CMS establish an audit process that includes penalties for covered entities that have been determined to be out of compliance with the requirement to use accurate 340B claims modifiers, and restatements for manufacturer rebate obligations if appropriate.

¹⁶ See: <https://www.federalregister.gov/public-inspection/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>.

¹⁷ See: <https://www.cms.gov/files/document/revise-part-b-inflation-rebate-340b-modifier-guidance.pdf>.

Response: CMS thanks these commenters for their feedback. At this time, CMS does not believe a modifier is needed to report drugs or biological products that were not purchased under the 340B Program. CMS believes the requirement under the updated 340B modifier guidance and CY 2024 OPPTS/ASC final rule for providers and suppliers to use a 340B modifier will provide the data required to identify and exclude 340B units from Part B inflation rebates.^{18, 19} Providers are required to maintain current knowledge of Medicare billing policies and to submit accurate claims. Providers are also required to maintain all documentation to support the validity of the services reported on the claim and ensure this information is available upon request. Submitting inaccurately coded claims also may result in False Claims Act liability (31 U.S.C. §§ 3729-3733).

As such, CMS expects providers to submit accurate claims and utilize the correct modifiers. If a provider fails to use or accidentally omits the modifier and needs to make a correction to a claim, institutional providers and covered entities may submit adjustments claims to add a modifier. CMS intends for all rebate calculations to be as accurate as possible and is providing a process for manufacturers to review rebate calculations, as described in section 60 of this revised guidance. Section 1847A(i)(8) of the Act precludes administrative or judicial review of the determination of units under this program, the determination of whether a drug is a Part B rebatable drug, and the calculation of the rebate amount.

Comment: A few commenters noted that CMS should clarify that the required use of a 340B claims modifier preempts any state or local law conflicting with the requirement or prohibiting such modifier.

Response: CMS thanks these commenters for their recommendations. We note that the use of 340B claims modifiers in Medicare Part B is a longstanding practice for many 340B covered entities paid under the OPPTS, and CMS is not aware of any state laws that purport to prohibit the use of 340B claims modifiers on Medicare Part B claims.

Comment: Some commenters recommended CMS establish a clearinghouse model to identify or verify that claims are subject to 340B pricing. Commenters noted that a clearinghouse could be operated by a third-party administrator and this entity could verify the accuracy of 340B modifiers on Medicare claims. One commenter recommended any third-party contractor that CMS engages with should allow 340B technology vendors to share data to reduce burden on covered entities to manually upload reports.

Response: CMS thanks these commenters for their feedback. CMS believes that requiring a claims modifier will provide the necessary data to exclude 340B units from Part B inflation rebates for claims with dates of service starting in calendar year 2024. For professional claims with dates of service during 2023, CMS will also remove all units in claims for Medicare suppliers that are listed by HRSA's OPAIS as participating in the 340B Program, by using EINs to identify these suppliers' Medicare Identification Numbers and the claims submitted with such identifiers. CMS will continue to consider other methods to identify and to remove 340B units

¹⁸ See: <https://www.federalregister.gov/public-inspection/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>.

¹⁹ See: <https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf>.

from Part B inflation rebate calculations and improve the integrity of the Part B Inflation Rebate Program.

Comment: One commenter recommended CMS use a 340B claims identification process modeled on the process that the commenter indicated is used by the state of Oregon and allows covered entities to identify 340B Medicaid Managed Care Organization claims on a quarterly basis through a retrospective clearinghouse model. The commenter stated this model would allow covered entities to maintain more of the program savings, would present less administrative burden than requiring a claims modifier, would be consistent with the statute and HRSA guidance, would avoid the possibility of discriminatory practices by MA plans, and would be consistent with the many contract pharmacy arrangements and in-house retail pharmacies that rely on virtual inventory systems in which identification of 340B claims is performed after the drugs are furnished and billed. The commenter also stated that a model similar to that used in the state of Oregon would be more accurate because it would provide covered entities and pharmacies more time to verify the 340B patient-entity relationship. The commenter recommended the Oregon model as the preferred solution, but also proposed an alternative hybrid arrangement in which covered entities would download and submit a file of all 340B claims submitted by the covered entity and its contract pharmacies for a specified period to CMS or a vendor. The commenter noted that the deadline for submitting the file would give covered entities sufficient time to retrospectively identify claims for 340B drugs and CMS sufficient time to calculate and submit its rebate requests to manufacturers.

Response: CMS thanks this commenter for their feedback. CMS will calculate the rebate amount due to CMS from a manufacturer of a Part B rebatable drug and is required by section 1847A(i)(1)(A) of the Act to invoice the manufacturer within six months after the end of a calendar quarter for quarters in 2025 and beyond. Using a similar model to the Oregon model described by the commenter, which allows covered entities to identify 340B claims on a quarterly basis, may not provide CMS with access to data on 340B units with sufficient time to calculate rebate amounts and invoice manufacturers within six months of the end of a calendar quarter, as required by statute. At this time, CMS has determined that the best way to identify 340B units for Part B rebatable drugs and exclude these units from Part B inflation rebate calculations is to require a 340B claim modifier.

Comment: One commenter submitted a white paper and fact sheet discussing 340B modifier usage. The paper and fact sheet included information on the importance of 340B modifiers and how the modifiers are used for 340B-eligible drugs. It also detailed recommendations, including that monitoring of 340B modifiers should include Part B and Part D drugs, that a system could be evaluated to support identification of 340B drugs at the point of sale, and that additional transparency measures should be considered. Another commenter referenced the white paper in their comments, noting the cited study found 61 percent of drug treatments for Part B separately payable drugs originating at rural referral centers and sole community hospitals used a 340B modifier. By comparison, the commenter noted that the study found 89 percent of treatments for Part B separately payable drugs originating at disproportionate share hospitals used a 340B modifier. The commenter raised concerns regarding compliance with 340B modifier usage for rural referral centers and sole community hospitals because CMS requires these entities to use

340B modifiers on Medicare claims and they therefore expected 340B modifier usage more similar to that of disproportionate share hospitals.

Response: CMS thanks these commenters for sharing input regarding 340B modifier usage. Section 340B(a)(4) of the Public Health Service Act specifies which covered entities participate in the program. There are situations in which it is appropriate for rural referral centers and sole community hospitals to not use the relevant 340B claims modifier, for example when drugs are subject to the orphan drug exclusion. Therefore, it is not unexpected that these types of entities could have lower rates of utilization of 340B modifiers than other entities such as disproportionate share hospitals. CMS does not believe that covered entities are currently underreporting 340B claims. CMS expects 340B covered entities to comply with the requirements to use 340B modifiers for drugs acquired through the 340B program. Submitting inaccurately coded claims may result in False Claims Act (31 U.S.C. §§ 3729-3733) liability as well. Providers must submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.

Comment: One commenter recommended CMS coordinate with HRSA to prevent the duplication of 340B discounts and inflation rebates. Another commenter had concerns regarding CMS' plans to use the HRSA OPAIS to determine which covered entities are eligible for 340B in 2023. The commenter noted that not all claims that are processed by a covered entity are purchased under the 340B Program. The commenter also stated that using this system would oversimplify the process to identify 340B claims and may lead CMS to exclude manufacturers from paying Part B rebates beyond CMS' intent.

Response: CMS thanks these commenters for their feedback. CMS intends to continue to consult with HRSA to mitigate 340B duplicate discounts. Regarding the commenter's concern with CMS plans to use the HRSA's OPAIS to determine which covered entities are eligible for 340B in 2023, CMS understands that not all claims processed by a covered entity are acquired under the 340B Program. CMS reiterates its note in initial memorandum that the exclusion of drug units for calendar quarters in 2023 using HRSA's OPAIS data is limited to the small percentage of entities participating in the 340B Program and not paid under the OPPIs, and thus not required to bill either the "JG" or "TB" modifier until January 1, 2024. Consistent with the CY 2024 OPPIs/ASC final rule and the updated 340B modifier guidance, hospitals that currently report the "JG" modifier may choose to continue to use it in CY 2024 or to transition to the use of the "TB" modifier before January 1, 2025.^{20, 21} For dates of service on or after January 1, 2025, CMS will remove units in claim lines identified as 340B units as those billed with the "TB" modifier.

Comment: One commenter noted that covered entities may require two modifiers when billing claims for dually eligible patients. Another commenter recommended CMS add the "UD" modifier as an acceptable 340B identifier. The commenter stated that because this modifier is often used for Medicaid claims, providers should be able to choose to use one regardless of line of

²⁰ See: <https://www.federalregister.gov/public-inspection/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>.

²¹ See: <https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf>.

business (i.e., Medicaid or Medicare). The commenter recommended CMS use this existing data to identify 340B units.

Response: CMS thanks this commenter for their input and recommendation. Under the CY 2024 OPPS/ASC final rule and updated 340B modifier subregulatory guidance, CMS is requiring hospitals that currently report the “JG” modifier to use the “TB” modifier beginning January 1, 2025.²² In CY 2024, these hospitals can continue to use the “JG” modifier or choose to transition to the use of “TB” modifier during that year. Consistent with the updated 340B modifier subregulatory guidance, CMS will remove separately payable units in claim lines with the “JG” and “TB” modifiers from final action claims with dates of service through December 31, 2024. For dates of service on or after January 1, 2025, CMS will remove units in claim lines identified as 340B units as those billed with the “TB” modifier. Section 1847A(i)(3)(B)(ii)(I) of the Act requires CMS to exclude units of drugs for which the manufacturer provides a rebate under the Medicaid Drug Rebate Program (MDRP) under section 1927 of the Act. As described in section 50.8.2 of this revised guidance, CMS will remove units in claim lines for dates of service during a quarter when the Medicare beneficiary has Medicaid coverage. CMS declines to add the “UD” modifier as an acceptable 340B identifier for Medicare claims because this modifier is intended for use by Medicaid and is not payable by Medicare.²³

Comment: Some commenters objected to the use of “JG” and “TB” modifiers for the purpose of identifying claims to exclude from Part B rebates and urged CMS not to require the use of these modifiers. Commenters argued that requiring use of these modifiers unnecessarily increases the administrative and financial burden on covered entities and contract pharmacies. A few commenters stated that requiring the use of a point-of-sale modifier to indicate a unit of a drug was acquired under the 340B Program is an unreliable way to identify these units and would have significant consequences for covered entities that use contract pharmacies. One commenter stated that requiring a point-of-sale modifier could increase the risk that 340B-acquired drugs are furnished to individuals who do not qualify as patients of a covered entity. The commenter stated that the modifier policy could deter contract pharmacies from acting as contract pharmacies due to the risk of submitting inaccurate claims. The commenter also noted that the increased financial burden from adding a 340B modifier may lead contract pharmacies to increase dispensing fees for covered entities.

Response: CMS thanks these commenters for their input. CMS notes that the 340B modifier requirement extends to covered entities but does not extend to contract pharmacies dispensing drugs under the Medicare Part D benefit. CMS also notes that the 340B modifier requirement is a claims-level modifier and generally will not be required to be reported at the point-of-sale. CMS understands that the modifier requirement entails operational changes to billing systems for some 340B covered entities (and other providers and suppliers as applicable) and therefore CMS has encouraged such entities to begin using the appropriate modifier as soon as possible. Due to these operational changes, CMS has provided time in 2023 for covered entities to implement the new modifier requirement and program guidance issued in December 2022 that stated that all 340B

²² See: <https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>.

²³ October 2023 Level II HCPCS file. See: <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>.

covered entities must include modifiers on applicable claim lines for dates of service beginning no later than January 1, 2024. As stated in section 50.8.1 of this revised guidance, for professional claims with dates of service during 2023, CMS will remove all units in claims for Medicare suppliers that are listed by the 340B OPAIS as participating in the 340B Program.

Comment: A few commenters noted that covered entities use different purchasing practices, including a virtual replenishment model that allows covered entities to review patient eligibility retroactively and track the accumulation of 340B-eligible drugs that are furnished. One commenter recommended CMS outline different purchasing practices in Part B rebate guidance and provide covered entities the ability to use different purchasing practices. The commenter also stated that accumulations of furnished 340B-eligible drugs may take longer than one calendar quarter, and CMS must identify a process to allow dispensers to update claims for up to a year after a drug is furnished. Another commenter noted that because pharmacies use virtual inventory systems and software systems that allow patient determinations to be made retrospectively, the point-of-sale modifier policy could incentivize pharmacies to switch from a virtual inventory system to a physical inventory system, which would be more costly and require more physical space.

Response: CMS thanks these commenters for their feedback. Covered entities may use different purchasing practices to acquire drugs under the 340B Program. If a covered entity uses a purchasing practice that takes longer than one calendar quarter to determine 340B eligibility of a claim, it may delay filing a claim for payment. Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. Therefore, for hospitals that may need more time to ensure they comply with the modifier requirements, they have 12 months from the date of service to do so. If a covered entity determines that a claim was incorrectly submitted and needs to make an adjustment to the claim to add a 340B modifier, it can do so for up to 12 months from the initial claim determination. CMS intends to consider a true-up or restatement process for the Part B Inflation Rebate Program for future rulemaking, which would allow CMS to account for any updates to claims data that occurred after the rebate amounts were calculated, including on the number of units.

Comment: One commenter noted that a point-of-sale modifier policy would require covered entities to make 340B eligibility determinations at the point of sale and could lead some covered entities to purchase all drugs at WAC, even for 340B-eligible patients, to comply with the prohibition on purchasing covered outpatient drugs through a group purchasing organization.

Response: CMS thanks this commenter for their input. Covered entities participating in the 340B Program as disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals must attest they will not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. CMS believes covered entities continue to have the opportunity to purchase drugs at or below the 340B ceiling price under the new modifier policy. Covered entities that are subject to the prohibition on group purchasing arrangements can continue to purchase covered outpatient drugs at the 340B price and, after dispensing a 340B drug to an eligible patient, have up to 12 months after the date of service to timely submit a claim for payment.

Comment: A couple of commenters raised concerns that a point-of-sale modifier policy could result in discriminatory payment practices by MA plans, as the modifier would allow plans to identify drugs purchased under the 340B Program.

Response: CMS thanks these commenters for their input. CMS does not have reason to believe that mandatory use of a 340B modifier by covered entities to identify Part B drugs purchased under the 340B Program would result in discriminatory payment practices by MA plans. CMS makes capitated payments to MA plans and plans determine reimbursement to providers for services.

Comment: Some commenters recommended CMS exclude all units billed by 340B participating providers instead of requiring modifiers. A few commenters recommended that CMS exclude all units that are identified with a status indicator of “K” and billed by 340B hospitals listed as participating in the 340B Program in the HRSA OPAIS.

Response: CMS thanks these commenters for their recommendations. At this time, CMS believes the most appropriate policy to remove 340B units from the calculation of Part B inflation rebates is to use claims modifiers starting in 2024. Excluding all units that are identified with status indicator of “K” and billed by 340B hospitals listed as participating in the 340B Program in the HRSA’s OPAIS data may result in over-excluding units from Part B inflation rebates, as not all units acquired by 340B hospitals are purchased under the 340B Program. Some 340B covered entities provide healthcare services to both 340B and non-340B patients, and the payment status indicator “K” does not differentiate between 340B and non-340B claims.

Comment: A few commenters requested CMS issue guidance establishing a process for manufacturers and covered entities to engage in dispute resolution on disputes related to units that manufacturers believe received both a 340B discount and a Part B inflation rebate. One commenter stated that covered entities have historically been reluctant to engage in duplicate discount disputes related to units that manufacturers believe received both a 340B discount and a Medicaid drug rebate, partly because of the lack of a clear process requiring covered entities to identify 340B claims and respond to good faith inquiries regarding duplicate claims. Another commenter recommended that CMS implement a dispute resolution process as soon as possible.

Response: CMS thanks these commenters for their input and recommendations. Section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units. Disputes on these topics will not be considered. Because of this limitation on administrative and judicial review, CMS is not providing an administrative dispute process. Manufacturers of Part B rebatable drugs that owe an inflation rebate can submit a Suggestion of Calculation Error if they identify a mathematical error in the calculation by CMS, which CMS may consider at its discretion.

Comment: One commenter recommended CMS apply the modifier requirement, or any requirement to exclude 340B units, only to drugs and biological products that could potentially be subject to a Part B inflation rebate. The commenter stated that the Part B inflation rebates apply only to single-source drugs and biological products, including some biosimilars, but excluding

vaccines and low Medicare spend drugs, and therefore the modifier requirement should only apply to these relevant drugs.

Response: CMS thanks this commenter for the recommendation. CMS disagrees that the 340B modifier requirement should apply to only Part B rebatable drugs. It is not possible to know which Part B drugs are rebatable prior to the start of an applicable calendar quarter. As CMS is required to calculate Part B inflation rebate amounts within six months of the end of an applicable calendar quarter for quarters in 2025 and later, it will determine the list of Part B rebatable drugs for the calendar quarter, including if a drug is multiple source or single source or low spend, by using the most recent information available following the end of the calendar quarter. CMS acknowledges that certain products, such as vaccines and qualifying biosimilars, are excluded from the definition of a Part B rebatable drug and that it is possible to identify these drugs as not rebatable prior to the start of an applicable calendar quarter. However, CMS does not believe it would be less burdensome or more operationally efficient for a covered entity to omit the 340B modifier from claims lines for products excluded from the definition of Part B rebatable drug because of the time and burden associated with cross-checking Medicare drug pricing files to determine a drug's disposition. Therefore, CMS is requiring 340B covered entities to include a 340B modifier, as applicable, on all separately payable claim lines for drugs acquired through the 340B program with dates of service beginning no later than January 1, 2024.

Removal of Units with a Rebate Under Section 1927 of the Social Security Act ([Section 50.8.2](#))

Comment: A few commenters supported removing drug units that are subject to a rebate under section 1927 of the Act. These are drug units where the manufacturer has been charged and paid a rebate to a state Medicaid agency.

Response: CMS thanks commenters for this feedback. As discussed in section 50.8.2 of the revised guidance, CMS will remove drug units subject to a rebate under section 1927 of the Act from unit counts when calculating Part B inflation rebates.

Comment: One commenter expressed concern that there may not be enough information available to support CMS' proposed methodology to exclude units that have already received a rebate under section 1927 of the Act (i.e., a Medicaid rebate). The commenter notes that states often pay a dually eligible beneficiary's Medicare Part B coinsurance for Part B drugs. However, the commenter is unsure if a Medicaid rebate is collected in these instances and if the entire rebate is collected or only a portion. The commenter further states that it believes CMS' proposed methodology overstates the extent to which Medicaid rebates are paid for Part B drugs.

Response: CMS thanks the commenter for this feedback. There are different types of dually eligible beneficiaries, some of whom receive assistance from Medicaid for their Medicare cost-sharing (Qualified Medicare Beneficiary (QMB) Plus, some Specified Low-Income Medicare Beneficiary (SLMB) Plus, QMB-only, and some other full dually eligible beneficiaries) and some of whom do not. Excluding all units furnished to dually eligible individuals may over-exclude units, as a manufacturer may not have paid a rebate under the MDRP. Therefore, CMS will exclude only units furnished to Medicare beneficiaries who may be eligible to receive Medicare

cost-sharing assistance from Medicaid, and in which case may have been subject to Medicaid rebates under the MDRP.²⁴ CMS acknowledges that this methodology may still over-exclude units, but data limitations around linking Medicare and Medicaid beneficiaries across different identification systems to determine if a section 1927 rebate was paid on a specific drug unit on a Medicaid claim prevent greater specificity at this time.

Comment: A few commenters recommended that CMS account for Medicaid rebates paid for dually eligible beneficiaries with Medicaid managed care. One commenter requested that CMS ensure the Medicaid managed care organizations submit information on their dually eligible beneficiaries in the Medicare Modernization Act (MMA) File so that the appropriate units can be excluded from Part B rebates. Another commenter asked CMS to clarify how it will exclude units for Medicaid managed care dually eligible beneficiaries.

Response: CMS thanks commenters for this feedback. CMS will exclude units for dually eligible beneficiaries with Medicaid managed care or fee-for-service Medicaid. The MMA File, which CMS will use to identify dually eligible beneficiaries and exclude units, includes data from both fee-for-service and managed care plans.

Comment: Several commenters expressed concern that CMS' process for identifying and removing claims for dually eligible beneficiaries may not identify claims for new Medicaid beneficiaries. Commenters noted there is typically a several months lag between when a beneficiary applies for Medicaid and when they are added to the database, which means claims for new beneficiaries may be processed after the patient was enrolled in Medicaid but before they are identified as a Medicaid beneficiary.

Response: CMS thanks commenters for this feedback. CMS will use the data available, such as state Medicare Modernization Act (MMA) Files, at the time of rebate amount calculation to exclude units furnished to dually eligible beneficiaries. As discussed in section 1847A(i)(1)(A) of the Act, CMS must issue, no later than six months after the rebate quarter, a report to each manufacturer of a Part B rebatable drug with the total units billed for the rebate quarter, the amount by which the specified amount exceeds the inflation-adjusted payment amount (if applicable), and the total rebate amount due. As described in section 60.1 of this revised guidance, CMS will issue manufacturers a Preliminary Rebate Report no later than five months after the rebate quarter. CMS is using the MMA File—not Medicaid claims—to identify units to be excluded. However, to the degree that there are changes to Medicaid enrollment reflected in the MMA File for the applicable quarter after the Preliminary Rebate Report has been issued, CMS is considering a restatement process for future rulemaking to account for any changes to claims data that occurred after the rebate amounts were calculated, including updates to MMA data that occurred after the initial rebate amounts were calculated. Such a process would account for any lags in Medicaid MMA data and ensure the correct rebate amount is billed.

²⁴ CMS will include only units furnished to dually eligible individuals where Medicaid never covers cost sharing for Part B drugs, which includes SLMB-only, Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries. CMS will exclude units furnished to QMB Plus, SLMB Plus, QMB-only, and other dually eligible beneficiaries because they may be eligible for cost sharing for Part B drugs.

Comment: One commenter recommended that CMS ensure that claims for dually eligible beneficiaries will be removed from the inflation rebates by requiring a mandatory “yes/no” field on claims to indicate dual eligibility. Another commenter suggested CMS require states collect these data points.

Response: CMS thanks commenters for this feedback. CMS notes these data are already collected and available through Medicaid enrollment data, and CMS does not want to unnecessarily increase the burden associated with the claims submission processes. CMS will rely on the MMA File, which states must submit at least monthly, to exclude units furnished to dually eligible beneficiaries. The MMA File will identify all full-benefit and partial-benefit dually eligible beneficiaries.

Removal of Units that Are Packaged into the Payment Amount for an Item or Service and Are Not Separately Payable ([Section 50.8.3](#))

Comment: One commenter expressed support for CMS’ confirmation that units that are not separately payable will be excluded from unit counts for rebate calculations.

Response: CMS thanks the commenter for this feedback. As described in section 50.8.3, because CMS will identify units for separately payable claim lines for Part B rebatable drugs only, no further action is necessary to remove units that are packaged into the payment amount for an item or service and are not separately payable.

Removal of Units When Drug is No Longer a Part B Rebatable Drug ([Section 50.8.4](#))

Comment: A couple of commenters requested that CMS promptly notify the manufacturer of a Part B rebatable drug when it learns of the first sale of a drug that is rated as therapeutically equivalent to the Part B rebatable drug. The commenter notes that this will ensure manufacturers have sufficient information to calculate their rebate obligations. Additionally, one of the commenters expressed concern that the FDA information CMS plans to use may be outdated or inaccurate and suggested CMS work with the FDA Office of Generic Drugs. This commenter further recommended CMS identify a specific date on which to evaluate FDA resources to determine if an approved drug meets the criteria for a Part B rebatable drug.

Response: As noted in section 50.8.4 of this revised guidance, CMS will use the first sale of a therapeutically equivalent drug as the date a Part B rebatable drug is no longer deemed a rebatable drug and will no longer be eligible for inflation rebates. CMS does not plan to notify manufacturers of Part B rebatable drugs of the date of first sale of a therapeutically equivalent drug. Manufacturers of Part B rebatable drugs can use information available in FDA’s Orange Book to determine if the Part B rebatable drug has a drug listed as therapeutically equivalent. CMS believes that this information is sufficient for manufacturers to assess their potential inflation rebate obligations. CMS declines to identify a specific date to evaluate FDA resources but agrees that communicating with FDA may be beneficial, and as noted in section 50.8.4 of this revised guidance, CMS may consult with FDA for technical assistance as needed.

Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who are Enrolled in Medicare Advantage Plans ([Section 50.8.5](#))

Comment: A couple of commenters urged CMS to include units furnished under MA in calculating Part B inflation rebates. One commenter expressed strong support for including units furnished under MA, noting the growing share of Medicare enrollees in MA plans and the potential to broaden the impact of the rebates. One commenter requested that CMS consider delaying the application of Part B inflation rebates to units furnished to people enrolled in MA plans until CMS identifies the source that it will use to determine the number of units to which Part B rebates apply.

Response: CMS appreciates the commenters' input. CMS believes the best available data source to identify MA units would be MA encounter data. CMS is in the process of determining what program changes would be necessary to successfully operationalize a policy that includes MA units in the calculation of Part B inflation rebates. Thus, at this time, CMS will not include MA units in Part B inflation rebate calculations due to operational considerations but may address this issue in future rulemaking.

Comment: Many commenters interpreted section 1847(i)(2)(A) of the Act to expressly define a Part B rebatable drug as a drug for which payment is made under Medicare Part B and, therefore, in the view of the commenters, to exclude units of drugs furnished under MA (Medicare Part C).

Response: Because CMS believes that program changes would likely be necessary to include MA units, at this time, CMS will not include MA units in the calculation of Part B rebates. CMS may address the issue of whether to include MA units in the calculation of Part B rebates in future policymaking and would solicit and consider public comments on this issue at that time.

Comment: A few commenters stated that units of rebatable drugs furnished under MA should be excluded from Part B rebatable drugs because they are not separately payable. These commenters noted that under section 1847A(i)(1)(B) of the Act, units that are packaged into the payment amount for an item or service and are not separately payable are excluded from the calculation of the total number of units to apply Part B rebates. Commenters also noted that CMS makes capitated payments to MA plans for provider-based services, including physician-administered drugs, which they noted would make drugs reimbursed by plans receiving those payments as ineligible under section 1847A(i)(1)(B) of the Act. One commenter recommended CMS exclude units furnished under MA from Part B inflation rebates because the Part B Inflation Rebate Program uses ASP-based payments to calculate inflation rebates and MA plans are not required to use ASP-based payment methodology for reimbursement.

Response: CMS appreciates commenters' input. As noted in the response above, CMS will not include MA units in the calculation of Part B rebates at this time due to operational considerations. CMS may address this issue in future policymaking and would solicit and consider public comments on this issue at that time.

Comment: One commenter recommended CMS use existing data sources, such as encounter data, to identify drugs furnished under MA. A few commenters expressed concern about the

reliability of MA encounter data. One commenter referenced a report by the HHS OIG (“The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight”) that found that CMS currently does not require MA plans to differentiate between paid and denied claims in encounter data.²⁵ A few commenters noted that complete encounter data is required to be submitted to CMS by MA plans roughly one year after the end of the plan service year, making it operationally challenging for CMS to use encounter data to calculate Part B rebates for units furnished under MA. One commenter recommended CMS use encounter data previously submitted by MA plans to estimate the quantities of rebates owed for Part B rebatable drugs and invoice manufacturers for an applicable calendar quarter using this estimate within six months of the end of the calendar quarter. The commenter recommended CMS update the estimated rebates owed during the “true-up” period using encounter data submitted. A different commenter noted that using estimates in the rebate calculation and relying on the “true-up” period to update the estimates would create substantial uncertainty about rebate liability for manufacturers. A few commenters stated that because there are significant operational challenges with identifying units of rebatable drugs furnished under MA, Congress intended that CMS exclude units furnished under MA from Part B inflation rebates.

Response: CMS appreciates commenters’ input regarding identifying units furnished under MA for purposes of calculating Part B rebates. CMS agrees that MA encounter data could be used to identify Part B drugs furnished under MA. At this time, CMS will not include MA units in the calculation of Part B rebates due to operational considerations, some of which were raised by commenters. As noted in the response above, CMS may address the issue of whether to include MA units in the calculation of Part B rebates in future policymaking.

Comment: One commenter recommended CMS create a system for MA plans to report quarterly unit data by HCPCS code, such that CMS would be able to use these data to calculate inflation rebates for MA units.

Response: CMS thanks the commenter for the recommendation. CMS will not include MA units in the calculation of Part B rebates at this time due to operational considerations. As noted in the response above, CMS may address the issue of whether to include MA units in the calculation of Part B rebates in future policymaking.

Removal of Units Subject to Discarded Drug Refunds ([Section 50.8.6](#))

Comment: A few commenters noted that CMS did not address discarded drug refunds in the initial memorandum and recommended CMS address this issue in revised Part B inflation rebate guidance.

Response: CMS thanks these commenters for the input. CMS added a new subsection in this revised guidance, section 50.8.6, to address the application of Part B inflation rebates to units of discarded drugs. In addition, CMS intends to address this policy in future rulemaking and will solicit comments on this policy at that time.

²⁵ See: <https://oig.hhs.gov/oei/reports/OEI-03-21-00380.pdf>.

Comment: A few commenters recommended CMS exclude units subject to discarded drug refunds from the calculation of Part B inflation rebates. Commenters noted that under section 1847A(i)(2)(A) of the Act, a Part B rebatable drug is defined as “a single-source drug or biological...for which payment is made under this part.” Commenters claimed that, since manufacturers provide refunds to CMS for Part B payment on these units through the discarded drug refund under section 1847A(h) of the Act, these units should not be eligible for inclusion in Part B rebates. Commenters also noted that the calculation of total units subject to Part B rebates is based on units “furnished” to Medicare beneficiaries during an applicable calendar quarter. Commenters contended that, since the units of discarded drugs subject to refunds are not furnished to Medicare beneficiaries, these units should be excluded from the calculation of units subject to Part B rebates. One commenter recommended CMS exclude units subject to discarded drug refunds by subtracting Part B discarded drug refunds from the Part B inflation rebate amount and then invoicing manufacturers based on the resulting net Part B rebate amount.

Response: CMS thanks these commenters for the input and understands commenters’ concerns. As stated in section 50.8.6 of this revised guidance, CMS believes it would balance fairness with the need to fulfill the requirements of section 11101 of the IRA to not apply Part B rebates to discarded drug units for which a refund is owed. CMS is exploring options to reconcile Part B inflation rebates with discarded drug refunds such that Part B rebates are not applied to discarded drug units for which a refund is owed. CMS may consider a proposal to exclude units of discarded drugs subject to discarded drug refunds from Part B inflation rebates in future rulemaking. Initially, CMS will include discarded units that are subject to discarded drug refunds in the calculation of Preliminary Rebate Reports and Rebate Reports. CMS is considering including a restatement process in future rulemaking and CMS intends to propose to use data available during any restatement process to remove units of discarded drugs subject to discarded drug refunds during the calculation of the rebate amount.

However, CMS disagrees with the commenters’ interpretation of the statute that because manufacturers refund CMS for some of the allowed payment for discarded drugs, these units of drugs are not eligible for inclusion in Part B inflation rebates. Section 1847A(i)(3)(B) of the Act prescribes that the total number of units of a rebatable drug is determined by the number of units furnished in an applicable calendar quarter, excluding units of drugs with respect to which the manufacturer provides a discount under the 340B Program, units with respect to which the manufacturer pays a Medicaid rebate, or units that are packaged into the payment amount for an item or service and are not separately payable. Discarded units of Part B rebatable drugs are not detailed in the exclusions from the total number of units under section 1847A(i)(3)(B)(ii) of the Act.

Moreover, Medicare payment is made to providers for discarded units of drugs. As CMS stated in section 50.8 of the initial memorandum, including units where Medicare payment was allowed will ensure that units that were furnished during a calendar quarter and for which a beneficiary has full financial liability will be counted in the total number of units (in addition to units where the Medicare program made payment).

CMS intends to address this issue in future policymaking and will solicit and consider public comments at that time.

Comment: One commenter stated that it is important CMS synchronize the payment of discarded drug refunds and Part B inflation rebates.

Response: CMS thanks this commenter for the input. CMS is required to invoice manufacturers for Part B inflation rebates on a quarterly basis, starting no later than September 30, 2025. Under the CY 2023 PFS final rule, CMS established that it will send discarded drug refund reports once annually.²⁶ In the 2024 PFS final rule, other than for the initial refund report, (which CMS intends to issue no later than December 31, 2024), CMS finalized that it will send annual refund reports for discarded drug refunds at or around the same time as the Preliminary Rebate Reports for the first quarter of the following year.²⁷ Due to the different invoicing timelines for these programs, CMS cannot completely synchronize the payment of discarded drug refunds and Part B inflation rebates.

Adjustments for Changes to HCPCS Codes ([Section 50.9](#))

Comment: One commenter noted that in the initial memorandum, CMS stated that it would apply a “conversion factor” when calculating the inflation-adjusted payment amount if there was a change to the rebatable drug’s billing and payment code between the benchmark quarter and the rebate quarter, such as a change to the code’s dose description. The commenter requested that CMS be transparent in the Rebate Reports if a conversion factor is used to calculate the rebate amount.

Response: 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.

Comment: One commenter stated that using only a dosage unit conversion factor for circumstances where a Part B rebatable drug was previously crosswalked to a HCPCS code with other products and was later crosswalked to a unique HCPCS code would not result in a fair conversion for the inflation-adjusted payment amount. The commenter further noted that it is possible a drug’s payment rate may be low during the payment amount benchmark quarter because it shares a HCPCS code with multiple drugs and ASP uses a volume-weighted calculation approach when there are multiple drugs in the HCPCS. The commenter states that if the rebatable drug is later crosswalked to a unique HCPCS code, the payment limit may increase even if the drug’s ASP is not increased because there are no other drugs in the code. The commenter recommends that for this scenario, CMS recalculate the payment amount for the payment amount benchmark quarter using just the rebatable drug’s ASP.

Response: CMS thanks the commenter for this feedback. The conversion factor approach will only be used when a rebatable drug’s applicable HCPCS code’s dose description changes. CMS revised section 50.4 to describe CMS’ policy for identifying the payment amount in the payment

²⁶ See: <https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other>.

²⁷ See: <https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other>.

amount benchmark quarter when a Part B rebatable drug was previously crosswalked to a HCPCS code with other products during the benchmark quarter and later billed under a unique HCPCS code. Consistent with this section of the revised guidance, CMS will identify the grouped HCPCS code's payment limit used by CMS for the benchmark quarter and will use that payment limit for the benchmark quarter payment amount. Additionally, CMS notes that single source drugs or biological products that are within the same billing and payment code as of October 1, 2003, per section 1847A(c)(6)(C)(ii) of the Act, will be excluded from Part B inflation rebates. Part B rebatable drugs that were crosswalked to a HCPCS code with other products after October 1, 2003, and later crosswalked to a unique HCPCS code will be included in Part B inflation rebates, if applicable, and a conversion factor will be used to determine the payment amount for the payment amount benchmark quarter in the event that the unit dosage is different for the new HCPCS code.

Reducing the Rebate Amount in the Case of a Part B Rebatable Drug Currently in Shortage on a U.S. FDA Shortage List ([Section 50.11](#))

Comment: A couple of commenters expressed support for the 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 B 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.

One commenter stated that a waiver may be appropriate initially, but CMS should reduce the rebate reduction amount over time to remove any incentive to keep a drug in shortage, aligning with the variable reduction approach proposed by CMS in the initial memorandum. A few commenters recommended that 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 B rebatable drugs (e.g., rare disease treatments, plasma-derived products, low- versus high-margin drugs, drugs used to treat serious medical conditions), as well as specific types of shortages (e.g., shortages resulting from quality issues versus shortages due to exogenous circumstances). One commenter requested that CMS explore the possibility of providing a waiver for plasma-derived products under two other circumstances: if there is a severe supply chain disruption and if CMS determines that without such reduction or waiver, the drug is likely to be described as in shortage during a subsequent period. A couple of commenters suggested CMS coordinate with FDA, which has knowledge of the relevant drug markets and conducts assessments of medical necessity and drug substitutes.

Response: CMS thanks commenters for their support and appreciates commenters' input regarding how this policy should be structured. As described in section 50.11 of this revised guidance, CMS will provide a variable reduction in the rebate amount based on the length of time

a Part B rebatable drug is in the status of “currently in shortage” on an FDA shortage list during a calendar quarter, with the reduction decreasing over time. To calculate the reduction in the rebate amount for a Part B rebatable drug, CMS will determine the number of days such drug is described as “currently in shortage” on an FDA shortage list in a calendar quarter, divide by the number of days in the calendar quarter, and then multiply that amount by a percentage that is decreased over time.

CMS will provide the same reduction in the rebate amount for Part B 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 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.²⁸

CMS understands that some drugs may face supply chain disruptions due to exogenous factors such as a natural disaster or other unique or unexpected event, 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 50.12 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 Part B rebatable biosimilar biological product when there is a severe supply chain disruption during a calendar quarter.

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 50.11 of this revised guidance, CMS will provide a higher reduction for plasma-derived Part B rebatable drugs described as “currently in shortage” on an FDA shortage list compared to non-plasma derived Part B rebatable drugs. Consistent with the statute, CMS will not provide a waiver or reduction in the rebate amount for a plasma-derived product either when there is a severe supply chain disruption (unless the plasma-derived product is a Part B rebatable biosimilar biological product) or if the plasma-derived product is likely to be described as in shortage during a subsequent period. CMS notes that generic Part B drugs (those approved under an ANDA submitted under 505(j) of the FD&C Act) do not meet the definition of “single source drug or biological product,” and thus are not Part B rebatable 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

²⁸ See: <https://www.fda.gov/media/131130/download?attachment#page=33>.

whereby a reduction in the rebate amount would differ depending on the cause of the shortage and may revise the policy set forth in this revised guidance in the future. Consistent with section 1847A(i)(3)(G)(i) of the Act and as described in section 50.11 of this revised guidance, CMS will reduce the rebate amount for each calendar quarter that a Part B rebatable drug appears in the status of “currently in shortage” at any point during the calendar quarter. CMS will require manufacturers to submit to CMS a request and justification for a rebate reduction for a Part B rebatable biosimilar biological product when there is a severe supply chain disruption, as described in section 50.12 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 Part B rebatable biosimilar biological product in order to receive consideration for a rebate reduction under the severe supply chain disruption policy. 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 few commenters recommended that CMS waive the rebate amount regardless of whether all NDCs for a Part B rebatable drug are in shortage, as a shortage for one NDC-11 can affect the availability of other NDC-11s. One commenter 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 B 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 B rebatable drug inflation rebates are calculated at the HCPCS code(s) level, if any NDC mapped to the HCPCS code(s) is described as “currently in shortage” on an FDA shortage list, CMS will apply the rebate reduction to all of the NDCs under the relevant HCPCS code(s). 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 B 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 Part B Rebatable Biosimilar Biological Product When There is a Severe Supply Chain Disruption ([Section 50.12](#))

Comment: A couple of commenters suggested modifications to CMS’ definitions, for example, by removing “for at least 90 days” from the severe supply chain disruption definition or adding cyberattacks to the “other unique or unexpected event” definition. One 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 ingredient, supplies, and shipping). Another commenter expressed concern that supply chain disruptions can cause swings in ASP 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 B 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 Part B rebatable biosimilar biological product 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 will consult with FDA in implementing the severe supply chain disruption provision, for technical assistance as needed. CMS understands the concerns regarding the effect of supply chain disruptions on ASP and consistent with the statute, will provide a reduction of the rebate amount (if any) when CMS determines there is a severe supply chain disruption during a calendar quarter. CMS may consider additional modifications to the severe supply chain disruption policy in the future.

Comment: A few 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. One commenter recommended that in the case of a shortage caused by a severe supply chain disruption, the waiver may be appropriate initially but should be reduced over time.

Response: CMS thanks these commenters for their input. CMS will provide a standard reduction in the rebate amount of 75 percent for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event. CMS will apply this reduction as described in section 50.12 of this revised guidance. CMS appreciates commenters' suggestion that it should exercise flexibility and consider the severity of the event that caused the severe supply chain disruption. As described in section 50.12 of this revised guidance, if a severe supply chain disruption continues into a fifth calendar quarter after the start of the natural disaster or other unique or unexpected event, the manufacturer of a Part B rebatable biosimilar biological product may request a reduction in the rebate amount for four more calendar quarters. To receive consideration for a rebate reduction for the fifth through eighth calendar quarters, the manufacturer would have to submit to CMS a request for an extension as described in section 50.12 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 50.12 of this revised guidance, for severe supply chain disruptions that occurred on or after January 1, 2023 but before August 2, 2024, CMS intends to announce a specific deadline for manufacturers to submit a request for a rebate reduction.

Financial Responsibility for the Medicare Part B Inflation Rebate Amount ([Section 50.13](#))

Comment: One commenter expressed support for CMS' proposed methodology to allocate Part B inflation rebates across manufacturers when single-source drugs with multiple manufacturers are assigned to the same HCPCS code.

Response: CMS thanks the commenter for their support.

Comment: Some commenters expressed concern that CMS' policy to allocate Part B inflation rebates based on shared HCPCS codes for a single-source drug or biological product does not appropriately assign financial responsibility. A few commenters opposed the proposed methodology, which they noted could result in a manufacturer owing a rebate even when ASP growth for the manufacturer's own NDC has been lower than inflation. One commenter noted that the initial memorandum assumes that each NDC is equally responsible for driving an increase in the payment amount for the rebate period and the policy has the potential to assign rebate liability to a manufacturer whose individual pricing for its respective NDC(s) increased at or below the rate of inflation. A few commenters recommended CMS revise its methodology to assess rebate liability against each manufacturer only in proportion to its actual responsibility for triggering the inflation rebate. A few commenters offered more specific recommendations, stating CMS should calculate inflation rebate liability at the NDC-11 level for HCPCS codes comprised of NDCs from multiple manufacturers. Additionally, a few commenters recommended CMS require providers to report associated product NDC-11s on claim forms and to reject claims without NDC-11s. Finally, one commenter suggested CMS reform HCPCS coding so that no single-source drugs share a HCPCS code.

Response: CMS appreciates commenters sharing their concerns and recommendations. CMS notes that Part B rebatable drugs, as single-source drugs or biological products, typically will have only one manufacturer. However, in cases when there is more than one manufacturer for a Part B rebatable drug, consistent with this revised guidance and the definition of “manufacturer” set forth in section 1847A(c)(6)(D) of the Act, CMS maintains that it will apportion financial responsibility for the rebate amount among manufacturers by dividing the sum of each manufacturer’s reported ASP units sold during the rebate quarter by the sum of all manufacturer-reported ASP units sold during the rebate quarter for all NDCs of the rebatable drug assigned to the HCPCS code. CMS believes that calculating Part B inflation rebates at the HCPCS code level, rather than at the NDC-11 level as some commenters recommended, is consistent with section 1847A(i)(3)(A) of the Act, which specifies how the rebate amount is calculated. Additionally, CMS believes these situations may be limited as most single-source drugs are assigned unique HCPCS codes. (CMS refers commenters to section 50.4 of the revised guidance for its policy regarding identification of the payment amount in the payment amount benchmark quarter for Part B rebatable drugs that were previously billed under a grouped HCPCS code during the benchmark quarter and were later assigned unique codes.) Calculating Part B inflation rebates at the NDC-11 level would require imposing new requirements on the claims submission process to require reporting of the NDC-11 on Part B claims, and CMS does not want to increase the burden associated with the claims submission process at this time. Furthermore, CMS clarified in section 30.1 of this revised guidance that single-source drugs or biological products that are within the same billing and payment code (i.e., HCPCS code) as of October 1, 2003, per section 1847A(c)(6)(C)(ii) of the Act, will be excluded from Part B inflation rebates. Finally, the comment suggesting CMS reform HCPCS coding is out of scope for this revised guidance.

Comment: One commenter reported that it identified at least one circumstance where the number of ASP units for an NDC in a HCPCS code are primarily paid as a bundle of all dialysis services provided and noted that these units should not be used to apportion rebate liability. The commenter recommended CMS revise its methodology to exclude NDCs for which the number of ASP-reported units are subject to bundled payment.

Response: CMS thanks the commenter for sharing this information. CMS is aware of the circumstance the commenter raised. In accordance with section 1847A(i)(3)(B)(ii)(II) of the Act, CMS will exclude units of drugs “that are packaged into the payment amount for an item or service and are not separately payable.” CMS also notes that claim lines for drugs for which payment is bundled under the End-Stage Renal Disease (ESRD) prospective payment system would not have a Medicare allowed amount that is greater than zero, and so such units will be excluded.

Ensuring Integrity of the Medicare Part B Drug Inflation Rebates ([Section 60](#))

Comment: A few commenters requested that CMS publish a schedule or anticipated release dates for Rebate Reports. One of these commenters indicated that delayed invoicing for rebates may impact tax and financial filings, which manufacturers will need to accommodate. Another of these commenters also requested that CMS provide advance notification to generic manufacturers that

they have a rebatable product(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 1847A(i)(1)(C) of the Act specifies that CMS may issue the Rebate Reports for calendar quarters in 2023 and 2024 no later than September 30, 2025, and section 60 of this revised guidance includes timing and other information regarding CMS' policies for issuing these Rebate Reports. CMS also notes in section 60 of this revised guidance that it intends to publish a regular release schedule or calendar of release dates in the future. Starting with the first calendar quarter of CY 2025 will follow the cadence described in section 60.1 of this revised guidance.

CMS will not provide advanced notice to manufacturers of Part B rebatable drugs. However, CMS will provide a Preliminary Rebate report to all manufacturers with a Part B 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 calendar quarter (see sections 60.1 and 60.2 of this revised guidance for additional information).

Comment: Many commenters provided suggestions on the proposed true-up process contemplated in the initial memorandum. Some commenters suggested that the rebate true-up should occur after three years rather than one year, as proposed in the initial memorandum. These commenters noted that a three-year true-up would align with the Average Manufacturer Price (AMP) restatement period under MDRP, which may trigger restatement of ASP data. One commenter requested that CMS true-up both underpayments and overpayments of rebate amounts due.

Response: CMS appreciates commenters' feedback and has determined to issue its process for restatements at a later point in time. 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 B rebatable drug for a rebate quarter 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 the September 30, 2025, deadline for sending Rebate Reports for rebate quarters in CY 2023 and CY 2024.

Comment: A commenter requested additional guidance from CMS on when and how manufacturers should restate ASP data.

Response: CMS appreciates this commenter's request. However, the ASP restatement process is out of scope for this revised guidance. Questions on ASP reporting, including the ASP restatement process, should be sent to the ASP mailbox (sec303aspdata@cms.hhs.gov). For information on the ASP restatement process, see the section 11 of the CMS Medicare Part B Drug ASP User Manual.²⁹

²⁹ See: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/Medicare-Part-B-ASP-Data-Collection-User-Guide.pdf>.

Process for Rebate Reports and Suggestion of Calculation Error ([Section 60.1](#))

Comment: Many commenters requested additional data and calculation information be included in Rebate Reports. Examples of additional data requests included total gross sales in Medicare, the calculated payment amount in the benchmark quarter, the applicable payment amount for the quarter, de-identified beneficiary ID, HCPCS code, CPI-U used, units furnished, place of service code, claim status, vial wastage modifiers, 340B modifiers, and 340B units excluded. One commenter suggested that CMS should indicate that pharmacies, providers, and states are responsible for validating claims data to ensure that claims for dually eligible beneficiaries are excluded from rebate calculations.

Response: CMS appreciates commenters' request for additional information. The information included in the Preliminary Rebate Report and Rebate Report will include information outlined under section 1847A(i)(1)(A) of the Act. CMS seeks to promote manufacturers' understanding of their Rebate Reports, and CMS will consider including additional information regarding calculation inputs in these reports to the extent feasible. The determination of the number of units and the calculation of the rebate amount, among other items, are not subject to administrative or judicial review per section 1847(i)(8) of the Act. CMS will perform checks to assess the integrity of this information and has outlined a process by which a manufacturer may suggest a mathematical error in determining the rebate amount in section 60.2 of this revised guidance. This Suggestion of Calculation Error process is intended to allow the manufacturer to notify CMS if the manufacturer in good faith believes that CMS has made a mathematical error in the rebate calculation.

Consideration of a restatement process for the Part B Drug Inflation Rebate Program is reserved for future rulemaking and CMS is not specifying the data and calculation information for the restatement process at this time.

Comment: One commenter recommended that CMS create a computer readable file format for rebate reports, such as ASCII delimited or fixed file format. One commenter suggested a modern data format with content similar to that provided in Coverage Gap Discount Program (CGDP).

Response: CMS appreciates the commenter's feedback on file formats and plans to assess feasibility of these file formats before invoice reporting commences.

Comment: One commenter suggested that CMS notify manufacturers if a Part B rebatable drug will have its inflation rebate 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 for an applicable calendar quarter due to the \$100 per individual per year exclusion.

Response: CMS will notify manufacturers when requests are granted for a rebate reduction due to a severe supply chain disruption. Per section 50.11 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. A reduction for a rebatable drug listed as "currently in shortage" will be applied to the rebate amount issued to manufacturers with eligible products via the Rebate Report.

All Rebate Reports will contain, at a minimum, the information described in section 60 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 the \$100 per individual per year exclusion applies and therefore will not receive a Rebate Report for that applicable calendar quarter.

Comment: A commenter requested that CMS clarify the date of receipt for purposes of determining the rebate payment due date. The commenter stated that the issue date for the Rebate Report is not necessarily the date of receipt.

Response: As noted in section 60.1 of this revised guidance, the date of receipt for purposes of determining the rebate payment due date is defined as the calendar day following the day the Rebate Report was posted. For example, if the Rebate Report is posted on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the 30-calendar-day payment period. Manufacturers will receive notice electronically when reports are posted and available to view.

Comment: Many commenters stated that a review period of 10 calendar days for Suggestion of Calculation Error does not provide sufficient time for manufacturers to review the Preliminary Rebate Report. Some commenters indicated this timeframe does not align with the time allotted for manufacturer calculations in MDRP or the industry standard of 30 days. One commenter indicated the review period of 10 calendar days 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; a couple of commenters suggested extending the review period to 37 days or 38 days; one commenter suggested 45 days; one commenter suggested 60 days.

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. Because the Rebate Reports covering calendar quarters in CY 2023 and CY 2024 will include calendar quarters for an entire calendar year, CMS has added an extended Suggestion of Calculation Error period for these applicable calendar quarters to 30 calendar days in section 60.2 of this revised guidance. The extended Suggestion of Calculation Error period will also provide manufacturers with additional time to become accustomed to the invoicing process and Rebate Reports.

Comment: 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 B rebatable drug that owes a Part B inflation rebate believes in good faith that CMS has made a mathematical error in the rebate calculation, the manufacturer may submit a Suggestion of Calculation Error to CMS as described in section 60.1 of this revised guidance. However, CMS notes that section 1847A(i)(8) of the Act precludes

administrative or judicial review on the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount.

Comment: A commenter stated that all disputes submitted under the Suggestion of Calculation Error process be reviewed by CMS rather than at CMS' discretion, as outlined in the initial memorandum.

Response: CMS intends to consider all in-scope submissions under the Suggestion of Calculation Error process (e.g., suggestions regarding a mathematical error). However, section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount. Accordingly, CMS will not consider disputes on the rebate calculation.

Comment: A few commenters suggested CMS limit the time during which CMS can identify and correct rebate report errors. A couple of these commenters suggested three to four years as a limit.

Response: CMS thanks commenters for their feedback on the CMS Identification of Error period. As outlined in the initial memorandum, CMS' ability to identify errors and correct rebate reports as needed is intended to be used to reflect meaningful updates to data. In response to comments requesting clarity on the scope of CMS' review and limitations to the lookback period, CMS has revised section 60 of this revised guidance to remove the CMS Identification of Error period. For future rulemaking, CMS is considering under what circumstances and at what points in time it may be appropriate for CMS to have discretion for a recalculation of a rebate amount, separate from revision of the rebate amount due to restatements, potentially including but not limited to instances of fraud or similar fault by the manufacturer.

Enforcement of Rebate Amount Payments by Manufacturers ([Section 70](#))

Comment: A couple of commenters requested that CMS issue CMPs only on the rebate amount and remove the potential CMP on unpaid true-up amounts. One of these commenters stated CMS does not have the authority under 1847A(i)(7) of the Act to impose CMPs on anything but the manufacturer's failure to pay the initial invoice.

Response: Section 1847(i)(7) of the Act indicates that manufacturers that fail to comply with section 1847A(i)(1)(B) will be subject to a CMP. CMS has removed the true-up process from this revised guidance and will use future rulemaking to address restatement processes as well as the related enforcement considerations.

Comment: A few commenters requested that CMS issue Part B 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 B 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 to situations wherein 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. As stated in section 1847A(i)(7) of the Act and section 70 of this revised guidance, the provisions of section 1128A of the Act, other than subsections (a) and (b), will apply to the CMP process for this inflation rebate program in the same manner as such provisions apply to a penalty or proceedings under section 1128A(a). CMS will continue to evaluate its policy options to promote manufacturers' compliance with their payment obligations under the Part B Drug Inflation Rebate Program. CMS intends to include information in the Rebate Report described in section 60 of this revised guidance to remind manufacturers that late or unpaid rebate payments may result in a CMP. CMS also intends to issue reminder notices regarding the due date of rebate payments. CMS plans to undertake rulemaking to establish a CMP process pursuant to section 1847A(i)(7) of the Act and may consider additional CMP process requirements in such rulemaking.

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

10. Introduction

The purpose of this revised guidance is to provide pharmaceutical manufacturers and other interested parties with information regarding the payment by manufacturers of inflation rebates for Part B rebatable drugs beginning January 1, 2023.³⁰

The requirements for this program are described in section 1847A(i) of the Social Security Act (hereinafter “the Act”) as amended by section 11101 of the Inflation Reduction Act. While section 1847A(c)(5)(C) of the Act permits the Secretary to implement the program using program instruction or otherwise, the Centers for Medicare & Medicaid Services (CMS) sought comments on the initial memorandum to benefit from manufacturer feedback and public input.

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 B inflation rebate provisions and specifies the requirements that will be applicable to manufacturers of Part B rebatable drugs.

The Inflation Reduction Act (IRA) (P.L. 117-169) was signed into law on August 16, 2022. Section 11101 of the IRA added a new section 1847A(i) to the Act, which establishes a requirement for manufacturers to pay Medicare Part B rebates for single-source drugs and biological products with prices that increase faster than the rate of inflation for a calendar quarter no later than 30 days after receiving an invoice from CMS.³¹ CMS will send the invoice no later than 6 months after the end of the calendar quarter, except that the Secretary has the flexibility under section 1847A(i)(1)(C) of the Act to delay the timeframe for reporting the information and invoicing manufacturers for the Part B inflation rebates until September 30, 2025, for calendar quarters beginning in 2023 and 2024. In accordance with section 1847A(i)(7) of the Act, manufacturers that do not pay the Medicare Part B inflation rebate amount owed for a calendar quarter for a Part B rebatable drug within 30 calendar days of receiving an invoice may be subject to a CMP of at least 125 percent of the rebate amount for such drug for such quarter. In general, CMS is implementing the Part B Inflation Rebate Program through program instruction and does not plan to require manufacturers to enter into agreements with the Secretary for this program at this time. However, CMS intends to pursue rulemaking to establish the civil monetary penalty process as required by section 1847A(i)(7). Section 1847A(i)(5) of the Act also provides for an adjustment to beneficiary coinsurance in cases where the price of Part B rebatable drugs increases faster than the rate of inflation. Through the CY 2024 Hospital Outpatient Prospective Payment System (OPPS) final rule and the CY 2024 Physician Fee Schedule (PFS) final rule, CMS

³⁰ “Part B rebatable drug” means a single-source drug or biological product (as defined section 1847A(c)(6)(D)), including a biosimilar biological product (as defined section 1847A(c)(6)(H)) but excluding a qualifying biosimilar biological product (as defined section 1847A(b)(8)(B)(iii)), for which payment is made under Part B, except such term shall not include such a drug or biological product if, as determined by the Secretary, the average total allowed charges for such drug or biological project under Part B for a year per individual that uses such a drug or biological product are less than the applicable threshold; or that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

³¹ “Days” means calendar days unless otherwise specified in this revised guidance.

codified the beneficiary coinsurance amount in the C.F.R. § 419.41 and C.F.R. §§ 410.152(m) and 489.30(b)(6), respectively. This revised guidance specifies the requirements and procedures for implementation of these provisions.

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.

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20. Overview

In accordance with section 1847A(i) of the Act, for calendar quarters beginning January 1, 2023, a manufacturer of a Part B rebateable drug will owe a rebate, to be deposited in the Federal Supplementary Medical Insurance Trust Fund, if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act (hereinafter called “specified amount”³²) exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act (see sections 50.2 and 50.7 of this revised guidance, respectively). The “inflation-adjusted payment amount” is calculated for each Part B rebateable drug by the Healthcare Common Procedure Coding System (HCPCS) code by increasing the payment amount in the payment amount benchmark quarter (for example, Average Sales Price (ASP) plus 6 percent or Wholesale Acquisition Cost (WAC) plus 3 percent) by the percentage by which the rebate period CPI-U for the calendar quarter exceeds the benchmark period CPI-U. Sections 50.4, 50.5, 50.6, and 50.7 of this revised guidance provide additional detail on relevant calculations. These rebates are subject to certain reductions and waivers, when applicable, as set forth in section 1847A(i)(3)(G) of the Act and described in sections 50.10, 50.11, and 50.12 of this revised guidance. Beginning April 1, 2023, when the specified amount for a Part B rebateable drug for a calendar quarter exceeds the inflation-adjusted payment for such quarter, beneficiary coinsurance for such drug will be equal to

³² “Specified amount” refers to the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act which is, for single-source drugs and biological products (including “selected drugs” with respect to a price applicability period under section 1192(c) of the Act), 106 percent of the amount determined under section 1847A(b)(1)(B), which is based on ASP, WAC, or the maximum fair price, as applicable, for the calendar quarter and, for biosimilar biological products, the payment amount under section 1847A(b)(1)(C), which is based on 100 percent of the ASP for the biosimilar biological product plus 6 percent of the ASP for the reference biological product (or 8 percent, for qualifying biosimilar biological products, as applicable per section 1847A(c)(6)(H)); however, qualifying biosimilar biological products are not Part B rebateable drugs for such calendar quarter).

20 percent of the inflation-adjusted payment amount for such quarter as described in section 40 of this revised guidance. We note that the summaries provided in this section 20 of this revised guidance are intended to provide an overview of the estimated Part B rebate calculation and do not encompass all adjustments, exclusions, and relevant details.

Identification of Part B Rebatable Drug and Exclusions (see section 30): Section 1847A(i)(2)(A) of the Act defines a “Part B rebatable drug” to mean a single-source drug or biological product (as defined section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847(b)(8)(B)(iii) of the Act), for which payment is made under Part B. Generic drugs (those approved under an Abbreviated New Drug Application (ANDA) submitted under 505(j) of the Food, Drug, & Cosmetic (FD&C) Act) do not meet the definition of “single source drug or biological product,” and thus are not Part B rebatable drugs.

Section 1847A(i)(2)(A)(i) excludes from the definition of a “Part B rebatable drug” a drug or biological if the average total allowed charges for such drug or biological under Part B per individual that uses the drug or biological is less than a threshold of \$100 in 2023 or, in future years, \$100 increased by the percentage increase in the CPI-U.³³ Section 1847A(i)(A)(ii) of the Act also expressly excludes vaccines described in section 1861(s)(10)(A) and (B).

Beneficiary Coinsurance Amount (see section 40): Beneficiary coinsurance will be equal to 20 percent of the inflation-adjusted payment amount for Part B rebatable drugs furnished on or after April 1, 2023, if the payment amount (see definition below) for the calendar quarter in which the drug was furnished exceeds the inflation-adjusted payment amount for that quarter (see sections 50.1, 50.2, and 50.7 of this revised guidance for detail on related calculations). For example, if the inflation-adjusted payment amount is the ASP plus 6 percent, the beneficiary coinsurance will be equal to 20 percent of ASP plus 6 percent.

Calculation of the Part B Drug Inflation Rebate Amount (see section 50): The Part B drug inflation rebate amount is the estimated amount equal to the product of the total number of units determined in accordance with section 1847A(i)(3)(B) of the Act (see section 50.8 of this revised guidance) and the amount, if any, by which the specified amount (see section 50.2 of this revised guidance) exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act (see section 50.7 of this revised guidance) for the drug or biological product for the applicable calendar quarter.

Treatment of Subsequently Approved Part B Rebatable Drugs (see section 50): The payment amount benchmark quarter for drugs first approved or licensed by the U.S. Food and Drug Administration (FDA) on or before December 1, 2020, is the calendar quarter beginning July 1, 2021.

The benchmark quarter CPI-U also varies based on when the rebatable drug was first approved or licensed by FDA, as discussed in section 50.5 of this revised guidance. The benchmark period CPI-U for drugs first approved or licensed by FDA on or before December 1, 2020, is the CPI-U

³³ The “CPI-U” means the consumer price index for all urban consumers (United States city average) as published by the BLS (<https://www.bls.gov/>). See §1847A(i)(2)(B).

for January 2021. The benchmark period CPI-U for drugs first approved or licensed by FDA after December 1, 2020, is the CPI-U for the first month of the first full calendar quarter after the day on which the drug was first marketed (see section 50.3 of this revised guidance for detail as to how CMS will determine the day on which the drug was first marketed).

Reducing the Rebate Amount for Part B Rebatable Drugs in Shortages and in Cases of Severe Supply Chain Disruptions (see section 50.10): Section 1847A(i)(3)(G) of the Act provides that CMS reduce or waive the rebate amount with respect to a Part B rebatable drug for an applicable calendar quarter in two cases: (1) when a Part B rebatable drug is described as currently in shortage on the shortage lists authorized under section 506E of the FD&C Act at any point during the calendar quarter; or (2) for a biosimilar biological product³⁴ when the Secretary determines there is a severe supply chain disruption during a calendar quarter, such as that caused by a natural disaster or other unique or unexpected event. CMS notes that generic drugs are not subject to the Part B inflation rebate program.

Process for Rebate Reports and Suggestion of Calculation Error (see section 60.1): Manufacturers of Part B rebatable drugs that owe inflation rebates will receive an invoice (i.e., “Rebate Report”) for each applicable calendar quarter. CMS will first issue a Preliminary Rebate Report with the information reported to the manufacturer, followed by a Rebate Report. Manufacturers of Part B 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 the calculation error, and provide supporting documentation (if applicable) within 10 calendar days of receiving their Preliminary Rebate Report.

Timing of Rebate Report for Applicable Calendar Quarters in CY 2023 and CY 2024 (see section 60.2): The statute provides CMS a transition period for invoicing manufacturers for each Part B rebatable drug for applicable quarters in calendar year (CY) 2023 and CY 2024 until not later than September 30, 2025. CMS will issue a single Rebate Report for applicable calendar quarters in CY 2023 and a single Rebate Report for applicable calendar quarters in CY 2024 no later than September 30, 2025. For both reports, CMS will include an extended Suggestion of Calculation Error period of 30 calendar days. Beginning with the first calendar quarter of 2025, the Rebate Report invoicing cycle as described in section 60 of this revised guidance will apply.

Enforcement for Rebate Amount Payments by Manufacturers (see section 70): Manufacturers that do not comply with the requirements to pay Part B drug inflation rebate amounts as set forth at section 1847A(i)(1)(B) of the Act may be subject to civil monetary penalties (CMPs) in an amount equal to at least 125 percent of the rebate amount for a drug for a calendar quarter in addition to the rebate amount.

Formulas (see section 80): Formulas and example calculations are set forth to illustrate the Part B drug inflation rebate calculations for various sections of this revised guidance.

³⁴ Biosimilar biological products are defined in section 1847A(c)(6)(H) of the Act.

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

- The process CMS intends to use to determine the number of units (section 50.8);
- The process CMS intends to use to identify and remove 340B units (section 50.8.1);
- The process CMS intends to use to identify and remove units for which a Medicaid drug rebate was paid for a covered outpatient drug (section 50.8.2);
- Operational considerations related to the inclusion of units furnished to beneficiaries who are enrolled in Medicare Advantage plans (section 50.8.5);
- Specific scenarios where CMS would consider reducing the rebate in case of a shortage (section 50.11);
- The process CMS intends to use to reduce the rebate amount due to severe supply chain disruptions (section 50.12);
- The process CMS intends to use to allocate the financial responsibility for the rebate amount for a calendar quarter where there is more than one manufacturer of the Part B rebatable drug (section 50.13); and
- The process CMS intends to use to ensure the integrity of the rebate determination process (section 60).

30. Identification of Part B Rebatable Drugs and Exclusions

CMS will use the processes described in this section to determine the Part B rebatable drugs for a calendar quarter.

30.1 Identification of Part B Rebatable Drugs

To identify Part B rebatable drugs for a calendar quarter, CMS will identify (1) single-source drugs and biological products (as defined in section 1847A(c)(6)(D) of the Act), including biosimilar biological products (as defined in section 1847A(c)(6)(H) of the Act), for which payment is made under Part B and (2) the applicable HCPCS codes for such drugs and biological products, and then apply the exclusions described in sections 30.2 and 30.3 of this revised guidance below. Generic drugs (those approved under an ANDA submitted under 505(j) of the FD&C Act) do not meet the definition of “single source drug or biological product,” and thus are not Part B rebatable drugs. In addition, multiple-source drugs (described in section 1847A(c)(6)(C) of the Act) and qualifying biosimilar biological products (as defined in section 1847A(b)(8)(B)(iii) of the Act) will be excluded. Single-source drugs or biological products that were within the same billing and payment code as of October 1, 2003, as required under section 1847A(c)(6)(C)(ii) of the Act, are treated as multiple-source drugs and excluded from Part B inflation rebates.

Approximately two months before the start of a calendar quarter, CMS will identify Part B rebatable drugs using available information to determine the beneficiary coinsurance percentage that is applicable for the calendar quarter (see section 40 of this revised guidance). Of note, for the calendar quarter beginning January 1, 2023, this step was not necessary because the beneficiary coinsurance provision in section 1847A(i)(5) of the Act applies beginning April 1, 2023. At the time CMS calculates the rebate amount (the amount due to CMS from a manufacturer of a Part B

rebatable drug under section 1847A(i) of the Act), which will generally occur within six months after the end of a calendar quarter (see sections 50 and 60 of this revised guidance), CMS will identify the Part B rebatable drugs for the calendar quarter using the most recent information available.

CMS will align these processes with the processes CMS uses to identify separately payable single-source drugs and biological products for purposes of determining quarterly payment limits for the ASP Pricing File. CMS will use the most recent available data sources, including data submitted to CMS by manufacturers pursuant to section 1927(b)(3)(A)(iii) of the Act or section 1847A(f)(2) of the Act, as applicable; information available at FDA.gov; and information contained within drug pricing compendia. For example, CMS will consider the ASP data submitted by manufacturers (including the date of first sale), FDA approval information (such as labeling and approval letters), therapeutic equivalents as determined by FDA (i.e., those listed in FDA's Orange Book³⁵), and available products shown in drug pricing compendia.

CMS will adopt this approach to ensure that CMS appropriately adjusts beneficiary coinsurance prospectively and accurately invoices manufacturers for rebates in accordance with section 1847A(i) of the Act. See section 40 of this revised guidance for discussion on how CMS will address situations when more recent data impact the calculation of beneficiary coinsurance.

On January 18, 2023, CMS held a Town Hall to discuss changes in payment and terminology of skin substitute products and to provide interested parties an opportunity to engage on this matter. In the CY 2024 PFS proposed rule, CMS did not include proposals for skin substitute policies but solicited comments from interested parties.³⁶ CMS noted that it aims to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes. In the CY 2024 PFS final rule, CMS solicited comments on potential changes to payment for skin substitutes and acknowledged taking these comments into consideration for future rulemaking.³⁷ However, HCPCS codes that describe products currently referred to as skin substitutes will be excluded for purposes of identifying Part B rebatable drugs at this time and, as such, will not be subject to the coinsurance adjustment described in section 40 of this revised guidance.

For purposes of identifying Part B rebatable drugs for a calendar quarter, CMS also will exclude drugs and biological products that are billed using a HCPCS code that represents an "unclassified," "unspecified," or "not otherwise classified" (NOC) drug or biological product or claims for such drugs and biological products when no other HCPCS code is applicable. Although CMS has a process to determine the allowed payment amount when such HCPCS codes are billed, current Medicare claims data do not allow CMS to determine the average total allowed charges for such drug or biological product for a year per individual that uses such a drug or biological product or identify units billed, which are steps that CMS has to perform to determine if a drug is a Part B rebatable drug. CMS notes that few Part B drugs and biological products are

³⁵ Accessible via <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

³⁶ See: <https://www.federalregister.gov/documents/2023/08/07/2023-14624/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other>.

³⁷ See: <https://www.federalregister.gov/public-inspection/2023-24184/medicare-and-medicaid-programs-calendar-year-2024-payment-policies-under-the-physician-fee-schedule>.

billed with such codes and the quarterly process for updating HCPCS codes, including establishing new HCPCS codes, provides an existing mechanism for CMS to use to minimize the number of Part B rebatable drugs that would be billed with such codes. CMS believes “unclassified,” “unspecified,” or NOC HCPCS codes are generally used to bill Medicare for new-to-market FDA-approved drug products until a specific HCPCS code is assigned; and so, CMS expects that the impact of this exclusion will be limited.

CMS is excluding separately payable radiopharmaceuticals for the purposes of identifying Part B rebatable drugs and, as such, these units will not be subject to the coinsurance adjustment described in section 40 of this revised guidance, even though some radiopharmaceuticals may appear on quarterly pricing files. Consistent with section 303(h) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), radiopharmaceuticals are not paid under section 1847A of the Act. Manufacturers of radiopharmaceuticals are therefore not required to report ASP under section 1927(b)(3) of the Act and are not otherwise required to report ASP data to CMS for separately payable radiopharmaceuticals. In addition, inconsistent payment methodologies across the outpatient setting result in data distortions that could inappropriately trigger an inflation rebate amount due to methodological differences in reimbursement.

30.2 Exclusion of Drugs Where the Average Total Allowed Charges Under Part B is Less Than \$100 per Individual Using Such Drug per Year Adjusted by Changes in the CPI-U

Pursuant to section 1847A(i)(2) of the Act, CMS will exclude from Part B rebatable drugs those single-source drugs and biological products identified in section 30.1 of this revised guidance with Medicare Part B average total allowed charges for such drug or biological product for a year per individual that uses such a drug or biological product below the applicable threshold, as determined by the Secretary.³⁸ In this revised guidance, CMS uses the term “applicable threshold” to mean \$100 for all four calendar quarters in 2023, and, for all four calendar quarters in 2024 and beyond, the applicable threshold will be \$100 as increased in accordance with section 1847A(i)(2)(B) of the Act.

For each HCPCS code identified in accordance with section 30.1 of this revised guidance, CMS will conduct the following steps: calculate the average total allowed charges for a year per individual that uses such drug or biological product; calculate the applicable threshold; and compare the average total allowed charges for a year per individual that uses such drug or biological product to the applicable threshold and identify exclusions. That is, CMS will exclude the single-source drugs and biological products for which the average total allowed charges for a year per individual that uses such drug or biological product is below the applicable threshold.

Formulas, with steps, to calculate the statutory threshold are below, and an example calculation is found in section 80.1 of this revised guidance:

³⁸ For Part B claim lines that do not have an “allowed charge amount,” CMS will use the Medicare paid (not adjusted for sequestration) amount plus the Medicare beneficiary paid amount to determine total allowed charges.

Step 1: Calculate Average Total Allowed Charges Per Unique Beneficiary

For each HCPCS code identified in accordance with section 30.1 of this revised guidance, CMS calculates the average total allowed charges for such drug or biological product for a year (as defined below) per individual that uses such drug or biological product as follows:

- CMS identifies available final action claims (as defined below) where separate payment was allowed for the HCPCS code for dates of service within a year (as defined below) that are contained within the CMS Medicare fee-for-service claims repository.
- Using claim lines from such final action claims with Medicare Part B allowed charges greater than zero, CMS sums the allowed charges and divides the summed amount by the number of unique beneficiaries (as defined below).
 - Special rule for single-source drugs and biological products that are assigned to more than one HCPCS code: For such single-source drugs and biological products, CMS sums the allowed charges for all HCPCS codes for such drug or biological product and divides the summed amount by the number of unique beneficiaries (across all of the HCPCS codes for that drug or biological product, excluding any HCPCS code that represents an “unclassified,” “unspecified,” or NOC drug or biological product).
- For each rebate quarter, CMS calculates the average total allowed charges for such drug or biological product for a year for the Part B rebatable drugs identified in accordance with section 30.1 of this revised guidance.

For purposes of this calculation:

- “Final action claim” means a non-rejected claim for which a Medicare payment has been made and for which all disputes and adjustments have been resolved.
- “Allowed charges” (also called “allowed amount”) means the amount that is inclusive of the beneficiary liability and Medicare payment for the covered Part B item or service.
- “Unique beneficiaries” means the unduplicated count of Medicare Beneficiary Identifiers who were furnished the covered Part B drug or biological product during a year.
- “A year” means the four consecutive calendar quarters beginning six calendar quarters before the applicable calendar quarter (see Figure 1 below). This method for identifying a year for purposes of identifying Part B rebatable drugs for a calendar quarter allows for a two-quarter lag, ensuring that CMS will use the most recent data available when applying this exclusion. For example, for the calendar quarter beginning July 1, 2023, CMS will use available final action Medicare Part B claims with dates of service beginning January 1, 2022, and ending December 31, 2022. Because most Medicare Part B claims for separately payable drugs and biological products are submitted and paid within 90 days of the date of service, claims from these four calendar quarters would be sufficiently complete after March 31, 2023, when CMS will conduct the process to identify Part B rebatable drugs for the calendar quarter beginning July 1, 2023, and would be applying the exclusion discussed in this section.

Step 2: Calculate the Applicable Threshold

CMS will calculate the applicable threshold as follows:

- For calendar quarters in 2023, the statutory threshold is \$100.
- For calendar quarters in 2024, the statutory threshold is equal to the 2023 threshold (i.e., \$100) increased by the percentage increase in the CPI-U for the 12-month period ending with June of the previous year in accordance with section 1847A(i)(2)(B)(i) of the Act.³⁹ If the resulting amount is not a multiple of \$10, CMS will round that amount to the nearest multiple of \$10, in accordance with section 1847A(i)(2)(C) of the Act.⁴⁰
- For calendar quarters in each subsequent calendar year, the statutory threshold is equal to the inflation-adjusted threshold for the prior calendar 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 ending with June of the previous year in accordance with section 1847A(i)(2)(B)(ii) of the Act. If the resulting amount is not a multiple of \$10, CMS would round that amount to the nearest multiple of \$10, in accordance with section 1847A(i)(2)(C) of the Act.⁴¹

CMS will determine the threshold for a quarter within a particular calendar year during the fourth calendar quarter of the prior calendar year. For example, the threshold for 2024 would be determined by CMS during the fourth calendar quarter of 2023. The 2024 threshold would apply to the four calendar quarters during 2024. That is, January 1, 2024 through March 31, 2024; April 1, 2024 through June 30, 2024; July 1, 2024 through September 30, 2024; and October 1, 2024 through December 31, 2024.

Step 3: Compare the Average Total Allowed Charges for a Year Per Individual that Uses Such Drug or Biological Product to the Applicable Threshold and Identify Exclusions

For each HCPCS code identified by CMS as described in section 30.1 of this revised guidance, CMS will compare the average total allowed charges for a year per individual that uses such drug or biological product, as calculated in step 1 above, to the applicable threshold, as calculated in step 2 above. If the average total allowed charges for a year per individual that uses such drug or biological product is less than the applicable threshold, the HCPCS code would be excluded for that calendar quarter. CMS will conduct this comparison on a quarterly basis. Drugs that are determined to have average total charges under Part B of less than \$100 per individual per year, adjusted by changes in the CPI-U, will be excluded from Part B drug inflation rebate calculations for the applicable calendar quarter. Drugs that are determined to meet this statutory threshold also will be excluded from beneficiary coinsurance adjustments.

In instances where a single-source drug or biological product is assigned to more than one HCPCS code during a year and the average total allowed charges for a year per individual that uses such drug or biological product is less than the applicable threshold, CMS will exclude all

³⁹ As an example, for calendar quarters in 2024, the applicable threshold will be adjusted by the percentage change in CPI-U from June 2022 to June 2023.

⁴⁰ 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.

⁴¹ The same rounding rule applies as described in the previous footnote.

such assigned HCPCS codes for such single-source drug or biological product for that calendar quarter.

In instances where a single-source drug or biological product was previously crosswalked to a HCPCS code with other products (hereinafter referred to as a grouped HCPCS code) (other than a NOC; see section 50.4 of this revised guidance for the treatment of drugs that were previously billed under a NOC code) during the *full* year (as defined above), CMS will calculate the average total allowed charges per individual per year for the drug based on payment limits for the previously grouped HCPCS code during the year. Such instances apply to certain drugs approved through the pathway established under section 505(b)(2) of the FD&C Act (hereinafter “section 505(b)(2) drug products”), drugs that were previously multiple-source drugs and all other drugs under the same HCPCS code were discontinued (applicable only if the sole remaining product was not approved under an ANDA), and to any other situations where a drug was previously in a grouped HCPCS code.

In instances where a single-source drug or biological product was initially billed under a grouped HCPCS code (other than a NOC) and was later billed under a unique HCPCS code for *some* of the year (as defined above), CMS will sum the total allowed charges on final action claims billed under the unique HCPCS code for the drug with dates of service on or after the Medicare effective date for this unique HCPCS code, and identify the unique beneficiaries on those claims. For the remaining prior quarter(s) during the relevant time period, CMS will sum the total allowed charges on final action claims for the previously grouped HCPCS code during the year and identify the unique beneficiaries with claims prior to the unique HCPCS code’s effective date. CMS will then sum the total allowed charges under both HCPCS codes across the full year, and divide by the total number of unique beneficiaries (de-duplicated between those identified under the previously grouped HCPCS code and the unique HCPCS code) to obtain the average allowed charges for a year per individual that uses the drug. If the average allowed charges for a year per individual that uses such drug or biological product is less than the applicable threshold, the HCPCS code would be excluded for that calendar quarter. CMS will conduct this comparison on a quarterly basis.

30.3 Exclusion for Certain Vaccines

In accordance with section 1847A(i)(2)(A)(ii) of the Act, CMS will exclude vaccines described in section 1861(s)(10) of the Act. This provision excludes influenza, pneumococcal, hepatitis B, and COVID-19 vaccines from the Part B inflation rebate. With respect to monoclonal antibodies that are used to treat COVID-19 that are covered and paid for under section 1861(s)(10) of the Act, these products will be excluded from the definition of Part B rebatable drug for applicable quarters until the end of the calendar year in which the March 27, 2020 Emergency Use Authorization (EUA) Declaration for Drugs and Biological Products under section 564 of the FD&C Act, or any successor document or amendment (“EUA Declaration”), ends. With respect to monoclonal antibodies that are used for pre-exposure prophylaxis of COVID-19 that are covered and paid for under section 1861(s)(10) of the Act as described in the CY 2024 PFS final rule, these products will be excluded from the definition of Part B rebatable drug for applicable

calendar quarters even after the year in which the EUA Declaration ends, so long as after the EUA Declaration is terminated, these products have an FDA-approved application or license.⁴²

40. Computation of Beneficiary Coinsurance and Amounts Paid Under Section 1833(a)(1)(EE) of the Social Security Act

In accordance with section 1847A(i)(5) of the Act, for a Part B rebatable drug furnished on or after April 1, 2023, if the specified amount as described in section 50.2 of this revised guidance for the calendar quarter in which the drug was furnished exceeds the inflation-adjusted payment amount for that quarter (as described in section 50.7 of this revised guidance), beneficiary coinsurance is equal to 20 percent of the inflation-adjusted payment amount. In the CY 2024 OPSS final rule and the CY 2024 PFS final rule, CMS codified the beneficiary coinsurance amount at 42 C.F.R. § 419.41 and 42 C.F.R. §§ 410.152(m) and 489.30(b)(6), respectively.⁴³ A formula for this calculation is below, and an example calculation is found in section 80.2 of this revised guidance.

Inflation-Adjusted Coinsurance = Inflation-Adjusted Payment Amount *multiplied by* .20

Adjusted Coinsurance Percentage = Inflation-Adjusted Coinsurance *divided by* Specified Amount for the Applicable Quarter

This coinsurance adjustment is applied as a percentage, as determined by the Secretary, to the payment amount for such calendar quarter. The coinsurance adjustment determination for a Part B rebatable drug will be made for the calendar quarter when the payment limit for such drug for that calendar quarter is determined. CMS will specify whether this coinsurance adjustment applies to a Part B rebatable drug for a calendar quarter in the quarterly pricing files on the CMS website. If the published payment limit for a calendar quarter is subsequently revised (either during the calendar quarter or after the calendar quarter ends) based on updated information (for example, a manufacturer submits revised ASP data to CMS), CMS will determine the beneficiary coinsurance percentage applicable to the revised payment limit.

Beginning with the April 2023 quarterly pricing files, the applicable beneficiary coinsurance percentage would be shown for each HCPCS code in the pricing files that are posted on the CMS website.⁴⁴ The percentage will be expressed as two digits with three decimal places, for example, 18.760. If adjusted beneficiary coinsurance does not apply, the percentage will show as 20.000. See Appendix A for an example of how a quarterly pricing file will show the beneficiary coinsurance percentages.

When a separately payable claim line for a Part B rebatable drug is processed and the coinsurance is less than 20 percent of the published payment limit, the Medicare payment to the billing

⁴² See: <https://public-inspection.federalregister.gov/2023-24184.pdf>.

⁴³ See: <https://www.federalregister.gov/d/2023-24293/p-602>; and <https://www.federalregister.gov/d/2023-24184/p-2104>.

⁴⁴ For example, the files posted at <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2023-asp-drug-pricing-files>.

healthcare provider will equal the difference between the Medicare payment limit and the applicable beneficiary coinsurance amount, after application of the Medicare Part B deductible, and prior to application of sequestration, as applicable. The calculation to determine the applicable beneficiary coinsurance amount will not be adjusted for sequestration.

50. Calculation of the Medicare Part B Drug Inflation Rebate Amount

The rebate amount for a Part B rebatable drug for a calendar quarter is described in this section and illustrated as a formula with examples in section 80 of this revised guidance.

50.1 Overview of the Calculation of the Medicare Part B Inflation Rebate Amount

Section 1847A(i)(3) of the Act specifies the calculation of the rebate amount for a Part B rebatable drug assigned to a billing and payment code for a calendar quarter for which a manufacturer must pay a rebate, as described in sections 30.1 through 30.3 of this revised guidance. For purposes of calculating the rebate, CMS will use the HCPCS codes identified in accordance with section 30.1 of this revised guidance as the billing and payment codes. The rebate amount is the estimated amount equal to the product of the total number of units determined in accordance with section 1847A(i)(3)(B) of the Act (see section 50.8 of this revised guidance) and the amount (if any) by which the specified amount (see section 50.2 of this revised guidance) exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act (see section 50.7 of this revised guidance) for the drug or biological product for a calendar quarter. The formula calculating the Part B rebate amount for the rebate quarter is shown below and in more detail in Section 80.3 of this revised guidance.

Part B Rebate Amount =

(Units of Part B rebatable drug furnished during the rebate quarter, minus exclusions) *multiplied by* (specified amount *minus* inflation-adjusted payment amount)

The “specified amount” refers to the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act which is, for single-source drugs and biological products, 106 percent of the amount determined under section 1847A(b)(4) of the Act—that is, the lesser of ASP or WAC—for the calendar quarter and, for biosimilar biological products, the payment amount under section 1847A(b)(1)(C) of the Act, which is based on 100 percent of the ASP for the biosimilar biological product plus 6 percent of the lesser of ASP or WAC for the reference biological product.⁴⁵ The specified amount will not be adjusted to account for sequestration. That is, CMS will not apply sequestration to the specified amount as part of the methodology to calculate a Part B inflation

⁴⁵ For single-source drugs and biological products, including “selected drugs” with respect to a price applicability period under section 1192(c) of the Act, the specified amount is 106 percent of ASP, WAC, or the maximum fair price, as applicable.

rebate amount.⁴⁶ See section 80 of this revised guidance for formulas reflecting the key steps to determine the rebate amount for a given Part B rebatable drug for a calendar quarter.⁴⁷

50.2 Identification of the Specified Amount for the Calendar Quarter

To identify the specified amount (as described in section 50.1 above) for the calendar quarter for each Part B rebatable drug, CMS will use the payment limit (as updated if applicable) determined in accordance with section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, for the calendar quarter. The payment limit during the applicable payment amount benchmark quarter may not reflect ASP, such as when WAC is lesser than ASP. CMS notes that when CMS restates the ASP or WAC for the applicable quarter, CMS will use the restated (i.e., corrected) payment amount for the purpose of determining the specified amount. In general, section 1847A(i)(3)(A)(ii)(I)(aa) and (bb) of the Act cross-reference provisions governing quarterly payment limits for single-source drugs and biological products that are typically, but not always, reflected in the quarterly pricing files. For purposes of determining the rebate amount for a Part B rebatable drug, CMS will use the most updated, published payment limit reported by manufacturers to determine the specified amount for the calendar quarter for each HCPCS code identified in accordance with section 30.1 of this revised guidance. If necessary, CMS may consider future policymaking to issue payment policies regarding the specified amount.

50.3 Identification of the Payment Amount Benchmark Quarter

For each Part B rebatable drug, CMS will identify the applicable payment amount benchmark quarter. The payment amount benchmark quarter for drugs first approved or licensed by FDA on or before December 1, 2020, is the calendar quarter beginning July 1, 2021. For subsequently approved drugs—that is, drugs approved or licensed by FDA after December 1, 2020—the payment amount benchmark quarter is the third full calendar quarter after the day on which the drug was first marketed. There may be cases where a drug was first approved or licensed on or before December 1, 2020, but not marketed or sold until after that date, that lack ASP or WAC data for the calendar quarter beginning July 1, 2021, and thus would not have data to calculate the payment amount in the payment amount benchmark quarter. In these cases, CMS will treat such drugs in the same manner as it will treat subsequently approved drugs and identify the payment amount benchmark quarter as the third full calendar quarter after the day on which the drug was first marketed. CMS intends to address this policy in future rulemaking and will solicit comments on this policy at that time.

CMS determined that the most appropriate data source for CMS to use in identifying the first marketed date is the date of first sale as reported to CMS by manufacturers in ASP data. CMS believes that ASP data will be the most current, accurate, and appropriate for identifying: (1) the day on which the drug was first marketed, and (2) which calendar quarter is the third full calendar quarter thereafter as the payment amount benchmark quarter for drugs first approved or licensed

⁴⁶ A sequestration payment adjustment, when applicable, is applied to a Part B claim to determine the Medicare payment amount—after determining coinsurance, deductible, Merit-based Incentive Payment (MIPS) adjustments, and any applicable Medicare Secondary Payment adjustments.

⁴⁷ CMS will not round values as part of the calculation steps detailed in section 50 of this revised guidance. The invoice amount due (detailed in section 60 of this revised guidance) will be rounded to the nearest cent.

by FDA after December 1, 2020. Because CMS already collects these data from manufacturers, using the date of first sale is administratively feasible. In addition, since manufacturers attest to the accuracy of their submitted ASP information and have the ability to update these data quarterly, CMS believes these data sources are the most accurate. Since section 1847A(i)(4)(B) of the Act specifies that the inflation rebate provisions in 1847A(i) apply to drugs first approved or licensed by FDA after December 1, 2020 beginning the later of the sixth full calendar quarter after the day on which the drug was first marketed or January 1, 2023, using the date of first sale to establish when the drug was first marketed will generally provide sufficient information to determine the payment amounts specified in 1847A(b)(4) or (b)(1)(C) of the Act, as applicable, for purposes of the rebate calculation.⁴⁸ When the date of first sale is missing from ASP data, CMS will use the marketing start date from alternative sources, such as the National Institutes of Health's (NIH's) DailyMed, which contains labeling submitted to FDA by companies for drugs and biological products.⁴⁹

CMS will use the earliest date of first sale of any NDC ever marketed under the same FDA application number (i.e., NDA or BLA) ever associated with the HCPCS code as of the rebate quarter. This approach allows CMS to retain the first marketed date for the drug even if the NDCs and/or HCPCS codes used to bill for the Part B rebatable drug changes over time. This first marketed date will apply to all NDCs within a HCPCS code and to all products and package sizes under the same FDA application.

For instance, Figure 1 below provides an example, for illustration purposes only, of the application of first marketed date based on the earliest date of first sale of any NDC ever marketed under any NDA or BLA ever associated with the HCPCS code as of the rebate quarter. In the below example, NDC1 (marketed under NDA 000000) is first sold on January 15, 2022 and NDC2 (also marketed under NDA 000000) is first sold on October 15, 2023. Both NDCs are marketed under an NDA associated with HCPCS code X0000. The first marketed date for HCPCS code X0000 would be January 15, 2022, because that date is the earliest date of first sale for any NDC that has ever been associated with an NDA or BLA within that HCPCS code as of the rebate quarter. If NDC2 were subsequently assigned to a new HCPCS code Y0000, the first marketed date for HCPCS Y0000 would similarly be January 15, 2022.

Further, in cases when NDCs that are marketed under different NDA/BLAs are assigned to the same HCPCS code (e.g., because different dosage forms and/or strengths are marketed under distinct NDAs/BLAs), CMS will use the same approach as described above. That is, CMS will use the first marketed date as the earliest date of first sale for any NDC ever marketed under an FDA application number (i.e., NDA or BLA) ever associated with that HCPCS code. Using the example in Figure 1 below, NDC3 (marketed under NDA 111111) was first sold on November 1, 2024, and first billed under HCPCS Y0000, and the first marketed date for HCPCS Y0000 would remain January 15, 2022, as noted above, given that HCPCS Y0000 includes NDC2, associated with NDA 000000. NDC3 was later assigned to a new HCPCS code Z0000. Following CMS' approach, the first marketed date for HCPCS code Z0000 is November 1, 2024, because that is

⁴⁸ CMS acknowledges that this approach may apply a different definition of the first marketing date than would apply with respect to Part D rebatable drugs under section 1860D-14B but section 1847A(i) of the Act relies on data from reporting systems that are already in place with respect to ASP data.

⁴⁹ See: <https://dailymed.nlm.nih.gov>.

the earliest date of first sale for any NDC ever marketed under NDA 111111, which is the only NDA ever associated with Z0000 as of the rebate quarter.

Figure 1: Example of Application of First Marketed Date at the FDA Approval Level

Rebate Quarter	HCPCS Code	NDC	FDA Application Number	Date of First Sale for NDC	HCPCS Code Effective Date	Date of First Sale for Any NDC in NDA/BLA	First Marketed Date
2023 Q2	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
2023 Q3	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
		NDC2	000000	10/15/2023	4/1/2023	1/15/2022	
2023 Q4	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
		NDC2	000000	10/15/2023	4/1/2023	1/15/2022	
2024 Q1	X0000	NDC2	000000	10/15/2023	4/1/2023	1/15/2022	1/15/2022
2024 Q2	X0000	NDC2	000000	10/15/2023	4/1/2023	1/15/2022	1/15/2022
2024 Q3	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
2024 Q4	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
		NDC3	111111	11/1/2024	7/1/2024	11/1/2024	
2025 Q1	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
	Z0000	NDC3	111111	11/1/2024	1/1/2025	11/1/2024	11/1/2024

50.4 Identification of the Payment Amount in the Payment Amount Benchmark Quarter

Section 1847A(i)(3)(C) of the Act specifies use of the “payment amount for the billing and payment code for such drug in the payment amount benchmark quarter” (“payment amount in the payment amount benchmark quarter”) in the determination of the inflation-adjusted payment amount. To identify the payment amount in the payment amount benchmark quarter for the Part B rebatable drug by HCPCS code, CMS will use the payment limit (as updated if applicable) for the applicable payment amount benchmark quarter determined in accordance with section 1847A of the Act.

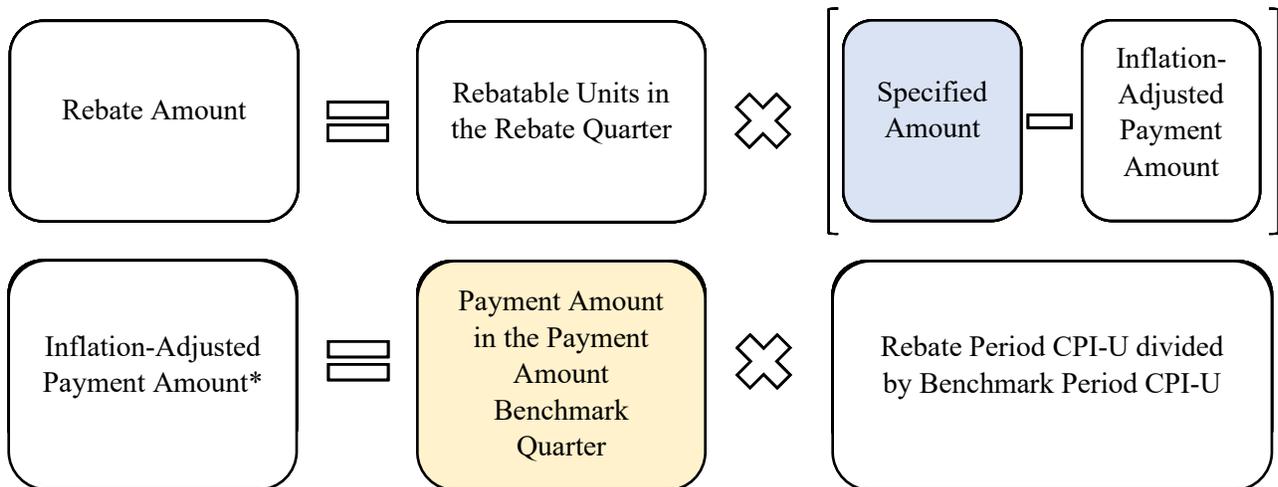
While the specified amount and the payment amount in the payment amount benchmark quarter are similar, the statutory requirements for determining these two amounts differ. The specified amount for a Part B rebatable drug, as set forth in section 1847A(i)(3)(A)(ii)(I) of the Act, is based on item (aa) (e.g., lesser of ASP+6 percent or WAC+6 percent) or (bb) (i.e., 100 percent of the ASP for the biosimilar biological product plus 6 percent of the lesser of ASP or WAC for the reference biological product). The payment amount in the payment amount benchmark quarter under section 1847A(i)(3)(C)(i) is based on various provisions within section 1847A of the Act (e.g., the lesser of 106% ASP or WAC, WAC+3 percent, and price substitutions). As such, it is possible that both amounts could be based on 106 percent of the ASP for the drug or biological product amounts, or they could differ—for example, the payment amount in the payment amount benchmark quarter might be a payment limit that is based on 103 percent of the WAC for the drug or biological product, but the specified amount is based on 106 percent of ASP. Table 1 and

Figure 2 below further illustrate the specified amount and payment amount in the benchmark quarter.

Table 1: Comparison of specified amount and payment amount in the payment amount benchmark quarter

Specified Amount		Payment Amount in the Payment Amount Benchmark Quarter	
Purpose in Rebate Calculation	Pricing Methodology Under 1847A(i)(3)(A)(ii)(I)	Purpose in Rebate Calculation	Pricing Methodology Under 1847A(i)(3)(C)(i)
Part B published payment limit for calendar quarter in which a rebate may be assessed	<ul style="list-style-type: none"> • Lesser of ASP+6% or WAC+6% • In the case of a biosimilar biological product, 100% of ASP for the biosimilar biological product + 6% of the lesser of ASP or WAC for the reference biological product 	Part B payment limit for the payment amount benchmark quarter, which is generally the quarter beginning July 1, 2021	<ul style="list-style-type: none"> • Various Part B pricing provisions consistent with section 1847A of the Act

Figure 2: Use of the specified amount and the payment amount in the benchmark quarter in rebate calculations



*See section 50.7 for information about identification and calculation of the inflation-adjusted payment amount.

Note that in the case of a clotting factor that is a Part B rebatable drug, the payment limit for the applicable payment amount benchmark quarter does not include the clotting factor furnishing fee payable under section 1842(o)(5)(C) of the Act.

Part B rebatable drugs may have been previously billed under a grouped HCPCS code during the benchmark quarter and later billed under unique HCPCS codes under certain situations, including certain section 505(b)(2) drug products and single-source drugs that were previously multiple-source drugs. For example, a multiple-source drug in an NDA may become a single-source drug if all its other therapeutically equivalent drugs are discontinued. To identify the payment amount in the payment amount benchmark quarter for such drugs, CMS will identify the grouped HCPCS code payment limit used by CMS for the benchmark quarter and use that payment limit for the benchmark quarter payment amount.

Example:

Drug A was first approved by the FDA on January 1, 2020. Drug A is a 505(b)(2) drug that is not therapeutically equivalent with Drug B, the listed drug relied on in Drug A's NDA. Drug A has two NDCs (NDC1 and NDC2) that were initially billed under a HCPCS code X1111 grouped together with Drug B (which has three NDCs – NDC3, NDC4, and NDC5).

Drug A's two NDCs were later reassigned to their own HCPCS code, Y1111, which was published in April 2023 and went into effect for Medicare starting with July 2023. Thus, starting in the third quarter of 2023 and onward, Drug A is in its own HCPCS code, but during the applicable benchmark quarter for Drug A (i.e., July 1, 2021 – September 30, 2021), Drug A was billed under the grouped HCPCS code X1111.

To identify the payment limit used during the applicable benchmark quarter for Drug A, CMS will use the payment limit applied to the grouped HCPCS code X1111 in the benchmark quarter, which is the third quarter of 2021.

For Part B rebatable drugs that were previously billed under a grouped, NOC code, CMS will use the payment amount in the payment amount benchmark quarter for the third full quarter after a drug was assigned a unique HCPCS code.

Additionally, the payment amount in the payment amount benchmark quarter will not be adjusted to account for sequestration. That is, CMS will not apply a sequestration reduction to the payment amount in the payment amount benchmark quarter as part of the methodology to calculate a Part B inflation rebate amount.

50.5 Identification of the Benchmark Period CPI-U

For each Part B rebatable drug by HCPCS code, as identified using the process in section 30.1 of this revised guidance, CMS will identify the applicable benchmark period CPI-U. The benchmark period CPI-U for drugs first approved or licensed by FDA on or before December 1, 2020, is the

CPI-U for January 2021 (which is 261.582⁵⁰). The benchmark period CPI-U for drugs first approved or licensed on or before December 1, 2020, but not marketed or sold until after that date, is the CPI-U for the first month of the third full calendar quarter after the day on which the drug was first marketed. The benchmark period CPI-U for drugs first approved or licensed by FDA after December 1, 2020, is the CPI-U for the first month of the first full calendar quarter after the day on which the drug was first marketed, which will be the date of first sale as reported to CMS by manufacturers in their ASP data or an alternative source, such as NIH's DailyMed. For further detail, refer to the discussion in section 50.3 of this revised guidance.

The benchmark period CPI-U for Part B rebatable drugs that were previously billed under a grouped, NOC code is the first month of the third full quarter after the drug was assigned a unique HCPCS code.

50.6 Identification of the Rebate Period CPI-U

As specified in section 1847A(i)(3)(F) of the Act, the rebate period CPI-U means the greater of the benchmark period CPI-U and the CPI-U for the first month of the calendar quarter that is two calendar quarters prior to the applicable calendar quarter in which the Part B rebatable drug is furnished. For each Part B rebatable drug by HCPCS code, CMS will identify which CPI-U is greater for the rebate quarter by accessing the BLS website.

Figure 3 below provides a summary of data timelines for Part B rebate calculations. This figure compares the data timeline for a Part B rebatable drug that is: first approved or licensed on or before December 1, 2020 and marketed before December 1, 2020; first approved or licensed after December 1, 2020 and first marketed on June 1, 2021; and first approved or licensed after December 1, 2020 and first marketed on January 1, 2022.

Figure 3: Summary of Data Timelines for Part B Drug Inflation Rebate Provisions

	2021												2022												2023											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Drug Licensed/Approved On or Before 12/1/2020																																				
Rebate Period 1							1			2						3		4			5			6												
Average Total Allowed Charges Calculation Period																																				
Payment Amount Benchmark Quarter																																				
Benchmark Period CPI-U																																				
Rebate Period 1 CPI-U (Greater Of)																																				
Drug Marketed 6/1/2021																																				
Rebate Period 1							1			2						3		4			5			6												
Average Total Allowed Charges Calculation Period																																				
Payment Amount Benchmark Quarter																																				
Benchmark Period CPI-U																																				
Rebate Period 1 CPI-U (Greater Of)																																				
Drug Marketed 1/1/2022																																				
Rebate Period 1																		1			2			3			4		5			6				
Average Total Allowed Charges Calculation Period																																				
Payment Amount Benchmark Quarter																																				
Benchmark Period CPI-U																																				
Rebate Period 1 CPI-U (Greater Of)																																				

Note: A drug will be included on the six full calendar quarters (denoted with the numbers in the figure) after the day the drug was marketed or the first quarter of 2023, whichever is later. The Rebate Period CPI-U is the greater of the benchmark period CPI-U or the CPI-U of the first month of the quarter two quarters prior to the rebate period. An enlarged version of this figure appears in Appendix B.

⁵⁰ Retrieved from BLS.gov on October 11, 2023.

50.7 Determination of Inflation-Adjusted Payment Amount

CMS will determine the inflation-adjusted payment amount for the Part B rebatable drug for a calendar quarter in accordance with section 1847A(i)(3)(C) of the Act. For each Part B rebatable drug by HCPCS code, CMS will use the payment amount in the payment amount benchmark quarter (see section 50.4 of this revised guidance), benchmark period CPI-U (see section 50.5 of this revised guidance), and rebate quarter CPI-U (see section 50.6 of this revised guidance). CMS will calculate the inflation-adjusted payment amount by increasing the payment amount in the payment amount benchmark quarter by the percentage by which the rebate period CPI-U for the calendar quarter exceeds the benchmark period CPI-U.

This calculation is equivalent to multiplying the payment amount in the payment amount benchmark quarter by the amount that is the result of dividing the rebate period CPI-U by the benchmark period CPI-U. See below for depiction of steps for this formula, and an example calculation is found in section 80.3 of this revised guidance:

Inflation-Adjusted Payment Amount =

(Payment amount for the benchmark quarter) *multiplied by* (Rebate period CPI-U *divided by* Benchmark period CPI-U)

Rebate Period CPI-U =

The greater of:

Benchmark Period CPI-U OR the CPI-U of the first month of the quarter that is two quarters prior to the rebate quarter.

50.8 Determination of the Total Number of Units

Beginning for calendar quarters starting on or after January 1, 2023, for each Part B rebatable drug by HCPCS code, for purposes of calculating the inflation rebate amount for units of the Part B rebatable drug where Medicare payment was allowed, CMS will determine the number of such units in accordance with section 1847A(i)(3)(B) of the Act. Including units where Medicare payment was allowed will ensure that units for which Medicare and some beneficiaries have financial liability will be counted in the total number of units. Section 1847A(i)(3)(B) of the Act prescribes that the total number of units is based on the number of units furnished in a calendar quarter, excluding units of drugs with respect to which the manufacturer provides a discount under the 340B Program, units with respect to which the manufacturer pays a Medicaid rebate, or units that are packaged into the payment amount for an item or service and are not separately payable (and described in sections 50.8.1 through 50.8.3 of this revised guidance). In addition, CMS will exclude units when a drug is no longer a Part B rebatable drug (described in section 50.8.4 of this revised guidance).

After identifying Part B rebatable drugs by HCPCS code (in accordance with section 30 of this revised guidance) using final action claims in the CMS Medicare fee-for-service claims

repository, CMS will determine the total number of units for each HCPCS code as follows. CMS identifies claim lines for such HCPCS code for dates of service in the calendar quarter, removes units in claim lines specified in subsections 50.8.1 through 50.8.4 of this revised guidance, as applicable, and sums the number of units in the remaining claim lines for which Medicare payment was allowed.

CMS will perform this process at least three months after the end of a calendar quarter to allow time for claims to be submitted, processed, and finalized. See section 60 of this revised guidance for a discussion of the rebate process.

50.8.1 Removal of 340B Units

Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes units of drugs for which the manufacturer provides a discount under the 340B program from the units of drugs for which a manufacturer may otherwise have a Part B inflation rebate liability. CMS will remove separately payable units in claim lines that are billed with the “JG” or “TB” modifiers from the identified final action claim lines described in section 50.8 above. On December 20, 2022, CMS issued program guidance that requires all 340B covered entities to include the “JG” or “TB” modifier, as applicable, on separately payable claim lines for drugs acquired through the 340B program with dates of service beginning no later than January 1, 2024.⁵¹ On November 2, 2023, CMS issued a final rule to utilize a single 340B modifier (“TB”), requiring hospitals that currently report the “JG” modifier to use the “TB” modifier beginning January 1, 2025.⁵² In CY 2024, these hospitals can choose to continue to use the “JG” modifier or choose to transition to the use of “TB” modifier during that year. Additionally, on December 14, 2023, CMS updated the December 20, 2022, guidance titled “Part B Inflation Rebate Guidance: Use of the 340B Modifiers” to align with the updated single modifier requirement.⁵³ Consistent with the CMS updated 340B subregulatory modifier guidance, CMS will remove separately payable units in claim lines with the “JG” and “TB” modifiers from final action claims with dates of service through December 31, 2024. While these modifiers have been required and utilized by 340B providers paid under the OPSS since CY 2018, this requirement may be new for other 340B covered entities, which CMS believes represents a small fraction of all entities participating in the 340B program.

For claims with dates of service during 2023, CMS will remove units in all institutional claim lines that were billed with the “JG” or “TB” modifiers and all other units in institutional claims submitted by critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments (PBDs).⁵⁴ For professional claims with dates of service during 2023, CMS will remove all units in claims for Medicare suppliers that are listed by the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System as participating in the 340B Program, by using employer identification numbers to identify these suppliers’ Medicare Identification Numbers and the claims submitted with such

⁵¹ See: <https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf>.

⁵² See: <https://www.federalregister.gov/public-inspection/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>.

⁵³ See: <https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf>.

⁵⁴ See: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-ops.pdf>.

identifiers. CMS notes that this exclusion of drug units for calendar quarters in 2023 is limited to the small percentage of entities participating in the 340B Program and not paid under the OPPS.

For claims with dates of service on or after January 1, 2024, CMS will remove units in claim lines identified as 340B units as those billed with the “JG” or “TB” modifiers.

For claims with dates of service on or after January 1, 2025, CMS will remove units in claim lines identified as 340B units as those billed with the “TB” modifier.

50.8.2 Removal of Units with a Rebate Under Section 1927 of the Social Security Act

To receive payment under Medicaid for covered outpatient drugs, manufacturers must participate in the Medicaid Drug Rebate Program (that is, have a drug rebate agreement in effect) and are required to report certain pricing and drug product information and pay Medicaid drug rebates for covered outpatient drugs furnished and paid for under the Medicaid state plan. States invoice manufacturers no later than 60 days after the end of each calendar quarter on the number of units of each dosage form and strength of each covered outpatient drug furnished and paid for under the state plan. This invoice includes units of covered outpatient drugs that are furnished to dually eligible beneficiaries when the claim for the drug is paid for by Medicare Part B and the beneficiary’s cost sharing is covered by Medicaid. To determine unit counts for rebate calculations, at this time, CMS will remove units from claims with dates of service during a month within a rebate quarter when the Medicare beneficiary has Medicaid coverage that may provide cost-sharing assistance. These are Qualified Medicare Beneficiary (QMB) Plus, Specified Low-Income Medicare Beneficiary (SLMB) Plus, QMB-only beneficiaries, and other full dually eligible beneficiaries. Units for rebatable drugs furnished to Medicare beneficiaries with Medicaid coverage that does not include cost-sharing assistance (i.e., SLMB Only, Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries) will be included in rebate calculations. CMS will identify the dates for which a beneficiary has Medicaid coverage with cost-sharing assistance using available information (for example the state MMA File of dually eligible beneficiaries) at the time the rebate amount is being calculated for a calendar quarter.

50.8.3 Removal of Units that Are Packaged into the Payment Amount for an Item or Service and Are Not Separately Payable

As described in section 50.8 of this revised guidance, CMS will only include claims lines with a Medicare allowed amount greater than zero. Because CMS will identify units for separately payable claim lines for Part B rebatable drugs only, no further action will be necessary to remove units that are packaged into the payment amount for an item or service and are not separately payable, such as drugs for which payment is packaged under the OPPS, Ambulatory Surgical Center (ASC) payment system, or those furnished in the Federally qualified health centers (FQHC) or rural health clinics (RHC) setting. CMS notes that claim lines for drugs for which payment is bundled under the End-Stage Renal Disease (ESRD) prospective payment system would not have a Medicare allowed amount that is greater than zero and such units will therefore be excluded under section 50.8 of this revised guidance.

Under the OPPTS/ASC final rule for CY 2024, CMS will except biosimilar biological products from the OPPTS threshold packaging policy when their reference biological products are separately paid. This means that CMS will pay separately for these biosimilar biological products even if their per-day cost is below the threshold packaging policy. Because units of these biosimilar biological products are not packaged into the payment amount for an item or service and are separately payable, they will be included in the Part B inflation rebate calculation.

50.8.4 Removal of Units When Drug is No Longer a Part B Rebatable Drug

As noted in section 30.1 of this revised guidance, multiple-source drugs are not Part B rebatable drugs. A single-source drug that is a Part B rebatable drug could become a multiple-source drug at the start of or during a calendar quarter. In such cases, CMS will identify the date of first sale, as discussed in section 50.3, of a drug product that is rated as therapeutically equivalent to such a drug under FDA's most recent publication of *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the FDA Orange Book⁵⁵) and determine whether the drug is no longer a Part B rebatable drug. CMS also may consult with FDA for technical assistance as needed. Units furnished on or after that date will be excluded from the units identified in accordance with section 50.8 of this revised guidance.

50.8.5 Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who are Enrolled in Medicare Advantage Plans

Section 1847A(i) of the Act requires the manufacturer of a Part B rebatable drug to pay a rebate that, generally, is calculated on the basis of the total number of units of that drug that were furnished in a calendar quarter, multiplied by the excess payment amount for the drug over a statutorily defined inflation-adjusted payment amount. The inclusion in this calculation of units of drugs that are furnished to Medicare beneficiaries who are enrolled in Medicare Advantage (MA) plans poses significant operational complexities. At this time, CMS is not establishing a policy on treatment of MA units in the calculation of Part B inflation rebates due to operational considerations but may establish policy on this issue in future policymaking.

50.8.6 Removal of Units Subject to Discarded Drug Refunds

Under the Infrastructure Investment and Jobs Act of 2021, section 90004, manufacturers are required to provide a refund to CMS for certain discarded amounts from separately payable single-dose container or single-use package drugs beginning January 1, 2023.⁵⁶ To implement the discarded drugs refund provision of the Infrastructure Investment and Jobs Act of 2021, in the CY 2023 PFS Final Rule, CMS finalized the requirement that providers and suppliers use the "JW" claim modifier on all Part B claims that bill for drugs and biological products to report discarded amounts of drugs from a single-dose container or from a single-use package.⁵⁷ CMS also finalized a requirement for providers and suppliers to use the "JZ" modifier on claims that

⁵⁵ Accessible via <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

⁵⁶ See: <https://www.congress.gov/117/plaws/publ58/PLAW-117publ58.pdf>.

⁵⁷ See: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>.

bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts to attest that no amount of drug was discarded and eligible for payment. As of October 1, 2023, claims for drugs from single-dose containers that do not use the modifiers as appropriate may be returned until claims are properly resubmitted.⁵⁸

Although Section 1847A(i)(3)(B)(ii) of the Act does not state that discarded units of drugs are excluded from Part B inflation rebates, CMS may consider a proposal to exclude units of discarded drugs that are subject to discarded drug refunds from Part B inflation rebates in future rulemaking. CMS believes it would balance fairness with the need to fulfill the requirements of section 11101 of the IRA to not apply Part B rebates to units of discarded drugs for which a refund is owed. CMS intends to address this policy in future rulemaking and will solicit comments on this policy at that time.

Initially, CMS will include all discarded units that are subject to inflation rebates in Preliminary Rebate Reports and Rebate Reports. CMS may consider a proposal to remove units of discarded drugs with a discarded amount above the applicable percentage, and therefore subject to discarded drug refunds, from the calculation of rebate amounts in any restatement process that may be included in future rulemaking.⁵⁹ CMS intends to propose to use a restatement process to remove units of discarded drugs that are subject to discarded drug refunds because information regarding units that are subject to discarded drug refunds will generally not be available in time to remove these units from the calculation of rebate amounts for Preliminary Rebate Reports or Rebate Reports. CMS will invoice manufacturers for discarded drug refunds on an annual basis and CMS is required to invoice manufacturers for Part B inflation rebates on a quarterly basis. Therefore, data regarding which units are subject to discarded drug refunds may not be available when CMS is required to invoice manufacturers for quarterly rebates. CMS intends to propose to use data available during a restatement process to remove units of discarded drugs that are subject to discarded drug refunds from the calculation of the rebate amount.

50.9 Adjustments for Changes to HCPCS Codes

When applicable, CMS will apply a conversion factor within the inflation rebate calculation if there has been a change to the billing and payment code's dose description or a new code is assigned. In these instances, CMS will maintain a crosswalk between such changes or codes to apply the provisions in section 1847A(i) of the Act appropriately. For example, a HCPCS code dose description that determines the amount of drug in each billing unit could be changed from 10mg to 5mg. If the payment amount in the payment amount benchmark quarter for such drug was \$200 based on 10mg and the rebate period payment amount is based on 5mg, CMS will apply a conversion factor of 0.5 to the payment amount in payment amount benchmark (yielding \$100). As shown in this example, the conversion factor will be based on the ratio of the current billing unit description to the prior billing unit description ($5\text{mg} / 10\text{mg} = 0.5$). CMS will apply the conversion factor before applying the percentage by which the rebate period CPI-U for the

⁵⁸ See: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>.

⁵⁹ The refund amount due from manufacturers is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter.

calendar quarter exceeds the benchmark period CPI-U to determine the inflation-adjusted payment amount.

In instances where a new HCPCS code is assigned for a Part B rebatable drug and the code dose description that determines the amount of drug in each billing unit remains the same (that is, only the alpha-numeric code was changed), CMS will carry over the benchmark quarter's payment amount, the payment amount benchmark quarter, and the benchmark quarter CPI-U. If applicable, as described above, CMS will apply a conversion factor, as appropriate, if there has been a change to the dose description.

50.10 Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions

The calculation of the estimated rebate amount for a Part B rebatable drug for a calendar quarter is subject to section 1847A(i)(3)(G) of the Act, which requires CMS to reduce or waive the rebate amount for a Part B rebatable drug with respect to a calendar quarter in two cases: (1) when a Part B 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 calendar quarter; or (2) when CMS determines there is a severe supply chain disruption during a calendar quarter for a biosimilar biological product, such as a disruption caused by a natural disaster or other unique or unexpected event. See Table 2 below for a summary of how CMS will reduce the rebate amount in each of these cases.

As described in section 30.1 of this revised guidance, generic drugs are not Part B rebatable drugs.

Table 2: Determination of Rebate Reduction Amount for Part B Rebatable Drugs

	Drug Shortage		Severe Supply Chain Disruption
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 B rebatable drug other than a plasma-derived product	Part B rebatable plasma-derived product	Part B rebatable biosimilar biological product
<i>First year</i>	25%	75%	75%
<i>Second year</i>	10%	50%	75%
<i>Subsequent years</i>	2%	25%	Not applicable

Note: The scope of drugs subject to Part B drug inflation rebates is limited to single source drugs and biological products. Generic drugs approved under an ANDA under section 505(j) of the FD&C Act do not meet the definition of "single source drug or biological product," and thus are not Part B rebatable drugs.

As described in section 50.11 of this revised guidance, for a Part B rebatable drug that is described as "currently in shortage" on an FDA shortage list at any point during a calendar quarter, CMS will apply a variable reduction of 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 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.

As described in section 50.12 of this revised guidance, CMS will provide a standard reduction of 75 percent in the rebate amount for a Part B rebatable biosimilar biological product when CMS determines that there is a severe supply chain disruption during the calendar quarter. CMS believes that severe supply chain disruptions generally take time to resolve and for purposes of the revised guidance, CMS is adopting a policy under which a determination of a severe supply chain disruption has occurred will be deemed to disrupt the supply chain for the quarter in which the event occurred and the three subsequent calendar quarters. CMS is limiting the maximum rebate reduction under the severe supply chain disruption policy to eight consecutive calendar quarters total. CMS believes providing a standard, time-limited reduction in this case could mitigate the likelihood of shortage while avoiding creating incentives for manufacturers to delay resolving a severe supply chain disruption 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 B rebatable drug and calendar quarter. Thus, if a biosimilar biological product that is described as “currently in shortage” on an FDA shortage list during a calendar quarter experiences a severe supply chain disruption during that same calendar quarters as the severe supply chain disruption rebate reduction was granted, the manufacturer may receive a rebate reduction under either the severe supply chain disruption policy or the shortage policy, but not both. Section 50.12 of this revised guidance describes how CMS will apply rebate reductions if a Part B rebatable biosimilar biological product that is “currently in shortage” on an FDA shortage list experiences a severe supply chain disruption or if a Part B rebatable biosimilar biological product is granted a severe supply chain disruption rebate reduction request and that product subsequently appears as “currently in shortage” on an FDA shortage list during the same four consecutive calendar quarters as for which the rebate reduction was granted.

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 to avoid an obligation to pay rebates. CMS will continue to evaluate these policies and may update them in future years. CMS underscores that generic drugs, which are the drugs most likely be in shortage,⁶⁰ are not Part B rebatable drugs and are not subject to Part B drug inflation rebates.

CMS will not provide a full waiver of the rebate amount for any Part B rebatable drugs in shortage or for any Part B rebatable biosimilar biological product when there is a severe supply chain disruption. CMS believes a full waiver of the rebate amount could create incentives for manufacturers to delay resolving a severe supply chain disruption or shortage for the purpose of avoiding an obligation to pay a rebate.

⁶⁰ See: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023>.

CMS notes that the shortage and severe supply chain disruption policies described below apply to the calculation of the rebate amount and will have no effect on the calculation of beneficiary coinsurance (described in section 40 of this revised guidance).

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

Section 1847A(i)(3)(G)(i) of the Act requires CMS to reduce or waive the rebate amount for a Part B 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 calendar quarter. To determine whether a Part B 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 calendar quarter, 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 biological products within their respective jurisdictions.⁶¹ To be eligible for a reduction of the rebate amount for a calendar quarter, which is calculated at the HCPCS code level, at least one NDC mapped to the HCPCS code must appear on an FDA shortage list as “currently in shortage” at any point during the calendar quarter.⁶² A Part B rebatable drug with a shortage status of “discontinued,” “to be discontinued,” or “resolved” will not be considered “currently in shortage.” CMS will monitor the status of a Part B 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 B rebatable drug described as “currently in shortage” on an FDA shortage list during a calendar quarter.

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

⁶¹ 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>.

⁶² For the purposes of this revised guidance, CMS uses the term “currently in shortage” to refer to Part B 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.

For a Part B rebatable drug for which the status changes from “currently in shortage” to “resolved” during a calendar quarter, CMS will count the number of days that such drug was described as “currently in shortage” during that calendar quarter for the calculation of the rebate reduction. When the status of a Part B rebatable drug changes from “currently in shortage” to “resolved” during a calendar quarter and then changes to “currently in shortage” during one or more of the subsequent three calendar quarters, CMS will apply the shortage policy as if there was a continuous shortage beginning with the quarter in which the drug has re-entered a shortage and move to the percent reduction applicable for the second four consecutive quarters. (In this scenario, once this drug enters its fifth quarter of shortage from the first quarter in which it was listed as “currently in shortage,” CMS would apply a 50 percent reduction for the fifth through eighth calendar quarters for a Part B rebatable drug that is a plasma-derived product and a 10 percent reduction for a Part B rebatable drug that is not a plasma-derived product). When the status of a Part B 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 four full consecutive calendar quarters 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 four consecutive calendar quarters. The formula for the calculation of the reduced quarterly rebate amount is below, and an example calculation is provided in section 80.4 of this revised guidance:

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

Because drugs and biological products on the FDA shortage lists are maintained at the NDC-10 level, and Part B rebatable drug inflation rebates are calculated at the HCPCS code level, if any NDC mapped to a HCPCS code is described as “currently in shortage” on the FDA shortage lists, CMS will apply the rebate reduction to all of the NDCs under the relevant HCPCS code. CMS will closely monitor market data for the Part B rebatable drugs for which the rebate is reduced to ensure the integrity of the application of the rebate reduction policy by the manufacturer.

50.12 Reducing the Rebate Amount for a Part B Rebatable Biosimilar Biological Product When There Is a Severe Supply Chain Disruption

Section 1847A(i)(3)(G)(ii) of the Act requires CMS to reduce or waive the rebate amount for a calendar quarter in the case of a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during a calendar quarter, such as a severe supply chain disruption caused by a natural disaster or other unique or unexpected event. (As above, CMS underscores that generic drugs are not Part B rebatable drugs and are not subject to Part B 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 Part B rebatable biosimilar biological product 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 calendar quarter, the manufacturer of a Part B rebatable biosimilar biological product must demonstrate in writing to CMS that: (1) a severe supply chain disruption has occurred during a calendar quarter, (2) the disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging of the Part B rebatable biosimilar biological product, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product, 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 a calendar quarter, 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 Part B rebatable biosimilar biological product(s), such as a change in the production or distribution of the Part B rebatable biosimilar biological product(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 Part B rebatable biosimilar biological product(s) for at least 90 days, with information about when the manufacturer expects supply of the Part B rebatable biosimilar biological product(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, 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 Part B biosimilar biological product(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 Part B rebatable biosimilar biological product(s), evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the Part B rebatable biosimilar biological product(s), 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 by a manufacturer of a Part B rebatable biosimilar biological product to CMS 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 January 1, 2023, 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 Part B rebatable biosimilar biological product for the calendar quarter in which the event that caused the severe supply chain disruption occurred and the three calendar quarters thereafter. CMS believes that severe supply chain disruptions generally take time to resolve and for purposes of the revised guidance, CMS is adopting a policy under which a determination of a severe supply chain disruption has occurred will be deemed to disrupt the supply chain for the quarter in which the event occurred and the three subsequent calendar quarters. 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 occurred or began.

If the manufacturer submits a timely request and all supporting documentation less than 60 days before the end of a calendar quarter, CMS will apply the rebate reduction to the next calendar quarter and the three subsequent calendar quarters thereafter. For example, if there is a hurricane on November 1, 2024 that causes a severe supply chain disruption and the manufacturer submits a rebate reduction request with supporting documentation on November 29, 2024, which CMS grants, CMS would reduce the rebate amount for the four calendar quarters beginning on January 1, 2025 and ending on December 31, 2025.

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 the fifth calendar quarter after the start of the natural disaster or unique or unexpected event, the manufacturer may request a reduction of the rebate amount for the fifth through eighth calendar quarters 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 Part B rebatable biosimilar biological product(s) continues to be affected by the severe supply chain disruption during the fifth through eighth calendar quarters. In accordance with the PRA, CMS intends to propose a collection of information addressing information that must be submitted by the manufacturer of a Part B rebatable biosimilar biological product to CMS 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 Part B rebatable biosimilar biological product in the marketplace and whether availability has returned to normal during a calendar quarter. 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 the fifth through eighth calendar quarters for that manufacturer's Part B rebatable biosimilar biological product. If the manufacturer's request is incomplete or untimely, CMS will deny the request. As previously mentioned, CMS believes that severe supply chain disruptions generally take time to resolve and for purposes of the revised guidance, CMS is adopting a policy under which a determination of a severe supply chain disruption has occurred will be deemed to disrupt the supply chain for the quarter in which the event occurred and the three subsequent calendar quarters.

A rebate reduction extension request and any new supporting documentation must be submitted at least 60 days before the start of the fifth calendar quarter. 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 January 1, 2023, 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 all of the NDC-11s under the relevant HCPCS code. CMS will closely monitor market data for the Part B rebatable biosimilar biological products 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 for severe supply chain disruption to eight consecutive calendar quarters 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 four calendar quarters for the same Part B rebatable biosimilar biological product for which a rebate reduction request was granted, the manufacturer will receive only one rebate reduction for that product for those four consecutive calendar quarters. For example, if the manufacturer of a Part B rebatable biosimilar biological product 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 four calendar quarters for the severe supply chain disruption caused by the first natural disaster but would not receive a 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 the fifth through eighth calendar quarters.

Beginning with the calendar quarter that begins on October 1, 2024, CMS will review rebate reductions request 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 Part B rebatable biosimilar biological product, and the product appears in the status of “currently in shortage” on an FDA shortage list during one of the same four calendar quarter(s) as for which the severe supply chain disruption reduction was granted, CMS will apply the 75 percent standard reduction to the four calendar quarters for which the severe supply disruption request was granted and will not grant any additional reduction for the “currently in shortage” status during those quarters. For any subsequent calendar quarters that the Part B rebatable biosimilar biological product 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 50.11 of this revised guidance. For example, if CMS grants a severe supply chain rebate reduction request for a Part B rebatable biosimilar biological product that was submitted on February 15, 2024 and that product appears as “currently in shortage” on an FDA shortage list from December 15, 2024 until May 15, 2025, CMS will apply a 75 percent reduction in the rebate amount to all four calendar quarters in 2024 and then will apply the variable reduction, as described in section 50.11 of this revised guidance, beginning with a reduction of 25 percent (or 75 percent in the case of a plasma derived product that is a biosimilar) for the first two calendar quarters of 2025.

If a Part B rebatable biosimilar biological product that is “currently in shortage” on an FDA shortage list experiences a severe supply chain disruption, the manufacturer may submit a request for a severe supply chain disruption rebate reduction. If granted, CMS will apply a 75 percent reduction in the rebate amount for the duration of four consecutive calendar quarters (i.e., the calendar quarter in which the event that caused the severe supply chain disruption occurred and the three calendar quarters thereafter) rather than the reduction under the shortages policy. If CMS receives the request and all supporting documentation describing the natural disaster or other unique or unexpected event causing the severe supply chain disruption less than 60 days before the end of a calendar quarter, CMS will apply the 75 percent rebate reduction to the next calendar quarter and the three subsequent calendar quarters thereafter. For example, if a Part B rebatable biosimilar biological product that is described as “currently in shortage” on an FDA shortage list in the calendar quarter beginning October 1, 2024 is granted a severe supply chain disruption rebate reduction request as a result of a natural disaster that occurs on October 20, 2024, CMS will apply a 75 percent reduction in the rebate amount for the duration of the calendar quarter in which the natural disaster occurred and the three subsequent calendar quarters thereafter (i.e., October 1, 2024 to September 30, 2025). In this same example, if the natural disaster instead occurs on November 20, 2024, CMS will apply the reduction under the policy for a Part B rebatable biosimilar biological product described as “currently in shortage” for the calendar quarter beginning October 1, 2024 and ending on December 31, 2024 and then a 75 percent reduction under the severe supply chain disruptions policy to the next calendar quarter and the three subsequent calendar quarters thereafter (i.e., January 1, 2025 to December 31, 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).⁶³ 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.

50.13 Financial Responsibility for the Medicare Part B Inflation Rebate Amount

Because Part B rebatable drugs are single-source drugs or biological products, they typically will have one manufacturer. However, a single-source Part B rebatable drug could have more than one manufacturer, such as in the circumstance where a rebatable drug is produced by one manufacturer and there also is one or more manufacturer(s) that is a repackager or relabeler or markets an authorized generic product. In such cases, the NDCs for all such manufacturers will, in most instances, be assigned to the same HCPCS code(s) and each manufacturer (including repackagers and relabelers) will be responsible for reporting ASP data to CMS, which includes sales volume. For each NDC assigned to the HCPCS code, CMS multiplies the number of units that are reported by the manufacturer in its ASP reporting (at the NDC-11 level) by the number of HCPCS code billing units per NDC-11 unit to identify the billing units sold during the rebate quarter. The formula for this calculation is below, and an example calculation may be found in section 80.5 of this revised guidance:

Number of Billing Units Sold = (Number of units reported by the manufacturer in ASP reporting, at the NDC-11 level) *multiplied by* (Number of HCPCS code billing units per NDC-11 reporting unit)

When calculating the rebate amount owed by each manufacturer for a Part B rebatable drug that has more than one manufacturer, as identified by CMS using the ASP sales data reported for the calendar quarter for which a rebate amount is calculated, CMS will apportion financial responsibility for the rebate amount among the manufacturers by dividing the sum of the individual manufacturer's HCPCS code billing units sold during the rebate quarter (for all NDCs of the manufacturer assigned to the HCPCS code, as reported in the ASP data submissions) by the sum of all manufacturers' HCPCS code billing units sold during the rebate quarter (for all NDCs of the rebatable drug assigned to the HCPCS code, as reported in the ASP data submissions). The formula for this calculation is below, and an example calculation is found in section 80.5 of this revised guidance:

(Sum of the **individual** manufacturer's billing units sold during the rebate quarter for

⁶³ 5 U.S.C. § 552(b)(3), (4).

all NDCs of the manufacturer assigned to the HCPCS code, as reported in the ASP data submissions) *divided by* (Sum of **all** manufacturers' billing units sold during the rebate quarter for all NDCs of the Part B rebatable drug assigned to the HCPCS code, as reported in the ASP data submissions)

60. Ensuring Integrity of the Medicare Part B Drug Inflation Rebates

Under section 1847A(i)(1) of Act, no later than six months after the end of each calendar quarter, CMS must report to each manufacturer⁶⁴ of a Part B rebatable drug the following information for the calendar quarter: (1) the total number of units of the billing and payment code(s) for each Part B rebatable drug; (2) the amount, if any, of the excess ASP increase (the amount by which the payment amount exceeds the inflation-adjusted payment amount) for a calendar quarter; and, (3) the rebate amount for the Part B rebatable drug.

CMS is adopting the process described below to help ensure the integrity of the information reported by CMS under section 1847A(i)(1) of the Act. Through Rebate Reports, CMS will provide the information identified above as specified in 1847A(i)(1) of the Act for an applicable calendar quarter. 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 six months after the end of the calendar quarter. This process is described in section 60.1 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 B 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 B 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 1847A(i)(1)(C) of the Act, CMS may delay reporting of rebate information for calendar quarters beginning in CY 2023 and CY 2024 until no later than September 30, 2025 (see section 60.2 of this revised guidance). Beginning with the calendar quarter beginning on January 1, 2025, Rebate Reports will be sent to manufacturers no later than six months after the end of the quarter. CMS intends to provide a regular release schedule or calendar of release dates for Rebate Reports in future calendar quarters. A summary of the full

⁶⁴ CMS will use the same approach used to identify the manufacturer that is responsible for reporting ASP data. See section 1847A(c)(6). Section 50.13 of this revised guidance addresses circumstances in which a single source Part B rebatable drug has more than one manufacturer.

timeline for reports and deadlines is illustrated below.

Table 3: Summary of Part B Drug Inflation Rebate Amount Reports and Deadlines

Milestone	Timing/Deadline
Part B Rebate – CMS must invoice manufacturers not later than 6 months after each calendar quarter	
Preliminary Rebate Report sent to Manufacturers	Not later than 5 months after the end of the calendar quarter
Manufacturer Reviews	Manufacturer Suggestion of Calculation Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 6 months after the end of the calendar quarter
Manufacturer Rebate Payment Due (if applicable)	Not later than 30 calendar days after receipt of the Rebate Report

CMS is considering options for establishing a standardized method and process at regular intervals to determine any appropriate adjustment to the rebate amount for a Part B rebatable drug for an applicable calendar quarter to account for 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 D 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 calendar quarter after issuing the Rebate Report for the applicable calendar quarter 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.

60.1 Process for Rebate Reports and Suggestion of Calculation Error

CMS will provide all manufacturers with at least one Part B rebatable drug, including when the rebate amount is \$0 (i.e., no rebate is owed), with a Preliminary Rebate Report within 5 months of the end of each applicable calendar quarter via the TPA's online portal.

Within 10 calendar days from the date of the receipt of the Preliminary Rebate Report, manufacturers of Part B rebatable drugs may provide CMS, for its discretionary consideration, with a Suggestion of Calculation Error in the manufacturer's Preliminary Rebate Report for Part B 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 50.1 of this revised guidance) for the Rebate Report. Manufacturers will receive the Rebate Report no later than 6 months after the end of the applicable calendar quarter except for Rebate Reports issued during the transition period (see section 60.2 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 that has been assigned to a HCPCS code for a product determined to be a Part B rebatable drug for the calendar quarter.

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 30-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 70 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 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part B 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.

60.2 Rebate Report for Calendar Quarters in CY 2023 and CY 2024

As permitted under section 1847A(i)(1)(c) of the Act, CMS is delaying Rebate Reports for calendar quarters in CY 2023 and CY 2024 until no later than September 30, 2025. The delayed issuance of the Rebate Reports and modifications during this transition approach simplifies payment procedures for manufacturers with Part B rebatable drugs.

CMS intends to issue a single Preliminary Rebate Report for calendar quarters in CY 2023 and a single Preliminary Rebate Report for calendar quarters in CY 2024 in summer 2025. CMS will provide manufacturers an extended Suggestion of Calculation Error period of 30 calendar days. CMS will then issue a single Rebate Report for calendar quarters in CY 2023 and a single Rebate Report for calendar quarters in CY 2024 no later than September 30, 2025. Rebate Reports for CY 2023 and CY 2024 will include the same information described in section 60.1 of this revised guidance. Payment will be due 30 calendar days after receipt. Failure to pay the rebate amount due timely and in full may result in enforcement action (see section 70 of this revised guidance). Additional information on how to submit a payment for a rebate amount due will be provided in separate program communications.

70. Enforcement of Rebate Amount Payments by Manufacturers

In accordance with section 1847A(i)(1)(B) of the Act, the manufacturer of a Part B rebatable drug is required to provide a rebate equal to the rebate amount specified in 1847A(i)(3) for the rebatable drug for the calendar quarter 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 1847A(i)(7) 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 B Drug Inflation Rebate Program in the future and may use that opportunity to address its enforcement approach.

In accordance with section 1847A(i)(7) of the Act, manufacturers that do not pay the Medicare Part B inflation rebate amount owed for a calendar quarter for a Part B rebatable drug may be subject to a CMP of at least 125 percent of the rebate amount, in addition to the rebate amount due under section 1847A(i)(3) of the Act, for such drug for such calendar quarter. The provisions of section 1128A of the Act, other than subsections (a) and (b), will apply to the CMP process for this inflation rebate program in the same manner as such provisions apply to a penalty or proceedings under section 1128A(a). CMS will establish a process for the Part B inflation rebate CMPs in future rulemaking. CMS intends to include information in the Rebate Report described in section 60 of this revised guidance to remind manufacturers that late or unpaid rebate payments may result in a CMP. CMS also intends to 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.

80. Formulas

80.1 Calculation for Exclusion of Drugs Where Average Total Allowed Charges Under Part B is Less than \$100 Per Individual Using Such Drug per Year Adjusted by Changes in the CPI-U

Formulas

Step 1: Calculate Average Total Allowed Charges Per Unique Beneficiary

- For each single-source drug and biological product assigned to only one HCPCS code: (Sum of allowed charges greater than \$0 on final action claims) *divided by* (Number of unique beneficiaries)

- For single-source drugs and biological products assigned to more than one HCPCS code: (Sum of allowed charges for all HCPCS codes on final action claims) *divided by* (Number of unique beneficiaries)

Note: For purposes of this step, in calculating allowed charges for a year per individual from all the HCPCS codes for that drug or biological product, CMS will exclude any HCPCS code that represents an “unclassified,” “unspecified,” or NOC drug or biological product. See section 30.2 of this revised guidance for a description of the \$100 statutory threshold.

Step 2: Calculate the Applicable Threshold

- For calendar quarters in 2023, the statutory threshold is \$100.
- For calendar quarters in 2024:

\$100 *multiplied by* (CPI-U for June 2023 *divided by* CPI-U for June 2022) (apply rounding to the nearest multiple of \$10)

- For calendar quarters in each subsequent calendar year:

Previous year’s threshold (without rounding) *multiplied by* (CPI-U for June one year before the calendar year *divided by* CPI-U for June two years before the calendar year) (apply rounding to the nearest multiple of \$10)

Example

The CPI-U’s used in the following example (both actual and illustrative)⁶⁵ are as follows:

- CPI-U June 2022 = 296.311
- CPI-U June 2023 = 305.109
- CPI-U June 2024 = 315.226

2023 threshold: **\$100 per statute**

Using the applicable CPI-U’s listed above, the thresholds for the calendar quarters in 2024 and 2025 are calculated as:

2024 threshold:

$100 * (305.109/296.311) = 102.969178$ (which rounds down to \$100 after applying CMS rounding) so the threshold for calendar quarters in 2024 = **\$100**

2025 threshold:

⁶⁵ Historical CPI-U’s were retrieved from the CPI for All Urban Consumers (CPI-U) table on BLS.gov on November 30, 2023. Future CPI-U’s are illustrative.

$102.969178 * (315.226/305.109) = 106.383496$ (which rounds up to \$110 after applying CMS rounding) so the threshold for calendar quarters in 2025 = **\$110**

Step 3: Compare the Average Total Allowed Charges for a Year Per Individual that Uses Such Drug or Biological Product to the Applicable Threshold and Identify Exclusions

For calendar quarters in 2023:

IF Average Total Allowed Charges Per Unique Beneficiary < \$100 **THEN** exclude from rebates (product is not a Part B rebatable drug)

IF Average Total Allowed Charges Per Unique Beneficiary \geq \$100 **THEN** include in rebates (product is a Part B rebatable drug, unless vaccine exclusion applies)

For subsequent calendar quarters:

IF Average Total Allowed Charges Per Unique Beneficiary < Applicable Threshold **THEN** exclude from rebates (product is not a Part B rebatable drug)

IF Average Total Allowed Charges Per Unique Beneficiary \geq Applicable Threshold **THEN** include in rebates (product is a Part B rebatable drug, unless vaccine exclusion applies)

80.2 Computation of Beneficiary Coinsurance and Amounts Paid Under Section 1833(a)(1)(EE) of the Social Security Act

Formulas

CPI-U Inflation Rate = (Current quarter CPI-U *minus* benchmark quarter CPI-U) *divided by* benchmark quarter CPI-U

Inflation-Adjusted Payment Amount = Benchmark quarter payment limit *multiplied by* (1 *added to* CPI-U Inflation Rate)

Inflation-Adjusted Coinsurance = Inflation-Adjusted Payment Amount *multiplied by* 0.20

Adjusted Coinsurance Percentage = Inflation-Adjusted Coinsurance *divided by* Inflation-Adjusted Payment Amount

Example

CPI-U January 2021 = 261.582

CPI-U April 2023 = 303.363

Rebate Quarter Specified Amount⁶⁶ = \$1,900

Payment Amount for the Benchmark Quarter = \$1,580

⁶⁶ The “specified amount” refers to the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act which is, for single-source drugs and biological products, 106 percent of the amount determined under section 1847A(b)(4) of the Act—that is, the lesser of ASP or WAC—for the calendar quarter and, for biosimilar biological products, the payment amount under section 1847A(b)(1)(C) of the Act, which is based on 100 percent of the ASP for the biosimilar biological product plus 6 percent of the lesser of ASP or WAC for the reference biological product.

A drug with a benchmark quarter of 1Q2021 is rebatable in 3Q 2023:

CPI-U Inflation Rate = $(303.363 \text{ minus } 261.582) \text{ divided by } 261.582 = 0.1597$

Inflation-Adjusted Payment Amount = $\$1,580 \text{ multiplied by } (1 \text{ added to } 0.1597) = \$1,832.33$

Inflation-Adjusted Coinsurance = $\$1,832.33 \text{ multiplied by } 20 \text{ percent} = \366.47

Inflation-Adjusted Coinsurance Percentage = $\$366.47 \text{ divided by } \$1,900$

Inflation-Adjusted Coinsurance Percentage = 19.29%

80.3 Calculation of the Medicare Part B Rebate Amount

Formulas

The following three equations depict the key steps to determine the rebate amount for a particular Part B rebatable drug for a calendar quarter.

Part B Rebate Amount =

(Units of Part B rebatable drug furnished during the rebate quarter, minus exclusions) *multiplied by* (specified amount for the calendar quarter *minus* inflation-adjusted payment amount)

Inflation-Adjusted Payment Amount =

(Payment amount for the benchmark quarter) *multiplied by* (Rebate period CPI-U *divided by* Benchmark period CPI-U)

Rebate Period CPI-U =

The greater of:

Benchmark Period CPI-U OR the CPI-U of the first month of the quarter that is two quarters prior to the rebate quarter.

Example #1

CMS is calculating the inflation-adjusted payment amount for Drug X (which was first sold in January 2020 and for which there is only one HCPCS code, X0000) for the calendar quarter January 1, 2024 through March 31, 2024. In this case, CMS will:

1. Identify the Medicare Part B payment limit for Drug X's HCPCS code, X0000, for the applicable payment amount benchmark quarter, which is July 1, 2021 through September 30, 2021.
 - For purposes of this example, \$1,000.
2. Identify the benchmark period CPI-U, which is the CPI-U for January 2021.

- The January 2021 CPI-U is 261.582.
3. Identify the rebate period CPI-U by identifying the greater of the January 2021 CPI-U or the July 2023 CPI-U (the first month of the calendar quarter that is two quarters before the calendar quarter in which the drug is furnished, i.e., January 1, 2024 through March 31, 2024).
 - For purposes of this example, the July 2023 CPI-U is 305.691, which is greater than the January 2021 CPI-U.
 4. Divide the rebate period CPI-U by the benchmark period CPI-U to identify the percentage by which the rebate period CPI-U for the calendar quarter exceeds the benchmark period CPI-U.
 - $305.691/261.582 = 1.1686239879$.⁶⁷
 5. Multiply the July 1, 2021 through September 30, 2021 Medicare Part B payment limit for Drug X's HCPCS code, X0000 (identified in step 1), by the percentage calculated in Step 4 to calculate the inflation-adjusted payment amount.
 - $\$1,000 * 1.1686239879 = \$1,168.6239879000$.

Example #2

CMS is calculating the inflation-adjusted payment amount for Drug Z (which was first approved/licensed by FDA after December 1, 2020, and for which the date of first sale was January 15, 2022), and for which the HCPCS code is Y0000 for the calendar quarter January 1, 2024 through March 31, 2024. In this case, CMS will:

1. Identify the Medicare Part B payment limit for Drug Z's HCPCS code, Y0000, for the payment amount benchmark quarter, which is October 1, 2022 through December 31, 2022 (the third full quarter after the date of first sale).
 - For purposes of this example, \$500.
2. Identify the benchmark period CPI-U, which is the CPI-U for April 2022 (first month of the first full quarter after the date of first sale).
 - April 2022 CPI-U is 289.109.
3. Identify the rebate period CPI-U by identifying the greater of the April 2022 CPI-U and the July 2023 CPI-U (the first month of the calendar quarter that is two quarters before the calendar quarter in which the drug is furnished, i.e., January 1, 2024 through March 31, 2024).
 - For purposes of this example, the July 2023 CPI-U is 305.691, which is greater than the April 2022 CPI-U.
4. Divide the rebate period CPI-U by the benchmark period CPI-U to identify the percentage by which the rebate period CPI-U for the calendar quarter exceeds the benchmark period CPI-U.
 - $305.691/289.109 = 1.0573555303$
5. Multiply October 1, 2022 through December 31, 2022 Medicare Part B payment limit for Drug Z's HCPCS code, Y0000 (identified in step 1), by the percentage calculated in Step 4 to calculate the inflation-adjusted payment amount.
 - $\$500 * 1.0573555303 = \528.6777651500

⁶⁷ CMS will not round values as part of these calculation steps. Rather, the invoice amount due will be rounded to the nearest cent.

80.4 Reducing the Rebate Amount in the Case of a Part B Rebateable Drug Currently in Shortage on an FDA Shortage Lists – Determination of Rebate Reduction for Part B Rebateable Drugs Changing Shortage Status

Formula

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

Example

Using the following illustrative values for a Part B rebateable drug that is not a plasma-derived product and for which a rebate amount is owed:

- Quarterly Rebate Amount: \$100
 - Listed as currently in shortage during Q1 (January 1 – March 31)
 - Listed as currently in shortage during the first half of Q2 (April 1 – May 15) and then changed to resolved for the second half of Q2 (May 16 – June 30). The drug is listed as currently in shortage for 45 out of 91 days in Q2, or about 50% of days in the quarter.⁶⁸
 - Reverting to currently in shortage for Q3, Q4, and Q1 of the subsequent year:
 - Percent Reduction for Q1-Q4 = 25%
- Percent Reduction for Q1 of Subsequent Quarter = 10%

Q1 Reduced Quarterly Rebate Amount = \$100 *multiplied by* (1 *minus* 0.25) *multiplied by* (1 *added to* \$100 *multiplied by* (1 *minus* 1))

- Q1 Amount = \$75.00

Q2 Reduced Quarterly Rebate Amount = (\$100 *multiplied by* (1 *minus* 0.25) *multiplied by* (45 *divided by* 91)) *added to* \$100 *multiplied by* (1 *minus* (45 *divided by* 91))

- Q2 Amount = \$87.64

Q3 Reduced Quarterly Rebate Amount = \$100 *multiplied by* (1 *minus* 0.25) *multiplied by* (1 *added to* \$100 *multiplied by* (1 *minus* 1))

- Q3 Amount = \$75.00

Q4 Reduced Quarterly Rebate Amount = \$100 *multiplied by* (1 *minus* 0.25) *multiplied by* (1 *added to* \$100 *multiplied by* (1 *minus* 1))

- Q4 Amount = \$75.00

Q1 of Subsequent Quarter Reduced Quarterly Rebate Amount = \$100 *multiplied by* (1 *minus* 0.10) *multiplied by* (1 *added to* \$100 *multiplied by* (1 *minus* 1))

- Q1 of Subsequent Quarter Amount = \$90.00

⁶⁸ The amounts in this example are rounded for the purposes of illustrating how CMS will calculate the reduced quarterly rebate amount for Part B rebateable 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.

Total Reduced Rebate Amount across Five Quarters = \$402.50
Total Rebate Amount Had Drug Not Been in Shortage = \$500.00

Table 4: Examples of Determination of Rebate Reductions for Part B Rebatable Drugs Changing Shortage Status

Shortage Timeline	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Drug A	No Shortage	No Shortage	No Shortage	No Shortage	Status changes to “Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	Status changes from “Currently in Shortage” to “Resolved”	“Resolved”
Percent Reduction for Drug A	0%	0%	0%	0%	25% * (days in shortage / days in calendar quarter)	25%	25%	25%	10%	10%	10% * (days in shortage / days in calendar quarter)	0%
Drug B	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	Status changes from “Currently in Shortage” to “Resolved”	“Resolved”	“Resolved”	Status changes from “Resolved” to “Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”
Percent Reduction for Drug B	25%	25%	25%	25%	10% * (days in shortage / days in calendar quarter)	0%	0%	10% * (days in shortage / days in calendar quarter)	2%	2%	2%	2%
Drug C	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”	Status changes from “Currently in Shortage” to “Resolved”	“Resolved”	“Resolved”	“Resolved”	“Resolved”	Status changes from “Resolved” to “Currently in Shortage”	“Currently in Shortage”	“Currently in Shortage”
Percent Reduction for Drug C	25%	25%	25%	25%	10% * (days in shortage / days in calendar quarter)	0%	0%	0%	0%	25% * (days in shortage / days in calendar quarter)	25%	25%

Drugs in this example are Part B rebatable drugs other than plasma-derived products.

*When a drug transitions shortage status, the rebate reduction factor will only apply to the number of days of the quarter that the drug status was “Currently in Shortage.”

80.5 Calculation to Apportion Financial Responsibility for a Drug Rebate Amount to Multiple Manufacturers Assigned the Same HCPCS Code

Formula

Number of Billing Units Sold = (Number of units reported by the manufacturer in ASP reporting, at the NDC-11 level) *multiplied by* (Number of HCPCS code billing units per NDC-11 reporting unit)

Example

HCPCS dose is 1mg; NDC1 comes as 1 bottle of 90 1mg tablets and NDC2 comes as 1 bottle of 120 1mg tablets. The HCPCS code billing unit is 1mg.

NDC1: The NDC-11 package includes 90 billing units. If the manufacturer sold 1,000 bottles of 90 1mg tablets (NDC-11), this would correspond to 90,000 billing units (1,000 ASP units (NDC-11s) x 90 HCPCS code billing units per NDC-11 unit).

NDC2: The NDC-11 package includes 120 billing units. If the manufacturer sold 1,000 bottles of 120 1mg tablets (NDC-11), this would correspond to 120,000 billing units (1,000 ASP units (NDC-11s) x 120 HCPCS code billing units per NDC-11 unit).

Formula

(Sum of the **individual** manufacturer's billing units sold during the rebate quarter for all NDCs of the manufacturer assigned to the HCPCS code, as reported in the ASP data submissions) *divided by* (Sum of **all** manufacturers' billing units sold during the rebate quarter for all NDCs of the Part B rebatable drug assigned to the HCPCS code, as reported in the ASP data submissions)

Example

A Part B rebatable drug has a manufacturer that produces the Part B rebatable drug (Manufacturer A) and another manufacturer that repackages the Part B rebatable drug (Manufacturer B) during the first calendar quarter of 2023. Each of those manufacturers reported ASP data for two NDC-11s that are assigned to the same HCPCS code as shown below. The example billing units are based on a HCPCS code description for the Part B rebatable drug at the NDC-11 level.

Manufacturer A

NDC 12345-0222-09; 10,000 sold (1 HCPCS code billing unit)

NDC 12345-0222-99; 1,000 sold (5 HCPCS code billing units)

Manufacturer B

NDC 98765-0333-09; 5,000 sold (1 HCPCS code billing unit)

NDC 98765-0333-99; 1,000 sold (5 HCPCS code billing units)

Manufacturer A's financial responsibility for the inflation rebate amount for that calendar quarter would be apportioned as follows:

- 1) Sum of Manufacturer A's HCPCS code billing units sold during the rebate quarter for all NDC-11s of the manufacturer assigned to the HCPCS code:

$(10,000 \times 1 \text{ HCPCS code billing unit}) + (1,000 \times 5 \text{ HCPCS code billing units}) = 15,000$
billing units

- 2) Sum of both Manufacturer A's and Manufacturer B's HCPCS code billing units sold during the rebate quarter for all NDC-11s of the Part B rebatable drug assigned to the HCPCS code:

$(10,000 \times 1 \text{ HCPCS code billing unit}) + (1,000 \times 5 \text{ HCPCS code billing units}) + (5,000 \times 1 \text{ HCPCS code billing unit}) + (1,000 \times 5 \text{ HCPCS code billing units}) = 25,000$ billing units

- 3) Divide the amount in step 1 by the amount in step 2:

$15,000 \text{ billing units for the Manufacturer A} / 25,000 \text{ total billing units for both manufacturers} = 0.6 \text{ or } 60\%$

In this example, Manufacturer A would be financially responsible for 60 percent of the rebate amount for the calendar quarter and Manufacturer B would be financially responsible for 40 percent of the rebate amount for the calendar quarter.

Appendix A: Example of Quarterly Pricing File with Beneficiary Coinsurance Percentage Specified (all data shown is illustrative only)

HCPCS Code	Short Description	HCPCS Code Dosage	Payment Limit	Coinsurance Percentage	Vaccine AWP%	Vaccine Limit	Blood AWP%	Blood limit	Clotting Factor	Notes	Scenario
JXXX1	Drug/Biological	1 ML	348.527	20.000						(blank)	<i>Part B rebatable drug where the drug's price is not outpacing inflation and the coinsurance adjustment therefore does not apply for the calendar quarter OR drug/biological is not a Part B rebatable drug</i>
JXXX2	Drug/Biological	1 MG	3.492	19.456						Inflation adjusted coinsurance applied	<i>Part B rebatable drug with the inflation adjusted coinsurance applied</i>
JXXX3	Clotting Factor	1 IU	1.342	16.587					1	Inflation adjusted coinsurance applied	A clotting factor that is a Part B rebatable drug with the inflation

HCPCS Code	Short Description	HCPCS Code Dosage	Payment Limit	Coinsurance Percentage	Vaccine AWP%	Vaccine Limit	Blood AWP%	Blood limit	Clotting Factor	Notes	<i>Scenario</i>
											adjusted coinsurance applied and the clotting factor furnishing fee is included in the payment limit
9XXXX	Section 1861(s)(10) Vaccine	0.5 ML	69.941	0.000	95	69.941					Vaccines that are excluded from Part B rebatable drugs and for which beneficiaries do not pay coinsurance

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

	2021												2022												2023											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Drug Licensed/Approved On or Before 12/1/2020																																				
Rebate Period 1							1																													
Average Total Allowed Charges Calculation Period																																				
Payment Amount Benchmark Quarter																																				
Benchmark Period CPI-U																																				
Rebate Period 1 CPI-U (Greater Of)																																				
Drug Marketed 6/1/2021																																				
Rebate Period 1							1																													
Average Total Allowed Charges Calculation Period																																				
Payment Amount Benchmark Quarter																																				
Benchmark Period CPI-U																																				
Rebate Period 1 CPI-U (Greater Of)																																				
Drug Marketed 1/1/2022																																				
Rebate Period 1																																				
Average Total Allowed Charges Calculation Period																																				
Payment Amount Benchmark Quarter																																				
Benchmark Period CPI-U																																				
Rebate Period 1 CPI-U (Greater Of)																																				

Note: A drug will be included on the six full calendar quarters (denoted with the numbers in the figure) after the day the drug was marketed or the first quarter of 2023, whichever is later. The Rebate Period CPI-U is the greater of the benchmark period CPI-U or the CPI-U of the first month of the quarter two quarters prior to the rebate period. This figure does not summarize every situation.