



## **CENTER FOR MEDICARE**

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**DATE:** February 9, 2023

**TO:** Pharmaceutical Manufacturers of Part D 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 D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of 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 pharmaceutical manufacturers as well as Medicare Part D Prescription Drug Plans (PDPs) and Medicare Advantage –Prescription Drug (MA-PD) plans (herein after referred to as Part D plan sponsors) regarding the payment by manufacturers of inflation rebates for the total units of Part D rebatable drugs that are dispensed under Part D and covered and paid for by Part D plan sponsors for each 12-month applicable period starting with the applicable period beginning October 1, 2022. An applicable period means a 12-month period beginning with October 1<sup>st</sup> of a year.

The requirements for this program are described in section 1860D-14B of the Social Security Act (herein referred to as “the Act,”) which was added to the Act by section 11102 of the Inflation Reduction Act (IRA) (P.L. 117-169). Section 1860D-14B(h) directs the Secretary to implement this program for 2022, 2023, and 2024 using program instruction or other forms of program guidance. In this memorandum, where noted, the Centers 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](mailto:IRAREbateandNegotiation@cms.hhs.gov) with the subject line “Medicare Part D Inflation Rebate Comments” by March 11, 2023.

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.

Pharmaceutical manufacturers that increase the price for a Part D rebatable drug faster than the rate of inflation (as measured by changes in the Consumer Price Index for all Urban Consumers,

CPI-U), as described in section 1860D-14B, are required to pay Part D drug inflation rebates to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for Part D rebatable drugs for each 12-month applicable period no later than 30 days after receiving an invoice from CMS.<sup>1</sup> The invoice will be sent no later than nine months after the end of each applicable period, except that CMS has the authority under section 1860D-14B(a)(3) to delay the timeframe for reporting the information and invoicing rebate amounts to manufacturers for the Part D drug inflation rebates until not later than December 31, 2025, for the first two applicable periods that occur beginning October 1, 2022, and October 1, 2023. At this time, CMS is not requiring manufacturers to enter into agreements with the Secretary of HHS for the implementation of this program. Pursuant to section 1860D-14B(f), there is no administrative or judicial review of determinations of units, the determination of whether a drug is a Part D rebatable drug, and the calculation of the rebate amount.

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<sup>1</sup> “Days” means calendar days unless otherwise specified in this memorandum.

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## 20. Overview

For each applicable period (a 12-month period beginning each October 1), manufacturers of Part D rebatable drugs will be responsible for paying inflation rebates for each dosage form and

strength of a Part D rebatable drug dispensed under Part D during these applicable periods, as applicable, no later than 30 days after receiving an invoice for these rebates from CMS. CMS intends to invoice manufacturers for such rebates not later than nine months after the end of each applicable period. Section 1860D-14B(d) of the Act requires that CMS use information submitted by certain entities in carrying out this section of the IRA. Specifically, the statute requires CMS to use information submitted by manufacturers under section 1927(b)(3), by states under section 1927(b)(2)(A), and by Part D plan sponsors.

Part D Rebatable Drug (see section 30): The statute defines a “Part D rebatable drug” to mean, with respect to an applicable period, a drug or biological that is a covered Part D drug as defined at section 1860D-2(e) (which has been defined at 42 CFR 423.100), and, as of the first day of the applicable period, is a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a biological licensed under section 351 of the Public Health Service Act (PHS Act), or is a drug approved under section 505(j) of the FD&C Act (if certain criteria are met), and as further described below.

The statute excludes from the definition of a “Part D rebatable drug” a drug or biological if the average annual total cost under Part D per individual that uses the drug is less than \$100 for the applicable period beginning October 1, 2022. The \$100 amount is increased by percentage increases in the applicable period CPI-U for subsequent applicable periods, as described below.<sup>2</sup>

Estimated Part D Drug Inflation Rebate Amount (see section 40): CMS intends to calculate the rebate amount separately for each dosage form and strength of a Part D rebatable drug (i.e., at the 9-digit National Drug Code, or NDC-9, level), and would calculate the total rebate amount to be paid by the manufacturer for each NDC-9 for an applicable period as the estimated amount equal to the product of two factors.<sup>3</sup> One factor in this rebate calculation is the amount by which the drug’s “annual manufacturer price”<sup>4</sup> (AnMP) for the applicable period (defined at section 1860D-14B(b)(2) and described in section 40.1) *exceeds* the “inflation-adjusted payment amount” for the drug (defined at section 1860D-14B(b)(3) and described in section 40.1).<sup>5</sup>

The AnMP is a multiple calendar quarter-weighted calculation based on the Average Manufacturer Price (AMP)<sup>6</sup> for the Part D rebatable drug, and the units of the drug sold in those

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<sup>2</sup> The “CPI-U” means the consumer price index for all urban consumers (United States city average) as published by the Bureau of Labor Statistics (<https://www.bls.gov/>). See section 1860D-14B(g)(5).

<sup>3</sup> This calculation is subject to the statutory provisions addressing shortages and severe supply chain disruptions, special treatment for new formulations, and reconciliation in the case of revised information. See sections 1860D-14B(b)(1)(A), (b)(1)(C), (b)(5)(B), and (b)(6).

<sup>4</sup> Annual Manufacturer Price (AnMP) is the price calculated for each dosage form and strength of a Part D rebatable drug for an applicable period by summing the products of the four calendar quarters of data for each applicable period of 1) each quarter’s AMP for the drug multiplied by 2) the quarterly units reported under section 1927 by the manufacturer for the drug, divided by the total number of units for the dosage form and strength of the drug for the applicable period reported by the manufacturer for the drug under section 1927. For drugs first approved or licensed after October 1, 2021, only three quarters of data would be used to calculate the AnMP (January through September) for the first applicable period after the drug is first marketed.

<sup>5</sup> Inflation-adjusted payment amount for a dosage form and strength of a Part D rebatable drug is determined by increasing the benchmark period manufacturer price by the percentage increase by which the applicable period CPI-U exceeds the benchmark period CPI-U. See section 1860D-14B(b)(3).

<sup>6</sup> Section 1860D-14(g)(6) defines Average Manufacturer Price (AMP) to have the meaning with respect to a Part D rebatable drug of a manufacturer given in section 1927(k)(1) with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. Average Manufacturer Price means, with respect to a covered outpatient drug of a manufacturer for a rebate

calendar quarters as reported by manufacturers under section 1927(b)(3). The AnMP is the average price that the manufacturer sold the Part D rebatable drug to retail community pharmacies over the 12-month applicable period, consistent with the definition at section 1927(k)(1)(A).

The “inflation-adjusted payment amount” for a dosage form and strength of a Part D rebatable drug for an applicable period is the “benchmark period manufacturer price”<sup>7</sup> for such dosage form and strength of the drug increased by the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U.<sup>8</sup> The benchmark period manufacturer price for a dosage form and strength of a Part D rebatable drug is also a multiple calendar quarter weighted average calculation, based on the AMP for the drug and the units sold of the drug in those calendar quarters. For Part D rebatable drugs first approved or licensed by FDA before October 1, 2021, the time period for establishing the benchmark period manufacturer price is the first three calendar quarters of 2021 (January through September).

The second factor is the total number of units of a dosage form and strength of a Part D rebatable drug dispensed under Part D and covered and paid for by Part D plan sponsors during the applicable period. CMS intends to determine the total number of units based on information reported to CMS by Part D plan sponsors on the Part D Prescription Drug Event (PDE) records for the 12-month applicable period. Beginning in 2026, the statute requires that Part D units that are subject to discounts under section 340B of the PHS Act, also known as the 340B Drug Pricing Program, be excluded from the total Part D units considered for purposes of calculating the Part D drug inflation rebates units. The statute does not require the exclusion of such 340B units from Part D rebatable drug units before this time, that is, 2026.

Transition Period for Billing of Rebates for First Two Applicable Periods (see section 50): The statute provides CMS a transition period for invoicing manufacturers for each Part D rebatable drug for the first two applicable periods (occurring between October 2022 and September 2023, and October 2023 through September 2024) until not later than December 31, 2025, as further described in section 50. Beginning with the applicable period beginning on October 1, 2025, the rebate invoice would be sent to manufacturers not later than nine months after the end of the applicable period. The invoice would report to each manufacturer: (1) the amount, if any, of the excess of the AnMP for each dosage form and strength of the drug for the applicable period compared to the inflation-adjusted payment amount for the dosage form and strength for the Part D rebatable drug for the applicable period; and, (2) the total rebate amount for each dosage form and strength of such Part D rebatable drug for an applicable period.

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period (calendar quarter), the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and, (ii) retail community pharmacies that purchase drugs directly from the manufacturer. See section 1927(k)(1).

<sup>7</sup> The “benchmark period manufacturer price” for a dosage form and strength of a part D rebatable drug and an applicable period is the sum of the products of the AMP with respect to each calendar quarter of the payment amount benchmark period and the ratio of the total number of reported units under section 1927(b)(3)(A)(iv) of such dosage form and strength of such part D rebatable drug with respect to each calendar quarter of the payment amount benchmark period to the total number of reported units under section 1927 of such dosage form and strength with respect to such payment amount benchmark period. See section 1860D-14B(b)(4).

<sup>8</sup> “Benchmark Period CPI-U” means the consumer price index for all urban consumers for January 2021. See section 1860D-14(g)(4).

Special Considerations in Calculating the Part D Drug Inflation Rebate Amount: As noted above, in determining the rebate amount for a dosage form and strength of a Part D rebatable drug for an applicable period, the statute provides that the rebate amount calculation is subject to the statutory provisions addressing drug shortages and severe supply chain disruptions, special treatment for new formulations, and reconciliation in the case of revised units information. See sections 1860D-14B(b)(1)(A), (b)(1)(C), (b)(5)(B), and (b)(6).

Additionally, the statute provides for the special treatment of certain drugs, including subsequently approved drugs, which are Part D rebatable drugs that are first approved or licensed by the Food and Drug Administration (FDA) after October 1, 2021, new formulations, and other considerations.

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

Treatment of New Formulations (see section 40.4): Under section 1860D-14B(b)(5)(B) that, in the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, CMS shall establish a formula to determine the rebate amount and the inflation-adjusted payment amount with respect to each such Part D rebatable drug and an applicable period consistent with the formula applied under section 1927(c)(2)(C) for a rebate period.<sup>9</sup>

Reduction or Waiver for Drug Shortages and Severe Supply Chain Disruptions (see section 40.5): The statute provides that CMS reduce or waive the rebate amount with respect to a Part D rebatable drug for an applicable period in three cases: (1) for a Part D rebatable drug that is described as currently in shortage on the FDA drug shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; (2) for a Part D rebatable drug that is a generic or biosimilar when CMS determines there is a severe supply chain disruption during an applicable period; and 3) for a generic Part D rebatable drug when CMS determines that without such a reduction or waiver in the rebate, the drug is likely to be described as in shortage on the FDA drug shortage list during a subsequent applicable period.

Reconciliation of Medicare Part D Drug PDE Units in Case of Revised Information (see section 50): The statute at section 1860D-14B(b)(6) also requires the establishment of a process for the

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<sup>9</sup> “Line Extension” is defined in statute at section 1860D-14B(b)(5)(B)(ii) to mean, “with respect to a Part D rebatable drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.” The same statutory term and definition are in section 1927(c)(2)(C) and is further defined in [Medicaid] regulation at 42 CFR 447.502, to mean, for a drug, a new formulation of the drug, but does not include an abuse deterrent formulation of the drug (as determined by the Secretary). “New formulation” is also defined at 42 CFR 447.502, to mean, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

reconciliation of Part D drug inflation rebates paid by manufacturers in situations where a Part D plan sponsor submits revisions to the number of units of the Part D rebatable drugs dispensed under Part D and covered and paid for by Part D sponsors for an applicable period, such that there is a need to reconcile overpayments or underpayments, as determined by CMS.

Civil Monetary Penalties for Non-Payment of Rebates (see section 60): Finally, pharmaceutical manufacturers that do not comply with the requirements to pay Part D drug inflation rebates as set forth at section 1860D-14B(a)(2) are subject to civil monetary penalties (CMPs) in an amount equal to 125 percent of the rebate amount for a drug for an applicable period.

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:

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

### **30. Identification of Part D Rebatable Drugs and Exclusions**

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

Section 1860D-14B(g)(1)(C)(ii) narrows the scope of Part D rebatable drugs approved under a 505(j) ANDA that may be subject to a Part D drug inflation rebate to certain cases where: (1) the reference listed drug approved under section 505(c) of the FD&C Act, including any “authorized generic drug” (as that term is defined in section 505(t)(3) of the FD&C Act), is not being marketed, as identified in the Food and Drug Administration's National Drug Code Directory (NDC Directory); (2) there is no other drug approved under section 505(j) of the FD&C Act that is rated as therapeutically equivalent (under the FDA's most recent publication of “Approved

Drug Products with Therapeutic Equivalence Evaluations”) and that is being marketed, as identified in FDA's NDC Directory; (3) the manufacturer is not a “first applicant” during the “180-day exclusivity period”, as those terms are defined in section 505(j)(5)(B)(iv) of the FD&C Act; and (4) the manufacturer is not a “first approved applicant” for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v) of the FD&C Act.

In order to evaluate whether a drug approved under a section 505(j) application would meet all of these criteria, CMS intends to use the Drugs@FDA database, the FDA’s Electronic “Orange Book,” and other sources to obtain the necessary information.<sup>10</sup> For example, with respect to identifying whether the reference listed drug or an authorized generic of the reference listed drug is being marketed, CMS intends to rely on information included in the FDA’s NDC Directory, per the statute.<sup>11</sup> Information included in the FDA Orange Book and the NDC Directory will help determine whether another therapeutically equivalent drug to the Part D rebatable generic drug is currently being marketed. To determine whether the manufacturer of the generic drug is a first applicant during the 180-day exclusivity period, or whether the manufacturer of the generic drug is a first approved applicant for a competitive generic drug therapy, CMS intends to consult with the FDA and refer to FDA website resources, including Drugs@FDA.

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

Section 1860D–14B(d)(1) of the Act specifies sources of information CMS shall use in carrying out the statutory section for Part D drug inflation rebates. One identified source of information that CMS must use is information submitted by manufacturers under section 1927(b)(3). Manufacturers are required to submit price and drug product information under section 1927 and their effectuated rebate agreements with the Secretary of HHS to participate in the Medicaid Drug Rebate Program (MDRP).<sup>12</sup> The Part D drug inflation rebate calculation will use data that manufacturers report under the MDRP, specifically the AMP data as defined in section 1927(k)(1) for each dosage form and strength of a drug, and the total number of units of the dosage form and strength of the drug that are reported each month that are used to calculate the monthly AMP. Manufacturers report these data to CMS for each dosage form and strength of a covered outpatient drug (COD) as defined in section 1927(k)(2)-(4) dispensed and paid for under the state plan.

Not every drug that may satisfy the definition of a Part D rebatable drug is marketed by a manufacturer that has an MDRP agreement in effect with the Secretary. As a result, information may not be reported under section 1927 for all Part D rebatable drugs, for purposes of calculating

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<sup>10</sup> Drugs@FDA: <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files>;  
Orange Book: <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>

<sup>11</sup> <https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory>

<sup>12</sup> Under the Medicaid Program, states may provide coverage of outpatient drugs as part of the medical assistance furnished to eligible individuals as an optional benefit as described in sections 1902(a)(10) and (a)(54) and 1905(a)(12) of Act. Section 1903(a) provides for federal financial participation (FFP) in state expenditures for these drugs. In general, for Medicaid or Part B payment to be made available for a covered outpatient drug, a manufacturer must enter into, and have in effect, a Medicaid National Drug Rebate Agreement (NDRA, or Agreement) with the Secretary of the Department of Health and Human Services (HHS) as set forth in section 1927(a). Additionally, in order to meet the requirement for a rebate agreement in section 1927(a), manufacturers must also meet the requirements of section 1927(a)(5), which require a manufacturer to enter into an agreement that meets the requirements of section 340B of the PHS Act, as well as section 1927(a)(6), which requires a manufacturer to enter into a master agreement with the Secretary of Veterans Affairs in compliance with [38 U.S.C. 8126](#) (see section 1927(a)(1)).

Part D drug inflation rebates under section 1860D-14B. Said differently, in cases where a Part D rebatable drug is marketed by a manufacturer that does not have an obligation to report pricing and drug product data under section 1927(b)(3), the manufacturer does not currently report information needed for CMS to be able to calculate Part D drug inflation rebates. Therefore, due to this operational issue, at this time, CMS intends that the Part D rebatable drugs of a manufacturer that does not have a Medicaid drug rebate agreement in effect with the Secretary under the MDRP would not be subject to Part D drug inflation rebates. CMS, however, intends to assess other means to collect this needed information and in order to subject the Part D rebatable drugs of such manufacturers to the required Part D inflation rebate in the future. CMS is soliciting comments on other sources for this information that would enable CMS to invoice manufacturers for Part D drug inflation rebates for Part D drugs of manufacturers that do not have a Medicaid drug rebate agreement in effect with the Secretary under the MDRP. In addition, certain drugs and biologicals are specifically excluded from the definition of COD under sections 1927(k)(2)(B) and (k)(3).<sup>13</sup> For example, vaccines are expressly excluded from the COD definition, and manufacturers with Medicaid drug rebate agreements participating in the MDRP are not required to report pricing and drug product information on such products and are not required to pay Medicaid rebates. As a result, Part D vaccines will be excluded from Part D drug inflation rebate calculations at this time.

Under either situation described above, if necessary reporting of manufacturer data does not occur, and thus the information required to calculate Part D drug inflation rebates is not available, no rebate amounts will be calculated for these Part D rebatable drugs and no rebates will be collected for the applicable period at this time.

CMS solicits comment on this approach and alternative approaches, specifically how to address the two situations noted above – one in which the manufacturer does not have an effectuated drug rebate agreement to participate in the MDRP, and the other, when a product may be specifically excluded from the definition of a COD and manufacturers may not be required to report pricing and drug product information on that product, which may be a Part D rebatable drug. CMS will carefully monitor how these exclusions from Part D inflation rebates may impact manufacturer behavior.

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

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

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<sup>13</sup> The definition of COD does not include, based on the limiting definition at section 1927(k)(3), a covered outpatient drug in situations where the COD is provided as part of, or as incident to and in the same setting, and for which payment may be made under title 1927, as part of payment for certain services, and not as direct reimbursement for the drug. Additionally, if a COD is not used for a medically accepted indication it is not a COD.

For purposes of this exclusion, and calculation of the statutory threshold, the “average annual total cost under [Part D] for such period per individual” would be calculated as follows:

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

CMS intends to define “individual who uses such a drug or biological” as each unique Medicare Part D beneficiary who was dispensed the Part D drug by a Part D plan sponsor during the applicable period. CMS intends to use the count of all such Part D Medicare beneficiaries to represent the number of individuals who use such drug or biological during the applicable period.

CMS intends to calculate the average annual total cost based on total gross covered drug costs for the Part D drug (at the NDC-9 level). CMS intends to divide the total gross covered drug costs for the drug by the number of unique Part D beneficiaries as described above that were dispensed the drug in that applicable year. CMS plans on using the PDE data that are available for the drug for October 1, 2022, through September 30, 2023, for this calculation for the first applicable period. Drugs that are determined to have an average annual total cost of less than \$100 per unique individual (who uses such a drug or biological) under Part D, will be excluded from the scope of Part D rebatable drugs for which Part D drug inflation rebates will be calculated for that first applicable period.

As noted below in section 40.3 of this memorandum regarding the treatment of Part D rebatable drugs that are first approved or licensed by FDA after October 1, 2021, the determination of whether the drug’s average annual total cost exceeds the threshold amount will be determined by first determining the average annual total cost under Part D based on the total gross covered drug

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<sup>14</sup> CMS intends to round any amount between \$0 and up to \$5 to \$0, and any amount between \$5.01 and up to \$10 to the next \$10.

costs for the drug for the applicable period that begins the next full applicable period after the drug is first marketed.

For example, if the Part D rebatable drug is first marketed in September 2023, total expenditures under Part D for the drug for the applicable period beginning October 1, 2024, would be used to determine whether the drug meets this exclusion for that rebate period. CMS plans to use this applicable period to determine the average annual total cost exclusion amount for the drug in this example because the payment amount benchmark period for a drug first marketed in September 2023 would be the first calendar year beginning after the day on which the drug is first marketed, which in this case would be calendar year 2024 (January through December). Moreover, in this example, rebates would be invoiced for the last three quarters of the applicable period after the payment amount benchmark period is established, which would be January 1, 2025, through September 30, 2025.

#### **40. Calculation of the Part D Drug Inflation Rebate Amount**

The Part D drug inflation rebate amount, as specified under section 1860D-14B(b) of the Act for each dosage form and strength of a Part D rebatable drug and applicable period is the estimated amount that is equal to the product of: (1) the total number of units of the dosage form and strength of each Part D rebatable drug dispensed under Part D and covered and paid by Part D plan sponsors during the applicable period; and, (2) the amount, if any, by which the AnMP for such dosage form and strength of such Part D rebatable drug for the applicable period *exceeds* the inflation-adjusted payment amount for the dosage form and strength of such Part D rebatable drug for the period, subject to certain considerations.<sup>15</sup>

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

The inflation-adjusted payment amount for a dosage form and strength of a Part D rebatable drug for an applicable period would be determined by increasing the benchmark period manufacturer price by the percentage by which the applicable period CPI-U, which is the CPI-U for the October month of the applicable period, exceeds the benchmark period CPI-U, which for drugs marketed on or before October 1, 2021, is the CPI-U for January 2021, and for drugs first approved or licensed after October 1, 2021, is the January CPI-U of the first calendar year

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<sup>15</sup> As noted elsewhere, this calculation is subject to the statutory provisions addressing shortages and severe supply chain disruptions, special treatment for new formulations, and reconciliation in the case of revised information. See sections 1860D-14B(b)(1)(A), (b)(1)(C), (b)(5)(B), and (b)(6).

"Rebate Amount" is expressly defined in section 1860D-14B(b) and is the estimated amount due to CMS from a manufacturer for each dosage form and strength of a Part D rebatable drug(s) for an applicable period, as applicable.

beginning after the drug is first marketed. The statute defines the applicable period CPI-U at section 1860D-14B(g)(5) to mean, with respect to an applicable period, the consumer price index for all urban consumers for the first month of such applicable period.

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

#### **40.1 Components of the Part D Drug Inflation Rebate Amount Calculation**

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

The amount by which the AnMP for each dosage form and strength of a Part D rebatable drug may exceed the inflation-adjusted payment amount would be determined by increasing the benchmark period manufacturer price by the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U, as defined below.

The primary data elements that would be used to calculate the Part D drug inflation rebates are AMP data reported under sections 1927(b)(3)(A)(i) and (ii) by manufacturers for each dosage form and strength of the drug, units data that are reported by manufacturers each month under section 1927(b)(3)(A)(iv) for each dosage form and strength of a drug, and PDE data for the total Part D units of the drug dispensed during the applicable period that are reported to the agency by Part D plan sponsors. The process by which each factor in the rebate amount calculation would be determined is described below and in section 70.

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

Under section 1927(b)(3)(A)(iv) of the Act, manufacturers report the total number of units used to calculate a covered outpatient drug's monthly AMP. The total units used for each quarter to calculate components of the AnMP and benchmark period manufacturer price will be the sum of the three months of units for the drug reported by the manufacturer. These AMP units that the manufacturers report represent the total units of a drug sold by the manufacturer for each month to retail community pharmacy purchasers as described under section 1927(k)(1)(A).

Manufacturers may include under certain circumstances non-retail community pharmacy sales units in the calculation of their AMPs for 5i AMP drugs as described in 42 CFR section 447.507.

CMS believes that these manufacturer-reported monthly AMP units under section 1927(b)(3)(A)(iv) would be the appropriate units to use in the calculation of the AnMP and the benchmark period manufacturer price for the Part D drug inflation rebates because using the total

units sold by the manufacturer for the dosage form and strength of the drug as reported will allow for the accurate calculation of both a weighted average AnMP as well as a benchmark period manufacturer price, as prescribed by the statute. CMS intends not to use the Medicaid units reported by states under section 1927(b)(2)(A) because these Medicaid units reported by the state only reflect units of the covered outpatient drug dispensed for which payment was made under the Medicaid state plan during the applicable calendar quarter, and not the total units of the drug sold by manufacturers to retail community pharmacy purchasers and wholesalers, which the manufacturer uses to calculate the AMP that is reported to CMS.

#### **40.1.2 Situations in Which Manufacturers Do Not Report Units**

It is possible that a manufacturer may not have sales or monthly units of a COD to report to the Medicaid Drug Program (MDP) system for a calendar quarter. This may occur because there may be a temporary interruption in sales of the COD, or there may be no sales immediately after the drug is first approved or licensed by FDA. In the case of a temporary interruption in sales because of a supply chain shortage or manufacturing issue, and the manufacturer has not been terminated from the MDRP such that the drug is no longer in the MDRP, under MDRP guidance, the manufacturer can report the prior quarter's AMP using "reasonable assumptions".<sup>16</sup> Given that no units would be reported, however, because of the lack of sales, that calendar quarter's data would not be used in calculating the AnMP or the benchmark period manufacturer price for the purposes of calculating Part D drug inflation rebates.

In the case of a subsequently approved drug, when there may not yet be any sales for a quarter, the MDRP also allows a manufacturer to make "reasonable assumptions" for the quarter with respect to pricing for their drug. Such assumptions must be documented and retained by the manufacturer. Given that no units may have been reported for a quarter, that quarter's data would not be used in calculating the AnMP or the benchmark period manufacturer price. If there are no sales of the drug for the entire payment amount benchmark period, the manufacturer's reported price using reasonable assumptions would be averaged over the calendar quarters of the payment amount benchmark period in order to determine the benchmark period manufacturer price. If there are sales reported for some of the calendar quarters in the benchmark period, only the quarters for which sales and units are reported would be used to calculate the benchmark period manufacturer price. If a manufacturer enters a termination date on a covered outpatient drug in the MDRP, the MDP automatically populates the next four quarters with the last AMP reported by the manufacturer for the dosage form and strength for the drug. CMS intends to only use the AMP for a calendar quarter in the calculation of an AnMP if there are units associated with the reporting of the AMP in the calendar quarter of an applicable period.

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<sup>16</sup> As noted in CMCS Manufacturer Release No. 78, dated June 26, 2007, and in regulation preamble (see Medicaid Program; Covered Outpatient Drugs Final Rule with Comment Period, 81 Fed. Reg. 5170 (CMS 2345-FC), February 1, 2016), in the absence of specific guidance, a manufacturer may make "reasonable assumptions" when reporting drug pricing and drug product data to CMS, provided that those assumptions are consistent with the requirements and intent of the Medicaid statute, federal regulations, the Medicaid National Drug Rebate Agreement (NDRA), and any relevant guidance issued by CMS. As noted in that Manufacturer Release, CMS requests that manufacturers not submit their reasonable assumptions to CMS, and should a manufacturer disregard those instructions and submit their assumptions, they will not be reviewed, and neither their receipt nor any subsequent inaction by CMS constitutes acquiescence by CMS to the submitted assumptions. Manufacturers must retain a record (written or electronic) outlining reasonable assumptions used in required reporting under the program as provided in the recordkeeping requirements at 42 C.F.R. section 447.510(f).

## **40.2 Steps to Calculate the Part D Drug Inflation Rebate**

The rebate amount that a manufacturer will be invoiced for with respect to each dosage form and strength of a Part D rebatable drug would be determined based on the following factors and steps:

### **40.2.1 Calculation of the AnMP**

Section 1860D-14B(b)(2) of the Act provides that the determination of an AnMP for a dosage form and strength of a Part D drug for an applicable period will be calculated as the sum of the products of: (1) the AMP for the dosage form and strength, as calculated by the manufacturer for a unit of such drug and reported to CMS by the manufacturer, for each calendar quarter of the applicable period (i.e., each of the four calendar quarters beginning with the calendar quarter beginning in October for Part D rebatable drugs that are first approved or licensed on or before October 1, 2021); and, (2) the ratio of the total units reported by manufacturers under section 1927(b)(3)(A)(iv) for each dosage form and strength for each calendar quarter of the applicable period to the total number of units of each dosage form and strength for all four calendar quarters in the applicable period (see formula in section 70.1).

Please note below in this section of the memorandum, and in the formula under section 70.2, that the calculation of the AnMP for a drug first approved or licensed after October 1, 2021, would only use three quarters of data rather than four quarters of data to establish the AnMP for the first applicable period. The three quarters that are used in calculating the AnMP for these drugs are the last three quarters of the applicable period that begins in the October of the year beginning after the drug is first marketed (January through September of that year after the drug is first marketed).

### **40.2.2 Calculation of Benchmark Period Manufacturer Price**

Calculating the rebate amount requires that a benchmark period manufacturer price as described at section 1860D-14B(b)(4) be determined for each dosage form and strength of a Part D rebatable drug. This is the price that would be increased by the percentage change in the applicable period CPI-U compared to the benchmark period CPI-U, and would become the inflation-adjusted payment amount as described at section 1860D-14B(b)(3).

The statute provides that such determination of the benchmark period manufacturer price be calculated as the sum of the products of (1) the AMP of such dosage form and strength, as calculated for a unit of such drug for each of the calendar quarters of the payment amount benchmark period,<sup>17</sup> and (2) the ratio of the total units reported by the manufacturer under section 1927(b)(3)(A)(iv) for each dosage form and strength for each calendar quarter of the payment amount benchmark period to units of each dosage form and strength for all four quarters in the payment amount benchmark period.

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<sup>17</sup> The payment amount benchmark period is defined at section 1806D-14B(g)(3) as the period beginning January 1, 2021, and ending in the month immediately prior to October 1, 2021. This payment amount benchmark period applies to Part D rebatable drugs that are first approved or licensed before October 1, 2021. Section 1860D-14B(b)(5)(A) provides that for Part D rebatable drugs that are first approved or licensed after October 1, 2021, the payment amount benchmark period is the first calendar year beginning the day on which the drug was first marketed.

There are different formulas that CMS would use to determine the benchmark period manufacturer price for Part D rebatable drugs that are first approved or licensed by FDA on or before October 1, 2021, and for Part D rebatable drugs first approved or licensed by FDA after October 1, 2021. (See sections 70.3 and 70.4 for description of the formulas referenced.)

- Benchmark Period Manufacturer Price for Part D Rebatable Drugs First Approved or Licensed On or Before October 1, 2021: As described above, the benchmark period manufacturer price would be calculated as the sum of the products of: (1) the AMP for the dosage form and strength of the drug for each of the three quarters (January through September 2021) reported by the manufacturer; and, (2) the total AMP units reported under section 1927(b)(3)(A)(iv) for each of the quarters divided by the total units reported for the three quarters.
- Benchmark Period Manufacturer Price for Part D Rebatable Drugs First Approved or Licensed After October 1, 2021: For Part D rebatable drugs first approved or licensed after October 1, 2021, the benchmark period manufacturer price would require a different calculation. (See further discussion in section 40.3 regarding Treatment of Subsequently Approved Drugs). CMS plans to use the four calendar quarters for the entire calendar year (January 1 to December 31) after the drug was first marketed,<sup>18</sup> using the same methods of calculations specified above. That is, the sum of the products of: (1) the AMP for the dosage form and strength of a drug for each calendar quarter in the payment amount benchmark period for the subsequently approved drug; and, (2) the total AMP units reported by the manufacturer under section 1927(b)(3)(A)(iv) for each of the corresponding quarters in the payment amount benchmark period divided by the total units reported for the four quarters.

The first applicable period after the benchmark period for these subsequently approved drugs would begin immediately after the payment amount benchmark period ends (i.e. December 31) and would extend from January 1 to September 30 of the year following the payment amount benchmark period. After the first applicable period, the regular applicable period, meaning a 12-month period beginning with October 1 of a year, as defined at section 1860D-14B(g)(7) would apply. For example, if a drug is first marketed in September 2024, the payment amount benchmark period would be based on the entire next calendar year, 2025, and the benchmark period manufacturer price would be determined using data from that payment amount benchmark period. The first applicable period for this drug, however, would begin January 1, 2026, and extend through September 30, 2026. The first full applicable period for this drug would be the 12-month applicable period that begins on October 1, 2026.

#### **40.2.3 Calculation of Inflation-Adjusted Payment Amount**

The inflation-adjusted payment amount for a dosage form and strength of a Part D rebatable drug for an applicable period would be the benchmark period manufacturer price determined in section 40.2.2 above for each dosage form and strength for a Part D rebatable drug for an

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<sup>18</sup> Note that the date that the drug is first marketed would be the date that the manufacturer reports for the drug as its “market date” to the Medicaid Drug Rebate Program. See section 40.3.

applicable period *increased* by the percentage by which the applicable period CPI-U exceeds the benchmark period CPI-U. (See section 70.5)

- Determination of Applicable Period CPI-U: The statute requires that CMS use the CPI-U of the first month of the applicable period; that is, the CPI-U as of October of the applicable period, as the applicable period CPI-U.
- Determination of Benchmark Period CPI-U: The statute requires that CMS use the CPI-U value as of January 2021 as the benchmark period CPI-U; for drugs approved or licensed after October 2021, the statute provides that CMS use the January CPI-U of the calendar year beginning after the drug is first marketed as the benchmark period CPI-U.

#### **40.2.4 Calculation of the Per Unit Part D Rebate Drug Inflation Rebate Amount**

The statutory formula at section 1860D-14B(b) for the Part D drug inflation rebate amount indicates, in part, that the per unit rebate amount is the amount, if any, by which the annual manufacturer price for such dosage form and strength of such Part D rebatable drug for the applicable period *exceeds* the inflation-adjusted payment amount for the dosage form and strength of such Part D rebatable drug for the period.

In this regard, the actual per unit rebate amount for each dosage form and strength of a Part D rebatable drug would be the amount, if any, by which the AnMP for such dosage form and strength of a Part D rebatable drug for the applicable period calculated under section 40.2.1 *exceeds* the inflation-adjusted payment amount for the dosage form and strength of the drug calculated under section 40.2.3. (See section 70.6). For example, if the benchmark period manufacturer price is \$1.00 and the percentage increase in CPI-U is 4 percent, then the inflation-adjusted payment amount for the drug is \$1.04. If the AnMP is \$1.07 for the applicable period, then the manufacturer owes 0.03 cents for each unit of Part D drug that was dispensed during the applicable period.

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

The statute defines “units” as the lowest dispensable amount (such as tablet or capsule, milligram of molecules, or grams) of the Part D rebatable drug, as reported under section 1927(b)(3). Part D PDE data would be used to determine the total number of units of the Part D rebatable drug dispensed under Part D during each 12-month applicable period for the inflation rebate calculation.

From the PDE data, CMS intends to obtain the total number of units of the Part D drug from the field “Quantity Dispensed” for each dosage form and strength, and the NDC of the drug from the field “Product Service ID” for each 12-month applicable period. Units reported in the Quantity Dispensed field on the PDE record are industry standard National Council for Prescription Drug Programs (NCPDP) defined values of each, milliliter, and grams. The unit for each NDC is not reported on the PDE record, but this information is available on FDA’s Comprehensive NDC SPL Data Elements File (NSDE) in the “Billing Unit” field. In order to identify the NCPDP

billing unit for each NDC, CMS intends to crosswalk the information from the PDE record to the NSDE file matching on the NDC.

In contrast to how units are reported under Medicare Part D, manufacturers can report the AMP for their drugs in the MDP with 10 different unit types (e.g., each, capsule, tablet, suppository, transdermal patch, injectable anti-hemophilic factor, millicurie, microcurie, gram, and milliliter). Given the difference between how units are reported between the two programs, in order to calculate Part D drug inflation rebates, CMS intends to compare the Part D rebatable drug units reported in the PDE record to the units reported in MDP for the monthly AMP. Based on initial analyses, CMS expects that the majority of units of the dosage forms and strength of each Part D rebatable drug reported in the PDE record will match the AMP units reported.

However, in the limited instances where the units do not match, CMS intends to convert the total units reported from the PDE to the AMP units that are reported by the manufacturer for the drug under section 1927. For example, if an NDC is reported as a unit of “each” in the PDE record, and as a unit of “grams” to Medicaid, CMS intends to multiply the unit of “each” times the total “grams” for each unit to convert the PDE units to AMP units. For example, if the product is dispensed in a 10-gram tube and the PDE record has this recorded as a unit of “1” for “each,” this will be converted to “10” for the purposes of Part D drug inflation rebates to conform to the Medicaid units of “grams” for this product.

CMS is exploring the option of adding a field to the PDE file layout to collect how the amount reported in the PDE “quantity dispensed” field is measured (e.g., each, milliliter, gram). This additional data element would facilitate the identification of unit types for each NDC and add an additional level of assurance for CMS and manufacturers that the unit used to calculate inflationary rebates is accurate. CMS recognizes that requiring the plans to report a unit type for each Part D rebatable drug on the PDE record would create a new reporting burden, create possible opportunities for error, and would still require a conversion to the AMP units. CMS is soliciting comment on this option. As discussed in more detail below, beginning in calendar year 2026, the Part D rebatable drug units identified as having been filled with a 340B acquired drug would be removed from the total units of Part D rebatable drugs that will be subject to a rebate as provided under section 1860D-14B(b)(1)(B).

#### **40.2.6 Calculation of Total Rebate Amount to be Paid by the Manufacturers**

The Part D drug inflation rebate amount, as specified under section 1860D-14B(b) for each dosage form and strength of Part D rebatable drug and applicable period, is the estimated amount that is equal to the product of: (1) the total number of units of the dosage form and strength of the Part D rebatable drug dispensed under Part D during the applicable period determined under section 40.2.5; and, (2) the amount, if any, by which the annual manufacturer price for such dosage form and strength of such Part D rebatable drug for the applicable period *exceeds* the inflation-adjusted payment amount for the dosage form and strength of such Part D rebatable drug for the period determined under section 40.2.4. (See section 70.7)

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

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

The current NCPDP Telecommunications Standard Version D.0 for pharmacy claims does not require a pharmacy to identify which drugs that were dispensed were purchased at a discount under the 340B program. Although the standard does include a field where a 340B indicator could be provided,<sup>19</sup> it is optional for pharmacies to use, based on trading partner agreements. In addition, the standard specifies that the indicator can only be used prospectively, so a pharmacy that makes the retrospective determination that the drug was purchased at 340B pricing cannot apply the modifier retrospectively to the claim. The NCPDP does allow use of an “N1” transaction<sup>20</sup> to retrospectively identify drugs purchased under the 340B pricing, but CMS understands that few pharmacies use this transaction. Consequently, CMS does not currently require or even accept a 340B indicator on the PDE record.

CMS believes that requiring that a 340B indicator be included on the PDE record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D. This indicator would need to be included on all pharmacy claims where a drug subject to a 340B discount was dispensed to a Part D beneficiary so that units submitted on such claims can be excluded from the inflation rebate calculation.

CMS is soliciting comment on whether submission of the 340B identifier on the pharmacy claim is the preferred mechanism to identify 340B units dispensed in Part D, or if there is a better alternative. In other words, CMS is interested in ascertaining the most reliable way to identify Part D claims filled with 340B units so these associated units can be excluded from the determination of units of Part D rebatable drugs beginning in 2026 in accordance with the statute.

#### **40.3 Treatment of Subsequently Approved Drugs for Part D Drug Inflation Rebate Purposes**

Section 1860D-14B(b)(5)(A) of the Act prescribes a different payment amount benchmark period and benchmark period CPI-U for Part D rebatable drugs first approved or licensed by the FDA after October 1, 2021. As specified in section 1860D–14B(b)(5)(A), the payment amount benchmark period for drugs first approved or licensed after October 1, 2021, is “the first calendar year beginning after the day on which the drug was first marketed” and the benchmark CPI-U

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<sup>19</sup> A pharmacy would use the “20” submission clarification code (420-DK) to indicate use of a 340B drug at the time of the adjudication or dispensing of the claim. See National Council on Prescription Drug Program (NCPDP) 340B Information Exchange Reference Guide Version 2.0, June 2019.

<sup>20</sup> If it is determined that a 340B drug was dispensed after the claim has been adjudicated, then an N1 transaction can be submitted with the 420-DK submission.

period is “January of the first year beginning after the date on which the drug was first marketed.”

To identify the “first marketed” date, CMS intends to use the market date that the manufacturer is required to report under section 1927(b)(3)(A)(v). CMS acknowledges that this approach may apply a different definition of the first marketing date than would apply with respect to Part B rebatable drugs under section 1847A(i) but has preliminarily concluded that section 1860D-14B is intended to refer to the reporting systems that are already in place under section 1927.

Given that the payment amount benchmark period for a drug first approved or licensed after October 1, 2021 (January through December, the year after the drug is first marketed), overlaps in part with a part of the start of the next applicable period (October through December), for the purposes of invoicing for Part D drug inflation rebates, for the first calendar year beginning after the date when the drug is first marketed (January through December), the agency would calculate and invoice a rebate amount that does not include Part D units for the first calendar quarter of the applicable period (October through December). Units from the first calendar quarter of the applicable period will not be included in the total units that will determine the inflation rebates that would have to be paid by the manufacturer for that applicable period because of the one quarter overlap between the payment amount benchmark period and the applicable period for rebates, where the payment amount benchmark price is still being established during that last calendar quarter of the calendar year (but first calendar quarter of the applicable period).

For example, if a manufacturer reports that its market date for a Part D rebatable drug is a date in the month of September 2023, the statute establishes a payment amount benchmark period as the first calendar year beginning after the day the drug is first marketed. The benchmark period manufacturer price for this drug would be established based on the data reported for the payment amount benchmark period, calendar year 2024. With an applicable period beginning on October 1, 2024, CMS intends to not include Part D units of the dosage form and strength of the drug for the first quarter of the applicable period (October 1 through December 31, 2024) in the total rebatable units for the October 1, 2024, through September 30, 2025, applicable period. Only Part D rebatable drug PDE units for the period January 1, 2025, through September 30, 2025, would be included, and rebates would be invoiced not later than nine months after the end of this applicable period for the dosage form and strength of the drug for the applicable period.

In this example, the AnMP for the Part D rebatable drug for the applicable period would be calculated using the AMP and units reported by the manufacturers under section 1927(b)(3) for the last three quarters of the applicable period, January 1, 2025, through September 30, 2025. That is because there is a one quarter overlap between the payment amount benchmark period and the applicable period for rebates, given that the payment amount benchmark price is still being established during that last calendar quarter of the calendar year (i.e., the first quarter of the applicable period). For subsequent applicable periods, the Part D rebatable drug’s AnMP would be calculated under the normal course and would be based on the AMP and units for the four calendar quarters for the full applicable period, October 1 through September 30.

Figure 1 below provides a summary of data timelines for Part D inflation rebate calculations. This figure compares the data timeline for a Part D rebatable drug that is first approved on

December 1, 2021 (a date which is after October 1, 2021, the threshold for this data timeline), compared to a drug first approved on or before October 1, 2021.

**Figure 1: Timeline of Benchmark and Applicable Periods**

|  | 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 on or Before 10/1/2021             |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Applicable Period 1                              |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Average Total Allowed Charges Calculation Period |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Benchmark Period                                 |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Benchmark Period CPI-U                           |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Applicable Period 1 CPI-U                        |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| New Drug Marketed 12/1/2021                      |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Applicable Period 1                              |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Average Total Allowed Charges Calculation Period |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Benchmark Period                                 |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Benchmark Period CPI-U                           |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |
| Applicable Period 1 CPI-U                        |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |      |     |     |     |     |     |     |     |     |     |     |     |

#### 40.4 Treatment of New Formulations of Part D Rebatable Drugs

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

Section 1927(c)(2)(C) provides for an alternative rebate calculation for line extension drugs under the MDRP, and CMS has issued guidance on how this calculation is performed for these purposes.<sup>21</sup> Section 1860D-14B(b)(5)(B)(ii) further states that for a Part D rebatable drug, “the term line extension means a new formulation of the drug, such as extended-release formulation, but does not include abuse-deterrent formulations of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended-release formulation.” This language mirrors language in section 1927(c)(2)(C) which defines the term “line extension” using exactly the same language. Regulatory definitions of “line extension” and “new formulation” were adopted through rulemaking for the MDRP and can be found at 42 CFR section 447.502. These are the definitions that would be used for the purposes of identifying new formulations of Part D rebatable drugs.

For purposes of the MDRP, section 1927(c)(2)(C) sets out an alternative rebate calculation for line extension CODs, and in order to determine whether the alternative rebate calculation applies to a COD, the manufacturer is responsible for determining whether there is one or more CODs that can potentially be the initial COD on which to base the alternative rebate calculation. The manufacturer would be required to consider all potential initial CODs for a line extension

<sup>21</sup> <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/unit-rebate-amount-calculation-for-line-extension-drugs-with-example/index.html> <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/unit-rebate-amount-calculation-for-line-extension-drugs-with-example/index.html>

reported to the MDRP each calendar quarter, and identify in the MDP system the single initial COD for the calendar quarter that had the highest additional rebate ratio, which is calculated as the quotient of the inflation rebate amount for the initial drug as a percentage of the initial drug's AMP for the calendar quarter. This rebate ratio is then multiplied by the AMP of the line extension drug.<sup>22</sup> The total rebate amount calculated under section 1927(c)(2)(C)(ii) is compared to the total rebate amount calculated under section 1927(c)(2)(C)(iii) and the higher amount is the applicable rebate for the line extension drug under Medicaid.

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

In the second step, an alternative rebate inflation amount for the Part D rebatable line extension drug will be calculated consistent with the formula applied under section 1927(c)(2)(C) for line extension drugs under Medicaid. That is, CMS intends to determine an inflation rebate amount ratio for the initial drug identified by the manufacturer in the last quarter of the Part D drug inflation rebate applicable period (explained further below) by dividing the inflation rebate amount for that initial drug for the applicable period by the AnMP for that initial drug for the applicable period, as calculated under section 1860D-14B(b). The ratio will then be multiplied by the AnMP of the Part D rebatable line extension drug for the applicable period. (See section 70.8 for an explanation of the calculation.)

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

Note that Medicaid rebates are calculated quarterly, and a different initial drug may be identified for each quarter by the manufacturer for a particular line extension drug. Part D drug inflation rebates are calculated based on a 12-month applicable period, and CMS therefore needs to identify which Part D initial drug to use for the alternative rebate inflation amount calculation, in order to ultimately calculate the Part D drug inflation rebates for a Part D rebatable line extension drug. For consistency, CMS intends to use the initial drug identified by the manufacturer in the last quarter of the Part D rebate applicable period to identify the initial drug for the line extension drug alternative rebate calculation. CMS intends to use the last quarter of the Part D rebate applicable period to identify the initial drug for the line extension drug, since it

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<sup>22</sup> In Medicaid, the alternative rebate calculation also includes the basic rebate for a COD, as defined in section 1927(c)(1). No such basic rebate is calculated for Medicare Part D drug inflation rebates.

is possible that for the other quarters in the applicable period, a different initial drug was identified by the manufacturer. This last quarter of the applicable period is also being selected because it is the last quarter of the applicable period, and likely the quarter in which the highest price would be in effect on the initial drug(s).

To provide an example of how this calculation would work, a Part D rebatable line extension drug has an AnMP of \$3.00 per dosage form and strength for an applicable period, and the rebate inflation amount calculated is \$0.50 per unit by comparing the AnMP for the drug for the applicable period with the inflation-adjusted payment amount. The initial drug for this line extension drug that is identified by the manufacturer for the last quarter of the applicable period has a rebate inflation amount of \$1.50 calculated under section 1860D-14B and an AnMP of \$4.00 for the applicable period.

As discussed above, consistent with the alternative rebate calculation found at section 1927(c)(2)(C), CMS would calculate the ratio of the inflation rebate of the initial drug to the AnMP of the initial drug (in this case, \$1.50/\$4.00, which is 0.38), and apply that ratio to the AnMP of the line extension drug (0.38 X \$3.00), which is \$1.14. The inflation rebate amount based on the alternative inflation rebate amount calculation is greater than the inflation rebate on the line extension drug calculated under section 1860D-14B(b), thus the rebate per unit of the Part D rebatable line extension drug is \$1.14 rather than \$0.50. CMS is soliciting comment on this approach to applying the Part D drug inflation rebate to Part D rebatable line extension drugs.

#### **40.5 Reducing or Waiving the Rebate Amount for Part D Rebatable Drugs in Shortage and in Cases of Severe Supply Chain Disruptions**

The calculation of the estimated rebate amount for a dosage form and strength of a Part D rebatable drug and an applicable period is subject to section 1860D-14B(b)(1)(C) of the Act, which requires CMS to reduce or waive the rebate amount for a Part D rebatable drug and an applicable period in three distinct cases: (1) a Part D rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; (2) a generic Part D rebatable drug or biosimilar,<sup>23</sup> when CMS determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event; and, (3) a generic Part D rebatable drug, if CMS determines that without such a reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period.

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 Part D rebatable drug or biological in shortage for the purpose of avoiding an obligation to pay a rebate.

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<sup>23</sup> A generic Part D rebatable drug (described in section 1860D-14B(g)(1)(C)(ii)) is a drug approved under section 505(j) of the FD&C Act that meets certain circumstances outlined in subsections (g)(1)(C)(ii)(I)(IV); a biosimilar is defined as a biological product licensed under section 351(k) of the PHSA.

#### 40.5.1 Reducing or Waiving the Rebate Amount in the Case of a Part D Rebatable Drug Currently in Shortage on the FDA Shortage List

To determine when a Part D rebatable drug is described as currently in shortage on a shortage list under section 506E of the FD&C Act at any point during the applicable period, CMS intends to use the FDA drug and biological 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 Center for Biologics Evaluation and Research (CBER) maintain FDA’s drug and biological shortage lists (herein referred to as the “FDA drug shortage list” or “shortage list”) via web pages with current lists of the drugs within their respective jurisdictions that are in shortage.<sup>24</sup> CMS intends that, to be eligible for a reduction or waiver of a rebate amount for an applicable period, at least one NDC-11 for the Part D rebatable drug must have its shortage status be described as “current” on the shortage list during an applicable period and must not have its status be designated as “discontinued,” “to be discontinued,” or “resolved.”<sup>25</sup>

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 D rebatable drug that is on the shortage list as “current” at any point during an applicable period. Options that CMS is considering include:

- A variable reduction in the rebate amount by the length of time that a Part D rebatable drug is on the FDA drug shortage list as “current” during an applicable period (e.g., number of days on the list during the applicable period divided by number of days in the applicable period), 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 applicable period, then reduce that percentage reduction by half in the second applicable period, and then continue to reduce the percentage reduction by half every applicable period thereafter.); and
- A limited standard reduction in the rebate amount for any Part D rebatable drug on the FDA drug shortage list as “current” during an applicable period, 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 particularly soliciting comment on the following questions:

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<sup>24</sup> 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>.

<sup>25</sup> Given that drugs and biological on the FDA shortage lists are maintained at the NDC-11 level, and Part D rebatable drug inflation rebates are calculated at the NDC-9 level, CMS would crosswalk the NDC-11 Part D rebatable drug in shortage to the relevant NDC-9. Thus, if any NDC-11 under the NDC-9 appears on the FDA drug shortage lists, CMS intends to apply our reduction or waiver policy to all of the Part D rebatable drugs under the relevant NDC-9. CMS would closely monitor market data for the Part D rebatable drugs whose rebate is reduced to ensure the integrity of the application of this provision by the manufacturer.

1. How should CMS reduce or waive the rebate amount in the case of a Part D rebatable drug that is “current” on the shortage list?
2. How might CMS adjust the rebate amount in cases where not all of the NDC-11s for the Part D rebatable drug are “current” on the shortage list?
3. Are there specific types of Part D 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 needs and how CMS would identify such drugs?
5. Are there certain scenarios where CMS should consider a greater or lesser reduction, or a waiver (e.g., due to the Part D 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 D rebatable drug on the shortage list so as to avoid a rebate obligation?

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

Section 1860D-14B(b)(1)(C)(ii) of the Act requires CMS to reduce or waive the rebate amount for an applicable period in the case of a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during the applicable period, such as a severe supply chain disruption caused by a natural disaster, or other unique or unexpected event. 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 D rebatable drug by a manufacturer and affects the ability of the manufacturer to fill orders or meet expected demand for its product for at least 90 days. This definition would not include interruptions in manufacturing due to matters such as routine maintenance, failure to comply with good manufacturing practice requirements, or insignificant changes made in manufacturing process for the drug as 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 generic Part D rebatable drug or biosimilar to demonstrate that (1) a severe supply chain disruption has occurred during an applicable period, (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 generic Part D rebatable drug or biosimilar; 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 submit the following supporting documentation to CMS to substantiate these three criteria:

1. A copy of the formal notification the manufacturer submitted to the FDA of a severe supply chain disruption through the FD&C Act 506C notification process<sup>26</sup> or a copy of the 506E notification to [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov);
2. A brief explanation (in 500 total words or fewer) detailing the specifics of the severe supply chain disruption, including which specific dosage forms and strengths of the generic Part D rebatable drug or biosimilar are affected. In order to demonstrate that a severe supply chain disruption directly affects the manufacturer itself, or a supplier of an ingredient or packaging or method of shipping or distribution that the manufacturer uses to make or distribute the generic Part D rebatable drug or biosimilar has occurred during an applicable period, CMS would expect the manufacturer to submit supporting documentation to show a change in the production or distribution of the generic Part D rebatable drug or biosimilar that leads to significant reduction in the U.S. supply of product and affects the manufacturer's ability to fill orders or meet expected demand for the generic Part D rebatable drug or biosimilar for at least 90 days. The manufacturer should also document when it expects that the severe supply chain disruption will be resolved and when it expects supply of the product 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 a geographic 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 generic Part D rebatable drug or biosimilar that resulted in the 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, for example, 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 section 1860D-14B(b)(1)(C)(ii) would be required to be made within 60 days of the first day a natural disaster or other unique or unexpected event occurred. If the manufacturer makes the request within 60 days, the request includes all the supporting documentation described above, and CMS determines that the information submitted warrants a reduction or waiver (e.g.,

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<sup>26</sup> <https://www.fda.gov/media/136486/download>

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 that manufacturer's generic Part D rebatable drug or biosimilar during the applicable period in which the severe supply chain disruption occurred.

If a severe supply chain disruption continues into the next applicable period, the manufacturer would be required to submit updated information on the severe supply chain disruption and the continued impact on the availability of the generic Part D rebatable drug or biosimilar within 60 days of the start of the next applicable period. If available evidence, such as market sales data, suggests that the availability of the manufacturer's generic Part D rebatable drug or biosimilar in the marketplace has returned to normal during an applicable period, CMS may ask the manufacturer to provide 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 soliciting comment on the definitions included in this section for "severe supply chain disruption," "natural disaster," and "other unique or unexpected event." CMS is soliciting comment on what CMS' policy should be if a severe supply chain disruption occurs during the same applicable period that a generic Part D rebatable drug or biosimilar appears as "current" on the FDA drug shortage list during an applicable period. 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.

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

If CMS determines that without a reduction or waiver to the rebate amount for an applicable period, a generic Part D rebatable drug is likely to be described as in shortage on the shortage list authorized under section 506E of the FD&C Act during a subsequent applicable period, the statute requires CMS to reduce or waive the rebate amount for the generic Part D rebatable drug for an applicable period. This statutory provision does not apply to biosimilars.<sup>27</sup>

In cases where a manufacturer of a generic Part D rebatable drug believes the drug is likely to be described as in shortage on the shortage list in the subsequent applicable period, the manufacturer of the generic Part D rebatable drug would be required to submit the following to CMS:

1. An explanation of the potential future shortage and why the manufacturer believes the generic Part D rebatable drug is likely to be described as in shortage on the shortage list in the next applicable period;
2. Any correspondence with the FDA related to a potential shortage;
3. The anticipated length of the shortage or potential shortage;

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<sup>27</sup> Section 1860D-14B(b)(1)(C)(iii) applies to generic Part D rebatable drugs (as so described), which are described more fully in section 1860D-14B(b)(1)(C)(ii), as those general Part D rebatable drugs described in section 1860D-14B (g)(1)(C)(ii).

4. An explanation of the activities the manufacturer is taking to avoid the potential drug shortage; and
5. An explanation for how the reduction or waiver of the rebate amount would reduce the likelihood of the drug ending up on the drug shortage list.

A request for a reduction or waiver of the rebate amount based on the circumstances set out under section 1860D-14B(b)(1)(C)(iii) would need to be made during the applicable period, and at least 60 days before the start of the next applicable period in order to qualify for the reduction for the current applicable period. CMS intends to review the submitted information, along with available market data, to determine if the generic Part D rebatable drug is likely to be described as in shortage on the shortage list in the next applicable period.

For requests made with less than 60 days remaining in the applicable period, and if CMS finds that the circumstances set out under section 1860D-14B(b)(1)(C)(iii) are satisfied, CMS intends to apply any reduction or waiver of the rebate amount to the next applicable period. For example, if CMS receives a request before August 2, 2023, for a reduction or waiver of the rebate amount for a generic Part D rebatable drug and CMS determines that it is likely that the generic Part D rebatable drug will be in shortage for the next applicable period (beginning October 1, 2023) if the reduction or waiver of the rebate amount is not granted, CMS intends to reduce or waive the rebate amount for the period beginning on October 1, 2022, and ending on September 30, 2023. If CMS receives the request on August 2, 2023, or after, and if CMS finds that the circumstances set out under section 1860D-14B(b)(1)(C)(iii) are satisfied, CMS intends to reduce or waive the rebate for the following applicable period beginning on October 1, 2023, and ending on September 30, 2024. If a manufacturer would like CMS to consider a reduction or waiver for subsequent applicable periods, the manufacturer would need to resubmit all the required materials above to CMS with updated information on the likely future shortage for the generic Part D rebatable drug during the next applicable period. The 60 days allows CMS to review the submitted information and make a determination on the reduction or waiver.

In summary, if the manufacturer makes the request by the deadline described above, the request includes all the components listed above, and CMS determines that a reduction or waiver is warranted (e.g., CMS may review the impact on the supply of the drug through claims and other data or historical data on previous drug shortages under similar circumstances as reported by the manufacturer) then CMS intends to reduce or waive the rebate for that generic Part D rebatable drug for the applicable period during which the request was made in an effort to assist the manufacturer in preventing or averting the inclusion of the generic Part D rebatable drug on the shortage list.

CMS is soliciting comment on the amount and duration for a reduction or waiver of the rebate amount, and applicable timelines for such reduction or waiver in this scenario. Finally, CMS is soliciting comment on the supporting documentation discussed above.

## **50. Ensuring Integrity of Part D Drug Inflation Rebate Payments**

Manufacturers of Part D 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 Report, for an

applicable period or shall be subject to a CMP equal to 125 percent of the rebate amount specified for each such drug in the Rebate Report in addition to the rebate itself.<sup>28</sup> The CMP is discussed further in section 60 of this memorandum.

The statute provides CMS with a transition period for invoicing manufacturers for inflation rebates for each Part D rebatable drug for the first two applicable periods (October 1, 2022, through September 30, 2023, and October 1, 2023, through September 30, 2024) until not later than December 31, 2025. Beginning with the applicable period beginning on October 1, 2024, Rebate Reports would be sent to manufacturers not later than nine months after the end of the applicable period. Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, would be reported to manufacturers no later than December 31, 2025.

The Preliminary Rebate Report and the Rebate Report would identify: (1) the total number of units for each dosage form and strength for the Part D rebatable drug for the applicable period; (2) the amount, if any, of the excess of the AnMP for each dosage form and strength of the Part D rebatable drug for the applicable period (the amount calculated per section 40.2); and, (3) the rebate amount for each dosage form and strength of such Part D rebatable drug for the applicable period.

CMS intends that manufacturers would first receive a Preliminary Rebate Report, per section 50.1, and will have the opportunity to suggest certain calculation errors; as described in section 50.3, CMS may exercise discretion to review such suggestions.<sup>29</sup> Manufacturers would receive the Rebate Report with the rebate amount due to CMS as described in section 50.1.

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 50.2. Under section 1860D-14B(f) of the Act, the statute precludes administrative or judicial review of the determination of units under this program, the determination of whether a drug is a Part D 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.

## **50.1 Timing of Rebate Reports and Payment**

CMS intends to provide all manufacturers of Part D rebatable drugs with a Preliminary Rebate Report within 6 months of the end of each applicable period. Manufacturers would have 10 days from the date of receipt of a Preliminary Rebate Report to review and suggest any calculation errors as outlined in section 50.2 below. The Preliminary Rebate Report would include the NDC of a drug that has been determined to be a Part D rebatable drug for the applicable period, the

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<sup>28</sup> “Rebate Report” is the report that CMS intends to provide to all manufacturers of Part D rebatable drugs no later than nine months after the end of each applicable period that would include the information from the Preliminary Rebate Report, including the rebate amount owed for each dosage form and strength of a Part D rebatable drug(s), corrected for any calculation errors at the discretion of CMS through the calculation error process.

<sup>29</sup> “Preliminary Rebate Report” is the report that CMS would provide to all manufacturers of Part D rebatable drugs that would list each NDC of a drug that has been determined to be a Part D rebatable drug for the applicable period; the total number of units for each dosage form and strength for the Part D rebatable drug for the applicable period; the amount, if any, of the excess of the AnMP for each dosage form and strength of the Part D rebatable drug for the applicable period; and, the rebate amount for each dosage form and strength of such Part D rebatable drug for an the applicable period.

rebate amount that is due for the Part D rebatable drug, and the amount by which the AnMP exceeds the inflation-adjusted payment amount for the dosage form and strength of the Part D rebatable drug for the applicable period. Following the opportunity to identify potential calculation errors per section 50.2, as applicable, manufacturers would receive the Rebate Report, which would include the same data elements at the Preliminary Report. The Rebate Report serves as the invoice for the rebate amount due, if any, and would include the rebate amount for the NDC of a drug that has been determined to be a Part D rebatable drug for the applicable period. 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 following the day in which the Rebate Report was issued. For example, if the Rebate Report is posted on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the thirty-day payment period.

CMS expects to issue additional guidance regarding the form and manner in which Rebate Reports would be sent to manufacturers. If the manufacturer does not pay the rebate amount in full as indicated on the Rebate Report, CMS intends to initiate the civil monetary penalty (CMP) process (see section 60 of this memorandum).

Section 1860D-14B(d) requires that information submitted by manufacturers under section 1927(b)(3) be used for the purposes of carrying out this Part D drug rebate program. Because changes in manufacturer data reported under section 1927(b)(3) can occur over time, and consistent with section 1860D-14B(b)(6) authority to reconcile in the case of revised Part D unit data, CMS intends to perform a one-time true up recalculation to allow for the revisions (discussed below) to occur based on changes in data reported by manufacturers under section 1927(b)(3) or in the units reported by Part D Plan Sponsors.

CMS intends to conduct a restatement process to true-up rebate amounts for all manufacturers one year after the rebate amounts are invoiced via the Rebate Report to manufacturers, as described under sections 1860D-14B(b)(6), and (d), and as outlined in section 50.3 of this memorandum.<sup>30</sup> As noted above, the statute at section 1860D-14B(a)(3) provides for a transition period for reporting the information and invoicing rebate amounts to manufacturers for the Part D drug inflation rebates for the two applicable periods that occur beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

## **50.2 Restatements of PDE Units Reported and True-up Rebate Report**

Section 1860D-14B(b)(6) of the Act requires that CMS establish, in the case of revised information submitted by Part D plan sponsors relating to Part D units dispensed, a method and process for reconciliation of rebate amounts paid by the manufacturer; that is, a method and process for determining adjustments, if any, and reconciliation of any overpayments and underpayments. Any identified underpayments made by the manufacturers would be required to be resolved not later than 30 days after receipt of such underpayment information as contained in

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<sup>30</sup> CMS is defining the true-up rebate amount to mean the rebate amount due to CMS from a manufacturer of a Part D rebatable drug(s) for each dosage form and strength of a Part D rebatable drug(s) (or due to a manufacturer from CMS, if applicable) performed using the most updated data to capture any potential price and/or unit restatements of AMP data and revisions in reporting by Part D plan sponsors of the units dispensed after the rebate amounts were calculated, corrected for any calculation errors.

the True-Up Rebate Report from CMS. The True-Up Rebate Report is the report that CMS intends to provide to all manufacturers of Part D rebatable drugs using certain updated data to calculate the True-Up Rebate Amount, corrected for any calculation errors, no later than a year after Rebate Amounts are invoiced for an applicable period to Part D rebatable drug manufacturers.

- CMS intends to perform a single, subsequent reconciliation or “true-up” for each applicable period subject to Part D inflation rebates approximately one year after the Rebate Reports for the applicable period are sent to manufacturers of Part D rebatable drugs, and the rebate amounts have been paid. This true-up would be performed to capture any potential price and/or unit restatements of AMP data by manufacturers and revisions in reporting by Part D plan sponsors of the units dispensed that occurred after the rebate amounts were calculated and paid.
- CMS intends to also use the most updated data available to re-run the calculation of the benchmark period manufacturer price amount used for the Part D rebatable drugs in each applicable period’s rebate amount calculations. That is because the benchmark period manufacturer price for each drug is based on the drug’s reported AMPs for the applicable period, which may also have been subject to manufacturer reporting revisions.

The true-up process could result in an increase, decrease, or no change to rebate amounts owed by manufacturers of Part D rebatable drugs. Once calculated, CMS intends to provide Preliminary True-up Rebate Reports to all manufacturers of Part D rebatable drugs, as applicable.<sup>31</sup> The true-up amount (if applicable) would be subject to the same calculation error process as the rebate amount previously described in section 50.1. Once that process has taken place, CMS intends to issue a True-up Rebate Report that would contain the 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 a manufacturer, CMS intends to reconcile payments owed. CMS expects to issue additional information regarding reconciling potential overpayments in future guidance.

### Summary of Part D Drug Inflation Rebate Amount Reports and Deadlines

| Milestone  | Timing/Deadline  |
|--|--|
| <b>Part D Rebate – CMS must invoice manufacturers not later than 9 months after the end of applicable period</b> |  |
| Preliminary Rebate Report sent to Manufacturers  | No later than 6 months after the end of the applicable period  |
| Manufacturer Reviews   | Manufacturer suggestions of calculation errors should be submitted to CMS no later than 10 days following receipt of the Preliminary Rebate Report |
| Rebate Report sent to Manufacturers  | Not later than 9 months after the end of the applicable period   |

<sup>31</sup> “Preliminary True-up Rebate Report” is the report that CMS intends to provide to all manufacturers of Part D rebatable drugs using updated AMP data and revised Part D PDE units data to calculate the True-Up Rebate Amount.

|   |   |
|---|---|
| Manufacturer Rebate Payment Due (if applicable)                                 | No later than 30 days after receipt of the Rebate Report  |
| <b>Part D Rebate True-Up – One Year after Rebate Report is sent</b>             |   |
| Preliminary True-Up Rebate Report sent to Manufacturers<br>Manufacturer Reviews | Approximately 1 year after Preliminary Rebate Report is sent<br>Manufacturer suggestions of calculation errors should be submitted no later than 10 days following the receipt of the Preliminary True-Up Rebate Report |
| True-Up Rebate Report sent to Manufacturers                                     | Approximately one year after Rebate Report is sent  |
| Manufacturer True-Up Rebate Payment Due (if applicable)                         | No later than 30 days after receipt of the True-Up Report   |

### **50.3 Manufacturer Suggestions of Calculation Errors in Preliminary Rebate Reports and Preliminary True Up Reports**

Manufacturers of Part D rebatable drugs may provide CMS, for its discretionary consideration, with suggestions of calculation errors in their Preliminary Rebate Report and Preliminary True-Up Rebate Report for Part D drug inflation rebate amounts owed (as described in sections 50.1 and 50.2) 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 1860D-14B(a)(3) expressly provides for a limitation of administrative or judicial review, specifically providing that there shall be no such review of the determination of units under this program, the determination of whether a drug is a Part D rebatable drug, or the calculation of the rebate amount under this program. Because of this limitation on administrative and judicial review, CMS is not providing an administrative dispute process. Manufacturers of Part D rebatable drugs that owe an inflation rebate could submit a suggestion of a calculation error if they identify a mathematical error in the calculation by CMS or an exclusion of a Part D rebatable drug 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 suggestions of calculation errors may be submitted in future communication. CMS reserves discretion to review or consider these suggestions as appropriate. The rebate amount would be invoiced to manufacturers on the Rebate Report and/or True Up Rebate Report, as applicable, 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 True Up Rebate Report to avoid a CMP.

## **50.4 CMS Identification of Errors**

CMS reserves the right to update or change the rebate amount and true-up amount due from manufacturers for applicable periods based on any calculation errors, or misreporting of manufacturer pricing or product data under section 1927(b)(3) that CMS identifies at any point after each applicable period ends. This process is separate and distinct from the manufacturer calculation error process described above, but could occur during the calculation error process, after Rebate Report and True Up Rebate Report invoices are submitted to manufacturers, or after the rebate amount or true-up rebate amount is 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.

CMS is soliciting comments on section 50 of the memorandum regarding processes to ensure the integrity of the rebate amount determination process.

## **60. Enforcement of Rebate Amount Payments by Manufacturers: Civil Monetary Penalties**

A manufacturer of a Part D rebatable drug that has failed to comply with the requirement at section 1860D-14B(a)(2) to pay an inflation rebate amount equal to the amount invoiced for each dosage form and strength with respect to such drug for an applicable period as reported by CMS in the Rebate Report and/or True Up Rebate Report would be subject to a CMP. Section 1860D-14B(e) sets forth the formula for determining the CMP amount, which would equal 125 percent of the rebate amount calculated under section 1860D-14B(b) for each dosage form and strength of a Part D rebatable drug for an applicable period.

In accordance with section 1128A of the Act, CMS will provide notice to the manufacturer with information regarding the CMP, including the opportunity to request a hearing as outlined in section 1128A. The CMP notice will include:

- Basis for the CMP;
- CMP amount due;
- Deadline for the manufacturer to respond with a hearing request or submit CMP payment;
- Method to submit CMP payment(s); and
- Information on the right to request a hearing.

The manufacturer will have 60 days from the date of receipt of the CMP Notice to submit a written request for a hearing or pay the CMP. The date of receipt is defined as the calendar day following the day in which the CMP notice is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A will apply. As set forth in section 1128A(f), if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP funds will be deposited in accordance with section 1128A(f).

## 60.1 Applicability to Restatements

Manufacturers that owe an additional rebate amount as determined during the restatement process on the True Up Rebate Report, discussed in section 50.2 of this memorandum, must pay the amount due or be subject to a CMP. In such cases, sections 60 and 60.1 would apply to the true up rebate amount. CMS intends to consider CMPs paid during the original invoicing cycle as final and not impacted by true-up amounts determined during the restatement process. CMP action during the restatement period would apply only to the additional rebate amount owed relevant to that process.

CMS is soliciting comments on section 60 of the memorandum regarding procedures related to CMPs for the failure to pay a Part D drug inflation rebate.

## 70. Formulas

### 70.1 Calculation of the AnMP for a Part D Rebatable Drug First Approved or Licensed on or Before October 1, 2021, and Part D Rebatable Drugs First Approved or Licensed After October 1, 2021, Starting with the Second Applicable Period After First Marketing:

Sum of the products of:

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

### 70.2 Calculation of the AnMP for a Part D Rebatable Drug First Approved or Licensed After October 1, 2021, for the Initial Applicable Period for the Drug:

Sum of the products of:

(AMP for calendar quarter beginning January) *multiplied by* (units for January calendar quarter/total units for 9-month period) +  
(AMP for calendar quarter beginning April) *multiplied by* (units for April calendar quarter/total units for 9-month period) +  
(AMP for calendar quarter beginning July) *multiplied by* (units for July calendar quarter/total units for 9-month period)

### **70.3 Calculation of the Benchmark Period Manufacturer Price for Drugs First Approved or Licensed on or Before October 1, 2021**

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

### **70.4 Calculation of Benchmark Period Manufacturer Price for Drugs First Approved or Licensed After October 1, 2021- the First Full Year After the Drug Was First Marketed**

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

### **70.5 Calculation of Inflation-Adjusted Payment Amount**

For Drugs first approved or licensed on or before October 2021: Benchmark Period Manufacturer Price *multiplied by* (CPI-U October applicable period/CPI-U January 2021)

For Drugs first approved or licensed after October 1, 2021: Benchmark Period Manufacturer Price *multiplied by* (CPI-U October applicable period/CPI-U January of year after drug is first marketed)

### **70.6 Calculation of Per Unit Rebate Amount**

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

The amount by which the Annual Manufacturer Price (AnMP) for the Part D Rebatable Drug for the Applicable Period *exceeds* the Inflation Adjusted Payment Amount.

### **70.7 Calculation of Total Rebate Amount Owed by Manufacturer per Dosage Form and Strength of a Part D Rebatable Drug:**

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

## 70.8 Calculation of the Part D Rebatable Line Extension Drug Inflation Rebate

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

1. Rebate amount for the Part D rebatable line extension drug determined under section 1860D-14B; or
2. Rebate amount that is determined by dividing the rebate amount for the initial drug of the Part D rebatable drug that is a line extension of that drug calculated under section 1860D-14B (initial drug determined by identifying the initial drug listed in MDP for the last quarter of the applicable period) *by* the AnMP for the initial drug for the applicable period *multiplied* by the AnMP for the line extension drug for the applicable period.

### Comment Solicitation

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