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CMS Final Regulation on the Medicare Part B and Part D Prescription Drug Inflation Rebate Program

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Enacted slightly less than three years ago, the Inflation Reduction Act amended the Medicare provisions of the Social Security Act to impose several discount requirements on pharmaceutical manufacturers. Besides the widely publicized and controversial drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D, a program that has existed in Medicaid since the Medicaid Drug Rebate Program (MDRP) was enacted in the 1990s. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. The Part B program applies to calendar quarters beginning with the first quarter of 2023, and the Part D program applies to 12-month periods beginning on October 1, 2022. Because of the limited time between enactment and the effective dates of the rebate programs, Congress directed the Centers for Medicare and Medicaid Services (CMS) to implement these two programs initially through program guidances. Accordingly, CMS issued first a preliminary guidance on each program, then, after a 30-day comment period, issued revised guidances on December 14, 2023. Although the two programs are distinct from one another, they share a lot of common features, and CMS has been developing them in tandem.

On July 31, 2024, CMS published a proposed regulation on each program that essentially codified the guidances with few changes.[1] On December 9, 2024, as part of its 2025 Physician Fee Schedule final regulation, CMS finalized the rules governing the inflation rebates, having made several changes in response to public comments.[2] This memorandum summarizes the chief provisions of the final regulation, pointing out the areas where the final regulation differs from the proposal.

I. MEDICARE PART B INFLATION REBATE PROGRAM

The Medicare Part B inflation rebate program is codified in new part 427 of Title 42 of the Code of Federal Regulations. Essentially, the program requires the payment of quarterly rebates for a "Part D rebatable drug" when its average sales price (ASP) for the quarter exceeds the ASP for a "benchmark quarter," adjusted for inflation. Unless otherwise specified, provisions in the final rule apply for all calendar quarters beginning with January 1, 2023.

A. Part B Rebatable Drugs

1. Definition

A drug for which inflation rebates are payable is called a "Part B rebatable drug," which is defined in the final regulation as "a single source drug or biological product, including a biosimilar biological product but excluding a qualifying biosimilar biological

[1] 89 Fed. Reg. 61,596 (July 31, 2024).
[2] 89 Fed. Reg. 97,710 (Dec. 9. 2024).

product, for which payment is made under Part B,"[3] subject to the exclusions described below. CMS identifies Part B rebatable drugs each quarter based on information reported by manufacturers to CMS under the Medicaid Drug Rebate Program (MDRP) and in ASP reports, information on FDA's website and in pricing compendia, and other sources.

2. Excluded Product Categories

The following categories of products are excluded from the definition of "Part B rebatable drugs":[4]

- Qualifying biosimilar biological products (as defined under section 1847A(b)(8)(B)(iii) of the Social Security Act)—i.e., biosimilars that are eligible for a temporary five-year increase in the Part B add-on payment;
- Products with historically excepted grouped billing and payment codes (i.e., single source drugs or biologics that were within the same billing and payment code as of October 1, 2003, which are treated as multiple source drugs under the Social Security Act);
- Drug or biological products billed under Not Otherwise Classified (NOC) codes;
- Separately payable radiopharmaceutical drugs or biological products not paid on the basis of ASP;
- Skin substitute products included with the suite of cellular- and tissue-based products that aid wound healing;
- Certain vaccines, including influenza, pneumococcal, hepatitis B, and COVID-19 vaccines, as well as certain monoclonal antibodies used for the treatment of COVID-19;
- Drugs approved under an abbreviated new drug application (ANDA);
- Certain monoclonal antibodies used for treatment or prophylaxis of COVID-19; and
- Drugs and biological products for which the Part B average total allowed charges for a year per individual that uses such drug or biological are below an "applicable threshold."

For this latter excluded product category, CMS calculates "average total allowed charges for a year per individual" by summing the allowed charges during a year from final action claims for all billing and payment codes applicable to the drug, and dividing that summed amount by the number of individuals who use such a drug or biologic with

[3] 42 C.F.R. § 427.20.
[4] *Id.* § 427.101(b).

allowed charges during the same year.[5] The year used is the four consecutive calendar quarters beginning six quarters before the applicable calendar quarter. Special rules apply to drugs that are moved from a grouped billing and payment code to a unique billing and payment code during a year.

The "applicable threshold" is defined to mean:[6]

- For all four calendar quarters in 2023, $100;
- For all four calendar quarters in 2024, $100 multiplied by (Consumer price increase for all urban consumers (CPI-U) for June 2023 divided by CPI-U for June 2022), rounded to the nearest multiple of $10; and
- For calendar quarters in 2025 and beyond, the unrounded applicable threshold calculated for the prior calendar year, increased by the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

B. Rebate Calculation

Under the final regulation, the Part B inflation rebate for a billing and payment code (i.e., a HCPCS code, or "code") is the per-unit rebate multiplied by the total number of billing units.[7]

1. Per-Unit Rebate Calculation[8]

The rebate per unit of a Part B rebatable drug assigned to a billing and payment code (i.e., a HCPCS code) for a calendar quarter is the excess of the "specified amount"—which represents the Part B payment amount for the code for the rebate quarter—over an inflation adjusted "payment amount" for the code for a benchmark quarter.

[5] *Id.* § 427.101(c)(1).
[6] *Id.* § 427.101(c)(2).
[7] *Id.* § 427.301.
[8] *Id.* § 427.302.

For single source drugs and biologicals, the specified amount is 106% of the ASP[9] or published wholesale acquisition cost (WAC), whichever is less. For biosimilars, the specified amount is 100% of the ASP of the biosimilar plus 6% of the lesser of ASP or WAC of the reference biological. If no ASP or WAC has been reported for all NDCs in a billing and payment code, CMS will use 106% of the WAC obtained through other sources to determine the specified amount.

The benchmark quarter payment amount is the payment limit for the billing and payment code published by CMS for the benchmark quarter. It is similar to the specified amount but can include variations besides the 106% formulas described above for drugs, biologicals, and biosimilars. These variations include 103% of the WAC where ASP is not available for a drug during the first quarter of sales, or 103% of the Medicaid average manufacturer price (AMP) if the ASP exceeds AMP by 5% and CMS has determined that a price substitution is warranted.

The benchmark quarter depends on drug's approval date and "first marketed date," as shown in column B of the following table:

A. Drug Dates	**B. Benchmark Quarter**	**C. Benchmark Quarter CPI-U**
Approval and "first marketed date" on or before Dec. 1, 2020	3Q 2021	CPI-U for January 2021
Approval and first marketed date after Dec. 1, 2020	Third full calendar quarter after the "first marketed date."	CPI-U for 1st month of 1st full calendar quarter after "first marketed date"
Approval before December 1, 2020 but first marketed date afterward	Third full calendar quarter after the "first marketed date."	CPI-U for 1st month of 1st full calendar quarter after "first marketed date"
Drug selected for price negotiation after last year of price negotiation ends (no inflation rebates payable while selected)	1st quarter of last year the drug was subject to price negotiation	CPI-U for July of year preceding the last year drug was subject to price negotiation

[9] Even for a single-source drug, a billing and payment code may contain multiple NDC-11s for different package sizes of the drug, or even multiple versions of a drug marketed by different manufacturers. In such cases, CMS calculates the ASP for the billing and payment code as a weighted average of the ASPs of the individual NDC-11s within the billing and payment code.

The "first marketed date" used to determine the benchmark period is the earliest first marketed date—i.e., date of first sale—of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter.[10]

The benchmark quarter payment amount must be adjusted for inflation before comparing it to the rebate quarter's specified amount. This is done by dividing the CPI-U for the rebate quarter by the CPI-U for the benchmark period and multiplying the result by the benchmark quarter payment amount. The CPI-U for the rebate quarter is the CPI-U for the first month of the calendar quarter that is two quarters before the rebate quarter. The CPI-U for the benchmark quarter is shown in column C of the above table.[11]

2. Total Number of Billing Units[12]

To determine the total inflation rebate for a billing and payment code, the per-unit rebate amount is multiplied by the total number of billing units for that code that were paid by Medicare Part B during the applicable quarter. CMS determines the number of billing units at least three months after the close of the applicable rebate quarter, using final action claims under Medicare Fee for Service (but not Medicare Advantage). The following are excluded from billing units:

- *340B drugs*: drugs for which the manufacturer provided a discount under the 340B Drug Discount Program. Beginning January 1, 2024, 340B covered entities were required to use modifiers "JG" or "TB" on claims for separately payable drugs acquired under the 340B program, and beginning January 1, 2025, they must use only the "TB" modifier. CMS will exclude units of 340B drugs identified with these modifiers. For 2023 and 2024, CMS will also exclude units in claims from suppliers that are included in the 340B covered entity database maintained by the Health Resources and Services Administration (HRSA), even if the claims lack these modifiers.
- *Medicaid rebate drugs*: CMS will exclude billing units from claims for Medicare beneficiaries who also have Medicaid coverage that may provide cost sharing assistance.
- *Packaged payment drugs*: CMS will exclude units that are not separately payable and whose payment is instead packaged into prospective payments such as the Outpatient Hospital Payment System and the Ambulatory Surgical Center payment system.

[10] *Id.* §§ 427.20, 427.302(c).
[11] *Id.* §§ 427.302(f), 427.302(g).
[12] *Id*. § 427.303.

- *Multiple source drugs*: Multiple source drugs are not subject to Part B inflation rebates, and a single source drug could become a multiple source during a quarter. CMS identifies the first marketed date of a newly launched drug that is therapeutically equivalent to a Part B rebatable drug using FDA's Orange Book, and to exclude all units of the rebatable drug as of the first day of the month following the first marketed date of the generic.
- *Medicare Advantage:* Because of operational difficulties, CMS is not including Medicare Advantage units in billing units, but states that it may do so in the future.
- *Discarded drug refunds*: Although the statute does not exclude drugs subject to discarded drug refunds from inflation rebate billing units, and neither did CMS's Part B inflation rebate guidance, CMS will do so by regulation in order to "balance fairness for manufacturers that owe refunds for billing units of discarded drugs with the need to fulfill the requirements of [the statute]."[13] This exclusion is takes effect in rebate quarters beginning with 1Q 2024.

CMS declined commenters' requests to exclude units from federal programs other than the Medicaid Drug Rebate Program and 340B Drug Discount Program, such as units purchased under the Federal Supply Schedule.[14] CMS also declined to provide manufacturers with claims-level data to verify CMS's excluded units, citing the absence of any such requirement in the statute, the constraints of its Rebate Report timing, and concerns about disclosure of protected health information.[15]

3. Apportioning Rebate Among Different Manufacturers

When a billing and payment code for a Part B rebatable drug contains NDCs marketed by different manufacturers, CMS will apportion the rebate among them according to the ratio of each manufacturer's reported ASP units (converted to billing units) to the sum of all manufacturers' billing units for the quarter.[16] Special rules apply for apportioning the rebate amount when all or some of the NDCs in a billing and payment code are missing reported units or the units reported are zero or negative.[17]

[13] 89 Fed. Reg. 98,252.
[14] *Id.* at 98,247.
[15] *Id.* at 98,248.
[16] 42 C.F.R § 427.301(b).
[17] *Id.* § 427.301(c).

4. Reducing the Rebate Amount for Drugs in Shortage and When There is a Severe Supply Chain Disruption[18]

CMS is required to reduce or waive the rebate amount owed by a manufacturer for a Part B rebatable drug in two cases: (1) when the drug is described as currently in shortage on an FDA shortage list at any point during the applicable period and (2) when CMS determines that there is a severe supply chain disruption during the applicable quarter for a biosimilar biological product. The statute left implementation of these requirements to CMS. Under the final rule, the rebate amount is not fully waived in either case so as to not incentivize manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption to avoid paying rebates.[19]

The preamble to the final rule provides the following table to describe the rebate reduction amounts:[20]

	Drug Shortage		**Severe Supply Chain Disruption**
Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		Four calendar quarters; manufacturer may request an extension for four additional quarters up to eight calendar quarters total
Percent Reduction	Part B rebatable drug other than a plasma-derived product	Part B rebatable plasma-derived products*	Part B rebatable biosimilar biological product
First four consecutive calendar quarters	25%	75%	75%
Second four consecutive calendar quarters	10%	50%	75%
Subsequent calendar quarters	2%	25%	Not applicable

* CMS established a greater percent reduction for plasma-derived products as compared to non-plasma derived products because the former rely on a variable supply of donated blood plasma that can affect downstream production and hamper the ability to promptly resolve a shortage. The rule defines a plasma-derived product as a licensed biological product that is derived from human whole blood or plasma as stated on the approved product labeling.

CMS has provided an FAQ with regard to the rebate reductions that can be located here: CMS FAQ.

[18] *Id.* §§ 427.400–427.402.
[19] *See* 89 Fed. Reg. 98,255.
[20] *Id.*

a) Drugs Currently in Shortage[21]

To determine whether a Part B rebatable drug is currently in shortage during a calendar quarter, CMS will use the shortage lists maintained by the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) pursuant to section 506E of the Federal Food, Drug, and Cosmetic Act (FDC Act). CMS does not consider an NDC-10 with a status of "to be discontinued," "discontinued," or "resolved" to be currently in shortage. At least one NDC-10 must be on such a shortage list for the drug to be currently in shortage. CMS takes responsibility for monitoring the status of a Part B rebatable drug on an FDA shortage list, so manufacturers do not need to submit any information to CMS to be eligible for a reduction of the rebate amount.

CMS uses the following formula to calculate the reduced total rebate amount:[22]

$$\text{Reduced Total Rebate Amount} = \left(\text{total rebate amount} \times \text{1 – applicable \% reduction} \times \text{\% of time drug in shortage during applicable calendar quarter}\right) + \left(\text{total rebate amount} \times \text{1 – \% of time drug in shortage during applicable calendar quarter}\right)$$

The percent of time a drug is in shortage during the calendar quarter is derived by counting the number of days such drug is currently in shortage and dividing it by the total number of days in that calendar quarter.

The final rule adds a clarification not present in the proposed rule regarding the starting point for the rebate reduction: the reduction will start in the first applicable quarter that the drug or biological is currently in shortage, even if the drug is not yet a Part B rebatable drug, or even if no rebate is owed during that quarter. For example, if a drug is on FDA's shortage list during 1Q 2025 but the ASP of the drug does not trigger an inflation rebate until 3Q 2025, the beginning of the rebate reduction "clock" will nevertheless begin in 1Q 2025, so that the drug will receive only two quarters of the 25% reduction when its inflation rebate is eventually triggered.[23] CMS's purported reason for this clarification is to discourage manufacturers from manipulating a shortage to coincide with a price increase.[24]

When the status of a 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 reduction as if there was a continuous shortage beginning with the quarter in which the drug has re-entered

[21] 42 C.F.R. § 427.401(b).
[22] *Id.* § 427.401(b)(1).
[23] *Id.* § 427.401(b)(2)(iii).
[24] 89 Fed. Reg. 98,258.

shortage.[25] For example, if a drug is in shortage in 1Q 2025, changes to resolved in 2Q and 3Q, then re-enters shortage in 4Q, it will be entitled to only one quarter of 25% reduction before moving to a 10% reduction. However, when the status of a shortage changes to resolved and either remains as resolved or is removed from the FDA list for at least four full consecutive calendar quarters and then subsequently is listed on a shortage list, CMS will treat the subsequent shortage as a new shortage and the applicable percent reduction for the first four consecutive quarters will apply.[26]

b) Severe Supply Chain Disruption for Biosimilars[27]

Unlike a reduction for a drug currently in shortage, in order to obtain a reduction on the basis of a severe supply chain disruption for a biosimilar, a manufacturer must obtain CMS approval of a written rebate reduction request. The rule establishes the following evaluation criteria for granting a reduction:

- A severe supply chain disruption has occurred during the applicable calendar quarter;
- The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the biosimilar; and
- The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

A severe supply chain disruption is defined as a change in production or distribution that is reasonably likely to lead to a significant reduction in the US supply of a Part B rebatable biosimilar and significantly affects the ability of the manufacturer to fill orders or meet expected demand for at least 90 days.[28] It 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. A natural disaster is defined as any natural catastrophe, with the expected types of events listed as examples.[29] "Other unique or unexpected event" is defined as any exogenous, unpredictable event outside of a manufacturer's control, including a geopolitical disruption, pandemic, or act of terror.[30]

[25] *Id*. 98,257.
[26] *Id.*
[27] 42 C.F.R. § 427.402.
[28] *Id.* § 427.400.
[29] *Id.*
[30] *Id.*

Information to substantiate the evaluation criteria must be submitted as part of a request for reduction. According to guidance provided on CMS's website, a manufacturer should email CMS of its intent to seek a reduction, and CMS will email the manufacturer the relevant form and instructions providing the necessary information securely. The deadline for submitting a request is 60 calendar days from the first day that the natural disaster or unexpected event occurred.[31] The reduction applies to the quarter in which the event occurred and the three subsequent applicable quarters.

CMS will review all rebate reduction requests within 60 days after receipt of all documentation, if feasible. No guidance is provided as to what factors determine if the timeline for response is feasible.

If a rebate reduction is granted, as noted in the table above, CMS will reduce the total rebate amount owed by the manufacturer by 75% for the quarter in which the event occurred and the three subsequent applicable calendar quarters. Upon request by a manufacturer (which must be made at least calendar 60 days prior to the start of the fifth calendar quarter), CMS may extend the reduction of 75% for an additional four calendar quarters if it determines that the disruption continues into a fifth applicable quarter. No reduction may extend beyond eight quarters. As with drugs currently in shortage, CMS will apply any reduction of the rebate amount to all NDCs under the relevant billing and payment code.

CMS will not apply multiple rebate reductions for the same drug and applicable calendar quarter.[32] If a biosimilar that is granted a reduction as a result of a severe supply chain disruption is also currently in shortage, the reduction will be based on the severe supply chain disruption and a reduction will not be granted based on the drug being currently in shortage during the applicable calendar quarters. Similarly, if a biosimilar that is currently in shortage also experiences a severe supply chain reduction, CMS will reduce the rebate in accordance with the severe supply chain disruption provision and will not grant a reduction for the drug being currently in shortage during the applicable calendar quarters. Presumably, once the reduction for a severe supply chain disruption ends, if a drug remains currently in shortage, it should receive the currently in shortage reduction.

The final rule provides that a denial of a rebate reduction request is final and is not subject to an appeals process. CMS will keep confidential as a trade secret or confidential commercial or financial information if it determines that the information

[31] *Id.* § 427.402(c)(2).
[32] *Id.* § 427.402(b)(4).

meets the requirements set forth in Exemptions 3 and/or 4 to the Freedom of Information Act.

C. Coinsurance Adjustment and Adjusted Medicare Payment[33]

Because payments for Medicare Part B rebatable Drugs typically include a beneficiary coinsurance that is 20% of the payment amount, Part B rebatable drugs whose payment amount exceeded the inflation-adjusted payment amount in a particular quarter may need an adjustment of the beneficiary coinsurance once the payment amount is adjusted through the inflation rebate.

The inflation-adjusted beneficiary coinsurance will be calculated for a particular calendar quarter by comparing the inflation-adjusted payment amount to the payment amount published in quarterly pricing files published by CMS. If the published payment amount in the quarter exceeds the inflation-adjusted payment amount, CMS will calculate the beneficiary coinsurance by multiplying the lower, inflation-adjusted payment amount by 0.20.[34] CMS publishes the adjusted beneficiary coinsurance on its website as Addendum A and B of the Part B Pricing Files as a percentage of the published payment amount. The percentage is expressed as two digits with three decimal places, for example, 18.760. If an adjusted beneficiary coinsurance does not apply, the percentage will show as 20.000. CMS notes that the beneficiary coinsurance will not be adjusted for sequestration.

Drugs that are excluded from Part B rebatable drugs—for example, separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products—are not subject to inflation-adjusted beneficiary coinsurance.[35] Drugs selected for price negotiation may also be Part B rebatable drugs and therefore may also be subject to the inflation-adjusted beneficiary coinsurance.

D. Rebate Reports and Payment Process[36]

For applicable quarters starting in 2025, CMS will provide each manufacturer of a Part B rebatable drug—even if their rebate amount due is $0—a Preliminary Rebate Report at least one month prior to the issuance of a Rebate Report for a calendar quarter.[37] A Preliminary Rebate Report will include information about each Part B rebatable drug (NDCs, billing and payment codes, benchmark quarter, and benchmark payment amount and CPI-U); the applicable calendar quarter's sales information

[33] *Id.* § 427.201.
[34] *Id.* § 427.201(b)(1).
[35] *Id.* § 427.101(b).
[36] *Id.* §§ 427.500–427.505.
[37] *Id.* § 427.501(b).

(applicable quarter's number of billing units, specified amount, CPI-U, and inflation-adjusted payment amount); and the rebate amount (the difference between the specified amount and inflation-adjusted payment amount, if any; any applied reductions due to drug shortages or supply chain disruptions, and the rebate amount due).

CMS will provide each manufacturer a Rebate Report no later than six months after the end of each applicable calendar quarter, which will have the same information as the Preliminary Rebate Report as well as any revisions based on CMS's reconciliation or any manufacturer's Suggestions of Error, discussed below.[38]

Although the statute does not require a reconciliation process, CMS is establishing one. CMS explains that reconciliation after the initial Rebate Report is necessary to promote the accuracy of the rebate amount for each drug for each applicable calendar quarter.[39] Also, exclusion of units subject to discarded drug refunds will not be possible before the Rebate Report but can be done before the reconciliation report.[40] CMS will provide for a "regular reconciliation" of the amounts reflected in a Rebate Report and a "discretionary reconciliation."[41] In the regular reconciliation process, CMS may issue to the manufacturer a preliminary reconciliation report, which adjusts the rebate amount due to updated claims and payment data used in the calculation of such rebate amount. After providing the manufacturer at least a month to review the preliminary reconciliation information, and after reviewing any manufacturer-suggested errors, but within 12 months after the issuance of the Rebate Report, CMS will issue a reconciled rebate amount. In the preamble, CMS explains that a longer reconciliation period, such as the 36-month reconciliation period for Part D inflation rebates, is not needed because the 12-month reconciliation period is sufficient for the ASP claims run-out period and the ASP restatement timing.[42]

As to discretionary reconciliation, CMS may, not later than three years after the date of receipt of the manufacturer's reconciled rebate amount, recalculate a rebate amount and provide the manufacturer a reconciled rebate amount when it identifies an agency error, such as a reporting system or coding error.[43] CMS may also recalculate and adjust the rebate amount at any time if CMS determines that the information used to calculate the rebate was inaccurate due to manufacturer misreporting.

[38] *Id.* § 427.501(c).
[39] 89 Fed. Reg. 98,267.
[40] *Id.* 98,267–268.
[41] 42 C.F.R. §§ 427.501(d)(1), 501(d)(2).
[42] 89 Fed. Reg. 98,268.
[43] 42 C.F.R. § 427.501(d)(2).

Applicable quarters for 2023 and 2024 have a different process and timeline.[44] For each of the four applicable calendar quarters in calendar year 2023 and 2024, respectively, CMS will produce, for each year, a single consolidated Preliminary Rebate Report by August 30, 2025, followed by a single consolidated Rebate Report by September 30, 2025.[45] In 2023, CMS will not conduct a regular reconciliation of the rebate amount. For 2024, CMS will perform one regular reconciliation for the applicable calendar quarters nine months after CMS issues the 2024 consolidated Rebate Report in order to include revisions to the information used to calculate the rebate amount. Such reconciliation will follow the same process as described above.

CMS will establish a standard method and process for manufacturers to access the Rebate Report (including any report of reconciled rebate amounts), submit Suggestions of Error, and pay the rebate amount.[46] This method and process will include an online portal administered by a CMS contractor. CMS intends to provide technical instructions separate from its rulemaking process to manufacturers of Part B rebatable drugs regarding how to access Rebate Reports and receive notifications alerting the manufacturer when information is available. CMS also intends to issue reminder notices to manufacturers regarding the due date of rebate payments. As stated above, the manufacturer that is responsible for paying a rebate will be identified using the same approach used for reporting ASP and MDRP data.[47]

The Act precludes administrative or judicial review of the determination of units, the calculation of the inflation rebate amount (or a subsequent reconciliation of the rebate amount, if applicable), or whether a drug is a Part B rebatable drug.[48] Nevertheless, in the final rule, CMS establishes a limited process for manufacturers to "suggest" to CMS any errors the Agency may have made as to these items that need to be corrected before the Rebate Report—or a subsequent reconciliation of the rebate amount, if applicable—is finalized.[49] CMS states that the Suggestion of Error process is not an administrative dispute resolution process.[50] The Suggestions of Error are limited to the mathematical steps involved in determining the rebate amount; the elements precluded from administrative or judicial review are not considered in-scope for the process. The manufacturer may submit a "Suggestion of Error" regarding the information in the Preliminary Rebate Report and the preliminary reconciliation of the rebate amount to CMS, for the Agency to consider at its discretion. CMS rejected commenters' requests

[44] *See* 42 U.S.C. § 1395w-3a(i)(1)(C) (allowing CMS to delay the reporting timeframe for 2023 and 2024 until September 30, 2025).
[45] Prop. 42 C.F.R. § 427.502(c).
[46] *Id.* § 427.504.
[47] 89 Fed. Reg. 98,265–266.
[48] 42 U.S.C. § 1395w-3a(i)(8).
[49] 42 C.F.R. § 427.503(a).
[50] 89 Fed. Reg. 98,265.

that the Agency provide claims-level data to permit verification of the number of units or the rebate amount, citing operational difficulties given statutory timelines and long claims run-out times.[51]

Starting in 2025, manufacturers have only 10 calendar days from the receipt of a quarterly Preliminary Rebate Report or a preliminary reconciliation of a rebate amount to submit a Suggestion of Error. CMS rejected requests to provide a period longer than 10 days.[52] However, manufacturers have 30 calendar days to submit Suggestions of Error for the four-quarter consolidated Rebate Reports for each of 2023 and 2024.

All rebates are due by the 30th calendar day after a manufacturer receives a Rebate Report or a report of a reconciled rebate amount.[53] A failure to timely pay the full rebate amount due may result in enforcement action, as described in the next section. Where a reconciled rebate amount is less than what the manufacturer paid, CMS will refund the total excess amount paid within 60 days after the receipt of the report with such reconciled rebate amount.

E. Enforcement and Penalties[54]

1. Civil Monetary Penalty

As discussed above, under the final rule, manufacturers must pay the rebate amount owed for a Part B rebatable drug within 30 calendar days after receipt of the Rebate Report. CMS may impose a civil money penalty on a manufacturer that fails to pay the full Part B inflation rebate amount as invoiced in the Rebate Report or any reconciled rebate amount that is greater than the amount invoiced in the Rebate Report by the applicable payment deadline (i.e., within 30 days of receiving a Rebate Report).

The civil money penalty is equal to 125% of the rebate amount for such drug for the applicable calendar quarter, and is payable in addition to the rebate amount due. Any late payments of a rebate amount due, including late payment of any reconciled rebate amounts greater than the amount reflected in the Rebate Report, are considered a violation subject to a potential civil money penalty. Once a civil money penalty is assessed due to a late payment, the penalty remains in effect even if the manufacturer pays the outstanding rebate amount. Payment of any civil money penalty will not eliminate the requirement for the manufacturer to pay any outstanding rebate amount due, including any rebate amount due following a reconciliation. In other words, a manufacturer is responsible for paying the full rebate amount owed in addition to any

[51] *Id.* 98,266.
[52] *Id.*
[53] 42 C.F.R. § 427.505(a).
[54] *Id*. § 427.600.

civil money penalty imposed because of late payment. Beyond the civil monetary penalty, CMS will not assess interest on overdue rebate amounts.[55]

The civil money penalty will be calculated based on the outstanding rebate amount due at the payment deadline, which is 30 calendar days after the date of receipt of a Rebate Report containing any rebate amount due. Any civil money penalty will be assessed before the next reconciliation process.

Civil money penalties will be tied to the missed payment deadline. Specifically, CMS will not modify a civil money penalty from a prior missed payment deadline based on a reduction in the rebate amount due following reconciliation, but also will not issue a second civil money penalty on that reconciled rebate amount. However, if a reconciled rebate amount resulted in an increase to the rebate amount due, CMS is able to impose a separate civil money penalty for the manufacturer's failure to provide an inflation rebate for the increase to the rebate amount due.

In addition to imposing civil monetary penalties for unpaid or late inflation rebates, CMS may also refer manufacturers to the DOJ, Department of the Treasury, or HHS-OIG for further review and investigation.[56]

2. Appeals Process[57]

If CMS determines to impose a civil money penalty on a manufacturer for failure to meet a payment deadline, it will send a written notice of that decision that includes a description of the basis for the penalty determination, the penalty amount, the penalty due date, and information regarding the manufacturer's right to a hearing and how to file the hearing request. CMS will apply existing appeal procedures for civil money penalties in 42 C.F.R. Part 423, subpart T (for civil money penalty determinations affecting Medicare Advantage organizations and Part D sponsors). The scope of appeals will be limited to (1) CMS determinations relating to whether the rebate payment was made by the payment deadline; and (2) the calculation of the penalty amount.

3. Collections[58]

In cases where the manufacturer did not request an appeal, collection of the civil money penalty follows expiration of the timeframe for requesting an appeal (i.e., 60 calendar days after the civil money penalty determination). In cases where a manufacturer requests a hearing and the decision to impose the civil money penalty is

[55] 89 Fed. Reg. 98,275.
[56] *Id*. at 98,273.
[57] 42 C.F.R. § 427.600(e).
[58] *Id*. § 427.600(d).

upheld, CMS will initiate collection of the civil money penalty once the administrative decision becomes final.

II. MEDICARE PART D INFLATION REBATE PROGRAM

As discussed in later sections of this memorandum, the final rule codifies policies set forth in the guidances and establishes new policies for the Part D inflation rebate program. In contrast to Part B inflation rebates, which apply in all calendar quarters beginning with January 1, 2023, Part D inflation rebates apply for applicable periods beginning with October 1, 2022.

A. Definitions

CMS codified the definitions of the following terms used in the Medicare provisions of the Social Security Act and the revised Medicare Part D Drug Inflation Rebate Guidance, and new definitions based on the policies set forth in the proposed rule, including but not limited to the following:[59]

- "Manufacturer" is defined consistently with the policies and practices adopted under 42 C.F.R. § 447.502 for purposes of manufacturer obligations under the MDRP;
- "Applicable period" means "a 12-month period beginning with October 1 of a year (beginning with October 1, 2022)";
- "Covered Part D Drug" has the same meaning as set forth in the Act and existing regulations, i.e., "a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal . . . and obtained at a network pharmacy or an out-of-network pharmacy"; and
- "Subsequently approved drug" means "a Part D rebatable drug first approved or licensed by the FDA after October 1, 2021."

B. Part D Rebatable Drug

1. Identifying Part D Rebatable Drugs

Inflation rebates are payable for Part D rebatable drugs. A "Part D rebatable drug" means, subject to the exclusion described below, "a drug or biological that is a covered Part D drug that, as of the first day of the applicable period," is:

- A brand name drug approved under an NDA;

[59] *Id*. § 428.20.

- A biologic, including a biosimilar, licensed under a BLA; or
- A generic drug approved under a section 505(j) ANDA in the case where:
  - The reference listed drug, including any authorized generic drug, is not being marketed as identified in FDA's NDC Directory;
  - There is no other drug approved under section 505(j) of the FDC Act that is rated as therapeutically equivalent in FDA's most recent publication of the Orange Book and is identified as being marketed in FDA's NDC Directory; and
  - The manufacturer is not a "first applicant" during the "180-day exclusivity period" as those terms are defined in the FDC Act.[60]

For each applicable period, CMS uses prescription drug event (PDE) records to identify all covered Part D drugs and matches these identified drugs with application numbers to determine whether each meets the criteria for Part D rebatable drugs above, as of the first day of the applicable period.[61]

2. Exclusion of Drugs With Costs Below Threshold

For each applicable period, CMS identifies drugs and biologicals with average annual total costs under Part D for such applicable period, per individual who uses such drug or biological, that are below the applicable threshold. Such drugs are excluded from the identification of Part D rebatable drugs. CMS calculates the average annual total cost based on gross covered drug costs for the Part D rebatable drug at the NDC-9 level. Then, CMS calculates the average annual total cost per individual who uses such drug or biological by dividing the gross covered prescription drug costs for the drug or biological by the number of individuals who use such drug or biological in the applicable period. For this calculation, CMS uses PDE data with gross covered costs greater than zero that are available for the drug with dates of service during that applicable period.

The applicable threshold began as $100 in the applicable period beginning October 1, 2022. For the applicable period beginning October 1, 2024 and subsequent applicable periods, the applicable threshold is the applicable threshold for the prior applicable period increased by the percentage increase in the CPI-U for the 12-month period beginning with October of the previous period.[62]

[60] *Id.*
[61] *Id.* § 428.101(a).
[62] *Id.* § 428.101(b)(2).

C. Rebate Calculation

Similar to the Part B program, the Part D inflation rebate for a Part D rebatable drug is the per-unit rebate multiplied by the total number of dispensed units.[63]

1. Per-Unit Rebate Calculation[64]

The per-unit rebate calculation under the Part D program follows the same logic as the Part B calculation: the rebate is the excess of a current average price over an inflation-adjusted average price for a previous benchmark period. However, the average price calculations, the current reporting period used, and the benchmark period are different, as is the terminology. The per-unit Part D inflation rebate is the excess of the "annual manufacturer price (AnMP)" for the "applicable period" (i.e., the period for which rebates are payable) over the AnMP for a benchmark period.

The applicable period is four quarters long, and the benchmark period is either three or four quarters long, as discussed below. The AnMPs for both the applicable period and the benchmark period are calculated the same way. The AnMP calculation borrows the quarterly AMP reported by the manufacturer under the MDRP; it is the weighted average of the four (or three) quarterly AMPs reported for the period. It is represented by the following formula:

$$\text{AnMP} = \frac{(\text{AMP}^{Q1} \times \text{AMP units}^{Q1}) + (\text{AMP}^{Q2} \times \text{AMP units}^{Q2}) + (\text{AMP}^{Q3} \times \text{AMP units}^{Q3}) + (\text{AMP}^{Q4} \times \text{AMP units}^{Q4})}{\text{Units}^{Q1\text{-}Q4}}$$

Since AMPs are calculated and reported under the MDRP at the NDC-9 level (that is, all package sizes within an NDC-9 family share the same AMP), the same is necessarily true of the AnMP: it will be the same for each NDC-11 within an NDC-9 family.

As under the Part B program, the benchmark period depends on the Part D drug's date of FDA approval. For a Part D drug approved on or before October 1, 2021, the benchmark period is the three-quarter period from January 1 to September 30, 2021. (Thus, for this default benchmark period, the above formula is revised by deleting the fourth quarter information.) For a Part D drug approved after that date, or for a Part D drug that was approved before that date but is not marketed until after it, the benchmark period is the first full calendar year after the drug's "first marketed date." Under a special rule, if a drug approved on or before October 1, 2021 had no quarterly AMPs reported for the first three quarters of 2021, its benchmark period becomes the first calendar year in which at least one quarterly AMP is reported to CMS. The Part D inflation rebate is the per-unit rebate multiplied by the total number of billing units. For a

[63] *Id.* § 428.201.
[64] *Id.* § 428.202.

drug that was selected for price negotiation but is no longer selected, the benchmark period is the last calendar year during which it was a selected drug.

The "first marketed date" is defined differently from the Part B inflation rebate program: it is defined to be the same as the Market Date reported by the manufacturer under the MDRP.[65] Market Date is defined in MDRP regulations as "the date on which the covered outpatient drug was first sold by any manufacturer."[66] Thus, under the MDRP, a drug retains the same Market Date regardless of how many times it changes owners. Presumably, the same applies to the "first marketed date" under the Part D program, and a manufacturer who acquires a Part D drug from another manufacturer retains the same first marketed date, and thus the same benchmark period, as the previous owner.

An "applicable period" (i.e., the period for which an inflation rebate is paid) is a 12-month period beginning on October 1.[67] The first applicable period for a drug begins on October 1 following the end of the benchmark period. For example, for drugs approved and marketed before October 1, 2021, the default benchmark period was the three-quarter period from January 1 through September 30, 2021, as discussed above, so the first applicable period for which rebates were due was October 1, 2022 through September 30, 2023. As another example, if a drug was approved on November 1, 2023, its benchmark period is calendar year 2024, and its first applicable period will be October 1, 2025 through September 30, 2026.

As under the Part B program, the benchmark AnMP must be adjusted for inflation, and that is done by multiplying it by the ratio of the applicable period CPI-U to the benchmark period CPI-U. The applicable period CPI-U is the CPI-U for October (the first month) of that period. The benchmark CPI-U for a drug approved on or before October 1, 2021 is the CPI-U for January 2021, and for a subsequently approved drug, the benchmark CPI-U is the CPI-U for January of the benchmark period (i.e., the January following the first marketed date).[68]

2. Total Dispensed Units[69]

To determine the total inflation rebate payable for a Part D drug for an applicable year, CMS will multiply the per-unit rebate by the number of units dispensed under Part D for that applicable year. The number of units will be obtained from Part D PDE records, which show the number of units dispensed. If the unit types from the PDE

[65] *Id*. § 428.20.
[66] *Id*. § 447.502.
[67] *Id*. § 428.20.
[68] *Id*. § 428.202(e).
[69] *Id*. § 428.203.

records do not match the unit type for which AMP was reported by the manufacturer, CMS will convert the PDE units to AMP units.

CMS excludes certain units in calculating the Part D inflation rebate. First, as discussed in Section II.B, a generic drug approved under an ANDA may be a Part D rebatable drug only if no therapeutically equivalent products are marketed and the reference listed drug is no longer marketed. It is possible that an ANDA drug could begin an applicable period as a Part D rebatable drug, but then a therapeutically equivalent drug could be approved during the period. At that point, the ANDA drug no longer qualifies as a Part D rebatable drug. CMS will identify when a therapeutic equivalent drug has been approved and entered the market by using FDA's Orange Book and the NDC Directory. CMS will exclude from the rebate calculation of a Part D rebatable generic drug any units dispensed on or after the first day of the month that the therapeutically equivalent drug has entered the market, based on its "marketing start date" identified in the NDC Directory.

Second, in accordance with a statutory exclusion to remove 340B units from rebate calculations beginning in 2026, CMS will establish a Medicare Part D claims data repository, to which 340B covered entities will submit data on claims billed to Medicare Part D. The required data will include, at a minimum, date of service, prescription number, fill number, and dispensing pharmacy national provider identifier (NPI). Covered entities will be required to submit these data within three months after the end of each quarter. CMS could then match these data with PDE records to identify Part D claims for drugs purchased under the 340B program, and remove those units from the manufacturer Part D inflation rebate recalculations. The alternative of requiring 340B indicators on pharmacy claims was rejected because pharmacies currently do not know at the time of dispensing whether a drug was purchased under the 340B program. CMS also rejected other alternatives for logistical reasons.[70]

Third, after consideration of comments received on the proposed rule, the final rule specifies that CMS will exclude from the total dispensed units all units associated with a Part D rebatable drug that has been billed as compounded.[71]

3. Line Extensions

Under the MDRP, line extensions of oral solid dosage form drugs are subject to an alternative rebate that is tied to the inflation rebate of the initial drug. This is designed to discourage manufacturers from making small changes to a drug and treating the changed version as a new drug in order to avoid inflation rebates that would be payable if the

[70] 89 Fed. Reg. 98,289–293.
[71] 42 C.F.R. § 428.203(b)(3).

changed version were treated as the same drug. With one exception not relevant here, line extensions are defined under the MDRP as "a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients."[72] Manufacturers report to the MDRP whether a drug is a line extension formulation, and if it is, they must identify the initial drug.

Congress borrowed the same idea for the Part D inflation rebate program and directed CMS to develop a special rebate calculation for line extensions of oral dosage form Part D drugs that is consistent with that under the MDRP.[73] Accordingly, CMS defines a line extension as a drug identified as such under the MDRP, and identifies the initial drug similarly.[74] The per-unit Part D inflation rebate for a line extension of an oral solid dosage form drug is the greater of the inflation rebate calculated in the ordinary fashion (i.e., without regard to the initial drug) or an alternative rebate. The alternative rebate is equal to the AnMP of the line extension for the applicable period multiplied by a ratio of the inflation rebate amount for the initial drug divided by the AnMP for the initial drug.[75] In other words, the Part D inflation rebate of the line extension is tied to the price increases of the initial drug.

4. Reducing Rebate Amount for Drugs in Shortage and When There is a Severe Supply Chain Disruption or Likely Shortage[76]

The bases for reductions for Part D rebatable drug inflation rebates are the same as those for Part B reductions, except that there is a third ground for a rebate reduction, which applies only to generic (ANDA) drugs: a drug likely to be in shortage. As with Part B rebate reductions, the statute left implementation of the reductions to CMS, which has determined not to fully waive the rebate amount in any case so as to not incentivize manufacturers to delay taking appropriate steps to resolve a current or likely drug shortage or severe supply chain disruption to avoid paying rebates.

The preamble to the final rule provides the following table to describe the rebate reduction amounts:[77]

	Drug Shortage	**Severe Supply Chain Disruption**	**Likely to be in Shortage**

[72] *Id*. § 447.502.
[73] 42 U.S.C. § 1395w-114b(b)(5).
[74] 42 C.F.R. § 428.204(a).
[75] *Id*. § 428.204(c).
[76] *Id*. §§ 428.300–428.303.
[77] 89 Fed. Reg. 98,296 tbl.60.

Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		One applicable period; manufacturer may request an extension for an additional applicable period for up to two applicable periods	
Percent Reduction	Part D rebatable drug other than a plasma-derived product or generic Part D rebatable drug	Part D rebatable plasma-derived product or generic Part D rebatable drug*	Part B rebatable biosimilar or generic Part D rebatable drug	Generic Part D rebatable drug
First applicable period	25%	75%	75%	75%
Second applicable period	10%	50%	75%	75%
Subsequent applicable periods	2%	25%	Not applicable	Not applicable

* Under the final rule, plasma-derived products receive greater percentages of rebate reductions than brand name drugs and biological products, including biosimilars. In addition, generic Part D rebatable drugs, defined as generic drugs approved under an ANDA under section 505(j) of the FDC Act that meets the sole source criteria, also receive greater percentages of rebate reductions because generic drugs are often low-margin product whose prices are tied to the marginal cost of production and are thus vulnerable to potential market exit and shortage when input costs increase.

CMS has provided an FAQ with regard to the rebate reductions that can be located here: CMS FAQ.

a) Drugs Currently in Shortage[78]

The reductions for Part D rebatable drugs currently in shortage do not differ in any meaningful way from those for Part B rebatable drugs. CMS will use the shortage lists maintained by FDA's CDER and CBER pursuant to section 506E of the FDC Act. CMS applies a reduction of the rebate amount at the NDC-9 level. CMS is responsible for monitoring the status of a Part D rebatable drug on an FDA shortage list, so manufacturers do not need to submit any information to CMS to be eligible for a reduction of the rebate amount.

CMS established the following formula to calculate the reduced total rebate amount:[79]

$$\text{Reduced Total} = \left[\text{total rebate amount} \times \text{1 – applicable \% reduction} \times \text{\% of time drug in shortage during applicable period}\right] + \left[\text{total rebate amount} \times \text{1 – \% of time drug in shortage}\right]$$

[78] 42 C.F.R. § 428.301.
[79] *Id.* § 428.301(b).

Rebate Amount during applicable period

The percentage of time a drug is in shortage during the applicable period is derived by counting the number of days such drug is currently in shortage and dividing it by the total number of days in that applicable period.

Consistent with CMS's approach to Part B rebatable drugs, the reduction for Part D rebatable drugs will start in the first applicable quarter that the drug or biological is currently in shortage, even if the drug is not yet a Part D rebatable drug, or even if no rebate is owed during that quarter.[80]

The preamble states that when the status of a drug changes from currently in shortage to resolved and them re-emerges on the list during the next applicable period, CMS will apply the shortage reduction as if there were a continuous shortage and move to the applicable percentage for the next applicable period.[81] When the status of a shortage changes to resolved and either remains as resolved or is removed from the FDA list for at least one applicable period and then subsequently is listed on a shortage list, CMS will treat the subsequent shortage as a new shortage and the applicable percent reduction for the first applicable period will apply.[82]

b) Severe Supply Chain Disruption for Generic Part D Rebatable Drugs and Biosimilars[83]

For a reduction on the basis of a severe supply chain disruption for a generic Part D rebatable drug or a biosimilar, a manufacturer must submit to CMS a written rebate reduction request, which must be granted for the reduction to occur. CMS established the following evaluation criteria for granting a reduction:

- A severe supply chain disruption has occurred during the applicable period;
- The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the biosimilar or the generic drug; and
- The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

[80] *Id.* § 428.301(b)(2); *see supra* note 23 and accompanying text.
[81] 89 Fed. Reg. 98,298.
[82] *Id.*
[83] 42 C.F.R. § 428.302.

The definitions of severe supply chain disruption, natural disaster, and other unique or unexpected event are the same as those for Part B rebate reductions.[84]

Information to substantiate the evaluation criteria must be submitted as part of a request for reduction, which must be submitted within 60 days after the natural disaster or unexpected event occurred or began.[85] According to guidance provided on CMS's website, a manufacturer should email CMS of its intent to seek a reduction, and CMS will email the manufacturer the relevant form and instructions providing the necessary information securely. CMS will apply a severe supply chain disruption rebate reduction to the applicable period in which the event occurred or began (or the following applicable period if the request is submitted less than 60 calendar days before the end of an applicable period) and the three subsequent applicable periods.[86] CMS will apply this rebate reduction at the NDC-9 level, even if the disruption affected only one NDC-11 in an NDC-9 family.[87]

As with Part B rebate reductions, CMS will review all rebate reduction requests within 60 days after receipt of all documentation, if feasible. No guidance is provided as to what factors determine if the timeline for response is feasible.

If a rebate reduction is granted, as noted in the table above, CMS will reduce the total rebate amount owed by the manufacturer by 75% for the first applicable period. Upon request by a manufacturer, CMS could extend the reduction of 75% for an additional applicable period. The request must be made at least 60 calendar days before the beginning of the second applicable period. CMS will apply any reduction of the rebate amount at the NDC-9 level.

CMS does not apply multiple rebate reductions for the same drug and applicable calendar quarter.[88] If a generic Part D rebatable drug or a biosimilar that is granted a reduction as a result of a severe supply chain disruption is also currently in shortage, the reduction will be based only on the severe supply chain disruption.[89]

A CMS denial of a rebate reduction request is final and not subject to an appeals process. CMS keeps confidential as a trade secret or confidential commercial or financial information if it determines that the information meets the requirements set forth in Exemptions 3 and/or 4 to the Freedom of Information Act.

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[84] *Id.* § 428.300.
[85] *Id.* § 428.302.
[86] *Id.* § 428.302(b)(1).
[87] *Id.* § 428.302(b)(3).
[88] *Id.* § 428.302(b)(4).
[89] *Id.* § 428.302(b)(4)(iii).

c) Generic Part D Rebatable Drugs Likely to be in Shortage[90]

This third ground for a rebate reduction—a drug likely to be in shortage—is only applicable to a generic Part D rebatable drug. As with a reduction for a severe supply chain disruption, a manufacturer must submit to CMS a written rebate reduction request, which must be granted for the reduction to occur. CMS has established the following evaluation criteria for granting a reduction:

- The generic Part D rebate drug is likely to be in shortage;
- The manufacturer is taking actions to avoid the potential drug shortage; and
- The reduction of the rebate amount would reduce the likelihood of the drug appearing on the FDA shortage list.

"Likely to be in shortage" is defined as a generic Part D rebatable drug that is likely to be described as currently in shortage during a subsequent applicable period without such rebate reduction.[91] CMS notes in the preamble that it does not intend to consider a drug as likely to be in shortage based solely upon the drug being currently in shortage.

The process and timing for rebate reduction requests on this basis are the same as those for severe supply chain disruptions. As with severe supply chain reductions, CMS limits the likely-to-be-in-shortage rebate reduction to two consecutive applicable periods per CMS determination of likelihood of shortage.

If CMS grants a likely-to-be-in-shortage rebate reduction for a drug that is currently in shortage for the same applicable period, CMS applies the higher 75% reduction to the entire applicable period for which the likely to be in shortage request was granted and does not grant any additional reduction for the shortage status during that applicable period. For any subsequent applicable periods when the drug appears as currently in shortage, CMS reduces the total rebate amount as directed for drugs currently in shortage. The preamble provides the following example:[92]

- CMS grants a likely to be in shortage rebate reduction request that was submitted on August 15, 2024 for the applicable period of October 1, 2024 – September 30, 2025.
- That drug is currently in shortage from September 15, 2025 – May 15, 2026.
- CMS will apply a 75% likely in shortage reduction for the applicable period of October 1, 2024 – September 30, 2025 and then apply the shortage reduction

[90] *Id*. § 428.303.
[91] *Id*. § 428.300.
[92] 89 Fed. Reg. 98,302.

beginning with a reduction of 75% for the applicable period beginning October 1, 2025.

If a drug is currently in shortage, and the manufacturer of such drug believes that it is likely to continue to be in shortage in the next applicable period, the manufacturer may submit a likely to be in shortage request to CMS. CMS will grant such a request and reduce the total rebate amount by 75% if it determines the criteria are met.[93]

D. Rebate Reports and Payment Process[94]

For applicable periods beginning on October 1, 2024, CMS will provide each manufacturer of a Part D rebatable drug—even if their rebate amount due is $0—a Preliminary Rebate Report at least one month prior to the issuance of a Rebate Report for a rebate period.[95] CMS explained that this step is intended to provide manufacturers additional notice and an opportunity to review the data for mathematical errors, and facilitate their understanding of the report.[96]

A Preliminary Rebate Report will include information about each Part D Rebatable Drug (e.g., NDCs, benchmark period CPI-U, payment amount benchmark period, and manufacturer price); the applicable period sales information (number of units dispensed under Part D, CPI-U, and AnMP for the Part D Rebatable Drug for the applicable period); the rebate due (the amount of excess AnMP for the applicable period payment amount, if any, and the inflation-adjusted rebate amount, including any applied reductions due to drug shortages or supply chain disruptions).[97] If the Part D rebatable drug is a line extension, the Preliminary Rebate Report will also include the NDC and the inflation rebate amount ratio for the initial drug, and the alternative total rebate.

CMS will provide each manufacturer a Rebate Report no later than nine months after the end of each applicable period, which will have the same information as the Preliminary Rebate Report as well as any revisions based on CMS's reconciliation or any manufacturer's Suggestions of Error.[98] The Rebate Report will act as the invoice of the manufacturer's rebate amount due.

Unlike the Part B inflation rebate program, the statute at 42 U.S.C. § 1395w-114b(b)(6) requires the Part D Inflation Rebate Program to provide a process to adjust the calculation of the rebate amount when necessary based on manufacturer updates of sales information (e.g., the number of units dispensed) or restatements of pricing information

[93] *Id.*
[94] 42 C.F.R. §§ 428.400–428.405.
[95] *Id.* § § 428.401(b)..
[96] 89 Fed. Reg. 98,305–306.
[97] 42 C.F.R. § 428.401(b)(1).
[98] *Id.* § 428.401(c).

(e.g., AMP), and to reconcile any underpayments in the rebate amount paid by the manufacturer due to such adjustments no later than 30 days after the date of receipt of information from CMS about such adjustments. To fulfill this statutory obligation, CMS established a reconciliation process to promote the accuracy of the rebate amount for each drug for each applicable period. CMS provides for two "regular" reconciliations—at 12 months and at 36 months after the issuance of the Rebate Report—in which it will reconcile the amounts reflected in a Rebate Report.[99] CMS noted that the 12-month and 36-month reconciliation period could help fully capture revised units: the 12-month reconciliation will capture the majority of the updates. whereas the second reconciliation process will capture the run-out for MDRP AMP restatements.

CMS's reconciliation process 12 months and 36 months after the Rebate Report also makes adjustments based on updated claims or payment data; CMS errors; or manufacturers' Suggestions of Error with which CMS agrees. CMS may also reconcile the amount due if the Agency determines, at any time, that the information used by CMS to calculate the rebate was inaccurate due to manufacturer misreporting (e.g., if the manufacturer has made a correction to previously submitted data; the reporting entity knows or should know that the information is inaccurate or misleading; or CMS becomes aware of manufacturer misreporting through DOJ or HHS-OIG enforcement investigations).[100] CMS may exercise discretion not to recalculate the rebate amount in these situations which are outside of the regular reconciliation process proposed.[101]

Apart from certain exceptions for applicable periods beginning on October 1, 2022, and October 1, 2023, CMS will conduct a preliminary reconciliation of the rebate amount for each applicable period at least one month before issuing either report with the reconciled rebate amount. The preliminary reconciliation will update, as applicable, the total number of rebatable units; the payment amount benchmark period and benchmark period manufacturer price; inflation-adjusted payment amounts if any inputs are restated within the reconciliation run-out period; and other updates. CMS will also review the relevant manufacturers' Suggestions of Error, if any, before issuing a report with the reconciled rebate amount, which will be issued within 12 months and 36 months after the issuance of the Rebate Report.

CMS may also, in its discretion, recalculate a rebate amount and provide a reconciled rebate amount based on the Agency's identification of an agency error no later than five years after the date of receipt by a manufacturer of a reconciled rebate amount

[99] *Id*. § 428.401(d).
[100] 89 Fed. Reg. 98,269.
[101] *Id.*

for the applicable period; or, at any time, if a revision is necessary because of a manufacturer's misreporting.[102]

Applicable periods beginning on October 1, 2022 and October 1, 2023 have a different timeline, given that the statute allows CMS to delay the reporting for those two applicable periods until December 31, 2025.[103] The Rebate Report for the applicable periods beginning October 1, 2022 and October 1, 2023 will be issued by December 31, 2025, with the Preliminary Rebate Report issued at least one month before that. Manufacturers will have 30 calendar days (instead of the usual 10) to submit Suggestions of Error. The report for the applicable period beginning October 1, 2022 will be reconciled 21 months after the Rebate Report is issued, with 10 calendar days for manufacturers to submit Suggestions of Error, whereas the report for the applicable period beginning October 1, 2023 will be nine months and 33 months after the relative Rebate Report is issued, which will include 13 months and 37 months of claims run-out and payment data, respectively. CMS will not exclude 340B units before January 1, 2026.[104]

The Act precludes administrative or judicial review of the determination of units, or the calculation of the rebate amount (or a subsequent reconciliation of the rebate amount, if applicable) under this subsection.[105] Nevertheless, as under the Part B program, the Agency will allow manufacturers to "suggest" to CMS any errors the Agency may have made in the Rebate Report—or a subsequent reconciliation. The manufacturer may submit a "Suggestion of Error" regarding the information in the Preliminary Rebate Report and the preliminary reconciliation of the rebate amount, for the Agency to consider at its discretion.[106] Starting in the applicable period starting October 1, 2024, manufacturers will have 10 calendar days from the receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate amount to submit this Suggestion of Error. When CMS issues its Rebate Report or reconciled rebate amount, it will include any revisions to the calculation of the rebate amount based on the Suggestion of Error and notify the manufacturer of such revision. The preamble clarifies that the Suggestion of Error process is not an administrative dispute resolution process. The process is limited to mathematical steps involved in determining the rebate amount, and the elements precluded from administrative or judicial review are not considered in-scope for the process.

[102] 89 Fed. Reg. 98,309.
[103] 42 U.S.C. § 1395w-114b(a)(3).
[104] 89 Fed. Reg. 98,310–311.
[105] 42 U.S.C. § 1395w-114b(f).
[106] 42 C.F.R. § 428.403.

All rebates are due by the 30th calendar day after a manufacturer receives a Rebate Report or a report of a reconciled rebate amount.[107] The date of receipt is defined as the calendar day after a report of a rebate amount is made available to the manufacturer. A failure to timely pay the full rebate amount due could result in enforcement action, as described in the next section. Where a reconciled rebate amount is less than what the manufacturer paid, CMS will refund the total excess amount paid within 60 days after the receipt of the report with such reconciled rebate amount.

CMS established a standard method and process for manufacturers to access the Rebate Report, including any report of reconciled rebate amounts, submit Suggestions of Error, and pay the rebate amount.[108] As stated above, the manufacturer that is responsible for paying a rebate is identified using the same approach used for reporting AMP. This method and process may include an online portal administered by a CMS contractor. CMS intends to provide technical instructions separate from its rulemaking process to manufacturers of Part B rebatable drugs regarding how to access Rebate Reports and how to receive notifications alerting the manufacturer when information is available. CMS also intends to issue reminder notices to manufacturers regarding the due date of rebate payments.

E. Enforcement and Penalties[109]

Under the final rule, civil money penalties will function in the same way for both the Part B and Part D inflation rebate programs. The above discussion on CMS's rules related to enforcement and civil money penalties under the Part B rebate program applies equally to Part D.

However, because the Part D rebate program has two regular reconciliations, payment is due no later than 30 days after issuance of a report of a reconciled rebate amount for each reconciliation under Part D. Similarly, any civil money penalty is assessed before the next 12- or 36-month reconciliation.

* * *

Please contact Alan Kirschenbaum (202-737-4283, AKirschenbaum@hpm.com), Michelle Butler (202-737-7551, MButler@hpm.com), or Sophia Gaulkin (202-900-2805, SGaulkin@hpm.com) if you have any questions about the final rule.

[107] *Id.* § 428.405(a).
[108] *Id.* § 428.404.
[109] *Id*. § 428.500.

Summary of Part B and Part D Inflation Rebate Programs

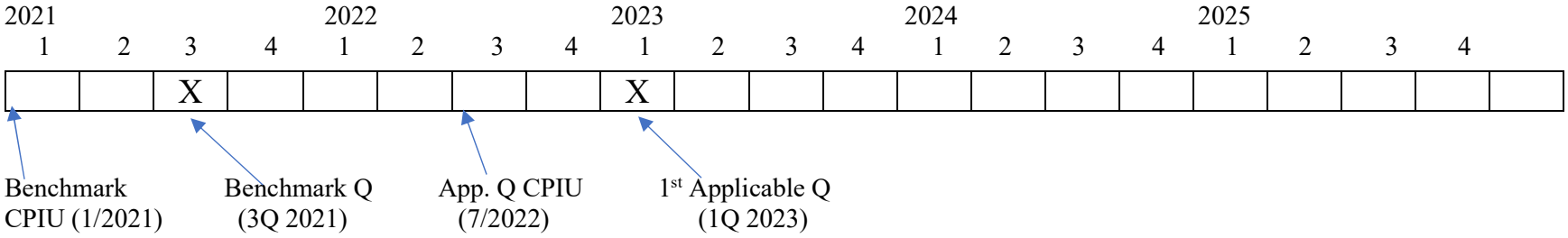
Feature	Part B	Part D
Drugs covered	NDA, BLA (including biosimilars)	NDA, BLA (including biosimilar), sole source ANDA[110]
Per-unit rebate amount	Rebate = (specified amount for applicable Q) – (benchmark Q payment amount x CPIU change)	Rebate = (AnMP for applicable period) – (benchmark period mfr. price x CPIU change)
First applicable period (for which rebates are due)	First applicable quarter = later of 1Q 2023 or 3rd Q after benchmark Q	Drug approved ≤ 10/1/2021: first applicable period = FY 2023[111] Drug approved > 10/1/2021: first applicable period = 1st FY after benchmark period
Benchmark period	Drug approved ≤ 12/1/2020: 3Q 2021 Drug approved > 12/1/2020: 3rd full Q after First Marketed Date	Drug approved ≤ 10/1/2021: 1Q–3Q 2021 Drug approved > 10/1/2021: 1st CY[112] after First Marketed Date
First Marketed Date	Date of first sale of any NDC-11 among all NDC-11s within a billing and payment code and approved under same application	Date of first sale by any manufacturer.
Prices that are compared	Applicable Q specified amount = For single source drug or biological: ASP+6% For biosimilar: ASP+6% of reference biological ASP Benchmark Q payment amount = published Part B payment limit for the quarter	Applicable period AnMP = weighted average of the 4 qAMPs in the applicable period Benchmark period mfr. price = weighted average of the 3 or 4 qAMPs in the benchmark period.
Applicable period CPIU	CPIU for 1st month of second Q before applicable quarter	CPIU for October of the applicable period
Benchmark period CPIU	Drug approved ≤ 12/1/2020: CPIU for January 2021 Drug approved > 12/1/2020: CPIU for 1st month of 1st full Q after First Marketed Date	Drug approved ≤ 10/1/2020: CPIU for January 2021 Drug approved > 10/1/2020: CPIU for January of benchmark period
Rebate reports (invoices)	2023 and 2024: by 9/30/2025 Subsequent years: 6 months after end of applicable Q.	FY 2023 and FY 2024: by 12/31/2025 Subsequent FYs: 9 months after applicable period
Reductions available	Currently in shortage; severe supply chain disruption	Currently in shortage; severe supply chain disruption of a generic or biosimilar; generic drug likely to be in shortage

[110] "Sole source ANDA" means that the reference listed drug (or any authorized generic of it) is no longer being marketed, no A-rated therapeutic equivalent is being marketed, and the ANDA drug has no exclusivity.
[111] "FY" = October 1 through September 30 of the following year (federal government fiscal year).
[112] "CY" = calendar year.

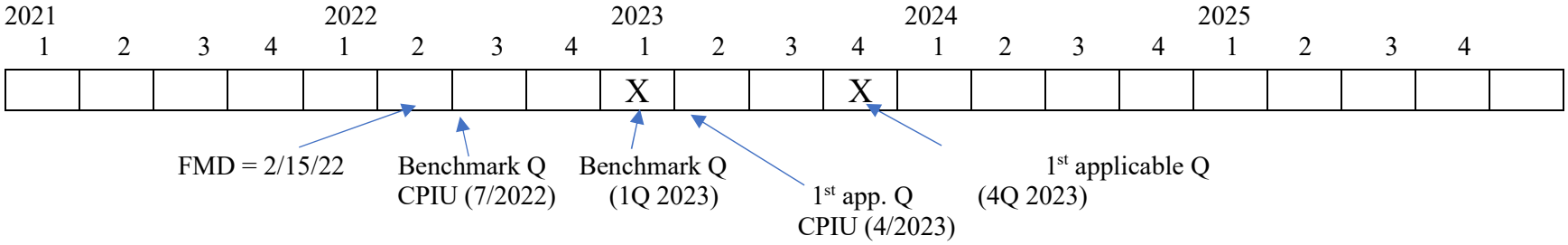
EXAMPLES

Part B

Drug approved on or before 12/1/2020:

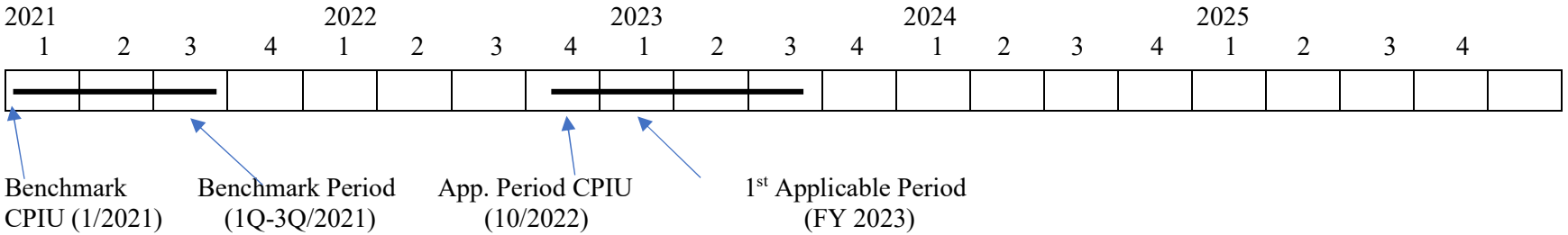


Drug approved after 12/1/2020:



Part D

Drug approved on or before 10/1/2021:



Drug approved after 10/1/2021: