Supporting Statement A

340B Drug Pricing Program Reporting Requirements

OMB Control No. 0915- 0176 - Extension

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) currently has approval under Office of Management and Budget (OMB) Control No. 0915-0176 to collect information associated with manufacturer audit guidelines. This collection of information helps fulfill the requirements of section 340B(a)(5)(C) of the Public Health Service Act (PHSA), which permits the Secretary of HHS and manufacturers of a covered outpatient drug to conduct audits of covered entities by procedures established in accordance with the Secretary related to the number, duration and scope of the audits.

See attached for a copy of section 340B of the PHSA for more information.

To date, there have been 45 requests for audits from manufacturers and four 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 Health Resources and Services Administration (HRSA) 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 online system, the HRSA Office of Pharmacy Affairs Information System (340B OPAIS). It is available to the public at: https://340bopais.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 manufacturer audit guidelines (61 FR 65406, December 12, 1996) and HRSA's 2011 policy release "Clarification of Manufacturer Audits of 340B Covered Entities," Release No. 2011-3 (See Attachment II).

HRSA developed manufacturer audit 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), HRSA 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 HRSA 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 HRSA 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, HRSA 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 HRSA. 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 HRSA 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

There are two situations in which information is 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 HRSA as evidence of good faith of attempts to resolve a dispute;
3. manufacturers must submit an audit work plan to HRSA;
4. manufacturers should submit the audit report to HRSA 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 HRSA 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.

3. Use of Improved Information Technology

The burden for these reporting elements is for a non-routine process and there are no forms associated with this information collection request (ICR); 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 Avoid Duplication

The information is collected for the purposes of the 340B Program and is not available elsewhere.

5. Involvement of 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 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 HRSA 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 and assists HRSA with addressing specific statutory mandates.

8. Consultation Outside the Agency

A 60-day Notice regarding agency information collection activities was published in *Federal* Register at Vol. 84, No. 117, p.28308-09 on June 18, 2019 (See attached). The Notice summarized the proposal to collect information from manufacturers pursing an audit of a covered entity and documentation related to an information dispute resolution process. The Notice was open for a 60-day comment period, which closed on August 19, 2019.

HRSA received one public comment document. The comment received addressed a policy related issue that is outside of the scope of this ICR. In the 30-day FRN, HRSA explained that the one public comment was received and because it was beyond the scope of the ICR, HRSA would not be addressing the comment in the notice.

9. Remuneration of Responses

Not applicable.

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 entities have security procedures in place and the usual security procedures will apply.

11. Questions of a Sensitive Nature

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
AUDITS					
Good faith Resolution[1]	10	1	10	60	600
Audit Notification of Entity[1]	14	1	14	6	84
Audit Workplan[1]	45	1	45	12	540
Audit Report[1]	14	1	14	12	168
Entity Response	14	1	14	12	168
DISPUTE RESOLUTION					
Mediation Request	10	4	40	15	600
Rebuttal	10	1	10	28	280
TOTAL	117		147		2440

[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 45 audit work plans 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:

Forty-five manufacturer audit work plans were received in the past 6 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 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:

HRSA estimates that most disputes will be resolved by interaction by the parties involved. Since the inception of 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 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 if the manufacturer opts to conduct an audit.

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Manufacturer Accountants and Auditors (Accountants and Auditors median hourly wage from BLS - https://www.bls.gov/oes/current/oes132011.htm)	252	$38	$9,576
Manufacturer and Covered Entity Lawyers (Lawyer median hourly wage from BLS - https://www.bls.gov/oes/current/oes231011.htm)	2,188	$69	$150,972
TOTAL:	2440		$160,548

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," an increased level of Federal effort will be required; most likely approximately 0.6 Full Time Equivalents (FTEs) at a GS-13 level ($99,172 x .6 = $59,503).

15. Change in Burden

The current burden hour inventory is 1,948 hours and this extension is requesting an increase to 2,440 hours. This increase reflects the slight increase in the number of requests that have been received since the last approval.

16. Plans for Analysis and Timetable of Key Activities

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. Exemption for Display of Expiration Date

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

18. Certifications

There are no exceptions to the certification.