: 4165-15-P

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; 340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

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

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: 340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process, OMB No. 0906-xxxx – New

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, created the 340B Drug Pricing Program in section 340B of the Public Health Service (PHS) Act. Eligible covered entity types are defined in section 340B(a)(4) of the PHS Act, as amended. Section 340B(a)(1) of the PHS Act instructs HHS to enter into pharmaceutical pricing agreements with manufacturers of covered outpatient drugs. Under section 1927(a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHS Act to receive payments from Medicaid or Medicare Part B for the manufacturer's covered outpatient drugs. When a manufacturer signs a pharmaceutical pricing agreement, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. Such prices are based on quarterly pricing reports that manufacturers must provide to the Secretary, which are calculated and verified by HRSA.

Section 340B(d)(3) to the PHS Act requires HHS to promulgate regulations establishing and implementing a binding 340B Administrative Dispute Resolution (ADR) process for certain disputes arising under the 340B Drug Pricing Program. Pursuant to the statute, the 340B ADR process is intended 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 has conducted an audit as authorized by section 340B(a)(5)(C) of the PHS Act, that a covered entity has violated the prohibition on diversion or duplicate discounts.

On April 19, 2024, HRSA published the 340B Drug Pricing Program; Administrative Dispute Resolution Regulation Final Rule (340B ADR Final Rule) (89 FR 28,643 (Apr. 19, 2024) (to be codified at 42 CFR part 10)). The 340B ADR Final Rule provides the requirements for filing a 340B ADR claim. The 340B ADR Final Rule requires the submission of a 340B ADR claim within 3 years of the date of the alleged violation and specifies that it is a remedy

open to all manufacturers and covered entities that participate in the 340B Drug Pricing Program. To initiate the 340B ADR process, a petitioner will email HRSA's Office of Pharmacy Affairs' (OPA) designated mailbox with its 340B ID or Labeler code and contact information, the 340B ID or Labeler code and contact information of the opposing party, and a brief description of the claim. Once a petition is filed, OPA reviews the petition to make sure the claim meets the requirements for the 340B ADR process, including whether: (1) the claim alleges a violation of an overcharge, duplicate discount, or diversion; (2) the claim has been filed within 3 years of the alleged violation; and (3) the petitioner has engaged in good faith efforts to resolve the claim. Both the petitioner and opposing party will be required to upload certain documentation to a secure 340B ADR workspace in the 340B OPA Information System to substantiate the claim. After an initial review of the claim and any supporting documentation, OPA staff will determine whether the requirements for filing a claim have been met, and if the claim is deemed complete, OPA will notify the parties. If the claim is deemed complete and all filing requirements are met, the claim will be assigned to a 340B ADR Panel. If the claim does not meet the filing requirements, the claim will not move forward for a 340B ADR Panel's review. Specific details concerning the 340B ADR Panel and requirements for filing a claim are outlined in the 340B ADR Final Rule and can be reviewed at https://www.hrsa.gov/opa/340b-administrative-dispute-resolution.

This information collection request is limited to the initiation of the 340B ADR process and the uploading of the related documents. Filing a claim though the 340B ADR process is a remedy open to all manufacturers and covered entities that participate in the 340B Drug Pricing Program, which can constitute a standardized federal information collection. Once the claim is assigned to a 340B ADR Panel for review, these subsequent steps, which encompass the 340B ADR process itself and ensuing correspondence with the parties involved in the process, are exempt from Paperwork Reduction Act requirements, pursuant to the Paperwork Reduction Act

exception listed at 44 U.S.C. 3518(c), which exempts administrative actions or investigations involving an agency against specific individuals or entities.

The only substantive change to the information collection request for this 30-day notice is that HRSA adjusted the estimated number of respondents based on the number of ADR requests received thus far. HRSA increased the estimate from 10 requests to 15 over the next three years.

A 60-day notice published in the **Federal Register** on August 7, 2024, 89 FR 64468 and 64469. HRSA received five public comments.

Three commenters representing pharmaceutical manufacturers explained that HRSA's estimate of 2.5 hours per response underestimates the significant burden manufacturers incur to access the ADR process. Some manufacturers noted that under the statute a manufacturer can only access the ADR process after it has completed an audit of a covered entity and argued HRSA's manufacturer audit guidelines impose significant burdens on manufacturers' ability to audit. HRSA notes that manufacturer audits of covered entities are a separate, pre-existing process and are not subject to this information request. This information collection request is limited specifically to the initiation of the 340B ADR process under the 2024 340B ADR Final Rule and the uploading of the related documents at the initial phase of the 340B ADR process.

One commenter requested that HRSA require manufacturers to present specific types of documentation and evidence to initiate a dispute. Another commenter requested that HRSA specify what "sufficient documentation" consists of for submitting an ADR claim. Under the 340B ADR Final Rule, petitioners have discretion regarding the documentation they submit as part of their initial submission to support their claims.

Other comments discussed elements of the ADR Final Rule, including defining what good faith efforts entail, how child site eligibility relates to diversion and what the definition of an overcharge should include, that are outside of the scope of this information collection request. After detailed analysis of the comments received, HRSA plans to maintain the burden hours as proposed in the 60-day notice.

Need and Proposed Use of the Information: HRSA is requesting approval for the initiation of the 340B ADR process and uploading of the related documents outlined in the 340B ADR Final Rule. The 340B ADR process is conducted pursuant to the requirements under section 340B(d)(3) of the PHS Act, which requires the establishment and implementation of the 340B ADR process for certain disputes arising under the 340B Drug Pricing Program. HRSA uses the information gathered in the 340B ADR initiation process to determine if the claim submitted meets the statutory requirements for filing a 340B claim and accessing the 340B ADR process.

Likely Respondents: Covered entities (or their membership organizations or associations) and manufacturers.

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
340B Claim Submission	15	1	15	2.5	37.5
Total	15		15		37.5

Maria G. Button,

Director, Executive Secretariat.

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