Supporting Statement A

340B Drug Pricing Program Reporting Requirements

OMB Control No. 0915- 0176

Terms of Clearance: For revision.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for a revision of Office of Management and Budget (OMB) approval for burden associated with the 340B Drug Pricing Program (340B Program) reporting and recordkeeping requirements. The requirements are currently approved under OMB number 0915-0176 which expires on May 31, 2016. To date, there have been 40 requests for audits from manufacturers and 4 requests for informal dispute resolution. In order to comply with P.L. 102-585, the burden estimate has been approved for the process of 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 (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 the 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 PHS Act. The Department of Health and Human Services' Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Office of Pharmacy Affairs (OPA) provides a list of eligible entities to each participating manufacturer (approximately 600 manufacturers) and has notified each covered entity of its eligibility to purchase drugs at a statutorily calculated ceiling price. The current list of both eligible entities and manufacturers has been placed on an electronic data retrieval system, the OPA 340B Database. It is available to the public at: https://opanet.hrsa.gov. This list is updated on a quarterly basis.

Covered entities which choose to participate in the 340B 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 requesting Medicaid reimbursement from a drug that has been discounted under the 340B Program. 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.

A covered entity must permit the manufacturer of a covered outpatient drug that signed an Agreement to audit covered entity 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. It is OPA's expectation that manufacturer audits would be conducted in accordance with 340B Program guidelines.

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) of the PHS Act 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) or (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 proposed 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 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 a voluntary informal dispute resolution process.

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); and

(f) The entity disputes the results of an audit performed by a manufacturer pursuant to section 340B(a)(5)(C).

If dispute resolution is desired, a party would submit a written request for a review of the dispute to the Director of the OPA. Upon receipt of a request for a review, a review committee will be assembled and 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 will 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.

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.

2. Purpose and Use of Information Collection

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

1. manufacturers should notify the entity in writing when it believes a violation has occurred;
2. manufacturers should submit documentation to OPA as evidence of good faith of attempts to resolve a dispute;

3. manufacturers must submit an audit work plan to OPA;
4. manufacturers should submit the audit report to the OPA and informational copies to the HHS OIG; and
5. the covered entity should provide a written response to the audit report.

These activities are necessary for the orderly conducting of audits and to provide the eligible entities with protection from potential abusive audit tactics.

Second, the informal 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, may provide a response or rebuttal. This information is necessary in order to ensure that the dispute will be resolved in a fair and equitable manner.

The revision to this package includes additional background information on the dispute resolution process and clarifies the need and proposed use of information regarding the manufacturer audit guidelines and the informal dispute resolution process. In addition, the burden has been revised to reflect comments received during the 60-day Federal Register Notice process.

3. Use of Improved Information Technology and Burden Reduction

The burden for these reporting elements 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/or electronic mail.

4. Efforts to Identify Duplication and Use of Similar Information

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

5. Involvement of Small Businesses or Other Small Entities

Smaller covered entities may be involved in both the audit and dispute process. They are able to submit limited information directly related to the dispute.

6. Consequences of Collecting the Information 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. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with 5 CFR 1320.5.

8. Comments in Response to the *Federal Register* Notice/Outside Consultation

None.

8A.

A 60-day Federal Register Notice was published in the *Federal Register* on December 23, 2015, Vol. 80, No. 246; pp. 79915-79917. There were five public comments.

HHS has reviewed all of the comments submitted during the 60-day public comment period for this ICR. Comments submitted included requests for standardized reporting forms. Commenters also expressed concern that burden hours were significantly understated. HHS has also considered the comments submitted regarding burden estimates values and believes that the burdens reflected in this ICR may have been understated. Adjusted burden estimates are included in the 30 day notice and are reflected in this supporting statement. Some of the comments received regarding the audit process are beyond the scope of this notice. Finally, HHS appreciates the comments received regarding the development of a formal dispute resolution process. HHS issued a Notice of Proposed Rulemaking (NPRM) on August 12, 2016 (81 FR 53381, August 12, 2016) to implement the Administrative Dispute Resolution Process pursuant to section 340B(d)(3) of the Public Health Service Act. The purpose of this formal ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers after a manufacturer audit reveals that a covered entity has violated the prohibition on diversion or duplicate discounts. HHS has historically encouraged manufacturers and covered entities to resolve disputes in good faith and the formal ADR process is not intended to replace those efforts, but rather it should be utilized in the event that good faith efforts to resolve disputes are not successful. The comment period for the NPRM closes on October 11, 2016.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

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 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. Justification for Sensitive Questions

This data collection does not request sensitive information from the respondent.

12. Estimates of Annualized Hour Burden

Reporting/Notification Burden:

Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
AUDITS							
Good faith Resolution[1] (http://www.bls.gov/oes/current/oes231011.htm)	10	1	10	60	600	$65	$39,000
Audit Notification of Entity[1] (http://www.bls.gov/oes/current/oes132011.htm)	10	1	10	6	60	$36	$2,160
Audit Workplan[1] (http://www.bls.gov/oes/current/oes231011.htm)	40	1	18	12	216	$65	$14,040
Audit Report[1] (http://www.bls.gov/oes/current/oes132011.htm)	8	1	8	12	96	$36	$3,456
Entity Response (http://www.bls.gov/oes/current/oes231011.htm)	8	1	8	12	96	$65	$6,240

DISPUTE RESOLUTION							
Dispute Request (http://www.bls.gov/oes/current/oes231011.htm)	10	4	40	15	600	$65	$39,000
Rebuttal (http://www.bls.gov/oes/current/oes231011.htm)	10	1	10	28	280	$65	$18,200
TOTAL	96		104		1948		$122,096

[1] Prepared by the manufacturer

Recordkeeping Burden:

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total Burden
Dispute Records	50	1	50

Basis for Burden Estimates:

There have been 40 audit workplans submitted to HRSA and only 4 requests for informal dispute resolution since the inception of the 340B Program. Of the four dispute resolution requests, two were 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 because the parties disputed the existence of any attempt of good faith resolution. The relatively small number is attributed to the success of the parties' attempts to resolve issues in good faith. HRSA has increased its efforts to answer questions, clarify policies, and resolve 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 40 manufacturer audit workplans were received in the past 4 years and we expect the numbers 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 workplans are pursued to the end of the process; with some issues being resolved informally at different stages, or the covered entity was subject another audit at the time of request.

Dispute Resolution:

The program estimates that most disputes will be resolved by interaction with the program. There have been only four disputes which reached the point of informal dispute resolution requests.

Recordkeeping Burden:

There has been very limited experience to date with Dispute Resolution record keeping. We do not expect the majority of audit requests to end up in a dispute resolution request.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

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 if the manufacturer opts to conduct an audit.

14. 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," an increased level of Federal effort will be required; most likely approximately 0.6 Full Time Equivalents (FTEs) at a GS-14 level ($105,000 x .6 = $63,000).

15. Explanation for Program Changes or Adjustments

The current burden hour inventory is 1,188 hours and this revision is requesting an increase to 1948 hours. This increase reflects comments received during the 60-day public comment period indicating that the current burden estimate is understated.

16. Plans for Tabulation, Publication, and Project Time Schedule

A 3-year clearance is being requested for this recurring data collection. There are no plans for tabulation, statistical analysis, or publication of the information collected.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is being requested. The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions Certifications

There are no exceptions to the certification.