

To: Jamie Wilson
Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget (OMB)

From:

Date: July 16, 2024

Subject: Non-Substantive Change Request – Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (OMB# 0938-1474)

This memo requests approval of non-substantive changes to the approved information collection, Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (OMB# 0938-1474).

BACKGROUND

The Inflation Reduction Act (IRA) requires manufacturers to pay a rebate to CMS if they raise their prices for certain drugs faster than the rate of inflation. The IRA instructs CMS to reduce the rebate amount owed when a drug is in shortage, experiencing a severe supply chain disruption, or is likely to be in shortage. In accordance with the revised Medicare Part B Drug Inflation Rebate Program Guidance and the revised Medicare Part D Drug Inflation Rebate Program Guidance, manufacturers must submit to CMS a request form along with supporting documentation to receive consideration for a reduction in the rebate amount when the manufacturer believes there is a severe supply chain disruption of a Part B or Part D rebatable biosimilar or Part D rebatable generic drug or a likely shortage of a Part D rebatable generic drug. The Rebate Reduction Request forms will be used by manufacturers of eligible drugs to request a reduction in the rebate amount owed in the event of a severe supply chain disruption or when a sole source generic Part D rebatable drug is likely to be in shortage. The forms will inform CMS' determinations regarding such rebate reduction requests.

The collection was last approved by OMB on July 11, 2024, and expires on July 31, 2027.

OVERVIEW OF REQUESTED CHANGES

OMB's approval on July 11, 2024, occurred before the Centers for Medicare and Medicaid Services (CMS) was able to upload the final supporting materials. CMS would like to display the final materials for transparency and to avoid stakeholder confusion that the materials displayed are not final. This non-substantive change request is to replace the materials from the 30-day package with the final versions. There are no other changes being made at this time and there are no program changes or burden adjustments.