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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: 340B Drug Pricing Program Reporting Requirements

OMB No. 0915-0176 – [Revision]

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, 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 participates in Medicaid must sign a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge enrolled covered entities a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities who choose to participate in the section 340B Drug Pricing Program must comply with the requirements of 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.

Section 340B(a)(5)(C) of the PHS Act permits the Secretary and manufacturers of a covered outpatient drug to conduct audits of covered entities in accordance with procedures established by the Secretary related to the number, duration, and scope of the audits. Manufacturers are 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. The manufacturer notifies the covered entity in

writing when it believes the covered entity has violated these provisions of the 340B Program. If the problem cannot be resolved, the manufacturer will then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to HRSA, Healthcare Systems Bureau, Office of Pharmacy Affairs (OPA) for review. OPA will review the documentation to determine if reasonable cause exists. Once the audit is complete, the manufacturer will submit copies of the audit report to OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the Health and Human Services (HHS) Office of Inspector General (OIG).

In response to the statutory mandate of section 340B(a)(5)(C) to permit the Secretary or manufacturers to conduct audits of covered entities and because of the potential for disputes involving covered entities and participating drug manufacturers, OPA developed an informal voluntary dispute resolution process for manufacturers and covered entities who, prior to filing a request for resolution of a dispute with OPA, should attempt in good faith to resolve the dispute. All parties involved in the dispute should maintain written documentation as evidence of a good faith attempt to resolve the dispute. To request voluntary dispute resolution of an unresolved dispute, a party submits a written request for a review of the dispute to OPA. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

HRSA published a notice in 1996 and a policy release in 2011 on manufacturer audit guidelines and the informal dispute resolution process (61 FR 65406 (December 12, 1996) and "Clarification of Manufacturer Audits of 340B Covered Entities," Release No. 2011-3).

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.

HHS has reviewed all comments submitted in response to the publication of a 60-day *Federal Register* notice requesting comments on this ICR. Comments submitted included requests for standardized reporting forms. Commenters also expressed concern that burden hours were significantly understated. HHS agrees that the burdens associated with this ICR may have been understated. Adjusted burden estimates are included in this 30-day notice. Finally, HHS appreciates the comments received regarding the development of a formal dispute resolution process. HHS is in the process of developing a regulation to establish and implement a binding administrative dispute resolution process pursuant to section 340(d)(3) of the PHS Act. Some of the comments received regarding the audit process are beyond the scope of this notice, and as such, HHS will not be addressing them in this notice.

Need and Proposed Use of the Information: HRSA is proposing the collection of information related to the manufacturer audit guidelines. These 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 OPA and informational copies to the HHS OIG; and
5. the covered entity should provide a written response to the audit report.

This information is necessary to ensure the orderly conduct of manufacturer audits. In addition, the informal dispute resolution process requires the participating manufacturer or covered entity requesting dispute resolution to provide OPA with a written request. The party alleged to have committed a section 340B violation may provide a response or rebuttal to OPA. This information is necessary to ensure that the dispute will be resolved in a fair and equitable manner.

Likely Respondents: Drug manufacturers and 340B covered entities.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

Form Name	Number. of Respondents	Number of 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 to Entity[1]	10	1	10	6	60
Audit Workplan[1]	40	1	18	12	216
Audit Report[1]	8	1	8	12	96
Entity Response	8	1	8	12	96
DISPUTE RESOLUTION					
Dispute Request	10	4	40	15	600
Rebuttal	10	1	10	28	280
TOTAL	96		104		1948

[1] Prepared by the manufacturer

Recordkeeping Burden:

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

Jason E. Bennett,

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