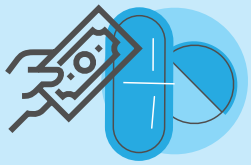
Frequently Asked Questions: Rebate Reductions under the Medicare Prescription Drug Inflation Rebate Program



In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law.

The IRA requires drug companies to pay a rebate if they raise their prices for certain drugs faster than the rate of inflation. This rebate is paid to Medicare and will be calculated and invoiced by the Centers for Medicare & Medicaid Services (CMS). The law establishes Medicare Part B prescription drug inflation rebates for single-source drugs and biologicals with prices increasing faster than the rate of inflation and provides for lower Part B beneficiary coinsurance on these drugs and biologicals. In addition, the law establishes Medicare Part D prescription drug inflation rebates for certain drugs and biologicals with prices increasing faster than the rate of inflation. Collectively, the program to implement these rebates is referred to as the Medicare Prescription Drug Inflation Rebate Program or the Inflation Rebate Program. CMS intends to update this list of questions and responses over time to provide information to the public. ***(Last Updated: July 19, 2024)***

Questions regarding this document may be directed to **IRARebateandNegotiation@cms.hhs.gov**.

Information on Process and Deadlines for Receiving a Rebate Reduction

Consistent with the IRA, CMS will reduce inflation rebates for certain Part B and Part D rebatable drugs as follows:

1. For Part B or Part D rebatable drugs when currently in shortage based on an FDA shortage list;
2. For Part B and Part D rebatable biosimilar biological products (hereinafter "biosimilars") and generic Part D rebatable drugs when CMS determines there is a severe supply chain disruption, such as that caused by a natural disaster or other unique or unexpected event, and
3. For generic Part D rebatable drugs when CMS determines that without a reduction, such drug is likely to be in shortage during a subsequent applicable period.

This document provides summary information to drug companies about the process and deadlines for receiving a rebate reduction in the above cases. CMS refers drug companies to the published **collection of information** approved under OMB control number 0938-1474, for more information. CMS also refers drug companies to the revised **Medicare Part B Drug Inflation Rebate Guidance** and the revised **Medicare Part D Drug Inflation Rebate Guidance**, which were published on December 14, 2023 and implemented policies relating to the Medicare Prescription Drug Inflation Rebate Program for 2022, 2023, and 2024. CMS has proposed to codify with limited modification the policies set forth in the Medicare Part B Drug Inflation Rebate Guidance and the revised Medicare Part D Drug Inflation Rebate Guidance, including policies related to rebate reductions for drug shortages, severe supply chain disruptions, and likely shortages, in proposed parts 427 and 428 of title 42, Chapter IV of the Code of Federal Regulations.[1] CMS intends that this FAQ reflect the policies established in revised guidance, as the proposed policies in the proposed rule remain subject to comment and change.

[1]CMS, Proposed Rule, "Medicare and Medicaid Programs: Calendar Year 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies," July 31, 2024.

Eligibility for a Rebate Reduction

Question: What products are eligible to receive a reduction in the inflation rebate amount?

Response: A Part B or Part D rebatable drug that is listed as currently in shortage on an FDA shortage list during a calendar quarter or 12-month applicable period, respectively, is eligible to receive a reduction in the rebate owed.

In general, eligibility for a potential rebate reduction under the "severe supply chain disruption" policy is limited to Part B and Part D rebatable biosimilars and generic Part D rebatable drugs for which a drug company submits a request to CMS.[2]

In general, eligibility for a potential rebate reduction under the "likely to be in shortage" policy is limited to generic Part D rebatable drugs for which a drug company submits a request to CMS.

Applying for a Rebate Reduction

Question: How can a drug company apply to receive a reduction in the inflation rebate amount for an eligible product?

Response: If a Part B or Part D rebatable drug is currently in shortage, drug companies are not required to submit a request to receive a rebate reduction. Instead, CMS will monitor the status of Part B and Part D rebatable drugs on the FDA shortage lists for the purpose of determining rebate reductions.[3] For Part B and Part D rebatable drugs on an FDA shortage list, the rebate reports (invoices) sent to drug companies will reflect the applicable percent reduction.

To receive a rebate reduction for a Part B or Part D rebatable biosimilar or a generic Part D rebatable drug when a drug company believes there is a severe supply chain disruption, the drug company generally must submit to CMS a **Severe Supply Chain Disruption Rebate Reduction Request**, in accordance with the published collection of information approved under OMB control number 0938-1474, demonstrating that:

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

For the purposes of applying rebate reductions, a "severe supply chain disruption" means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a Part B or Part D rebatable biosimilar or generic Part D rebatable drug by a drug company and significantly affects the ability of the drug company to fill orders or meet expected demand for the Part B or Part D rebatable biosimilar or generic Part D rebatable drug in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

[2]If CMS determines there is a severe supply chain disruption for an NDC-11, CMS will apply any reduction of the rebate amount to a Part D rebatable drug at the NDC-9 level. Similarly, if CMS determines there is a severe supply chain disruption for an NDC-11 assigned to a HCPCS code, CMS will apply any reduction of the rebate amount to all the NDCs under the relevant HCPCS code.

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

With limited exceptions, if CMS grants the request, the reduction in the rebate amount will generally apply for four calendar quarters starting with the quarter in which the event occurred, for a Part B biosimilar, and for the applicable period in which the event occurred, for a generic Part D rebatable drug or biosimilar. If a drug company believes a severe supply chain disruption continues into a fifth consecutive calendar quarter or second consecutive applicable period after the start of the natural disaster or other unique or unexpected event, the drug company may request an extension of the reduction of the rebate amount one time by submitting a **Severe Supply Chain Disruption Rebate Reduction Extension Request**.

To receive a rebate reduction when a drug company believes their generic Part D rebatable drug is likely to be in shortage in a subsequent applicable period, the drug company generally must submit to CMS a **Likely to be in Shortage Rebate Reduction Request**, in accordance with the published collection of information approved under OMB control number 0938-1474, demonstrating that:

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

For the purposes of applying rebate reductions, "likely to be in shortage" means a generic Part D rebatable drug is likely to be described as currently in shortage during a subsequent applicable period without such rebate reduction.

With limited exceptions, if CMS grants the request, the reduction in the rebate amount generally will apply for the applicable period in which the request is submitted. If a drug company believes a likely shortage continues into a second consecutive applicable period after the start of the first applicable period in which the generic Part D rebatable drug is likely to be in shortage, the drug company may request an extension of the reduction of the rebate amount one time by submitting a **Likely to be in Shortage Rebate Reduction Extension Request**.

To request a rebate reduction when a drug company believes there is a severe supply chain disruption or likely shortage, the drug company should first email **IRARebateandNegotiation@cms.hhs.gov** to indicate its intention to submit a request for a reduction in the rebate amount and specify whether the request is for a severe supply chain disruption or likely shortage. CMS will then provide the drug company with the relevant request form(s) and access to a Box folder, or alternative submission process approved by CMS, specific to the drug company's request, to allow for secure submission of the materials relating to the rebate reduction request.

Question: What are the deadlines for a drug company to submit a rebate reduction request?

Response: Drug companies are not required to submit rebate reduction requests for Part B and Part D rebatable drugs listed as currently in shortage on an FDA shortage list.

To receive a rebate reduction when a drug company believes there is a severe supply chain disruption, a drug company must submit to CMS a **Severe Supply Chain Disruption Rebate Reduction Request** form and supporting documentation as follows:

- No later than 11:59 pm Pacific Time (PT) on October 1, 2024 for a natural disaster or other unique or unexpected event that occurred or began on or after January 1, 2023 but before August 2, 2024 for a Part B rebatable biosimilar.
- No later than 11:59 pm PT on October 1, 2024 for a natural disaster or other unique or unexpected event that occurred or began on or after October 1, 2022 but before August 2, 2024 for a generic Part D rebatable drug or biosimilar.

- Within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began for a natural disaster or other unique or unexpected event that occurs or begins on or after August 2, 2024 for a Part B rebatable biosimilar or generic Part D rebatable drug or biosimilar.

A **Severe Supply Chain Disruption Rebate Reduction Extension Request** form and any new supporting documentation must be submitted at least 60 calendar days before the start of the second applicable period in order for CMS to consider a rebate reduction extension. The exception to this is if the initial request is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began. In these cases, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of the applicable period in which the initial reduction is applied.

To receive a rebate reduction when a drug company believes their generic Part D rebatable drug is likely to be in shortage, the drug company must submit to CMS the **Likely to be in Shortage Rebate Reduction Request** form and supporting documentation before the start of the next applicable period in which the generic Part D rebatable drug is likely to be in shortage for CMS to consider a rebate reduction. Specifically,

- For complete requests submitted at least 60 calendar days before the start of the next applicable period in which the generic Part D rebatable drug is likely to be in shortage, CMS will apply any reduction of the rebate amount during the applicable period in which the request is submitted.
- For complete requests submitted with less than 60 calendar days remaining in the applicable period, CMS will apply any reduction of the rebate amount during the next applicable period in which the generic Part D rebatable drug is likely to be in shortage.

A **Likely to be in Shortage Rebate Reduction Extension Request** form and any new supporting documentation must be submitted at least 60 calendar days before the start of the second applicable period in which the drug company believes the generic Part D rebatable drug is likely to be in shortage in order for CMS to consider a rebate reduction extension.

CMS Decisions on Rebate Reduction Requests

Question: How will a drug company know if their rebate reduction request was granted?

Response: CMS will notify a drug company via email from **IRARebateandNegotiation@cms.hhs.gov** as to whether their rebate reduction request for a severe supply chain disruption or likely shortage was granted or denied. If a drug company elects to submit one rebate reduction request for multiple affected products, CMS may grant the reduction request for some products in the request and deny the reduction request for others. In these cases, a drug company may receive one email for all the products listed in the request or separate emails for products for which the request was granted and denied. In addition, the rebate reports (invoices) sent to drug companies by CMS also will reflect the applicable percent reductions.

Question: Can a drug company appeal CMS' decision to deny a rebate reduction request?

Response: Consistent with the statute's limitation on administrative or judicial review, CMS' decisions to deny a rebate reduction request are final and will not be subject to an appeals process.

Limitations on Rebate Reductions

Question: Can a drug company qualify for multiple rebate reductions for the same product during the same time period?

Response: CMS will not apply multiple reductions for the same Part B rebatable drug and calendar quarter or the same Part D rebatable drug and 12-month applicable period. For example, if a drug company believes a generic Part D rebatable drug is eligible for a rebate reduction under the severe supply chain disruption policy and the

likely to be in shortage policy for the same event and calendar quarter or applicable period, the drug company should submit a rebate reduction request under the policy they believe best aligns with their circumstances. If a drug company submits multiple rebate reduction requests for the same Part B or Part D rebatable drug and calendar quarter or applicable period, CMS would grant no more than one rebate reduction for such drug and calendar quarter or applicable period. CMS refers drug companies to the revised **Medicare Part B Drug Inflation Rebate Guidance** and the revised **Medicare Part D Drug Inflation Rebate Guidance**, as well as the published **collection of information** approved under OMB control number 0938-1474, for more information about the requirements for submitting and receiving a rebate reduction request under each of these policies.

Differences between Rebate Reduction Requests Submitted to CMS and Notifications Regarding Drug Shortages and Manufacturing Interruptions Submitted to FDA

Question: How do the rebate reduction requests submitted to CMS differ from notifications submitted to FDA regarding drug shortages and manufacturing interruptions?

Response: As instructed by the IRA, CMS will use the FDA shortage lists maintained on the webpages of the FDA Center for Drug Evaluation and Research (CDER) and FDA Center for Biologics Evaluation and Research (CBER) to determine whether to reduce the rebate amount for a Part B or Part D rebatable drug that is currently in shortage during a calendar quarter or 12-month applicable period, respectively. The IRA does not instruct CMS to use the FDA shortage lists in making determinations regarding severe supply chain disruptions or likely shortages. As such, CMS considers severe supply chain disruptions and likely shortages to be generally distinct from current drug shortages identified on FDA's shortage lists for purposes of providing a rebate reduction for an eligible drug or biological product and will not use these lists to determine whether there is a severe supply chain disruption or likely shortage.

While certain information that must be submitted to CMS as part of a rebate reduction request for the Medicare Prescription Drug Inflation Rebate Program may overlap with the requirements for submitting notices to FDA related to drug and biological product discontinuances and manufacturing disruptions ("506C notifications"), the CMS criteria for determining whether a request qualifies for a rebate reduction differ from the requirements for submission of a 506C notification to FDA. In addition, CMS does not have access in the ordinary course to the information in 506C notifications.

Overview of Rebate Reduction Request Process and Deadlines

	Drug Shortage	Severe Supply Chain Disruption	Likely to be in Shortage
Eligibility for a Rebate Reduction	Part B or Part D rebatable drug	Part B or Part D rebatable biosimilar or generic Part D rebatable drug for which a drug company submits a request to CMS	Generic Part D rebatable drug for which a drug company submits a request to CMS
Process to Request a Rebate Reduction	No request required CMS will monitor the FDA shortage lists	A drug company must email CMS and submit a Severe Supply Chain Disruption Rebate Reduction Request, or Extension Request, and all supporting documentation in accordance with the published collection of information approved under OMB control number 0938-1474	A drug company must email CMS and submit a Likely to be in Shortage Rebate Reduction Request, or Extension Request, and all supporting documentation in accordance with the published collection of information approved under OMB control number 0938-1474
Deadline for Initial Request		No later than 11:59 pm PT on October 1, 2024 for a natural disaster or other unique or unexpected event that occurred on or after January 1, 2023 but before August 2, 2024 for a Part B rebatable biosimilar, or on or after October 1, 2022 but before August 2, 2024 for a generic Part D rebatable drug or Part D rebatable biosimilar Within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began for a natural disaster or other unique or unexpected event occurring on or after August 2, 2024 for a Part B or Part D rebatable biosimilar or generic Part D rebatable drug	Before the start of the applicable period in which the generic Part D rebatable drug is likely to be in shortage
Deadline for Extension Request		No later than 11:59 pm PT on October 1, 2024 for a natural disaster or other unique or unexpected event that occurred on or after January 1, 2023 but before August 2, 2024 for a Part B rebatable biosimilar, or on or after October 1, 2022 but before August 2, 2024 for a generic Part D rebatable drug or Part D rebatable biosimilar At least 60 calendar days before the start of the second applicable period or fifth calendar quarter in which the Part B or Part D rebatable biosimilar or generic Part D rebatable drug continues to be affected by the severe supply chain disruption[4]	At least 60 calendar days before the start of the second applicable period in which the generic Part D rebatable drug is likely to be in shortage

[4]In cases where the initial request for a generic Part D rebatable drug or Part D rebatable biosimilar is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of the applicable period in which the initial reduction applied.

Determination of Rebate Reduction Amount for Part B or Part D Rebatable Drugs

	Drug Shortage		Severe Supply Chain Disruption	Likely to be in Shortage
Duration of Reduction	Indefinite for as long as drug is "currently in shortage" on an FDA shortage list; the reduction is based on the amount of time a drug is "currently in shortage" and decreases over time		One year; drug company may request an extension of the reduction for an additional year for up to two consecutive years total	
Percent Reduction in Rebate Owed	Part B or Part D rebatable drug other than a plasma-derived product or generic drug	Part B or Part D plasma-derived product or Part D rebatable generic drug	Part B or Part D rebatable biosimilar or generic Part D rebatable drug	Generic Part D rebatable drug
First year	25%	75%	75%	75%
Second year	10%	50%	75%	75%
Subsequent years	2%	25%	Not applicable	Not applicable
Application of Reduction[5]	For a Part B rebatable drug, CMS will apply the rebate reduction to all of the NDCs under the relevant HCPCS code(s) if any NDC-10 assigned to the HCPCS code(s) is currently in shortage[6] For a Part D rebatable drug, CMS will apply the rebate reduction to the entire Part D rebatable drug at the NDC-9 level if any NDC-10 for a Part D rebatable drug is currently in shortage		For a Part B rebatable biosimilar, CMS will apply the rebate reduction to all the NDC-11s under the relevant HCPCS code if CMS grants a drug company's request for an NDC-11 For a generic Part D rebatable drug or Part D rebatable biosimilar, CMS will apply the rebate reduction to the entire generic Part D rebatable drug or Part D rebatable biosimilar at the NDC-9 level if CMS grants a drug company's request for an NDC-11	For a generic Part D rebatable drug, CMS will apply the rebate reduction to the entire generic Part D rebatable drug at the NDC-9 level if CMS grants a drug company's request for an NDC-11

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

[5]Although the NDC information used for rebate reductions for drugs currently in shortage are applied based on the NDC-10 level, a drug company requesting a rebate reduction based on a severe supply chain disruption or likely shortage should submit information at the NDC-11 level.

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