Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request Information Request Title: 340B Drug Pricing Program Reporting Requirements, OMB Number 0915-0176 – Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443-1984.

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

Information Collection Request Title: Drug Pricing Program Reporting Requirements OMB No. 0915-0176 – [Extension]

Abstract: Section 340B of the Public Health Service Act (PHS Act "Limitation on Prices of Drugs Purchased by Covered Entities") instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS to comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program) and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which

are based on quarterly pricing data reported by manufacturers to the Centers for Medicare & Medicaid Services (CMS). When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that 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 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 covered entity.

Section 340B(a)(5)(C) of the PHS Act permits the Secretary of HHS 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 the 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 completed, 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 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).

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 covered 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.

This information is necessary to ensure the orderly conduct of manufacturer audits. Also, 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 340B Program 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 during an audit. 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 for both covered entities and manufacturers. 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]	43	1	43	12	516
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	111		120		2,392

[1] Prepared by the manufacturer

Recordkeeping Burden:

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

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Division of the Executive Secretariat.

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