Drug Pricing Program Reporting Requirements
SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collected

This is a request for an extension of Office of Management and Budget (OMB) approval for burden associated with the Drug Pricing Program reporting and recordkeeping requirements. The requirements are currently approved under OMB number 0915-0176 which expires on February 28, 2013. To date, there have been six requests for audits and three requests for informal dispute resolution. In order to comply with P.L. 102-585, burden has been approved for the process for audits and other disputes in the event that such a request is made.

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992" (the "Act"), enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (HHS) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed that amount determined under a statutory formula.

The covered entities eligible to receive 340B pricing under this formula are defined by statute under section 340B(a)(4) of the Public Health Service Act. The Office of Pharmacy Affairs (OPA) provides a list of eligible entities to each participating manufacturer (approximately 800 manufacturers) and has notified each covered entity of its eligibility to purchase drugs at the discounted prices. The current list of both eligible entities and manufacturers has been placed on an electronic data retrieval system for public access and an Internet site. This list is continually updated on a quarterly basis.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

The participating entity must permit the manufacturer of a covered outpatient drug who signed the Agreement with the Secretary, HHS, to audit its records that directly pertain to the entity's compliance with section 340B(a)(5)(A) and (B) requirements with respect to drugs of the manufacturer. Manufacturer audits must be conducted in accordance with guidelines developed by the Secretary, HHS, section 340B(a)(5)(C).

The OPA developed manufacturer guidelines pursuant to section 340B(a)(5)(C). All audits will be conducted in accordance with Government Auditing Standards, Current revision, developed by the Comptroller General of the United States. A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. Consistent with Government auditing standards, the organization performing the audit shall coordinate with other auditors, when appropriate, to avoid duplicating work already

completed or that may be planned. Only one audit will be permitted at any one time. When specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's failure to comply with section 340B(a)(5)(A) and (B), the OPA shall determine whether an audit should be performed by the (1) Government or (2) a manufacturer, and, if so, which manufacturer.

The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of Section 340B. The manufacturer must then submit an audit work plan describing the audit to the OPA for review. The work plan will be reviewed for reasonable purpose, scope, and a determination that only those records of the covered entity that directly pertain to the potential violation will be accessed.

Reports must be prepared at the completion of the audit. Copies of the audit report will be prepared in accordance with the reporting standards for performance audits in Government Auditing Standards, Current Revision. The manufacturer will submit copies of the audit report to the OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit informational copies of the audit report to the HHS Office of Inspector General and the Health Resources Services Administration (HRSA) Administrator. The cost of the audit shall be borne by the manufacturer, as provided by section 340B(a)(5)(C) of the PHS Act.

Because of the potential for audit and other disputes involving covered entities and participating drug manufacturers the OPA has developed an informal dispute resolution process. Section 340B (a)(5)(D) of the PHS Act and section IV(a) of the Agreement provide the covered entity with "notice and hearing," if the entity is believed to be in violation of section 340B(a)(5)(A) or (B). Further, section IV(b) of the Agreement provides the manufacturer with "notice and hearing," if the manufacturer is believed to be in violation of the Agreement.

The types of disputes resolved by these procedures include:

(a) A manufacturer believes a covered entity is in violation of the prohibition against resale or transfer of a covered outpatient drug provided in section 340B(a)(5)(B) of the PHS Act, or the prohibition against duplicate discounts or rebates provided in section 340B(a)(5)(A) of the PHS Act;

(b) A covered entity believes that a manufacturer is charging a price for a covered outpatient drug that exceeds the ceiling price as determined by section 340B(a)(1) of the PHS Act;

(c) A manufacturer is conditioning the sale of covered outpatient drugs to a covered entity on the entity's provision of assurances or other compliance with the manufacturer's requirements that are based upon section 340B provisions;

(d) A manufacturer has refused to sell a covered outpatient drug to a covered entity at or below the ceiling price as determined by section 340B(a)(1) of the PHS Act;

(e) A manufacturer believes a covered entity is dispensing a covered outpatient drug in an unauthorized service (e.g., inpatient services or ineligible clinics within the same health system);

(f) HHS or a manufacturer believe that a covered entity has not complied with the audit requirements of section 340B(a)(5)(C) of the PHS Act; and

(g) The entity disputes the results of an audit performed by a manufacturer pursuant to section 340B(a)(5)(C) or the OPA's determination of the audit.

The Associate Administrator of the Healthcare Systems Bureau shall appoint a committee to review the documentation submitted by the disputing parties and make a determination. A minimum of three individuals shall be appointed (one of whom shall be designated as a chairperson) either on an ad hoc, case-by-case basis, or as regular members of the review committee. The chairperson shall be from the OPA and the committee members shall be from other sections of the Public Health Service (e.g., chief pharmacist, auditor) or a HRSA contractor.

If dispute resolution is desired, a party must submit a written request for a review of the dispute to the Director of the OPA. Upon receipt of a request for a review, the chairperson of the review committee will send a letter to the party alleged to have committed a violation. The letter will include: (1) the name of the party making the allegation(s), (2) the allegation(s), (3) documentation supporting the party's position, and (4) a request for a response to or rebuttal of the allegations within 30 days.

Upon receipt of the response or rebuttal, the review committee chairperson shall review all documentation. The request and rebuttal information shall be reviewed for: (1) evidence that a good faith effort was made to resolve the dispute, (2) completeness, (3) adequate documentation supporting the issues, and (4) the reasonableness of the allegations.

The reviewing committee may, at its discretion, invite parties to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.

The reviewing committee shall propose to dismiss the dispute, if it conclusively appears from the data, information, and factual analyses contained in the request for a review and rebuttal documents that there is no genuine and substantial issue of fact in dispute. This proposed finding of the committee will be submitted to the Director of the OPA for consideration and approval. A written decision of dismissal shall be sent to each party and shall contain the review committee's findings and conclusions in detail and reasons why the request for a review did not raise a genuine and substantial issue of fact.

With all other proposed findings, the review committee shall prepare a written document containing the findings and detailed reasons supporting the proposed decision. The document is to be signed by the chairperson and each of the other committee members. The chairperson shall submit the proposed findings to the Director of the OPA for consideration and approval. Once approved the written decision will be sent with a transmittal letter to both parties.

If the covered entity or the manufacturer does not agree with the OPA's determination, the covered entity or the manufacturer may appeal such a determination to an appeals officer appointed by the Administrator of HRSA.

2. Purpose and Use of Information

There are two situations in which HRSA foresees information that will be needed from participating manufacturers and/or covered entities. First, the proposed manufacturer audit guidelines contain the following reporting/notification requirements:

(1) manufacturers must notify the entity in writing when it believes a violation has occurred;

(2) manufacturers must submit an audit work plan;

(3) manufacturers must submit the audit report to the OPA and informational copies to the Office of Inspector General and the PHS Office of Audit Services; and

(4) the covered entity must provide a written response to the audit report.

These activities are necessary to provide the eligible entities with protection from potential abusive audit tactics.

Second, the proposed formal dispute resolution process requires the participating manufacturer or covered entity requesting dispute resolution to provide the OPA with a written request. The party alleged to have committed a section 340B violation, will be required to provide a response or rebuttal. This information is necessary in order to provide a fair hearing - that the dispute will be resolved in a fair and equitable manner.

The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of Section 340B.

3. Use of Improved Information Technology

The burden for these reporting requirements is for a non-routine process and there are no forms of any kind; therefore, there are no data collection instruments. The manner of communication is at the discretion of the participants typically including letters by U.S. mail, facsimile, and electronic mail.

4. Efforts to Identify Duplication

The information is collected for the purposes of this program and is not available elsewhere.

5. Involvement of Small Entities

Smaller covered entities may be involved in both the audit and dispute process but can submit minimum information to document their case.

6. Consequences If Information Collected Less Frequently

It is in the interest of both the participating manufacturers and the covered entities to submit required information in a timely manner. Only in this way can the OPA monitor activities and evaluate compliance with the statute.

7. Consistency With Guidelines in 5 CFR 1320.6

This information collection fully complies with 5 CFR 1320.6.

8. Consultation Outside Agency

The notice requesting public comment required in 5 CFR 1320.8(d) was published in the Federal Register on October 26, 2012, (77 FR 65392). Three comments were received.

HRSA received three comments in response to the Federal Register Notice on October 26, 2012, (77 FR 65392). One commenter indicated that they believed that estimated burden for the entire compliance oversight and audit process may be substantially underestimated. The additional perspective is of assistance, however, the comment included estimated time for activities beyond that associated with procedural reporting and notification requirements imposed through the final guidelines (Federal Register Final Notice, December 12, 1996, (Vol. 61, No. 240, pp. 65406-65413)). Accordingly, the time and effort a manufacturer may expend to set up a particular compliance monitoring system is not required by the guidance, and has not been included. Likewise, the time inherent in completing the onsite portion of an audit is not included. HRSA will continue to work with manufacturers and covered entities to improve estimates for the burden associated with these guidelines and whether additional categories should be included.

Two other comments were received from groups representing manufacturers in which they also indicated that HRSA had underestimated the burden on manufacturers substantially. In both cases the comments provided criticism and suggestions on additional considerations to take into account, however, no alternative times were offered. HRSA will take into account these comments in evaluating burden in the future as more manufacturers have utilized the process from beginning to end. Additional comments were made regarding clarifications to patient definition that extend beyond the scope of this notice. One commenter also offered suggestions on how to improve availability and access to data. These perspectives will be taken into account as HRSA reviews potential changes to the process.

HRSA consulted in January 2013 with a manufacturer that was one of the few manufactures with experience with the entire process. In response to this consultation and the comments received, a number of elements on the burden estimate have been revised: (1) An estimate to engage in good faith resolution has been included; (2) time required to provide the audit work plan and audit report has been increased; and (3) the wage rate utilized in this document has been increased substantially.

The ability to resolve these issues through consultation is significantly hampered by the circumstances. Only a handful of manufacturers and covered entities have utilized these processes. It is anticipated that there is a wide variance on the time and effort involved depending upon the nature and the facts surrounding the dispute, the volume of purchases, the specific issues involved, the approach adopted by the manufacturer and covered entity as well as the compliance systems in place for the covered entity and manufacturer. Stakeholders have ongoing opportunities to share their perspective and experience with the process.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

Any proprietary or confidential information will be used only for internal purposes. The information will be kept in locked file cabinets, and only authorized personnel will have access to the files. Copies of the audit reports will be sent to the Office of the Inspector General and the HHS Cost and Audit Management Branch which generally handles these types of reports. These departments already have security procedures in place and the usual security procedures will apply.

11. Questions of a Sensitive Nature

There are no sensitive questions.

12. Estimates of Annualized Hour Burden

Reporting/Notification Burden:

Reporting/ Notification Requirement	No. of Respon-dents	Responses per Respondent	Total Responses	Hours/ Response	Total Burden Hours	Wage Rate	Total Hour Cost
AUDITS							
Good faith Resolution[1]	10	1	10	40	400	$125	$50,000
Audit Notification of Entity[1]	10	1	10	4	40	$125	$5,000
Audit Workplan[1]	8	1	8	10	80	$125	$10,000
Audit Report[1]	6	1	6	10	60	$125	$7,500
Entity Response	6	1	6	8	48	$125	$6,000
DISPUTE RESOLUTION							
Mediation Request	10	4	40	10	400	$125	$50,000
Rebuttal	10	1	10	16	160	$125	$20,000
TOTAL	50		80		1,188	$125	$148,500

Prepared by the manufacturer

Recordkeeping Burden:

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total Burden
Dispute Records	50	0.5	25

Basis for Burden Estimates:

There have been six audit workplans submitted to HRSA and only three requests for informal dispute resolution since the inception of the program. Of the three dispute resolution requests, one was terminated by HRSA due to non-participation by one of the parties, another was dismissed due to lack of standing, and the last was terminated where the parties disputed the existence of any attempt of good faith resolution. The relatively small number is attributed to the success of the good faith resolution of the parties. HRSA has increased its efforts in answering questions, clarifying policies and resolving all issues that might otherwise have escalated to the level of a formal request for audit or dispute resolution. Most problems are found to be the result of miscommunication or misunderstandings that are quickly resolved. HRSA anticipates that greater utilization of the audit process will correlate with an increase in dispute resolution requests.

Audits:

The first six manufacturer audit workplans were received in the past year and we expect it to continue to increase. This is in part attributed to the amendment to section 340B(a)(5)(D) which now requires an audit prior to holding covered entities liable to manufacturers for violations of 340B(a)(5)(A) or (B). The numbers also reflect the fact that not all audit notifications are pursued to the end of the process; with some issues being resolved informally at different stages. Also, it is possible that the entity alleged to have violated the statute will alter the suspect behavior rendering audit activity unnecessary.

Dispute Resolution:

Again, the program estimates that most disputes will be resolved by interaction with the program. There have been only three disputes which reached the point of informal dispute resolution, however with the changes to the program and increased utilization of manufacturer audits, this is anticipated to increase.

Recordkeeping Burden

There has been very limited experience to date with Dispute Resolution record keeping. We expect most if not all audit requests will end up in a dispute resolution request.

13. Estimates of Annualized Cost Burden to Respondents

There are no required capital or startup costs or operation or maintenance costs; the only costs are the staff time required to prepare and submit the reports.

14. Estimates of Annualized Cost to the Government

As the requests for audits and dispute resolution have increased so has the estimated burden. If requests for audit or dispute resolution are received at the level estimated above in Item 12, titled, "Estimates of Annualized Hour Burden," some level of Federal effort will be required; probably totaling approximately. 6 FTE at a GS-14 level ($105,000 x .6 = $63,000).

15. Changes in Burden

The burden is now estimated to 1188. This is increased from 785 in the notice published for comment (77 FR 65392) with revisions being done as noted above in Item 12, titled "Estimates of Annualized Hour Burden." The burden estimate in the OMB inventory was 134 hours when last extended.

16. Time Schedule, Publication and Analysis Plans

The program does not plan to tabulate or use the information for publication purposes.

17. Exemption for Display of Expiration Date

There are no standard instruments, forms, or screens for this activity.

18. Certifications

This project fully complies with the requirements in 5 CFR 1320.