Supporting Statement – Part A

Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (CMS-10858, OMB 0938-NEW)

Under the authority in sections 11101 and 11102 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program codified in section 1847A(i) and section 1860D-14B of the Social Security Act ("the Act"), respectively.

The purpose of this information collection request (ICR) is for CMS to collect information from manufacturers of Part B rebatable biosimilar biological products and generic Part D rebatable drugs and biosimilars that are requesting rebate reductions to inform CMS' determinations regarding such rebate reduction requests. As discussed in the Medicare Part B Drug Inflation Rebate Program Revised Guidance ("Part B revised guidance")[1] (p. 77), for purposes of this information collection, to identify the manufacturer that is responsible for a Part B rebatable drug, CMS will use the same approach used to identify the manufacturer that is responsible for reporting Average Sales Price (ASP) data in accordance with section 1847A(c)(6) of the Act. As discussed in the Medicare Part D Drug Inflation Rebate Program Revised Guidance ("Part D revised guidance")[2] (p. 65), for purposes of this information collection, to identify the manufacturer that is responsible for a Part D rebatable drug, CMS will use the same approach used by the Medicaid Drug Rebate Program (MDRP) under section 1927(k)(5) of the Act.

This ICR includes the following forms:

- Severe Supply Chain Disruption Rebate Reduction Request Form (Appendix A)
- Severe Supply Chain Disruption Rebate Reduction Extension Request Form (Appendix B)
- Likely to be in Shortage Rebate Reduction Request Form (Appendix C)
- Likely to be in Shortage Rebate Reduction Extension Request Form (Appendix D)

To fulfill the statutory requirements for information collection and program burden, CMS is requesting OMB approval for this new collection that focuses on information that manufacturers must submit to CMS for the agency to consider a reduction to the rebate amount owed by a manufacturer for a severe supply chain disruption or when a sole source generic Part D rebatable drug is likely to be in shortage.

A. Background

[1] https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.

[2] https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.

Medicare Part B Drug Inflation Rebate Program

In accordance with section 1847A(i) of the Act, for calendar quarters beginning January 1, 2023, a manufacturer of a Part B rebatable drug will owe a rebate, to be deposited in the Federal Supplementary Medical Insurance Trust Fund, if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. As defined in section 1847A(i)(2)(A) of the Act, a "Part B rebatable drug" means a single-source drug or biological product (as defined section 1847A(c)(6)(D)), including a biosimilar biological product (as defined section 1847A(c)(6)(H)) but excluding a qualifying biosimilar biological product (as defined section 1847A(b)(8)(B)(iii)), for which payment is made under Part B, except such term shall not include such a drug or biological product if, as determined by the Secretary, the average total allowed charges for such drug or biological product under Part B for a year per individual that uses such a drug or biological product are less than the applicable threshold; or that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10) of the Act. Section 1847A(i)(3)(G)(ii) of the Act requires CMS to reduce or waive the rebate amount for a Part B rebatable biosimilar biological product when there is a severe supply chain disruption during a calendar quarter, such as a disruption caused by a natural disaster or other unique or unexpected event.

As described in section 50.12 of the Part B revised guidance, to receive consideration for a rebate reduction when there is a severe supply chain disruption during a calendar quarter, the manufacturer of a Part B rebatable biosimilar biological product must submit to CMS a request for a reduction of the rebate amount owed. CMS has defined a severe supply chain disruption to mean 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 rebatable biosimilar biological product by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product 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. As further described in section 50.12 of the Part B revised guidance, if a manufacturer of a Part B rebatable biosimilar biological product is granted a reduction of the rebate amount owed as a result of a severe supply chain disruption during a calendar quarter that continues into the fifth calendar quarter after the start of the natural disaster or other unique or unexpected event, the manufacturer may submit an extension request for a reduction of the rebate amount for the fifth through eighth calendar quarters.

This ICR does not address rebate reductions for Part B rebatable drugs currently in shortage, which are determined based on the Food and Drug Administration (FDA) drug and biological product shortage lists under section 506E of the Federal Food, Drug and Cosmetic (FD&C) Act and, therefore, do not require the submission of a rebate reduction request. For more information on how CMS will reduce the rebate amount for a Part B rebatable drug described as currently in shortage on an FDA shortage list, please refer to section 50.11 of the Part B revised guidance.[3]

[3] https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.

Medicare Part D Drug Inflation Rebate Program

In accordance with Section 1860D-14B of the Act, for each 12-month applicable period, starting with the applicable period beginning October 1, 2022, a manufacturer of a Part D rebatable drug will owe a rebate, to be deposited in the Federal Supplementary Medical Insurance Trust Fund, if the annual manufacturer price of the Part D rebatable drug exceeds the inflation-adjusted payment amount. As defined in Section 1860D-14B(g)(1) of the Act, a "Part D rebatable drug" means, with respect to an applicable period, a drug or biological described at section 1860D-14B(g)(1)(C)[4] that is a covered Part D drug as defined under section 1860D-2(e). A generic drug is only subject to the Part D drug inflation rebate if it is a sole source generic. The definition of a Part D rebatable drug does not include a drug or biological if, as determined by the Secretary, the "average annual total cost" for such drug or biological under Part D for a year per individual that uses such a drug or biological is less than the applicable threshold. Section 1860D-14B(b)(1)(C)(ii) of the Act requires CMS to reduce or waive inflation rebates for 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 disruption caused by a natural disaster or other unique or unexpected event. Section 1860D-14B(b)(1)(C)(iii) of the Act further requires CMS to reduce or waive inflation rebates for a generic Part D rebatable drug when CMS determines that without such a reduction or waiver, such drug is likely to be described as in shortage during a subsequent applicable period.

As described in section 40.5.2 of the Part D revised guidance, to receive consideration for a rebate reduction when there is a severe supply chain disruption during an applicable period, the manufacturer of a generic Part D rebatable drug or biosimilar must submit to CMS a request for a reduction of the rebate amount owed. CMS has defined a severe supply chain disruption to mean a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a generic Part D rebatable drug or biosimilar by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product 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. If a manufacturer of a generic Part D rebatable drug or biosimilar is granted a reduction of the rebate amount owed as a result of a severe supply chain disruption during an applicable period and the severe supply chain disruption continues into a second applicable period after the start of the natural disaster or other unique or unexpected event, the manufacturer may submit a request for an extension of the reduction of the rebate amount for that second applicable period.

As described in 40.5.3 of the Part D revised guidance, to receive consideration for a rebate reduction when a generic Part D rebatable drug is likely to be in shortage in a subsequent applicable period, the manufacturer of such generic drug must submit to CMS a request for a

[4] A drug or biological described in section 1860D-14B(g)(1)(C) is a drug or biological that, as of the first day of the applicable period involved 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 certain criteria in section 1860D-14B(g)(1)(C)(ii); or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act.

reduction of the rebate amount owed. If a manufacturer of a generic Part D rebatable drug is granted a reduction of the rebate amount owed when CMS determines the drug is likely to be in shortage during a subsequent applicable period, and the manufacturer expects the likelihood of shortage to continue into a second applicable period, the manufacturer may submit a request for an extension of the reduction of the rebate amount for that second applicable period.

This ICR does not address rebate reductions for Part D rebatable drugs currently in shortage, which are determined based on the FDA drug and biological product shortage lists under section 506E of the FD&C Act and, therefore, do not require the submission of a rebate reduction request. For more information on how CMS will reduce the rebate amount for a Part D rebatable drug described as currently in shortage on an FDA shortage list, please refer to section 40.5.1 of the Part D revised guidance.[5]

B. Justification

1. Need and Legal Basis

The Act requires that CMS reduce or waive the rebate amount for a Part B biosimilar biological product and generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption, such as a disruption caused by a natural disaster or other unique or unexpected event during a calendar quarter or applicable period, respectively. The statute also requires that CMS reduce or waive the rebate amount for a generic Part D rebatable drug if CMS determines that without such reduction or waiver, the drug is likely to be described as in shortage on the shortage list in effect under section 506E of the FD&C Act during a subsequent applicable period. CMS does not have the information necessary to determine whether or when manufacturers of Part B rebatable biosimilar biological products and generic Part D rebatable drugs or biosimilars experience a severe supply chain disruption or whether or when a generic Part D rebatable drug is likely to be in shortage, as required by sections 1847A(i)(3)(G)(ii), 1860D-14B(b)(1)(C)(ii), and 1860D-14B(b)(1)(C)(iii) of the Act. Key elements of information and supporting documentation needed for CMS to make a determination regarding a severe supply chain disruption and the likelihood of a future shortage are held by manufacturers and are not available to CMS. For CMS to determine whether there is a severe supply chain disruption or a likely future shortage, in accordance with sections 1847A(i)(3)(G)(ii), 1860D-14B(b)(1)(C)(ii), and 1860D-14B(b)(1)(C)(iii) of the Act, a manufacturer must submit a request and supporting documentation (as described in Appendix A, B, C, and D, as applicable) to CMS to receive consideration for a rebate reduction.

2. Information Users

Sections 1847A(i)(3)(G)(ii) and 1860D-14B(b)(1)(C)(ii) of the Act require CMS to reduce or waive the rebate amount for a Part B biosimilar biological product and generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption, such as a

[5] https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.

disruption caused by a natural disaster or other unique or unexpected event during a calendar quarter or applicable period, respectively. Section 1860D-14B(b)(1)(C)(iii) of the Act requires CMS to reduce or waive the rebate amount owed by a manufacturer if CMS determines that without such reduction or waiver, the manufacturer's generic Part D rebatable drug is likely to be in shortage in a subsequent applicable period. CMS will use the information submitted electronically through a secure platform by a manufacturer requesting a reduction to determine whether a Part B rebatable biosimilar product or generic Part D rebatable drug or biosimilar is eligible for a reduction in the rebate amount.

3. Use of Information Technology

A manufacturer should complete a rebate reduction request, if applicable, by first emailing IRARebateandNegotiation@cms.hhs.gov to indicate its intention to submit a request for a reduction in the rebate amount. Within 5 business days of receipt, CMS will respond by providing the manufacturer with (1) a PDF of the rebate reduction request form (available as Appendix A, B, C, and D of this ICR), and (2) access to a Box folder, or similar secure file sharing management platform approved by CMS, specific to the manufacturer's request. CMS continues to evaluate options for manufacturer form submissions and may revise the submission method in the future.

A rebate reduction request must be submitted by an authorized representative of the manufacturer of the Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar. An authorized representative includes (1) the chief executive officer (CEO) of the manufacturer, (2) the chief financial officer (CFO) of the manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority as an authorized representative to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

4. Duplication of Efforts

The information collection on whether a manufacturer submitted a notification to FDA to report an interruption in manufacturing as specified under section 506C of the FD&C Act ("506C notification") is information already collected by FDA. However, not all manufacturers submitting a rebate reduction request may trigger the statutory requirements for submission of 506C notifications to FDA. In addition, 506C notifications submitted to FDA by manufacturers are not made publicly available. As such, CMS believes the manufacturer is best positioned to submit a timely copy of the 506C notification to CMS. Other information collected does not duplicate any existing information collection efforts and cannot be obtained from other sources.

5. Small Businesses

The impact of this collection on a manufacturer is estimated to be the same regardless of the size of the manufacturer. To minimize burden, CMS is allowing manufacturers to submit one request

per severe supply chain disruption or likely shortage, as applicable, for multiple affected products.

6. Less Frequent Collection

Should CMS forgo this information request, CMS would have limited information to make a determination regarding whether a severe supply chain disruption has occurred or whether a generic Part D rebatable drug is likely to be in shortage for purposes of reducing the rebate amount. By allowing manufacturers to submit one request for multiple affected products, if applicable, CMS seeks to alleviate more frequent collection. This information cannot be collected less frequently because a manufacturer electing to request a reduction in the rebate amount must only submit the information once as part of a rebate reduction request. If CMS grants the rebate reduction request and the manufacturer elects to request an extension of the rebate reduction, the manufacturer must submit updated information once as part of an extension request, if applicable.

7. Special Circumstances

Information collected through the rebate reduction request forms may contain proprietary, trade secret, or other confidential information. CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure, to the extent allowable by law, if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)).[6]

There are no special circumstances that would require this information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

[6] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

- Submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

A 60-day notice was published in the Federal Register on January 29, 2024 (89 FR 5548). CMS received six comments from six entities in response to the 60-day notice. Of the six comments, five were relevant to this ICR. The comments identified issues/themes/concerns including but not limited to: the burden on manufacturers to report the requested information, duplication with information collected by FDA, and the process and format for submitting the requested information.

A 30-day notice was published in the Federal Register on June 3, 2024 (89 FR 47563). CMS received one out-of-scope comment on this ICR. Attached as a supplemental document in this ICR is a summary of comments and our responses. A crosswalk document describing the changes from the 30-day package to the current package is also attached.

Outside Consultation
In the development of the Information Collection Request for the Rebate Reduction Request forms, CMS sought input from other federal agencies, such as FDA.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for completing the information collection. A manufacturer must submit a request and supporting documentation to CMS to receive consideration for a reduction in the rebate amount owed.

10. Confidentiality

As discussed in section 50.12 of Part B revised guidance and sections 40.5.2 and 40.5.3 of Part D revised guidance, CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).[7] In addition to the protections under FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. § 1905 requires executive branch employees to protect such information. CMS will protect confidential and proprietary information as required by applicable law.

[7] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimates (Hours & Wages)

A manufacturer must complete and submit the information requested on the applicable Severe Supply Chain Disruption Rebate Reduction Request Form (Appendix A) or Likely to be in Shortage Rebate Reduction Request Form (Appendix C) for CMS to make a determination regarding a severe supply chain disruption or likelihood of a future shortage, respectively. After submission, a manufacturer may be considered for a reduction of the rebate amount owed for their applicable Part B rebatable biosimilar biological product(s) and/or generic Part D rebatable drug(s) or biosimilar(s) for a severe supply chain disruption or for their applicable generic Part D rebatable drug(s) for a likelihood of a future shortage. For the purposes of this burden estimate and cost to federal government, Appendix A and Appendix C are collectively referred to as the "Rebate Reduction Request Form" due to CMS approximating the estimates for each form to be similar due to the questions on the forms requiring about the same amount of time for a manufacturer to collect and submit the information on the applicable form.

A manufacturer that is granted a reduction of the rebate amount owed and seeks an extension of the reduction must complete and submit the information requested on the applicable Severe Supply Chain Disruption Rebate Reduction Extension Request Form (Appendix B) or Likely to be in Shortage Rebate Reduction Extension Request Form (Appendix D) in order to be considered for an extension of the rebate reduction. For the purposes of this burden estimate and cost to federal government, Appendix B and D are collectively referred to as the "Rebate Reduction Extension Request Form" due to CMS approximating the estimates for each form to be similar due to the questions on the forms requiring about the same amount of time for a manufacturer to collect and submit the information on the applicable form.

The burden estimates for the information collection required for the Rebate Reduction Request Form and the Rebate Reduction Extension Request Form are detailed in this section.

To derive wage estimates, CMS used data from the Bureau of Labor Statistics' May 2023 National Industry-Specific Occupational Employment and Wage Estimates for Pharmaceutical and Medicine Manufacturing[8] to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with collecting the information needed to complete and submit the applicable Rebate Reduction Request Form or Rebate Reduction Extension Request Form.

CMS will allow manufacturers to submit one request form for multiple affected products, which is expected to reduce manufacturer burden by not requiring multiple forms and submissions for drugs affected by the same event or circumstance. CMS believes that the manufacturer is well

[8] See May 2023 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at https://www.bls.gov/oes/current/naics4_325400.htm.

positioned to provide the requested information as some of the information needed for CMS to make a determination in accordance with sections 1847A(i)(3)(G)(ii) and 1860D-14B(b)(1)(C)(ii)-(iii) of the Act is not otherwise available to CMS in the normal course. Thus, the manufacturer is required to submit a request and supporting documentation on the applicable forms in order to receive consideration for a rebate reduction.

Estimated Burden for Rebate Reduction Request Form

The estimated median hourly wage, the adjusted hourly wage (cost per hour) to include the cost of fringe benefits and overhead, total burden hours, and total cost to submit the Rebate Reduction Request Form are presented in Table 1. Although CMS estimates the impact on a manufacturer to be the same regardless of the size of the manufacturer, there is some uncertainty to the estimate in Table 1 as some manufacturers may take less time to compile all the information needed to complete and submit the Rebate Reduction Request Form, especially if the manufacturer has already compiled and submitted some of this information to the FDA, which collects related information through the 506C notification process,[9] while other manufacturers may take more time. Given this uncertainty, the burden estimates from Table 1 (base estimates) are provided along with a high estimate and a low estimate in Table 2.

CMS estimates that few manufacturers will submit a Rebate Reduction Request Form due to the statutory specifications regarding eligible rebatable drugs, as well as the policy criteria established in revised inflation rebate program guidance. CMS anticipates collecting a total of 10 Rebate Reduction Request Forms per year. Two additional low estimates and one high estimate are provided in Table 1 below to illustrate the possible variability for this burden estimate of multiple forms submitted.

CMS expects a manufacturer will have a team preparing the Rebate Reduction Request Form. CMS expects this team to consist of chief executives, lawyers, pharmacists, and business operations specialists. The estimates below account for the burden of preparing and submitting the Rebate Reduction Request Form:

- CMS estimates it will take a business operations specialist, or a team of business operations specialists, 16 hours, on average, at $89.88 per hour, to collect information and provide brief explanations detailing the specifics of the severe supply chain disruption or likely shortage, including determining changes in drug production and distribution and when supply is expected to meet demand. The business operations specialist, or team, will also submit information on how the manufacturer plans to resolve or mitigate the severe supply chain disruption or likely shortage. CMS also expects this business operations specialist, or team, to compile supporting documentation providing

[9] Section 506C of the Federal Food, Drug and Cosmetic Act (FD&C Act) requires manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain drugs and biological products or an interruption in the manufacture of certain drugs and biological products that is likely to lead to a meaningful disruption in supply of those products in the United States.

evidence of the severe supply chain disruption and likely shortage and submit such information as part of their request to CMS.

- CMS also estimates it will take a pharmacist, or team of pharmacists, 8 hours, on average, at $126.98 per hour, to evaluate the impact and duration of a severe supply chain disruption or determine the likelihood of shortage and anticipated duration of the potential shortage.
- CMS estimates it will take a lawyer, or team of lawyers, 5 hours, on average, at $230.00 per hour, to review the submission and determine which information, if any, on the form or in the supporting documentation is considered proprietary and protected under Exemption 3 and/or Exemption 4 of the Freedom of Information Act.
- CMS estimates that it will take a Chief Executive, on average, 2 hours, at $230.00 per hour, to review the Rebate Reduction Request Form and supporting documentation and certify the submission. Certification must be done by the (1) CEO, (2) CFO, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

The cost estimates for one-time costs are presented in Table 1 below. For the anticipated 10 Rebate Reduction Request Form submissions, CMS estimates a total burden of 310 hours (31 hrs. per form submitted * 10 forms submitted) and total cost of $40,639.20 for all 10 developed and submitted forms ($4,063.92 per form * 10 forms submitted).

TABLE 1: SUMMARY OF ICR BURDEN FOR DEVELOPING AND SUBMITTING REBATE REDUCTION REQUEST FORM(S)

Occupation Title	Median Hourly Wage	Cost per hour*	# Hours	# Respondents	Total Burden Hours	Total Cost
Business Operations Specialist(s) (13-1000)	$44.94	$89.88	16	10	16	$14,380.80
Pharmacist(s) (29-1051)	$63.49	$126.98	8	10	8	$10,158.40
Lawyer(s) (23-1011)	$115.00	$230.00	5	10	5	$11,500.00
Chief Executive (11-1011)	$115.00	$230.00	2	10	2	$4,600.00
Total (10 Forms)	**-**	**-**	**310**	**10**	**310**	**$40,639.20**
Total (1 Form)	**-**	**-**	**31**	**1**	**31**	**$4,063.92**

Total (5 Forms)	**-**	**-**	**155**	**5**	**155**	**$20,319.60**
Total (15 Forms)	**-**	**-**	**465**	**15**	**465**	**$60,958.80**

** As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies.*

An additional low estimate and high estimate is provided in Table 2 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimates (Table 1 Totals) have been reduced by half for each labor category. For the high estimate, the required time and cost associated with each labor category from the base estimates have been doubled.

TABLE 2: COST RANGE ESTIMATES FOR DEVELOPING AND SUBMITTING REBATE REDUCTION REQUEST FORM(S)

	Hours per Form	**Cost per 1 Form**	**Cost per 5 Forms**	**Cost per 10 Forms**	**Cost per 15 Forms**
Low Estimate	15.5	$2,031.96	$10,159.80	$20,319.60	$30,479.40
Base Estimates (from Table 1)	31	$4,063.92	$20,319.60	$40,639.20	$60,958.80
High Estimate	62	$8,127.84	$40,639.20	$81,278.40	$121,917.60

Estimated Burden for Rebate Reduction Extension Request Form

A manufacturer that seeks an extension of the reduction of the rebate amount owed must submit an extension request using the applicable Rebate Reduction Extension Request Form.

The estimated median hourly wage, the adjusted hourly wage (cost per hour) to include the cost of fringe benefits and overhead, total burden hours, and total cost to submit the Rebate Reduction Extension Request Form are presented in Table 3. Although CMS estimates the impact on a manufacturer to be the same regardless of the size of the manufacturer, there is some variability to the estimate in Table 3 as some manufacturers may take less time to complete and submit the Rebate Reduction Extension Request Form while others may take more time. Given this variability, the burden estimates from Table 3 (base estimates) are provided along with a high estimate and a low estimate in Table 4.

CMS anticipates collecting a total of 10 Rebate Reduction Extension Request Forms per year. Two additional low estimates and one high estimate are provided in Table 3 below to illustrate the possible variability for this burden estimate of multiple forms submitted.

CMS expects the manufacturer to have a similar team, if not the exact same team, to prepare the Rebate Reduction Extension Request Form as the team that prepared the Rebate Reduction Request Form.

The cost estimates for one-time costs are presented in Table 3 below. For the anticipated 10 Rebate Reduction Extension Request Form submissions, CMS estimates a total burden of 310 hours (31 hrs. per form submitted * 10 forms submitted) and total cost of $40,639.20 for all 10 developed and submitted forms ($4,063.92 per form * 10 forms submitted).

TABLE 3: SUMMARY OF ICR BURDEN FOR DEVELOPING AND SUBMITTING REBATE REDUCTION EXTENSION REQUEST FORM(S)

Occupation Title	Median Hourly Wage	Cost per hour*	# Hours	# Respondents	Total Burden Hours	Total Cost
Business Operations Specialist(s) (13-1000)	$44.94	$89.88	16	10	16	$14,380.80
Pharmacist(s) (29-1051)	$63.49	$126.98	8	10	8	$10,158.40
Lawyer(s) (23-1011)	$115.00	$230.00	5	10	5	$11,500
Chief Executive (11-1011)	$115.00	$230.00	2	10	2	$4,600.00
Total (10 Forms)	**-**	**-**	**310**	**10**	**310**	**$40,639.20**
Total (1 Form)	**-**	**-**	**31**	**1**	**31**	**$4,063.92**
Total (5 Forms)	**-**	**-**	**155**	**5**	**155**	**$20,319.60**
Total (15 Forms)	**-**	**-**	**465**	**15**	**465**	**$60,958.80**

** As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies.*

An additional low estimate and high estimate is provided in Table 4 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimates (Table 3 Totals) have been reduced by half for each labor category. For the high estimate, the required time and cost associated with each labor category from the base estimate have been doubled.

TABLE 4: COST RANGE ESTIMATES FOR DEVELOPING AND SUBMITTING REBATE REDUCTION EXTENSION REQUEST FORM(S)

	Hours per Form	Cost per 1 Form	Cost per 5 Forms	Cost per 10 Forms	Cost per 15 Forms
Low Estimate	15.5	$2,031.96	$10,159.80	$20,319.60	$30,479.40
Base Estimates (from Table 3)	31	$4,063.92	$20,319.60	$40,639.20	$60,958.80
High Estimate	62	$8,127.84	$40,639.20	$81,278.40	$121,917.60

Since CMS anticipates collecting a total of 10 Rebate Reduction Request Forms and 10 Rebate Reduction Extension Request Forms per year, the total burden estimate represents this in Table 5 below.

TABLE 5: SUMMARY OF BURDEN FOR SUBMISSIONS OF REBATE REDUCTION REQUEST FORMS AND REBATE REDUCTION EXTENSIONS REQUEST FORMS

	Total Burden Hours	Total Cost
Base Estimate (n = 10) (from Table 1)	310	$40,639.20
Base Estimate (n = 10) (from Table 3)	310	$40,639.20
Total (n = 20)	**620**	**$81,278.40**

13. Capital Costs

There are no anticipated capital costs associated with this information collection.

14. Cost to Federal Government

The federal government estimated cost is based on the efforts expended by CMS staff with the following assumptions to receive, review, and process data from manufacturers that submit rebate reduction requests and rebate reduction extension requests.

Estimates

To generate salary estimates reflected in Table 6, CMS used the 2024 General Schedule (GS) Locality Pay Tables[10] published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region. In this regard, Table 6 presents the GS grade and step, number of full-time employees (FTE) required, the hourly basic wage plus the cost of fringe

[10] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/html/DCB_h.aspx.

benefits and overhead (calculated at 100 percent of salary), the number of anticipated hours, and the estimated cost. The estimates below in Table 6 also show the total cost to the government for submission of one form and the anticipated combined 20 forms (10 Rebate Reduction Request Forms and 10 Rebate Reduction Extension Request Forms). Staffing estimates are based on CMS duties as follows:

- CMS will develop policies and procedures for determining whether to grant a request or deny a request; and
- Review and analyze the information submitted by manufacturers in the forms and as part of the supporting documentation.

TABLE 6: TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT THE REBATE REDUCTION REQUESTS

Task	**Estimated Cost**
Rebate Reduction Requests Review Personnel, Wage (plus cost of fringe benefits and overhead), and Hours	
GS-13 (step 1): (3 FTEs x $113.04 x 24 hours)	$8,138.88
GS-14 (step 1): (2 FTEs x $133.58 x 24 hours)	$6,411.84
GS-15 (step 1): (2 FTEs x $157.12 x 6 hours)	$1,885.44
Senior Executive Service*: ($188.54 x 2 hours)	$377.08
Total Cost to Government (1 Form)	$16,813.24
Total Cost to Government (20 Forms)	$336,264.80

** The Senior Executive Service pay range has a minimum rate of basic pay equal to 120 percent of the rate for GS-15 (step 1).*

15. Changes to Burden

This a new information collection request. Changes made in response to the comments received on the 60-day notice (89 FR 5548) did not require revisions to the previous burden estimate. However, the data from the Bureau of Labor Statistics was updated and published on April 3, 2024 from the May 2022 estimates, to the May 2023 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry. Tables 1 through 5 of section 12 Burden Estimates (Hours & Wages) were updated accordingly. Also, OPM published the 2024 GS Locality Pay Table on their website and Table 6 of section 14 Cost to Federal Government was updated accordingly. Non-burden-related changes incorporated in the 30-day public notice are included in the 60- to 30-Day Rebate Reduction Request Cross Walk.

16. Publication/Tabulation Dates

The results of this information collection will not be published for statistical use or analysis.

17. Expiration Date

The expiration date and OMB control number will be displayed within the data collection information technology system.

18. Certification Statement

There are no exceptions to the certification statement.