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CENTER FOR MEDICARE

DATE: February 9, 2023

TO: Pharmaceutical Manufacturers of Part B Rebatable Drugs and Other Interested Parties

FROM: Dr. 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: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments

10. Introduction

The purpose of this memorandum is to provide initial guidance (to be followed with revised guidance later) to manufacturers regarding the payment by manufacturers of inflation rebates for Part B rebatable drugs beginning January 1, 2023.¹

The requirements for this program are described in section 1847A(i) of the Social Security Act (hereafter “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, CMS is seeking comments on this memorandum to benefit from manufacturer feedback and public input. In this memorandum where noted, the Center for Medicare & Medicaid Services (CMS) is voluntarily seeking comment on certain topics. Please send comments on policies where comments are solicited below to IRAREbateandNegotiation@cms.hhs.gov with the following subject line “Medicare Part B Inflation Rebate Comments” by March 11, 2023.

¹ “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 product 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).

Due to timing constraints to implement the adjustment to beneficiary cost sharing for April 2023, CMS is issuing guidance on certain topics in this memorandum as final, without a comment solicitation:

- Determination of Part B Rebatable Drugs (section 30);
- Computation of Beneficiary Coinsurance and Amounts Paid Under Section 1833(a)(1)(EE) of the Social Security Act (section 40); and
- Identification of the Specified Amount for the Calendar Quarter, Payment Amount Benchmark Quarter, Benchmark Quarter CPI-U, and Rebate Period CPI-U as well as the Determination of Inflation-Adjusted Payment Amount and Adjustments for Changes to HCPCS Codes (subsections 50.2-50.7 and 50.9).

CMS may, in revised guidance, make changes to any policies in this memorandum, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issue.

The Inflation Reduction Act (P.L. 117-169) was signed into law on August 16, 2022. Section 11101 of the Inflation Reduction Act 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.² 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 will 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 will establish a process for the Part B inflation rebate CMPs pursuant to regulations as required by section 1847A(i)(7). Section 1847A(i)(5) of the Act also provides for an adjustment to beneficiary cost sharing in cases where the price of Part B rebatable drugs increase faster than the rate of inflation. This memorandum specifies the initial requirements and procedures for implementation of these provisions.

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² “Days” means calendar days unless otherwise specified in this memorandum.

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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 rebatable 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 (hereafter called “specified amount”³) exceeds the inflation-

³ “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

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 memorandum, respectively). The “inflation-adjusted payment amount” is calculated for each Part B rebatable drug by HCPCS code by increasing the payment amount in the payment amount benchmark quarter (for example, ASP plus 6 percent or 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 50.3, 50.4, 50.5, 50.6, and 50.7 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 memorandum. Beginning April 1, 2023, when the specified amount for a Part B rebatable drug for a calendar quarter exceeds the inflation-adjusted payment for such quarter, beneficiary coinsurance for such drug will be equal to 20 percent of the inflation-adjusted payment amount for such quarter as described in section 40 of this memorandum. We note that the summaries provided in this section 20 are intended to provide an overview of the estimated Part B rebate calculation and do not encompass all adjustments, exclusions, and relevant details.

Part B Rebatable Drug (see section 30): Section 1847A(i)(2)(A) 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)), but excluding a qualifying biosimilar biological product (as defined in section 1847(b)(8)(B)(iii)), for which payment is made under Part B.

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 a formula based on the percentage increase in the CPI-U.⁴ Section 1847A(i)(A)(ii) 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 section 50.2) 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 for detail on related calculations). For example, if the inflation-adjusted payment amount is the Average Sales Price (ASP) plus 6 percent, the beneficiary coinsurance will be equal to 20 percent of ASP plus 6 percent.

Estimated 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) and the amount, if any, by which the specified amount (see section 50.2) exceeds the inflation-adjusted payment amount

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 rebatable drugs for such calendar quarter).

⁴ The “CPI-U” means the consumer price index for all urban consumers (United States city average) as published by the Bureau of Labor Statistics (<https://www.bls.gov/>). See §1847A(i)(2)(B).

determined in accordance with section 1847A(i)(3)(C) of the Act (see section 50.7) for the drug or biological product for the applicable calendar quarter.

Subsequently Approved Part B Rebateable Drugs (see section 50): 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 drugs first 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. Identification of the appropriate benchmark quarter is discussed in section 50.3.

The benchmark quarter CPI-U also varies based on when the rebateable drug was first approved or licensed by FDA, as discussed in section 50.5 of this memorandum. 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. 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 for detail as to how CMS will determine the day on which the drug was first marketed).

Reduction or Waiver for Drug Shortages and Severe Supply Chain Disruptions (see section 50.10): Section 1847A(i)(3)(G) provides that CMS reduce or waive the rebate amount with respect to a Part B rebateable drug for an applicable calendar quarter in two cases: (1) when a Part B rebateable drug is described as currently in shortage on the shortage lists authorized under section 506E of the Federal Food, Drug, and Cosmetic Act (FD&C Act) at any point during the calendar quarter; or (2) for a biosimilar biological product⁵ when the Secretary 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.

Civil Monetary Penalties for Non-Payment of Rebates (see section 70): Pharmaceutical manufacturers that do not comply with the requirements to pay Part B drug inflation rebates as set forth at section 1847A(i)(1)(B) of the Act are subject to civil monetary penalties (CMPs) in an amount equal to at least 125 percent of the rebate amount for a drug for an applicable calendar quarter.

CMS is soliciting comment on the various topics addressed in this memorandum. More specific comment solicitations may be included in each section of the memorandum.

- 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);

⁵ Biosimilar biological products are defined in section 1847A(c)(6)(H) of the Act.

- Specific scenarios where CMS should consider reducing or waiving the rebate in case of a shortage (section 50.11);
- The process CMS intends to use to reduce or waive 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. Determination of Part B Rebatable Drugs

CMS is issuing final guidance on this section and intends to 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 intends to 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 Healthcare Common Procedure Coding System (HCPCS) codes for such drugs and biological products, and then apply the exclusions described in sections 30.2 and 30.3 below. 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.

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 (see section 40 of this memorandum). 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 generally occurs within six months after the end of a calendar quarter (see sections 50 and 60 of this memorandum), CMS intends to confirm the Part B rebatable drugs for the calendar quarter using the most recent information available.

CMS intends to 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. 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 intends to consider the average sales price (ASP) data submitted by manufacturers (including the date of first sale), Food and Drug Administration (FDA) approval information (such as labeling and approval letters), therapeutic equivalents as determined by FDA (i.e., those listed in FDA's Orange Book), and available products shown in drug pricing compendia.

CMS intends to 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 memorandum for discussion on how CMS intends to address situations when more recent data impacts the calculation of beneficiary coinsurance.

As discussed in the CY 2023 Medicare Physician Fee Schedule Final Rule (87 CFR 69650-69655), CMS aims to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes. On January 18, 2023, CMS held a Town Hall to discuss this issue further and to provide an opportunity to further engage interested parties on this matter. CMS anticipates addressing coding and payment for skin substitutes in future rulemaking. While CMS considers making changes to the Medicare Part B payment policies for such products, HCPCS codes that describe products currently referred to as skin substitutes will not be counted for purposes of identifying Part B rebatable drugs for a calendar quarter during 2023 and, as such, will not be subject to the coinsurance adjustment described in section 40 of this memorandum.

For purposes of identifying Part B rebatable drugs for a calendar quarter, CMS does not intend to count drugs and biological products that are billed using a HCPCS code that represents an "unclassified," "unspecified," or "not otherwise classified" 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 would have to perform in order to determine if a drug is a Part B rebatable drug. CMS notes that few Part B drugs and biological products are 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 "not otherwise classified" 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.

30.2 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

Pursuant to section 1847A(i)(2) of the Act, CMS intends to exclude from Part B rebatable drugs those single source drugs and biological products identified in section 30.1 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. In this memorandum, 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, CMS intends to 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.⁶ That is, CMS intends to 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.

Step 1: Calculate Average Total Allowed Charges Per Unique Beneficiary

For each HCPCS code identified in accordance with section 30.1, 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.

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 “not otherwise classified” drug or biological product).

- CMS will calculate the average total allowed charges for such drug or biological product for a year on a quarterly basis for the Part B rebatable drugs identified in accordance with section 30.1.

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.

⁶ “HCPCS code” means the Healthcare Common Procedure Coding System code to which a Part B rebatable drug has been assigned.

- “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 would use the most recent data available when applying this exclusion. For example, for the calendar quarter beginning July 1, 2023, CMS intends to 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 would 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 intends to calculate the applicable threshold as follows:

- For calendar quarters in 2023, the threshold is \$100.
- For calendar quarters in 2024, the threshold will be equal to the 2023 threshold (i.e., \$100) updated by the inflation factor (as measured by changes in the CPI-U) in accordance with section 1847A(i)(2)(B)(i) 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.⁷
- For calendar quarters in each subsequent calendar year, the threshold will be equal to the inflation-adjusted threshold for the prior calendar year (that is, the amount before CMS applied rounding, if applicable) updated by the inflation factor 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.⁸

CMS intends to 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

⁷ CMS will round any amount between \$0 and up to \$5 down to \$0, and any amount equal to or more than \$5 and up to \$10 up to the next \$10.

⁸ The same rounding rule applies as described in the previous footnote.

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.

For the purposes of calculating the applicable threshold, “inflation factor” means the percentage increase in the consumer price index for all urban consumers (CPI-U) as published by the Bureau of Labor Statistics (United States city average) for the 12-month period ending with June of the previous year. For example, for calendar quarters in 2024, the inflation factor used to adjust the applicable threshold will be the percentage change in CPI-U from June 2022 to June 2023.

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, CMS intends to 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 would conduct this comparison on a quarterly basis.

In instances where a single source drug or biological product is assigned to more than one HCPCS code 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 intends to exclude all such assigned HCPCS codes for such single source drug or biological product for that calendar quarter.

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 COVID-19 monoclonal antibodies that are covered and paid for under the Medicare Part B preventive vaccine benefit, these products would be excluded from the definition of Part B rebatable drug for applicable calendar quarters until the end of the calendar year in which the March 27, 2020 Emergency Use Authorization Declaration for Drugs and Biological Products under section 564 of the FD&C Act ends.

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

CMS is issuing final guidance on this section. 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 memorandum (e.g., lesser of ASP plus 6 percent or WAC plus 6 percent) 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 memorandum), beneficiary coinsurance is equal to 20 percent of the inflation-adjusted payment amount. This coinsurance adjustment is applied as a percent, as determined by the Secretary, to the payment amount for such calendar quarter. The coinsurance adjustment determination for a Part B rebatable drug would be made for the calendar quarter when the payment limit for such drug for that calendar quarter is determined. CMS intends to 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 would 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.⁹ 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 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.

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

The rebate amount for a Part B rebatable drug for a calendar quarter would be determined as described in this section and illustrated as a formula in section 80.3.

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 memorandum. For purposes of calculating the rebate, CMS intends to use the HCPCS codes identified in accordance with section 30.1 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 below) and the amount (if any) by which the specified amount (see section 50.2 below) exceeds the inflation-adjusted payment amount

⁹ For example, the files posted at <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2023-asp-drug-pricing-files>

determined in accordance with section 1847A(i)(3)(C) of the Act (see section 50.7 below) for the drug or biological product for a calendar quarter.

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 ASP for the reference biological product. The specified amount will also be adjusted to account for sequestration. See section 80.3 for formulas reflecting the key steps to determine the rebate amount for a given Part B rebatable drug for a calendar quarter.

50.2 Identification of the Specified Amount for the Calendar Quarter

CMS is issuing final guidance on this subsection. To identify the specified amount (as described in section 50.1 above) for the calendar quarter for each Part B rebatable drug, CMS intends to 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. CMS notes that when CMS restates the ASP or WAC for the applicable quarter, CMS intends to 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) cross reference provisions governing quarterly payment limits for single source drugs and biologicals 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 intends to use the most updated data reported by manufacturers to determine the specified amount for the calendar quarter for each HCPCS code identified in accordance with section 30.1.

50.3 Identification of the Payment Amount Benchmark Quarter

CMS is issuing final guidance on this subsection. 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. The payment amount benchmark quarter for drugs first approved or licensed by FDA after December 1, 2020, is the third full calendar quarter after the day on which the drug was first marketed.

CMS has preliminarily 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 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 has preliminarily concluded that section 1847A(i) is intended to refer to the reporting systems that are already in place with respect to ASP data.

CMS believes that these 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 by FDA after December 1, 2020. Because CMS already collects these data from manufacturers, using the date of first sale will be 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 would be the most accurate. Since section 1847A(i)(4)(B) of the Act specifies that the inflation rebate applies to drugs first approved or licensed by FDA after December 1, 2020, beginning the later of the 6th 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.

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

CMS is issuing final guidance on this subsection. 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” 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 intends to use the payment limit (as updated if applicable) for the applicable payment amount benchmark quarter determined in accordance with section 1847A of the Act. The payment amount for the payment amount benchmark quarter and the specified amount (see section 50.2 of this memorandum) are both used when determining whether a rebate is owed (see section 50.7). While these amounts are similar, the statutory requirements for determining these two amounts differ. The specified amount for a Part B rebatable drug specified under section 1847A(i)(3)(A)(ii)(I) is based on item (aa) (i.e., lesser of ASP+6% or WAC+6%) or (bb) (i.e., 100 percent of the ASP for the biosimilar biological product plus 6 percent of the ASP for the reference biological product). The payment amount is based on various provisions within section 1847A of the Act (e.g., WAC+3% 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. 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.

50.5 Identification of the Benchmark Period CPI-U

CMS is issuing final guidance on this subsection. For each Part B rebatable drug by HCPCS code, as identified using the process in section 30.1, 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 261.582), and 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 as described in section 50.3, will be the date of first sale as reported to CMS by manufacturers in their ASP data. For further detail, please refer to the discussion in section 50.3 of this memorandum.

50.6 Identification of the Rebate Period CPI-U

CMS is issuing final guidance on this subsection. As specified in section 1847A(i)(3)(F) of the Act, the rebate period CPI-U, with respect to a calendar quarter in which the Part B rebatable drug is furnished, 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 such calendar quarter. For each Part B rebatable drug by HCPCS code, CMS will identify which CPI-U is greater for the applicable rebate quarter by accessing the Bureau of Labor Statistics website.

Figure 1 below provides a summary of data timelines for Part B rebate calculations.

Figure 1: Summary of Data Timelines for Part B 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 Marketed 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)																																				
New 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)																																				
New 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 new drug will be included on the 6 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.

50.7 Determination of Inflation-Adjusted Payment Amount

CMS is issuing final guidance on this subsection. 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 intends to use the payment amount in the payment amount benchmark quarter (see section 50.4), benchmark period CPI-U (see section 50.5), and rebate quarter CPI-U (see section 50.6). CMS would

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, as shown in the formulas in section 80.3 of this memorandum.

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, Jxxxx) for the calendar quarter January 1, 2024 -March 31, 2024. In this case, CMS would:

1. Identify the Medicare Part B payment limit for Drug X's HCPCS code, Jxxxx, for the applicable payment amount benchmark quarter, which is July 1, 2021 through September 30, 2021.
 - For purposes of this example, \$1000.
2. Identify the benchmark period CPI-U, which is the CPI-U for January 2021.
 - The January 2021 CPI-U is 261.582.¹⁰
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 280.001 (*illustrative*), 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.
 - $280.001/261.582 = 1.0704138664$.
5. Multiply the July 1, 2021 through September 30, 2021 Medicare Part B payment limit for Drug X's HCPCS code, Jxxxx, (identified in step 1) by the percentage calculated in Step 4 to calculate the inflation-adjusted payment amount.
 - $\$1000 * 1.0704138664 = \1070.414 .

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 Qxxxx for the calendar quarter January 1, 2024 through March 31, 2024. In this case, CMS would:

¹⁰ Retrieved from BLS.gov on January 17, 2023.

1. Identify the most recent Medicare Part B payment limit for Drug Z's HCPCS code, Qxxxx, for the applicable 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 289.109.¹¹
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 295.021 (*illustrative*), 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.
 - $295.021/289.109 = 1.02044903479$
5. Multiply October 1, 2022 through December 31, 2022 Medicare Part B payment amount for Drug Z's HCPCS code, Qxxxx, (identified in step 1) by the percentage calculated in Step 4 to calculate the inflation-adjusted payment amount.
 - $\$500 * 1.02044903479 = \510.225

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 intends to 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 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). 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 Drug Pricing 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 memorandum).

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

¹¹ Retrieved from BLS.gov on January 17, 2023.

units in claim lines specified in subsections 50.8.1 through 50.8.4 of this memorandum, as applicable, and sums the number of units in the remaining claim lines for which Medicare payment was allowed.

CMS intends to 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 memorandum for a discussion of the rebate process, which includes a true-up process.

CMS solicits comments on the process CMS intends to use to determine the number of units discussed in this section.

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 were 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, 2024.¹² While these modifiers have been required and utilized by 340B providers paid under the Outpatient Prospective Payment System (OPPS) since calendar year (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). As this requirement entails operational changes to billing systems for some 340B covered entities (and other providers and suppliers as applicable), CMS encourages such entities to begin using the appropriate modifier as soon as possible, and no later than January 1, 2024.

For claims with dates of service during 2023, CMS intends to 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). For professional claims with dates of service during 2023, CMS intends to remove all units in claims for Medicare suppliers that are listed by the Health Resources and Services Administration (HRSA) as participating in the 340B Drug Pricing Program, by using employer identification numbers to identify these suppliers’ Medicare Identification Numbers and the claims submitted with such 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, and thus not required to bill either the JG or TB modifier until January 1, 2024. CMS is soliciting comments on the identification and removal of 340B units for calendar quarters in 2023.

¹² <https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf>

For dates of service on or after January 1, 2024, CMS intends to remove units in claim lines that were identified as being 340B units by being billed with the “JG” or “TB” modifiers.

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

In order 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 dispensed 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 dispensed and paid for under the state plan. This invoice includes units of covered outpatient drugs that are furnished to dual 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. At this time, CMS intends to remove units in claim lines for dates of service during a quarter when the Medicare beneficiary has Medicaid coverage. CMS intends to identify the dates for which a beneficiary has Medicaid coverage using available information (for example the State Medicare Modernization Act File (“MMA file”) of dual eligible beneficiaries) at the time the rebate amount is being calculated for a calendar quarter. CMS is soliciting comments on the exclusion of all drug units for the dates of service during a quarter when an individual has dual coverage under Medicare and Medicaid. Additionally, CMS is soliciting comments on other state data sources that would facilitate identification of drug units for which a state received a Medicaid drug rebate for a dual eligible individual.

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 memorandum, CMS intends to only include claims lines with a Medicare allowed amount greater than zero. Because CMS intends to 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 hospital outpatient prospective payment system (OPPS), Ambulatory Surgical Center (ASC) payment system, or those administered 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 would therefore be excluded under section 50.8 of this memorandum.

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

As noted in section 30.1 of this memorandum, 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 intends to identify the date of first

sale 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 Orange Book¹³) and determine whether the drug is no longer a Part B rebatable drug. Units furnished on or after that date will be excluded from the units identified in accordance with section 50.8 of this memorandum.

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 speaking, 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. Accordingly, CMS seeks comment from the public on operational considerations, such as the best source of information to determine the number of units of a drug furnished to MA enrollees and how to remove units in accordance with section 1847A(i)(3)(B)(ii) of the Act.

50.9 Adjustments for Changes to HCPCS Codes

CMS is issuing final guidance on this subsection. When applicable, CMS will apply conversion factors within the inflation rebate calculation if there has been a change to the billing and payment code for the Part B rebatable drug, for example, when a Part B rebatable drug is assigned to a HCPCS code and then the HCPCS code is changed (such as a change to the code dose description) or a new code is assigned. In these instances, CMS will maintain a crosswalk between such changes or codes in order to apply the provisions in section 1847A(i) appropriately. For example, a HCPCS code dose description that determines the amount of drug in each billing unit could be changed from 10 mg to 5 mg. If the payment amount in the payment amount benchmark quarter for such drug was \$200 based on 10 mg and the rebate period payment amount is based on 5 mg, 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 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 payment amount in the payment amount benchmark quarter, the payment amount benchmark quarter, and the benchmark quarter

¹³ Accessible via <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>

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 Reduction or Waiver of the Rebate Amount for Part B Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions

In calculating the estimated rebate amount for a Part B rebatable drug for a calendar quarter, section 1847A(i)(3)(G) of the Act requires the Secretary to reduce or waive the rebate amount for a Part B rebatable drug for a calendar quarter in two cases: (1) when a Part B rebatable drug is described as currently in shortage on the shortage lists established under section 506E of the Federal Food, Drug and Cosmetics Act (FD&C Act) at any point during the calendar quarter; or (2) for a biosimilar biological product¹⁴ when the Secretary 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 intends to structure this policy such that it provides a period of financial relief for manufacturers in certain circumstances but does not create incentives for misuse of the reporting process established under 506E of the FD&C Act or for manufacturers to intentionally maintain their drug or biological in shortage for the purpose of avoiding an obligation to pay a rebate.

50.11 Reducing or Waiving the Rebate Amount in the Case of a Part B Rebatable Drug on the Shortage List

To determine when a Part B rebatable drug is described as currently in shortage on a shortage list at any point during the calendar quarter, CMS intends to use the FDA drug shortage lists, which are authorized 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 the FDA's drug shortage lists (herein referred to as "FDA drug shortage lists" or "shortage lists") via web pages with current lists of the drugs and biologics within their respective jurisdictions that are in shortage.¹⁵ To be eligible for a reduction or waiver of the rebate amount for a calendar quarter, a Part B rebatable drug must have a shortage status described as "current" on a FDA drug shortage list at any point during the calendar quarter, and not designated as "discontinued," "to be discontinued," or "resolved."

CMS is soliciting comment on the amount and duration of the reduction that should be applied, and scenarios when a waiver may be considered, for a Part B rebatable drug that is on the shortage list at any point during a calendar quarter. Options that CMS is considering include:

¹⁴ Biosimilar biological products are defined in section 1847A(c)(6)(H) of the Act.

¹⁵ See shortage list here: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>; CBER list: <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-shortages-and-discontinuations>

- A variable reduction in the rebate amount by the length of time that any Part B rebatable drug is on the FDA drug shortage list as “current” during a calendar quarter (e.g., number of days on the list during the calendar quarter divided by number of days in the calendar quarter), whereby the amount of reduction would decrease over time (e.g., CMS could provide an initial reduction in the rebate amount of a certain percentage in the first four calendar quarters, then reduce that percentage reduction by half in the second four calendar quarters, and then continue to reduce the percentage reduction by half every four calendar quarters thereafter); and
- A limited standard reduction in the rebate amount for any Part B rebatable drug on the FDA drug shortage list with a reporting process under which manufacturers may request a higher reduction or waiver for certain types of shortages (e.g., drugs that fill a critical need or shortages due to exogenous circumstances).

CMS is also seeking comment on the following areas:

1. How should CMS reduce or waive the rebate amount in the case of a Part B rebatable drug that is on the shortage list?
2. How might CMS adjust the rebate amount in cases where not all of the NDC-11s for the Part B rebatable drug are “current” on the shortage list?¹⁶
3. Are there specific types of Part B rebatable drugs where CMS might reduce or waive the rebate amount differently, and why would such an approach be necessary?
4. Are there specific causes for or types of a shortage where CMS might reduce or waive the rebate amount differently, such as drugs that treat certain conditions or address critical need, and how CMS would identify such drugs?
5. Are there certain scenarios where a greater reduction, or a waiver, would be appropriate (e.g., due to the Part B rebatable drug’s level of price increases over time, impact on manufacturer’s solvency, or certain market factors)?
6. What safeguards would be necessary to ensure that a reduction or waiver of the rebate amount did not create incentives for a manufacturer to intentionally maintain a Part B rebatable drug on the shortage list so as to avoid a rebate obligation?

50.12 Reducing or Waiving the Rebate Amount for a Severe Supply Chain Disruption for a Part B Rebatable Biosimilar Biological Product

Section 1847A(i)(3)(G)(ii) of the Act requires the Secretary to reduce or waive the inflation rebate amount for a calendar quarter in the case of a Part B rebatable drug that is a biosimilar biological

¹⁶ CMS notes that the FDA drug shortage list is maintained at the NDC-11 level. CMS intends to crosswalk the NDC-11 Part B rebatable drug in shortage to the relevant HCPCS code(s) to identify whether a Medicare Part B rebatable drug is in shortage. Thus, if any NDC-11 under the HCPCS code appears on the FDA drug shortage list, CMS intends to adjust the Part B rebatable drug’s rebate amount. CMS will closely monitor market data for the Part B rebatable drugs whose rebate is reduced to ensure the integrity of the application of this provision by the manufacturer.

product 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 intends to define a severe supply chain disruption to mean a change in production or distribution that leads to a reduction in the U.S. supply of a Part B rebatable drug that is a 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 U.S. for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, failure to comply with good manufacturing practice requirements, or insignificant changes in manufacturing so long as the manufacturer expects to resume operations within 90 days.

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 believes this list of potential causes for a severe supply chain disruption is sufficiently broad in scope. CMS intends to define a natural disaster as any natural catastrophe, including, but not limited to, any: 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 intends to define “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.

In order for CMS to reduce or waive the rebate under these conditions, CMS intends to require a manufacturer of a Part B rebatable drug that is a biosimilar biological product to demonstrate that: (1) a severe supply chain disruption has occurred during a calendar quarter, (2) that disruption directly affects the manufacturer itself, or a supplier of an ingredient or packaging or 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) that the severe supply chain disruption was due to a natural disaster or other unique or unexpected event.

Before CMS will consider whether a reduction or waiver of the rebate amount is warranted under these circumstances, CMS would require a manufacturer to demonstrate that a severe supply chain disruption has occurred during a calendar quarter for a Part B rebatable biosimilar biological product by submitting the following supporting documentation to CMS:

1. A copy of the formal notification the manufacturer submitted to the FDA of a supply chain disruption through the 506C notification process or a copy of the 506E notification to drugshortages@fda.hhs.gov;
2. A brief explanation (in 500 words or fewer) to CMS detailing the specifics of the severe supply chain disruption, including which specific dosage form(s) and strength(s) of the Part B rebatable biosimilar biological product are affected. In order to demonstrate that a severe supply chain disruption has occurred during a calendar quarter, the manufacturer must submit supporting documentation to show a change in the production or distribution

of the Part B rebatable biosimilar biological product that leads to a significant reduction in the U.S. supply of product and affects the manufacturer's ability to fill orders or meet expected demand for the Part B rebatable biosimilar biological product for at least 90 days. The manufacturer should also indicate when it expects that the severe supply chain disruption will be resolved and when it expects supply of the Part B rebatable biosimilar biological product to return to meet demand.

3. A brief explanation (in 500 total words or fewer) of the natural disaster or other unique or unexpected event the manufacturer is claiming caused the severe supply chain disruption, when the natural disaster or other unique or unexpected event occurred, and the expected duration for the severe supply chain disruption; and
4. Evidence of a manufacturer's physical presence in a geographic area where a natural disaster or other unique or unexpected event occurred; or if the manufacturer is not physically present in an area where a natural disaster or other unique or unexpected event occurred, but is still claiming a severe supply chain disruption due to a natural disaster or other unique or unexpected event, evidence of the impact the natural disaster or other unique or unexpected event had on the supply chain of the Part B rebatable biosimilar biological product that resulted in a severe supply chain disruption or evidence of the impact on a supplier of an ingredient or packaging or method of shipping or distribution that the manufacturer uses. Such evidence would include records documenting manufacturer ownership of the physical plant where the event occurred, records of insurance claims filed regarding the natural disaster or other unique or unexpected event, news reports, and other such documents.

The request for a reduction or waiver of the rebate amount based on the circumstances set out under this provision would be required to be made within 60 days of the first day a natural disaster or other unique or unexpected event occurs. If the manufacturer makes the request within 60 days of the start of the severe supply chain disruption, the request includes all the components listed above, and CMS determines that the information submitted warrants a reduction (e.g., CMS may check that the natural disaster or unique or unexpected event occurred in the location reported or CMS may review the impact on the supply of the drug through claims and other data), then CMS would reduce or waive the otherwise applicable rebate for the quarter for that manufacturer's Part B rebatable biosimilar biological product.

If a severe supply chain disruption continues into the next calendar quarter, the manufacturer would be required to submit updated information on the severe supply chain disruption and the continued impact on the availability of the Part B rebatable biosimilar biological product within 60 days of the start of the next calendar quarter. If available evidence, such as market sales data, suggests that the availability of the manufacturer's Part B rebatable drug in the marketplace has returned to normal during a calendar quarter, CMS may ask the manufacturer to provide additional evidence that the severe supply chain disruption continues to exist.

CMS is soliciting comment on the amount and duration for which CMS might reduce or waive the rebate amount in this scenario.

CMS is also seeking comments on the definitions included in this section for “severe supply chain disruption,” “natural disaster,” and “other unique or unexpected event.” CMS is seeking comment on what CMS’ policy should be if a severe supply chain disruption occurs during the same calendar quarter that a Part B rebatable drug that is a biosimilar biological product appears as “current” on the FDA drug shortage list during a calendar quarter. CMS is soliciting comments on whether there are any ways to enact this policy that may reduce the likelihood of future severe supply chain shortages. Finally, CMS is soliciting comment on the supporting documentation discussed above.

50.13 Financial Responsibility for 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 would, in most instances, be assigned to the same HCPCS code(s) and each manufacturer (including repackagers and relabelers) would be responsible for reporting ASP data to CMS, which includes sales volume. When calculating the rebate amount owed by manufacturers for a single source 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 intends to apportion financial responsibility for the rebate amount among the manufacturers by dividing the 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) by the sum of all manufacturers’ 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 also appears in section 80.5.

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 of the NDC-11 to identify the billing units sold during the rebate quarter. See section 80.6 for this formula.

For example, a Part B rebatable drug has a manufacturer (Manufacturer A) and also one manufacturer that is a repackager (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 HCPCS code as shown below. The example billing units are based on a HCPCS code description for the Part B rebatable drug.

Manufacturer A

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

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

Manufacturer B

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

NDC 98765-0333-99; 1,000 sold (5 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 billing units sold during the rebate quarter for all NDC-11s of the manufacturer assigned to the HCPCS code

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

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

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

- 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.

CMS solicits comments on the process to allocate the financial responsibility for the rebate amount for a calendar quarter when there is more than one manufacturer of the Part B rebatable drug as discussed in this section.

60. Ensuring Integrity of Part B Inflation Rebates

Manufacturers of Part B rebatable drugs that owe inflation rebates would be required to pay such rebates not later than 30 days after receiving an invoice, referred to as a Rebate Report¹⁷, for each calendar quarter or shall be subject to a civil monetary penalty (CMP) (see section 70 of this memorandum). In accordance with 1847A(i)(1)(C) of the Act, CMS may delay reporting rebate information, discussed below, for calendar quarters beginning in CY 2023 and CY 2024 until no

¹⁷ "Rebate Report" is the report that CMS would provide to all manufacturers of Part B rebatable drugs no later than six months after the end of each applicable period that will identify the total number of units of the billing and payment code(s) for each Part B rebatable drug for the calendar quarter, the amount, if any, by which the payment amount exceeds the inflation-adjusted payment amount for a calendar quarter, and the rebate amount due.

later than September 30, 2025. Beginning with the calendar quarter beginning on October 1, 2025, Rebate Reports would be sent to manufacturers no later than six months after the end of the quarter.

In accordance with section 1847A(i)(1), the Preliminary Rebate Report¹⁸ and the Rebate Report will identify: (1) the total number of units of the billing and payment code(s) for each Part B rebatable drug for the calendar quarter; (2) the amount, if any, by which the average sales price increase exceeds the inflation-adjusted payment amount for a calendar quarter as described in sections 50.1 and 50.2; and, (3) the rebate amount as described in section 50.1 and illustrated as an equation in section 80.3.

CMS intends that manufacturers would first receive a Preliminary Rebate Report, per section 60.1 below, and would have the opportunity to suggest certain calculation errors. As described in section 60.2, CMS may exercise discretion to review such suggestions. Manufacturers would receive the Rebate Report with the rebate amount due to CMS as described in section 60.1. Approximately one year after the rebate amount is invoiced through the Rebate Report, CMS intends to conduct a true-up of rebate amounts. The true-up process is described in section 60.3. 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.

CMS solicits comments on this section with respect to the approach to ensure the integrity of the rebate determination process.

60.1 Timing of Reports and Payment

CMS intends to provide all manufacturers of Part B rebatable drugs with a Preliminary Rebate Report no later than five months after the end of each calendar quarter. CMS may elect to delay issuing the first Preliminary Rebate Report and Rebate Report for calendar quarters in CY 2023 and CY 2024 as permitted under section 1847A(i)(1) of the Act.

Manufacturers would have 10 days to review the Preliminary Rebate Report for potential calculation errors, further described in section 60.2 below. The Preliminary Rebate Report will include the total number of units of the billing and payment code(s) for each Part B rebatable drug for the calendar quarter; the amount (if any) of excess average sales price increase for the Part B rebatable drug for the given quarter; and the rebate amount for the Part B rebatable drug for the given quarter.

¹⁸ “Preliminary Rebate Report” is the report that CMS would provide to all manufacturers of Part B rebatable drugs that will identify the total number of units of the billing and payment code(s) for each Part B rebatable drug for the calendar quarter, the amount, if any, by which the payment amount exceeds the inflation-adjusted payment amount for a calendar quarter, and the rebate amount due.

Following the opportunity to identify potential calculation errors per section 60.2, for which CMS may use discretion to review such suggestions, manufacturers will receive the Rebate Report, which will include the same data elements as the Preliminary Rebate Report; the Rebate Report serves as the invoice for the rebate amount due, if any. Manufacturers would have 30 days from the date of receipt of the Rebate Report to pay the rebate owed. The date of receipt would be defined as the calendar day after the day on which the Rebate Report was issued. For example, if the Rebate Report is issued on August 29, 2026, then August 30, 2026 would be the date of receipt and therefore day one of the 30-day payment period.

CMS expects to issue additional guidance regarding the form and manner in which Rebate Reports will be sent to manufacturers. If the manufacturer does not pay the rebate amount in full as indicated on the Rebate Report, CMS will initiate the civil monetary penalty process (see section 70 of this memorandum).

For each calendar quarter, CMS would conduct a one-time true-up recalculation to allow for updated ASP data submitted by a manufacturer, CMS revision of payment limits, revisions to the CPI-U, and any updates to claims data that occurred after the rebate amounts were calculated on the number of units and ASP. This recalculation will true-up rebate amounts for all manufacturers approximately one year after CMS sends the Rebate Report to manufacturers, as outlined in section 60.3 of this memorandum. The true-up process would use the same calculations as described in section 50.7 of this memorandum and follow the same reporting process as described in section 60.

<u>Milestone</u>	<u>Timing/Deadline</u>
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 suggestions of calculation errors should be submitted to CMS not later than 10 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 days after receipt of the Rebate Report
Part B Rebate True-Up – One year after Rebate Report is sent	
Preliminary True-Up Rebate Report sent to Manufacturers ¹⁹	Approximately 1 year after Preliminary Rebate Report is sent

¹⁹ “Preliminary True-up Rebate Report” is the report that CMS would provide to all manufacturers of Part B rebatable drugs using updated data to calculate the True-Up Amount no later than 1 year after the Preliminary Rebate Report.

Manufacturer Reviews	Manufacturer suggestions of calculation errors should be submitted to CMS not later than 10 days following the receipt of the Preliminary True-Up Rebate Report
True-Up Rebate Report sent to Manufacturers ²⁰	Approximately one year after Rebate Report is sent
Manufacturer Rebate True-Up Payment Due (if applicable)	Not later than 30 days after receipt of the True-Up Report

60.2 Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True-Up Reports

Manufacturers of Part B rebatable drugs may provide suggestions of calculation errors in their Preliminary Rebate Report and Preliminary True-up Rebate Report (as described in section 60.3 below) to CMS, for its discretionary consideration, if the manufacturer believes that there is a calculation error to be corrected before the Rebate Report or True-Up Rebate Report is finalized.

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. No disputes on these topics will 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 a calculation error if they identify a mathematical error in the calculation by CMS or an exclusion specified in statute that was not applied in their Preliminary Rebate Report and Preliminary True-Up Rebate Report, which CMS may consider at its discretion.

Manufacturers should notify CMS, share the suggestion of a calculation error, and provide supporting documentation (if applicable) within 10 days after receiving their Preliminary Rebate Report or Preliminary True Up Rebate Report. CMS expects to issue additional information regarding how the suggestions of calculation errors may be submitted in future communication.

CMS reserves discretion to review or consider these suggestions as appropriate. The final determination on the rebate amount will be invoiced to manufacturers in the Rebate Report or True Up Rebate Report, at which time payment must be submitted to CMS as the statute requires, no later than 30 days after receipt of the Rebate Report or the True Up Rebate Report to avoid a CMP.

60.3 Restatements and True-Up Report

CMS would perform a single, subsequent reconciliation or “true-up” for each applicable calendar quarter subject to Part B rebates approximately one year after sending Rebate Reports to manufacturers. This true-up calculation will be performed to capture any potential changes related

²⁰ “True-up Rebate Report” is the report that CMS would provide to all manufacturers of Part B rebatable drugs using updated data to calculate the true-up amount, corrected for any calculation errors, as appropriate, approximately 1 year after the Rebate Report.

to revised ASP data submitted by a manufacturer, CMS revision of payment limits, revisions to the CPI-U, and any updates to claims data that occurred after the rebate amounts were calculated.

This true-up could result in an increase, decrease, or no change to the rebate amount owed by manufacturers for the calendar quarter for the Part B rebatable drug. Once calculated, CMS would provide a Preliminary True-up Rebate Report to all manufacturers of Part B rebatable drugs. The true-up amount (if any) will be subject to the same calculation error process as the rebate amount, described in section 60.2 of this memorandum. Once that process has taken place, CMS would issue a True-up Rebate Report to manufacturers that will contain the final true-up amount. The manufacturer would be required to pay the true-up amount within 30 days of receipt to avoid applicability of a CMP. In the event that the true-up results in an amount owed to the manufacturer, CMS would reconcile payments owed. CMS expects to issue additional information regarding reconciling potential overpayments in future guidance.

60.4 CMS Identification of Errors

CMS reserves the right to update or change the rebate amount and the true-up amount due from manufacturers for the calendar quarter based on any calculation errors, or misreporting of manufacturer pricing or product data, that CMS identifies at any point, after each calendar quarter ends. This could occur during the calculation error dispute process, after invoices are reported to manufacturers, or after rebate or true-up invoices are paid to CMS. In this event, the affected manufacturer(s) would be notified directly and CMS would provide information on the process and timing for resolution.

70. Enforcement of Rebate Payments by Manufacturers: Civil Monetary Penalties

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 (i.e., Rebate Report or True-Up Rebate Report) will be subject to a CMP of at least 125 percent of the rebate amount for such drug for such quarter.

CMS will establish a process for the Part B inflation rebate CMPs pursuant to regulations. 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).

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

Step 1: Calculate Average Total Allowed Charges Per Unique Beneficiary

- For each 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: Allowed charges in this case are from all of the HCPCS codes for that drug or biological product, excluding any HCPCS code that represents an “unclassified,” “unspecified,” or “not otherwise classified” drug or biological product.

Step 2: Calculate the Applicable Threshold

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

\$100 *multiplied by* (CPI-U for July 2022 *divided by* CPI-U for June 2023), rounded to the closest multiple of 10.
- For calendar quarters in each subsequent calendar year:

Previous year’s threshold (without rounding) *multiplied by* (CPI-U for July two years before the calendar year *divided by* CPI-U for June of the year before the calendar year).
The resulting number is rounded to the closest multiple of 10.

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
IF Average Total Allowed Charges Per Unique Beneficiary > \$100 **THEN** include in rebates
(subject to other applicable exclusions)

For subsequent calendar quarters:

IF Average Total Allowed Charges Per Unique Beneficiary < Applicable Threshold **THEN** exclude from rebates

IF Average Total Allowed Charges Per Unique Beneficiary > Applicable Threshold **THEN** include in rebates (subject to other applicable exclusions)

80.2 Calculation of the Payment Amount in the Payment Amount Benchmark Quarter

The payment amount in the payment amount benchmark quarter = the payment limit (based on various provisions within section 1847A of the Act) for the payment amount benchmark quarter

The payment amount benchmark quarter for drugs approved or licensed on or before December 1st 2020 is the calendar quarter beginning July 1, 2021

The payment amount benchmark quarter for drugs approved or licensed after December 1st 2020 is the third full calendar quarter after the day on which the drug was first marketed

80.3 Calculation of the Part B Rebate Amount

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* (the per unit rebate amount)

Inflation-Adjusted Payment Amount =

(Payment amount for the payment amount 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.

80.4 Per Unit Rebate Amount

The per unit rebate amount for a dosage form and strength of a Part B rebatable drug is equal to:

The Specified Amount for the Calendar Quarter *minus* the Inflation Adjusted Payment Amount

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

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

Sum of **all** manufacturers' 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

80.6 Calculation to Identify the Number of Billing Units Sold During the Rebate Quarter

For each NDC assigned to the HCPCS code:

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

Comment Solicitation

Please send comments on policies where comments are solicited above to IRAREbateandNegotiation@cms.hhs.gov with the subject line “Medicare Part B Inflation Rebate Comments” by March 11, 2023.

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	<i>A clotting factor that is a Part B rebatable drug with the inflation</i>

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

