Supporting Statement A

Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program

OMB Control No. 0915-0327 – Revision

A. Justification

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA) currently has approval under Office of Management and Budget (OMB) Control No. 0915-0327, to collect information in support of 340B covered entity recertification and registration, as well as registration of covered entity contract pharmacy arrangements and manufacturer pharmaceutical pricing agreement (PPA), the PPA addendum, and pricing data from manufacturers. This collection of information helps fulfill the requirements of the following provisions of section 340B of the Public Health Service Act (PHSA):

a. Section 340B(a)(4) – *Registration of covered entities*
b. Section 340B(a)(7)(E) – *Recertification of covered entities*
c. Section 340B(a)(1) – *Pharmaceutical Pricing Agreement*
d. Section 340B(a)(1) – *Pharmaceutical Pricing Agreement, Addendum*
e. Section 340B(d)(1)(B)(i)(II) – *Manufacturer Quarterly Pricing Data Submission*

See Attachment I for a copy of section 340B of the PHSA for more information.

HRSA notes that the previously approved collections are mostly unchanged except that HRSA has transitioned completely to an online system versus hardcopy instruments. In doing so, some of the instruments contain minor revisions to increase program efficiency and integrity. In addition, the STD and TB forms have been combined so that their language is consistent.

2. Purpose and Use of Information

To ensure ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency and integrity, HRSA developed a process of registration for covered entities to address specific statutory mandates. Section 340B(a)(9) of the PHSA requires HRSA to notify manufacturers of the identities of covered entities and of their status pertaining to certification and annual recertification in the 340B Program pursuant to section 340B(a)(7) of the PHSA and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHSA.

In addition, section 340B(a)(1) of the PHS Act requires each participating manufacturer to enter into an agreement with the Secretary to offer covered outpatient drugs to 340B covered entities.

Finally, section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities.

The information collected as part of this request is captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (340B OPAIS). HRSA's Office of Pharmacy Affairs (OPA) staff use the collected information to verify eligibility of covered entities during registration, confirm covered entities' eligibility during annual recertification, and ensure that covered entities can make administrative changes to their information throughout the course of their participation in the Program. OPA staff also ensure that manufacturers have signed a PPA and PPA addendum and ensure that manufacturers can make administrative changes to their information throughout the course of their participation in the Program. OPA staff also review and verify 340B pricing data submitted by manufacturers and the final 340B ceiling price is posted in the secure pricing system. Covered entities are also able to access the system and view the HRSA-verified 340B ceiling price to ensure that they are receiving covered outpatient drugs at or below the statutorily mandated 340B ceiling price.

3. Use of Improved Information Technology

Information collection via this request is entirely collected online. For both registration and recertification, covered entities can enter their information into the registration component of the 340B OPAIS. Manufacturers can also enter information into the registration component of the 340B OPAIS, including their PPA and PPA addendum. Administrative changes for both covered entities and manufacturers can be made via the registration component of the 340B OPAIS. Manufacturers can either manually enter the requested information into the pricing component of the 340B OPAIS or upload their file into the system. The upload capability of the pricing component of the 340B OPAIS reduces the burden on the user and reduces the errors that might occur from manually entering multiple lines of data.

4. Efforts to Avoid Duplication

This information collection does not duplicate any other effort as these instruments are the only way for providing this information to HRSA.

5. Involvement of 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 for both entities and manufacturers is voluntary and when the entity voluntarily decides to enroll and participate in the Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs.

6. Consequences if Information Collected Less Frequently

Registration of covered entities is collected once the entity enrolls into the Program. There is no need to collect registration information more frequently. Recertification information is collected annually as required by section 340(a)(7)(E) of the PHSA and the consequence of collecting this information less frequently would not adhere to a statutory requirement. Collection of information pertaining to the PPA and PPA addendum is collected once when a manufacturer enrolls into the Program. Pricing data is collected on a quarterly basis as well pursuant to sections 340B(a)(1) and 340B(d)(1)(B)(i) of the PHSA and collecting this information less frequently would not adhere with these provisions of the statute.

7. Consistency with the Guidelines of 5 CFR 1320.5

The information collected as part of this request assist HRSA with addressing specific statutory mandates.

8. Consultation Outside the Agency

A 60-day Notice was published in the *Federal Register* on May 9, 2019, vol. 84, No. 90; pp. 20373-75 (See Attachment II). There were four public comments received. Some comments addressed policy issues that were outside of the scope of the information collection request (ICR). HRSA responded to technical comments that pertain to the ICR and revised the draft instruments based on the technical comments received. See Attachment III for comments. See Attachment IV for summary of comments received.

9. Remuneration of Responses

Not applicable.

10. Assurance of Confidentiality Provided to Respondents

Application and eligibility information regarding covered entities that is collected for this submission is submitted via a secure online system – the 340B OPAIS. Authorized users only have access to the system for their individual accounts. Some information related to covered entity and manufacturer participation in the Program is publicly viewable.

Confidentiality of manufacturer pricing data is strictly prohibited to authorized manufacturer and covered entities in accordance with section 340B(d)(1)(B)(iii) of the PHSA.

11. Questions of a Sensitive Nature

This data collection does not request sensitive information from the respondent.

12. Estimates of Annualized Hour Burden

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Respondent	Total Burden Hours
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Hospitals*	248	1	248	2.00	496
Certifications to Enroll Hospital Outpatient Facilities	665	8	5,320	0.50	2,660
Hospital Annual Recertifications	2,481	10	24,810	0.25	6,203
Registrations and Recertifications for Entities Other Than Hospitals					
340B Registrations for Community Health Centers*	360	3	1,080	1.00	1,080
340B Registrations for STD/TB Clinics*	535	1	535	1.00	535
340B Registrations for Various Other Eligible Entity Types*	392	1	392	1.00	392
Community Health Center Annual Recertifications	1,277	7	8,939	0.25	2,235
STD & TB Annual Recertifications	4,033	1	4,033	0.25	1,008
Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics	4,472	1	4,472	0.25	1,118
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	2,048	11	22,528	1.00	22,528
Other Information Collections					
Submission of Administrative Changes for any Covered Entity	19,322	1	19,322	0.25**	4,831
Submission of Administrative Changes for any Manufacturer	350	1	350	0.50	175

Pharmaceutical Pricing Agreement and PPA Addendum	200	1	200	1	200
Manufacturer Data Required to Verify the 340B Ceiling Price	600	4	2,400	.5	1,200
Total	36,983		94,629		44,660

*Revised since last OMB submission, but burden was not affected.
**Burden changed from .50 to .25 due to the 340B OPAIS improvement.
*** While there are a total of 26 instruments collections requested, this annualized burden table lists 13 forms as some of the forms have the same information, but may be intended for a certain entity. In the table above, we have included the burden hours for each impacted respondent.

340B Program Registrations & Certifications for Hospitals: refers to an electronic process whereby eligible hospitals register for the program via the 340B OPAIS and obtain certifications of government ownership/operation or government contracts, as appropriate. It is estimated that approximately 248 new respondents per year take 2 hours to gather the information and complete these forms to register in the program, resulting in a total annual burden of 496 hours (248 x 2 = 496 hours) for Hospitals.

Certifications to Enroll Hospital Outpatient Facilities: refers to an electronic process whereby eligible hospitals additionally register outpatient facilities via the 340B OPAIS. It is estimated that 665 hospitals will each register approximately 8 outpatient facilities, taking 0.50 hours per facility to gather the information and complete the enrollment process, resulting in a total annual burden of 2,660 hours ((665 x 8) x 0.50 = 2,660 hours).

Hospital Annual Recertification: refers to an electronic process where hospitals verify their information in the 340B OPAIS and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 2,481 hospitals will each recertify approximately 10 participating locations. Gathering the necessary information and completing the recertification process will take 0.25 hours per location, resulting in a total annual burden of 6,202 hours ((2,481 x 10) x 0.25 = 6,202 hours).

340B Registrations for Community Health Centers: refers to an electronic process whereby eligible Consolidated Community Health Centers and Federally Qualified Health Center Look-a-likes register for the program via the 340B OPAIS. It is estimated that 360 health centers will each register approximately 3 outpatient facilities, taking 1 hour per facility to gather the information and complete the enrollment process, resulting in a total annual burden of 1,080 hours ((360 x 3) x 1 = 1,080 hours).

340B Registrations for STD & TB Clinics: refers to an electronic process whereby eligible STD and TB clinics register for the program via the 340B OPAIS. It is estimated that 535 entities take 1 hour to gather the information and complete this form to register in the program, resulting in a total annual burden of 535 hours for these entities (535 x 1 = 535 hours).

340B Registrations for all over Covered Entities: refers to an electronic process by which

other eligible grant recipients (e.g. Black Lung Clinics, Comprehensive Hemophilia Treatment Centers, Native Hawaiian Health Centers, Ryan White Programs, Tribal Contract/Compact Health Centers, family planning, and Urban Indian Health Centers) register for the program via the 340B OPAIS. It is estimated that 392 entities take 1 hour to gather the information and complete this form to register in the program, resulting in a total annual burden of 392 hours for these entities (392 x 1 = 392 hours).

Community Health Centers Annual Recertification: refers to an electronic process where health centers verify their information in the 340B OPAIS and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 1,277 health centers will each recertify approximately 7 participating locations. Gathering the necessary information and completing the recertification process will take 0.25 hours per location, resulting in a total annual burden of 1,008 hours ((1,277 x 7) x 0.25 = 1,008 hours).

STD & TB Clinics Annual Recertification: refers to an electronic process whereby participating STD and/or TB clinics verify their information in the 340B OPAIS and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 4,033 STD/TB clinics take 0.25 hours to gather the information and recertify, resulting in a total annual burden of 1,008 hours (4,033 x 0.25 = 1,008 hours).

Annual Recertification for all Other Entities: refers to an electronic process where all other participating covered entities verify their information in the 340B OPAIS and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 4,472 covered entities other than Hospitals, Community Health Centers, and STD/TB Clinics take 0.25 hours to gather the information and recertify, resulting in a total annual burden of 1,118 hours (4,472 x 0.25 = 1,118 hours).

Contract Pharmacy Services Registration: refers to an electronic process where covered entities record their contract pharmacy arrangements in the 340B OPAIS. It is estimated that 2,048 entities will each register approximately 11 contract pharmacy locations, taking 1 hour to gather the information and complete this process, resulting in a total annual burden of 22,528 hours ((2,048 x 11) x 1 = 22,528 hours).

Administrative Change Form for Covered Entities: refers to an electronic process whereby 340B covered entities request changes to their records in the 340B OPAIS. It is estimated that 19,322 entities take 0.25 hours each to gather the information and complete this form to request change in the 340B public database, resulting in a total annual burden of 4,831 hours (19,322 x 0.25 = 4,831 hours).

Administrative Changes for any Manufacturer: refers to an electronic process whereby participating drug manufacturers request changes to their records in the 340B OPAIS. It is estimated that 350 manufacturers take 0.50 hours each to gather the information and complete this form to request change in the 340B public database, resulting in a total annual burden of 175 hours (350 x 0.50 = 175 hours).

Pharmaceutical Pricing Agreement (PPA) and PPA Addendum: Pursuant to the PHSA,

manufacturers that participate in the Medicaid program sign the PPA agreeing to charge 340B covered entities at or below a statutorily defined maximum price known as the 340B ceiling price, for covered outpatient drugs. It is estimated that 200 manufacturers take 1 hour to read and complete PPA, resulting in a total annual burden of 200 hours (200 x 1= 200 hours).

Manufacturer Data Required to Verify 340B Ceiling Price Calculations: refers to the drug product and pricing data that manufacturers must submit to the pricing component of the 340B OPAIS on a quarterly basis. It is estimated that 600 manufacturers will take 0.50 hours each to gather and upload or otherwise submit their information to the database on a quarterly basis, resulting in a total annual burden of 1200 hours ((600 x 4) x 0.5 = 1,200 hours).

13. Estimates of Annualized Cost Burden to Respondents

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Hospital Authorizing Official (CEO, CFO, Executive Director, President, VP) (Chief Executive median hourly wage from BLS- http://www.bls.gov/oes/current/oes111011.htm)	14,189	$96	$1,362,144
Non-Hospital Authorizing Official and Hospital 340B Primary Contact (Program Manager, Director, etc.) (General and Operations Managers median hourly wage from BLS - http://www.bls.gov/oes/current/oes111021.htm)	5,141	$60	$308,460
Contract Pharmacy Authorizing Official (Pharmacist median hourly wage from BLS http://www.bls.gov/oes/current/oes291051.htm)	22,528	$60	$1,351,680
Manufacturer Authorizing Official (General and Operations Managers median hourly wage from BLS - http://www.bls.gov/oes/current/oes111021.htm)	1,575	$60	$94,500
TOTAL:	43,433		$3,116,784

14. Estimates of Annualized Cost to the Government

This is an ongoing information collection request. The estimated average federal cost to implement the manufacturer and covered entity requirements in the 340B OPAIS pricing and registration systems will be approximately $4 million per year. The HRSA contractor will develop and maintain the system on an annual basis.

Description	Time	Salary	Annual Cost
Pricing & Registration Database Maintenance/Enhancement Contract	Yearly	N/A	$4,000,000
Public Health Analyst (hospital registrations) - GS-13/1	75% of time	$99,172	$74,379
Public Health Analyst (hospital registrations) – GS-13/1	75% of time	$99,172	$74,379
Public Health Analyst (hospital registrations) – GS-13/1	75% of time	$99,172	$74,379
Public Health Analyst (non-hospital registrations) – GS-12/1	75% of time	$83,398	$62,548
Public Health Analyst (recertifications) – GS-13/1	75% of time	$99,172	$74,379
Program Management Officer (pricing) – GS-13/1	75% of time	$99,172	$74,379
Program Management Officer (pricing) – GS-13/1	75% of time	$99,172	$74,379
Branch Chief – GS-14/1	50% of time	$117,191	$58,595
Total per year:			**$4,567,417**

15. Change in Burden

Currently, there are 27,594 reporting and record keeping burden hours in the OMB inventory. HRSA is requesting 43,433 burden hours, an increase of 15,839 hours. The anticipated burden has increased due to updates made to the estimated number of covered entity respondents and responses per respondent based on 2018 registration and recertification data. In addition, we have modified the way respondents and responses are counted to more accurately reflect the number of organizations registering for the program and the number of locations registered by each of those organizations.

16. Plans for Analysis and Timetable of Key Activities

A three year clearance is being requested for this recurring data collection. There are no plans for tabulation, statistical analysis or publication of the information collected.

17. Exemption for Display of Expiration Date

No exemption is being requested. The expiration date will be displayed.

18. Certifications

There are no exceptions to the certification.