SUPPORTING STATEMENT
Temporary Regulation
REG-112805-10

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

Section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111-152 (124 Stat. 1029 (2010)) imposes an annual fee on manufacturers and importers of branded prescription drugs that have gross receipts of over $5 million from the sales of these drugs to certain government programs (covered entity/covered entities).

The temporary regulations describe how the IRS will administer the branded prescription drug fee. Section 51.7T(b) of the temporary regulations provides that the IRS will send each covered entity notification of its preliminary fee calculation by May 15 of the fee year. If a covered entity chooses to dispute the IRS' preliminary fee calculation, the covered entity must follow the procedures for submitting an error report that are established in §51.8T.

2. USE OF DATA

The IRS will use the data voluntarily supplied by a covered entity that disputes its preliminary fee calculation to verify the accuracy of the data and the calculation used to determine the covered entity's fee.

3. USE OF IMPROVED INFORMATION TECHNOLOGY TO REDUCE BURDEN

IRS publication, regulations, notices and letters are to be electronically enabled on an as practicable basis in accordance with the IRS Reform and Restructuring Act of 1998.

4. EFFORTS TO IDENTIFY DUPLICATION

We have attempted to eliminate duplication within the agency wherever possible.

5. METHODS TO MINIMIZE BURDEN ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

Not applicable.

6. CONSEQUENCES OF LESS FREQUENT COLLECTION ON FEDERAL PROGRAMS OR POLICY ACTIVITIES

Not applicable.

7. SPECIAL CIRCUMSTANCES REQUIRING DATA COLLECTION TO BE INCONSISTENT WITH GUIDELINES IN 5 CFR 1320.5(d)(2)

Not applicable.

8. CONSULTATION WITH INDIVIDUALS OUTSIDE OF THE AGENCY ON AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, CLARITY OF INSTRUCTION AND FORMS, AND DATA ELEMENTS

On November 29, 2010, the Internal Revenue Service (IRS) released Notice 2010-71 (2010-50 IRB 822), which proposed an approach to implementing the section 9008 fee and requested comments on the proposed approach. The proposed approach included an opportunity to report certain information to the IRS relevant to the fee calculation and provided that the IRS would provide each covered entity with notice of a preliminary fee calculation. This notice was modified and superseded by Notice 2011-9 (2011-6 IRB 459), which was released on January 14, 2011.

On April 29, 2011, the IRS released Rev. Proc. 2011-24 (2011-20 IRB 787), which established a process for covered entities to submit claimed errors in their preliminary fee calculations for consideration prior to final fee calculations for 2011. On May 27, 2011, the IRS released Notice 2011-46 (2011-25 IRB 887) to defer the due date for submission of error reports and the last possible date for sending final fee calculations for 2011.

In developing the dispute resolution process described in the temporary regulations, the IRS consulted with the Departments of Health and Human Services, Defense, and Veterans Affairs. Programs within these departments will supply the IRS with sales data and will assist the IRS in the dispute resolution process.

9. EXPLANATION OF DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS

Not applicable.

10. ASSURANCE OF CONFIDENTIALITY OF RESPONSES

A covered entity's submission of information regarding its fee will be treated as return information that is generally confidential as required by 26 USC 6103.

11. JUSTIFICATION OF SENSITIVE QUESTIONS

Not applicable.

12. ESTIMATED BURDEN OF INFORMATION COLLECTION

A covered entity that disputes its preliminary fee calculation will need to submit supporting data to the IRS. We estimate that 45 covered entities will dispute the IRS' 2011 preliminary fee calculation. The estimated burden per covered entity will be 40 hours. The total recordkeeping requirement is 1800 hours.

Estimates of the annualized cost to respondents for the hour burdens shown are not available at this time.

13. ESTIMATED TOTAL ANNUAL COST BURDEN TO RESPONDENTS

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information are not available at this time.

14. ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

Not applicable.

15. REASONS FOR CHANGE IN BURDEN

For fee year 2011, only 36 fee payers submitted error reports. We project 45 fee payers may submit error reports in the future.

16. PLANS FOR TABULATION, STATISTICAL ANALYSIS AND PUBLICATION

Not applicable.

17. REASONS WHY DISPLAYING THE OMB EXPIRATION DATE IS INAPPROPRIATE

We believe that displaying the OMB expiration date is inappropriate because it could cause confusion by leading covered entities to believe that the dispute resolution process is available to them until the expiration date.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT ON OMB FORM 83-I

Not applicable.

Note: The following paragraph applies to all of the collections of information in this submission:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of section 9008 of the ACA and any related Internal Revenue Code provision. A covered entity's submission of information regarding its preliminary fee calculation will be treated as return information that is generally confidential as required by 26 USC 6103.

REASON FOR EMERGENCY SUBMISSION

The reason for this emergency submission is to provide as soon as possible fee payers with guidance regarding the branded prescription drug fee they must pay for the first time beginning on September 30, 2011.