Supporting Statement For Paperwork Reduction Act Submissions: Dispute Resolution for Discarded Drug Refunds

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 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. In the Calendar Year 2023 Physician Fee Schedule proposed rule, we are proposing at §414.940, implementation of section 90004 of the Infrastructure Act which includes a proposed dispute resolution process, which requires collection of information.

We propose that 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 CMS should use the proposed corrected data.

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 propose that each manufacturer have an opportunity to dispute the report by submitting an error report as described in this section.

2. Information Users

Manufacturers of drugs or biologicals 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 would evaluate error reports and would decide whether the information (such as number of discarded billing units or refund amount calculation) requires correction based on the information provided. We propose that if we find that a different refund amount is owed than what was stated on the report, we would issue a new report with updated discarded amounts and/or refund. We propose that if we disagree with the dispute, we would notify the manufacturer that refund amount on the report is still owed and should be paid.

3. Use of Information Technology

This collection of information does not involve 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 the proposed error report would contain very specific information regarding the refund amount owed and the amount of discarded drug, there is very little opportunity for automation. We anticipate a very small number of error reports per year (10 or less), therefore, it would not be cost effective to develop such a collection system.

4. Duplication of Efforts

This information collection does 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

We are proposing 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, every October. Therefore, the submission of error reports from manufacturers to CMS is also proposed 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 propose implementation of an annual process (including the collection of error reports).

7. Special Circumstances

The collection of error reports, as proposed, does not have any special circumstances.

8. Federal Register/Outside Consultation

The 60-day notice published as part of the proposed rule that published on July 29, 2022 (87 FR 45860).

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 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. Burden Estimates (Hours & Wages)

Consistent with the estimated annual burden per respondent/recordkeeper for similar error reports utilized to implement the Branded Prescription Drug Fee (76 FR 51310), we estimate the annual burden per respondent/recordkeeper to be 40 hours. If we anticipate no more than

10 disputes per year, the total annual reporting and/or recordkeeping burden would be 400 hours (10 error reports per year x 40 hours per respondent). Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2021) for Category 43-6014 (Secretaries and Administrative Assistants), the mean hourly wage for an administrative assistant is $19.75.[1] We have added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $39.50 ($19.75 + $19.75). Therefore, we estimate an annual cost of this burden to be $15,800 ($39.50/hour x 400 hours).

13. Capital Costs

There are no additional recordkeeping or capital costs.

14. Cost to Federal Government

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

Task	**Estimated Cost**
3 GS-13:2 x $102.71 x 20 hours	$6,162.60
2 GS-14:2 x $121.38 x 20 hours	$4,855.20
3 GS-15:3 x $142.77 x 4 hours	$1,713.24
Total Costs to Government	**$12,731.04**

15. Changes to Burden

This is a new information collection request.

16. Publication/Tabulation Dates

The data collected will not be made public.

17. Expiration Date

1 https://www.bls.gov/oes/current/oes436014.htm

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

18. Certification Statement

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