Supporting Statement A

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

OMB Control No. 0906-XXXX

Terms of Clearance: "None".

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 Fed. Reg. 28643 (Apr. 19, 2024) (to be codified at 42 C.F.R. 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.

HRSA is requesting this information collection to implement the requirements as outlined in the Final Rule. This information collection is only applicable to the initiation of a 340B ADR claim.

2. Purpose and Use of Information Collection

The information provided in this collection will be used by 340B ADR panels. The 340B ADR panel is a group of OPA staff members selected from a roster of OPA staff appointed by the Secretary, to review and evaluate petitions submitted by covered entities and manufacturers to resolve a dispute. The 340B ADR Panel will conduct a review of the claims. The 340B ADR Panel will review all documents gathered during the 340B ADR process to determine if a violation of overcharge, diversion or duplicate discounts has occurred. 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.

3. Use of Improved Information Technology and Burden Reduction

The 340B Office of Pharmacy Affairs Information System (OPAIS) will be used as a platform for submitting and the repository for maintain information submitted related to a 340B ADR petition. Additionally, information may be submitted via email to 340BADR@hrsa.gov.

4. Efforts to Identify Duplication and Use of Similar Information

The information collected is specific to each individual dispute.

5. Impact on Small Businesses or Other Small Entities

The collection information for participating in the 340B Program for both covered entities and manufacturers may impact small entities. HRSA expects the burden associated with collection of this information to be low. Participation in the 340B ADR process for both entities and manufacturers is voluntary.

6. Consequences of Collecting the Information Less Frequently

There is no frequency requirement for this data collection. Submissions are voluntary.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

On April 19, 2024, HRSA published the 340B Drug Pricing Program; Administrative Dispute Resolution Regulation Final Rule (340B ADR Final Rule) (89 Fed. Reg. 28,643 (Apr. 19, 2024) (to be codified at 42 C.F.R. part 10)).

A 60-day notice published in the Federal Register on August 7, 2024, vol. 89, No. 152; pp. 64468-69. HRSA received five public comments.

Three commenters explained that HRSA's estimate of 2.5 hours per response grossly underestimates the significant burden manufacturers incur to access the ADR process. Some comments explained that a manufacturer can only access the ADR process after it has completed an audit of a covered entity and HRSA's manufacturer audit guidelines impose significant burdens on manufacturers' ability to audit, thereby effectively denying manufacturers access to the ADR process. This information collection request is limited only to the initiation of the 340B ADR process and the uploading of the related documents at the initial phase of the 340B ADR process. It does not include audits performed by manufacturers of covered entities. Though manufacturer audits of covered entities are a prerequisite to filing

an ADR claim for manufacturers, those audits are a separate investigative process and are not subject to this information request.

One commenter requested that HRSA require manufacturers to present specific types of documentation and evidence to initiate a dispute. One commenter requested that HRSA specify what "sufficient documentation" consists of for submitting an ADR claim. Documentation provided by the petitioner is left to the discretion of the submitter in order to substantiate initiation of their position as part of the claim.

The other comments discussed specifics elements of the ADR rule, including defining what good faith efforts entail, how child site eligibility relates to diversion and what the definition of an overcharge should include. These comments are outside of the scope of this information collection request. After detailed analysis of the comments received, HRSA is moving forward with the burden hours as stated in the 60-day notice.

Section 8B:

Not applicable.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

340B Office of Pharmacy Affairs Information System (OPAIS) is a secure system that only allows access to registered and logged in users. Users only have access to the ADR petitions that they are a party to. The 340B statute (42 U.S.C. § 256b(d)(1)(B)(iii)) requires protection of privileged pricing data from unauthorized re-disclosure. Data will be kept private to the extent allowed by law.

11. Justification for Sensitive Questions

There are no sensitive questions for this information collection.

12. Estimates of Annualized Hour and Cost Burden

Likely respondents include covered entities (or their membership organizations or associations) and manufacturers. There is no set frequency of response, because submission is voluntary and based on a stakeholder's circumstance if initiation of a petition is necessary. Burden was estimated based on the number of petitions submitted to date, including the breakdown between covered entities and manufacturers making ADR submissions.

12A. Estimated Annualized Burden Hours

Type of Respondent	Collection Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Covered entities	ADR Submission	14	1	2.5	35
Manufacturers	ADR Submission	1	1	2.5	2.5
Total		**15**			**37.5***

* Rounds up to 38 hours in ROCIS.

No forms are required in this collection, instead this information collection will consist of documents submitted for the initiation of the ADR process in OPAIS or email. 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.

12B.

The Department of Labor was used to determine appropriate wage rates for respondents (http://www.bls.gov/bls/blswage.htm). The Median hourly wage was used.

Bureau of Labor Statistics (BLS) occupation code(s) were used. Attorneys have historically submitted information on behalf of covered entities and manufacturers, therefore BLS occupation code 23-1011 was used to identify the median hourly wage.

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate (x2)	Total Respondent Costs
Lawyer	37.5	$140.16	$5,256
Total			$5,256

Hourly Wage Rate based on the United States Department of Labor, Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes231011.htm). Hourly wage doubled to account for benefits.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

Other than their time, there is no cost to respondents. This information collection request is limited only to the initiation of the 340B ADR process and the uploading of the related documents at the initial phase of the 340B ADR process. It does not include audits performed by manufacturers of covered entities. Though manufacturer audits of covered entities are a prerequisite to filing an ADR claim for manufacturers, those audits are a separate investigative process and are not subject to this information request.

14. Annualized Cost to Federal Government

This information collection request is non-routine. The estimated average federal cost to implement the manufacturer and covered entity ADR submissions are included in the 340B OPAIS system annual system costs for registration and pricing and will be approximately $4 million per year. The HRSA contractor will develop and maintain the system on an annual basis. The GS-14 Pharmacist will also spend approximately 25% of their time annually reviewing incoming ADR submissions. The annual salary is $139,335, which is multiplied by 1.5 to account for overhead costs in the table below (bringing the total to $209,092.5)

Description	Time	Salary (x 1.5)	Annual Cost
OPA Information System Maintenance/Enhancement Contract	Yearly	N/A	$4,000,000
Pharmacist (ADR Coordinator) - GS-14/1	25% of time	$209,092.5	$52,273.125
Total per year:			**$4,052,273.125**

15. Explanation for Program Changes or Adjustments

This is a new information collection. Changes in cost burden are not discussed in this section.

16. Plans for Tabulation, Publication, and Project Time Schedule

Information collected will not be published or tabulated. The information collected in the 340B ADR process is confidential and proprietary in nature, therefore, cannot be publicly disclosed. The 340B statute (42 U.S.C. § 256b(d)(1)(B)(iii)) requires protection of privileged pricing data from unauthorized re-disclosure.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.