

Supporting Statement A
Dispute Resolution for Discarded Drug Refunds
(CMS-10835, OMB 0938-1435)

Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) (hereinafter is referred to as “the Infrastructure Act”) amended section 1847A of the Social Security Act (hereinafter is referred to as “the Act”) to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug or biological (hereafter, drug) that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. A refundable single-dose container or single-use package drug does not include a radiopharmaceutical or imaging agent, certain drugs requiring filtration, and certain new drugs. There are two aspects to implementation of this provision (one finalized in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) final rule and one finalized in the CY 2024 PFS final rule) that require collection of information.

First, in the CY 2023 PFS final rule, we finalized at §414.940 the implementation of section 90004 of the Infrastructure Act including a dispute resolution process, which requires collection of information. We finalized that the dispute must include the following information on an error report: (1) Manufacturer name and address; (2) The name, telephone number, and email address of one or more employees or representatives of the manufacturer with whom the Secretary may discuss the claimed errors; (3) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation; and (4) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of how the manufacturer established that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

Second, we finalized an application process through which manufacturers can request increased applicable percentage for a drug in the CY 2024 PFS final rule. Paragraph (3)(B)(ii) of the new section provides that, in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may, through notice and comment rulemaking, increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. In the CY 2024 PFS final rule, we finalized modifications to §414.940 to establish an application process so manufacturers may request that CMS consider whether an increased applicable percentage would be appropriate for a particular drug in light of its unique circumstances.

In the CY 2024 final rule, we finalized that, to request we consider increasing the applicable percentage for a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling for the drug; (3) justification for the

consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage.

The final rule adds 135 hours of burden at a cost of \$7,528.

This collection of information request does not include any reporting instruments. The requirements are provided in the aforementioned rules as codified in the CFR.

A. Justification

1. Need and Legal Basis

As a part of implementing section 90004 of the Infrastructure Act, we recognize the need for establishing a dispute resolution process because of the nature of determining the estimated total allowed charges for a given calendar quarter and the methods by which the estimated refund amount is determined. Although a dispute resolution process is not expressly required by section 1847A(h) of the Act, we believe that proactively establishing such a process will aid in the successful implementation of this provision. We finalized in the CY 2023 PFS that each manufacturer has an opportunity to dispute the report by submitting an error report as described in this section.

In addition, we recognize that there are products subject to the discarded drug refund provision that may indeed have a unique circumstance, and an increased applicable percentage for these products would have to be determined through future notice and comment rulemaking as required by the statutory provision. Although we finalized an increased applicable percentage for one drug with unique circumstances in the CY 2023 final rule and we finalized an increased applicable percentage for two categories of drugs with unique circumstances in the CY 2024 final rule, we believe a formal application process provides drug manufacturers a transparent avenue to provide CMS with information that could justify that a drug has a unique circumstance and should have an increased applicable percentage. The finalized application process is advantageous to manufacturers because it provides a clear process in regulation by which an increased applicable percentage can be requested, particularly because of the statutory requirement that these determinations be made through notice and comment rulemaking.

2. Information Users

Error Report: Manufacturers of drugs for which refunds are owed may submit an error report to CMS. This error report will contain information as described in the background section above. CMS will use this information to evaluate the refund amount and make any corrections or adjustments to the refund amount if CMS finds there was indeed an error. We will evaluate error reports and will decide whether the information (such as number of discarded billing units or refund amount calculation) requires correction based on the information provided. In the CY 2023 final rule, we finalized that if we find that a different refund amount is owed than what was stated on the report, we will issue a new report with updated discarded amounts and/or refund. We finalized that if we disagree with the dispute, we will notify the manufacturer that refund amount on the report is still owed and should be paid.

Application process for increased applicable percentage: In the CY 2024 PFS final rule, we finalized that manufacturers of drugs or biologicals may apply for an increased applicable percentage (based on unique circumstances) on an annual basis, which we finalized to be submitted to CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply (for example, applications for increased applicable percentages effective January 1, 2025 are due to CMS by February 1, 2024). We finalized that we will discuss our analyses of applications in the PFS rulemaking immediately following the application period, and to communicate in the proposed rule whether we consider the drug to have unique circumstances that warrant an increased applicable percentage. We will also include proposals, if any, for increased applicable percentages, along with a summary of any applications for which we determined not to propose an increase in the applicable percentage.

3. Use of Information Technology

The collection of information for neither the error report nor the unique circumstance application involves use of automated, electronic, mechanical, or other technological collection techniques. An electronic collection system of such information is not currently available. We would require a signature from respondents and if CMS had the capability of accepting electronic signatures, we could consider that the error report be submitted electronically.

Since both the error report and the application process for increased applicable percentage contain very specific information, regarding the refund amount owed and the amount of discarded drug for the error report, and regarding the FDA-approved label, drug properties, and/or minimum fill amount for the unique circumstance application, there is very little opportunity for automation. We anticipate a very small number of error reports (10 or less per year) and increased applicable percentage applications (30 or less per year), therefore, it would not be cost effective to develop novel collection systems.

4. Duplication of Efforts

These information collections do not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Manufacturers of drugs and biologicals are generally not considered small businesses. Therefore, the collection of error reports does not impact small businesses.

6. Less Frequent Collection

Error report: We finalized in the CY 2023 PFS final rule that reports described in section 1847A(h) of the Act be sent from CMS to manufacturers of refundable single-dose container or single-use package drug once annually. Therefore, the submission of error reports from manufacturers to CMS is to be done once annually. We would not be able to decrease the frequency of the collection of error reports to adequately address disputes in a timely manner.

Less frequent error reports could have negative impacts on implementation such as delaying payment of refunds. We considered a quarterly process for implementation of this provision, but thought it less burdensome for CMS resources and for manufacturers to administer the process annually (including the collection of error reports).

Application process for increased applicable percentage: In the CY 2024 final rule, we finalized a process through which drug manufacturers will have the opportunity to submit a unique circumstance application once annually. Since we are implementing all aspects of section 1847A(h) of the Act through notice-and-comment rulemaking (generally, on an annual basis through the PFS CY rule), we cannot have a more frequent application process. As we anticipate new drugs subject to the discarded drug refund provision to be marketed each year, and that some manufacturers will make changes to their packaging to reduce liabilities under the provision, a process with application periods less frequent than once a year would pose a disadvantage to manufacturers.

7. Special Circumstances

Neither the finalized collection of error reports nor the finalized application process for increased applicable percentage has any special circumstances.

8. Federal Register/Outside Consultation

Serving as the 60-day notice, the proposed rule (CMS-1784-P; RIN 0938-AV07) published in the Federal Register on August 7, 2023 (88 FR 52262). While the rule's collection of information request was posted on our website for public review, it was not submitted to OMB. We are addressing that oversight by submitting the proposed collection of information request in May 2024. We did not receive any comments pertaining to this collection of information request.

The final rule (CMS-1784-F; RIN 0938-AV07) published in the Federal Register on November 16, 2023 (88 FR 78818).

9. Payments/Gifts to Respondents

Respondents will not receive any payments or gifts as a condition of complying with this information collection request. Although the respondents will not receive payments or gifts, the end result of the dispute or application for an increased applicable percentage may result in a change to the refund amount owed by the respondent.

10. Confidentiality

We are not providing any assurance of confidentiality to the respondents.

11. Sensitive Questions

There is no collection of information that is of a sensitive nature.

12. Collection of Information Requirements and Associated Burden Estimates

Wage Estimates

To develop our cost estimates, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Industry-Specific Occupational Employment and Wage Estimates (https://www.bls.gov/oes/2023/may/oes_dc.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs, and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Secretaries and Administrative Assistants	43-6014	27.88	27.88	55.76

We are adjusting our employee hourly wage estimates by a factor of nearly 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Associated Burden Estimates

Consistent with the estimated annual burden per respondent/recordkeeper for similar error reports utilized to implement the Branded Prescription Drug Fee (August 18, 2011; 76 FR 51310), we estimate the annual burden per respondent/recordkeeper (secretaries and administrative assistants) to be 40 hours.

Under §414.940, the dispute must include the following information: (1) Manufacturer name and address; (2) The name, telephone number, and email address of one or more employees or representatives of the manufacturer with whom the Secretary may discuss the claimed errors; (3) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation; and (4) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of how the manufacturer established that an error occurred, the proposed correction to the error, and an explanation of why the Secretary should use the proposed corrected data instead.

Anticipating no more than 10 disputes per year, we estimate a total annual burden of 400 hours (10 error reports per year x 40 hr per respondent) at a cost of \$22,304 (400 hr x \$55.76/hr).

Separately, we estimate that the burden per respondent/applicant of drafting and submitting the unique circumstance application to be 5 hours. We anticipate 25 applications in the initial year

that applications are available. In the initial year, we estimate a one-time burden of 125 hours (25 applications x 5 hr per respondent/applicant) at a cost of \$6,970 (125 hr x \$55.76/hr) to draft and submit the application.

Once a manufacturer has applied for a drug and a decision has been made regarding whether an increased applicable percentage is appropriate, the manufacturer does not need to apply again.

In subsequent years we expect a smaller number of applications. When evaluating the approval dates of these 25 drugs, we find that there is a range of 0 to 4 drugs per year approved that would be expected to owe a refund of more than \$50,000 per year. From 2010—2020, the mean number of such approvals is 1.45 per year. If rounded up, we estimate that we will typically receive 2 applications per year except the initial application year. In this regard we estimate an annual burden of 10 hours (2 applications x 5 hr per respondent/applicant) at a cost of \$558 (10 hr x \$55.76/hr) to draft and submit the application.

To request that we consider increasing the applicable percentage for a particular refundable drug, we finalized that a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification could include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study.

Burden Summary

CFR Section	Respondents	Responses Per Respondent	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
414.940	10 manufacturers	1	10 error reports	40	400	55.76	22,304
414.940	25 manufacturers	1	25 applications in the initial year	5	125	55.76	6,970
414.940	2 manufacturers	1	2 applications in subsequent years	5	10	55.76	558
TOTAL	37 manufacturers	1	37	varies	535	55.76	29,832

Collection of Information Instruments and Instruction/Guidance Documents

Not applicable. This collection of information request does not include any reporting instruments. The requirements are provided in the aforementioned rules as codified in the CFR.

13. Capital Costs

There are no additional recordkeeping or capital costs.

14. Cost to Federal Government

The calculations for employees’ hourly salary were obtained from the OPM website, with an additional 100% to account for fringe benefits.

Task	Estimated Annual Cost
3 GS-13:2 x \$102.71 x 40 hours	\$12,325.20
2 GS-14:2 x \$121.38 x 40 hours	\$9,710.40
3 GS-15:3 x \$142.77 x 8 hours	\$3,426.48
Total	\$25,462.08

15. Changes to Burden

In the CY 2024 PFS final rule, we finalized an application process through which each manufacturer can request that we consider increasing the applicable percentage for a particular drug based on unique circumstances. Under this process, by February 1 of the calendar year prior to the year the increased applicable percentage would apply, manufacturers will submit to CMS: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested applicable percentage. The burden imposed on respondents consists of the drafting and submission of the request for unique circumstance consideration.

In the initial year, we estimate that the burden per respondent/applicant of drafting and submitting the unique circumstance application to be 5 hours. We anticipate 25 applications in the initial year that applications are available. In the initial year, we estimate a one-time burden of 125 hours (25 applications x 5 hr per respondent/applicant) at a cost of \$6,970 (125 hr x \$55.76/hr) to draft and submit the application.

Once a manufacturer has applied for a drug and a decision has been made regarding whether an increased applicable percentage is appropriate, the manufacturer does not need to apply again.

In subsequent years we expect a smaller number of applications. When evaluating the approval dates of these 25 drugs, we find that there is a range of 0 to 4 drugs per year approved that would be expected to owe a refund of more than \$50,000 per year. From 2010—2020, the mean number of such approvals is 1.45 per year. If rounded up, we estimate that we will typically receive 2 applications per year except the initial application year. In this regard we estimate an annual burden of 10 hours (2 applications x 5 hr per respondent/applicant) at a cost of \$558 (10 hr x \$55.76/hr) to draft and submit the application.

To request that we consider increasing the applicable percentage for a particular refundable drug, we finalized that a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification could include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study.

CFR Section	Respondents	Responses Per Respondent	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
414.940	25 manufacturers	1	25 applications in the initial year	5	125	55.76	6,970
414.940	2 manufacturers	1	2 applications in subsequent years	5	10	55.76	558
TOTAL	27 manufacturers	1	27	varies	135	55.76	7,528

16. Publication/Tabulation Dates

The data collected will not be made public.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

The finalized collection does not involve any exceptions to the certification statement identified in line 19 of OMB Form 83-I.

B. Collection of Information Employing Statistical Methods

The collection of information requirements for this data collection do not employ statistical methods.