

SUPPORTING STATEMENT
REV. PROC. 2011-

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 IRS will administer the fee. This administration includes, among other things, the calculation and collection of the fee.

In Notice 2011-9 the IRS describes how it will administer the fee. Part II of this Notice provides that the IRS will send each covered entity notification of its preliminary fee calculation by May 16, 2011. If a covered entity disputes the IRS' preliminary fee calculation, the covered entity must follow the procedures for submitting an error report that are established in the proposed revenue procedure.

2. USE OF DATA

The IRS will use the data voluntarily supplied by a covered entity that disputes its 2011 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

In developing the dispute resolution process described in the revenue procedure, 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 2011 preliminary fee calculation will need to submit supporting data to the IRS. We estimate that 119 covered entities will dispute the IRS' 2011 preliminary fee calculation. The estimated burden per covered entity will be 40 hours. The total reporting and recordkeeping requirement is 4,760 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

New collection of information. .

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 a covered entity with a dispute resolution process for a fee that the covered entity must pay by September 30, 2011. By May 16, 2011, the IRS will provide a covered entity with a preliminary fee calculation. If a covered entity disputes the IRS' preliminary fee calculation, the covered entity must submit, as described in section 4.01 of the proposed revenue procedure, an error report, postmarked by June 1, 2011, to the IRS. A covered entity must include in its error report an explanation of the error and the data to substantiate the claimed error. The IRS must resolve fee disputes by July 15, 2011, in order to provide a covered entity with a final fee determination by August 15, 2011.

