services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the September meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include a discussion of the role of health information technology within state newborn screening programs and general updates on ACHDNC projects focused on newborn screening. Agenda items are subject to changes as priorities dictate and the final meeting agenda will be available on ACHDNC's website: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Information about the ACHDNC, a roster of members, as well as past meeting summaries are also available on the ACHDNC website.

Members of the public will have the opportunity to provide comments. Requests to offer oral comments will be accepted in the order they are requested and may be limited as time allows. Public participants may also submit written statements. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on September 19, 2019. Visit the ACHDNC website for information on registration, *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.,* parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Maria G. Button,

Director, Division of the Executive Secretariat.

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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, the Paperwork Reduction Act of 1995, 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 must be received no later than October 7, 2019.

ADDRESSES: Submit your comments, including the ICR 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 Lisa Wright-Solomon, 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 ICR title for reference.

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

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''), which 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 that 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. 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 by procedures established 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 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. Prior to filing a request for resolution of a dispute with OPA, the parties involved 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 in 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.

A 60-day notice was published in the **Federal Register** on June 18, 2019, vol. 84, No. 117; pp. 28308–09. There was one public comment received. The comment received addressed a policy issue that is beyond the scope of this information collection request; therefore, HRSA will not be addressing the comment in this notice.

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]	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		2,440

[1] Prepared by the manufacturer.

* Since the first public review of the ICR, HRSA has received several audit work plans from manufacturers. HRSA has decided to update its proposed burden hours to reflect the increase in submissions.

RECORDKEEPING BURDEN

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

Maria G. Button,

Director, Division of the Executive Secretariat.

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