

DEPARTMENT OF HEALTH & HUMAN
SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: Wednesday, July 24, 2024
TO: All Drug Manufacturers
FROM: Dr. Meena Seshamani, MD, PhD
Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Prescription Drug Inflation Rebate Program: Rebate Reduction Requests

The Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act information collection request (ICR) forms are now final and available for viewing on [OMB's website](#).

Drug companies must complete the appropriate form(s) and provide supporting documentation as described in the ICR to be considered for a rebate reduction related to a severe supply chain disruption or likely shortage. Instructions on how to submit a request are included in the ICR and are available on the CMS website at <https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare>.

The deadline for drug companies to submit a Likely to be in Shortage Rebate Reduction Request is August 2, 2024, to receive consideration for a rebate reduction for a generic Part D rebatable drug for the applicable period that began on October 1, 2023. Likely to be in Shortage Rebate Reduction Requests submitted after August 2, 2024, will be considered for a rebate reduction for the next applicable period starting October 1, 2024. The deadline for drug companies to submit a Severe Supply Chain Disruption Rebate Reduction Request is 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 (Part B rebatable biosimilar) or occurred or began on or after October 1, 2022, but before August 2, 2024 (generic Part D rebatable drug or biosimilar). Severe Supply Chain Disruption Rebate Reduction Requests for natural disasters or other unique or unexpected events that occurred or began on or after August 2, 2024, will be due on or after October 2, 2024.

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.

Please email questions about this announcement to IRAREbateandNegotiation@cms.hhs.gov.