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 Making the Collection of Information Necessary

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 (PHS) Act:

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. 340B(a)(5)(A)(ii) – *Establishment of Mechanism*
f. Section 340B(a)(9) – *Notice To Manufacturers*
g. Section 340B(d)(1)(B)(i)(II) – *Manufacturer Quarterly Pricing Data Submission*

Furthermore, Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS (Secretary) that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program.

2. Purpose and Use of Information Collection

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 PHS Act 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 PHS Act and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHS Act.

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.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except several forms have been revised to increase program efficiency and integrity. Below are descriptions of each of the forms and revisions that are captured in both the registration and pricing component of the 340B OPAIS.

Enrollment/Registration/Recertification

To enroll and certify the eligibility of federally funded grantees and other safety net health care providers, HRSA requires covered entities to submit administrative information (e.g., shipping and billing arrangements, Medicaid participation), certifying information (e.g., Medicare Cost Report information, documentation supporting the hospital's selected classification), and attestation from appropriate grantee-level or entity-level authorizing officials and primary contacts. To maintain accurate records, HRSA requests entities submit modifications to any administrative information that they submitted when initially enrolling into the Program. Covered entities participating in the 340B Program have an ongoing responsibility to immediately notify HRSA in the event of any change in eligibility for the 340B Program. Covered entities must comply with the statutory mandates of the Program and, at least annually, they need to certify the accuracy of the information provided and continued maintenance of their eligibility.

Registration and annual recertification information is entered into the 340B OPAIS by covered entities and verified by HRSA staff according to 340B Program requirements. The following forms are being revised:

- 340B Registration, Recertification and Change Requests for Shipping Address: HRSA is providing additional clarification for covered entities to complete the shipping address section in 340B OPAIS to improve transparency and assist in determining the exact shipping address location and relationship to the covered entity. The information collected will help determine whether the shipping address is a pharmacy, health care delivery site, or other receiving location. The information

collected will also help determine if the location should be listed as a shipping address or potentially registered separately in OPAIS as a contract pharmacy or covered entity. Reviewing shipping addresses has become difficult and inefficient for both the covered entity and HRSA because it can involve sending the task back to the covered entity, sometimes multiple times, before HRSA can appropriately act on the task. The burden will not be significantly affected since the requested language facilitates a more efficient review with fewer exchanges between the covered entity and HRSA.

- 340B Registration and Recertification for Sexually Transmitted Disease (STD) and Tuberculosis (TB) Grantees: HRSA is requesting that STD and TB grantees provide supporting documentation to demonstrate 340B eligibility pursuant to section 340B(a)(4)(K) of the PHS Act during initial registration as well as during recertification if requested to ensure compliance. The requested documentation will include a copy of the federal grant notice of award that identifies the grantor, grant number, period of funding, and recipient information. If the entity is a subgrantee then they will also need to provide a copy of the executed written subrecipient agreement that includes the name and address of the recipient and subrecipient, the grant and notice of funding opportunity number, and the terms and conditions of support. This new requirement streamlines the verification process and enhances program integrity for STD and TB entity types. This requirement will slightly increase the burden on covered entities since eligible covered entities should already have this documentation readily available prior to registering and recertifying for the 340B Program.
- 340B Program Registrations, Recertifications, and Change Requests for Family Planning: HRSA is requesting to collect the time period that assistance was received for Family Planning covered entities. The addition of these fields is consistent with information collected from Ryan White, STD, and TB entities at registration and recertification and will support HRSA's ability to verify a Family Planning covered entity's eligibility in the 340B Program as outlined in section 340B(a)(4)(C) of the PHS Act. This collection of time period information is a minor addition that will not significantly affect the burden on covered entities, as the time period when assistance was received is a readily available data point for Family Planning covered entities.
- 340B Recertification and Change Requests for Street Address: HRSA is providing additional clarification for covered entities that revise their street address in 340B OPAIS to assist in determining continued eligibility as outlined in section 340B(a)(4) of the PHS Act. OPAIS will prompt the covered entity to state if they are still receiving federal funding that makes them eligible for the 340B Program and/or if the service remains open at the old address. The answers to these questions will help determine the next appropriate action taken by the covered entity and HRSA. The collection of this information will not increase the burden on covered entities because it provides increased transparency and facilitates a more efficient review with fewer exchanges between the covered entity and HRSA.
- 340B Program Registrations, Recertifications, and Change Requests for Urban Indian and Tribal Contract/Compact with IHS (FQHC628) Covered Entities: HRSA is requesting the Tribal Agreement number in OPAIS for registrations and recertifications for Urban Indian and FQHC638 covered entities. This helps increase

program integrity by providing information that can be used to verify the eligibility of a specific grant for a specific entity. This collection of information is not expected to significantly increase burden as this information is readily available to covered entities on the agreements they have with their granting organization.

- 340B Program Registrations, Recertifications, and Change Requests for Hospitals: HRSA is revising a hospital qualification field in OPAIS from the language "File Date" to "Date/Time Prepared" to match Centers for Medicare & Medicaid Services (CMS) language on Worksheet S of a hospital's most recently filed Medicare Cost Report (MCR). This eliminates confusion for covered entities and clarifies what HRSA considers the "file date." This update will not change the burden on covered entities.
- 340B Program Registrations, Recertifications, and Change Requests for Hospitals: HRSA is revising a hospital qualification field in OPAIS from the language "Medicare Provider Number" to "CMS Certification Number" to match CMS language on Worksheet S of the hospital's most recently filed MCR. This provides consistency with CMS language as they no longer use the term "Medicare Provider Number." This update does not impact burden on covered entities as there is no action needed to be taken on the covered entities' part for this change to occur.
- 340B Program Registrations for Hospitals: HRSA is clarifying Worksheet S instructions for hospitals to include a copy of their signed, dated, and electronically encrypted Worksheet S from the latest filed MCR. This language will be updated on the initial registration instructions as well as in the actual registration. This updated language clarifies the exact documentation required for submission which results in fewer exchanges with covered entities. This update does not impact burden on covered entities.
- 340B Program Registrations for Hospitals: HRSA is revising an instructional update and clarifying the registration form language for trial balance and cost center information to clarify that entities should submit a trial balance that clearly indicates unique and separate reimbursable outpatient costs and charges for each service being registered. This update will not change the burden on covered entities as there is no new or revised collection requirement.

Contract Pharmacy Certification

There are no changes being made to Contract Pharmacy Certification from prior submissions. There is no change in burden on the covered entities.

PPA and Addendum

There are no changes being made to PPA and Addendum from prior submissions. There is no change in burden on the manufacturers.

Pricing Data Submission, Validation, and Dissemination

There are no changes being made to Pricing Data Submission, Validation, and Dissemination from prior submissions. There is no change in burden on the manufacturers.

3. Use of Improved Information Technology and Burden Reduction

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 Identify Duplication and Use of Similar Information

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

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 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 of Collecting the Information 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. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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

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

A 60-day notice published in the *Federal Register* on August 7, 2025, vol. 90, No. 150; pp. 38167- 38169. There were 16 public comments (please note that the 30-day FRN cites 14 public comments, but HRSA noticed a miscounting of the comments, and is adjusting the

total comments accordingly).

ISSUE	Summary of Comments	Actions to Address Comments
Shipping Address Clarifications	Some covered entities disagree with the additional clarifying questions identifying wholly owned pharmacies and health care service delivery sites.	HRSA developed the new shipping address submission process to streamline communication with covered entities and improve efficiency. The policy on what qualifies as a shipping address remains unchanged.
New documentation requirements for STD entities.	Some covered entities are concerned that the proposed documentation to support STD eligibility will strain small and community-based STD clinics with limited administrative staff and funding.	The new requirements for STD covered entities are intended to improve transparency, program integrity, and enable HRSA to more effectively confirm and maintain eligibility for all stakeholders.
Request for technical assistance to implement STD written agreements	Some entities are concerned about the timeline and support needed to comply with the STD written agreements. Therefore, they request that technical assistance be provided by OPA and/or Apexus to help implement these new requirements and an implementation period to execute the changes.	HRSA understands the operational challenges described in the comments and will take these concerns into account; however, this documentation is necessary to provide oversight. HRSA will continue to provide outreach and technical assistance to ensure covered entities understand documentation requirements and can comply with them in a timely manner.
Trial Balance Language	Some stakeholders are concerned with the language update regarding entities that should submit a trial balance that clearly indicates unique and separate reimbursable outpatient costs and charges for each service being requested. They are concerned this will create a burden or result in inappropriate modification or termination.	HRSA is clarifying the required elements of a trial balance for hospitals registering a child site to ensure compliance with program requirements. The criteria for what qualifies as a child site remain unchanged.

A 30-day notice published in the *Federal Register* on January 8, 2026, vol. 91, No. 714; pp. 714-717.

9. Explanation of any Payment/Gift to Respondents

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. Justification for Sensitive Questions

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

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

Note: This burden table is a little different than the burden table included on the 30-day FRN posted on January 8, 2026. HRSA realized that the "Manufacturer Data Required to Verify 340 B Ceiling Price" needed to also be included.

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****
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Hospitals*	172	1	172	2.00	344
Certifications to Enroll Hospital Outpatient Facilities*	1,036	6	6,216	0.50	3,108
Hospital Annual Recertifications*	2,699	13	35,087	0.25	8,772
Registrations and Recertifications for Covered Entities Other Than Hospitals					
340B Registrations for Community Health Centers*	350	3	1,050	1.00	1,050

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours****
340B Registrations for STD/TB Clinics**	341	1	341	1.25	426
340B Registrations for Various Other Eligible Entity Types***	177	1	177	1.25	221
Community Health Center Annual Recertifications*	1,840	7	12,880	0.25	3,220
STD and TB Annual Recertifications*	6,412	1	6,412	0.25	1,603
Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics*	3,407	1	3,407	0.25	852
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	4,376	11	48,136	1.00	48,136
Other Information Collections					
Submission of Administrative Changes for any Covered Entity*	24,829	1	24,829	0.25	6,207
Submission of Administrative Changes for any Manufacturer	471	1	471	0.50	236
Manufacturer Data Required to Verify 340 B Ceiling Price	600	4	2,400	0.5	1,200
PPA and Addendum	73	1	73	1.00	73
Total	46,783		141,651		75,448

*Minor revisions to the language on the forms since the last OMB submission, but burden has not been impacted.
** Average Burden was increased from 1 to 1.25, compared to the prior version of this package.
*** Average Burden was increased from 1 to 1.25, compared to the prior version of this package. This is due to an additional field being added for Family Planning covered entities.

**** Total Burden Hours are rounded up to the nearest whole number.

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 172 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 344 hours (172 x 2 = 344 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 1,036 hospitals will each register approximately 6 outpatient facilities, taking 0.50 hours (30 minutes) per facility to gather the information and complete the enrollment process, resulting in a total annual burden of 3,108 hours (1,036 x 6) x 0.50 = 3,108 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 2,699 hospitals will each recertify approximately 13 participating locations. Gathering the necessary information and completing the recertification process will take 0.25 hours (15 minutes) per location, resulting in a total annual burden of 8,772 hours (2,699 x 13) x 0.25 = 8,772 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 350 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 1,050 hours ((350 x 3) x 1 = 1,050 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 341 entities take 1.25 hours (1 hour, 15 minutes) to gather the information and complete this form to register in the program, resulting in a total annual burden of 426 hours for these entities (341 x 1.25 = 426 hours).

340B Registrations for all other 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 177 entities take 1.25 hours (1 hour and 15 minutes) to gather the information and complete this form to register in the program, resulting in a total annual burden of 221 hours for these entities (177 x 1.25 = 221 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 1,840 health centers will each recertify approximately 7 participating locations. Gathering the

necessary information and completing the recertification process will take 0.25 hours (15 minutes) per location, resulting in a total annual burden of 3,220 hours ((1,840 x 7) x 0.25 = 3,220 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 6,412 STD/TB clinics take 0.25 hours (15 minutes) to gather the information and recertify, resulting in a total annual burden of 1,603 hours (6,412 x 0.25 = 1,603 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 3,407 covered entities other than Hospitals, Community Health Centers, and STD/TB Clinics take 0.25 hours (15 minutes) to gather the information and recertify, resulting in a total annual burden of 852 hours (3,407 x 0.25 = 852 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 4,376 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 37,906 hours ((4,376 x 11) x 1 = 48,136 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 24,829 entities take 0.25 hours (15 minutes) each to gather the information and complete this form to request change in the 340B public database, resulting in a total annual burden of 6,207 hours (24,829 x 0.25 = 6,207 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 471 manufacturers take 0.50 hours (30 minutes) each to gather the information and complete this form to request change in the 340B public database, resulting in a total annual burden of 236 hours (471 x 0.50 = 236 hours).

Manufacturer Data Required to Verify 340 B Ceiling Price: refers to an electronic process where manufacturers submit quarterly pricing data. The purpose is to conduct the comparison between the submitted data and data obtained from the Centers for Medicare & Medicaid Services as well as a third-party commercial database. The burden imposed on manufacturers is low because the information requested is readily available and utilized by manufacturers in other areas. It is estimated that 600 manufacturers take 0.50 hours (30 minutes), 4 times per year, to complete this form, resulting in a total burden of 1,200 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 73 manufacturers take 1 hour to read and complete PPA, resulting in a total annual burden of 73 hours (73 x 1= 73 hours).

12B. Estimates of Annualized Cost Burden to Respondents

The total respondent costs are based on the type of respondent who will be responsible for completing each form, also known as the authorizing official. Hourly median wages are from May 2024 Occupational Employment and Wage Statistics tables, multiplied by 2 to account for overhead.[1]

Type of Respondent	Forms Included	Total Burden Hours	Hourly Median Wage Rate (x2)	Total Respondent Costs
Hospital Authorizing Official (CEO, CFO, Executive Director, President, VP) (Chief Executive, BLS-11-1011)	• 340B Program Registrations & Certifications for Hospitals • Certifications to Enroll Hospital Outpatient Facilities • Hospital Annual Recertifications • Submission of Administrative Changes for any Covered Entity	18,431	$198.48	$3,658,184.88
Non-Hospital Authorizing Official and Hospital 340B Primary Contact (Program Manager, Director, etc.) (General and Operations Managers, BLS 11-1021)	• 340B Registrations for Community Health Centers • 340B Registrations for STD/TB Clinics • 340B Registrations for Various Other Eligible Entity Types • Community Health Center Annual Recertifications • STD and TB Annual Recertifications • Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics	7,372	$99.00	$729,828.00
Contract Pharmacy Authorizing Official (Pharmacist, BLS 29-1051)	Contracted Pharmacy Services Registration	48,136	$132.20	$6,363,579.20

[1] Bureau of Labor Statistics. Occupational Employment and Wage Statistics Tables – May 2024. Retrieved November 21, 2025 from https://www.bls.gov/oes/tables.htm

Type of Respondent	Forms Included	Total Burden Hours	Hourly Median Wage Rate (x2)	Total Respondent Costs
Manufacturer Authorizing Official (General and Operations Managers, BLS 11-1021)	Submission of Administrative Changes for any Manufacturer Manufacturer Data Required to Verify 340 B Ceiling Price PPA and Addendum	1,509	$99.00	$149,391.00
TOTAL:		75,448		$10,900,983.08

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

Other than their time, there is no cost to respondents.

14. Annualized Cost to Federal 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. HRSA employee salary is based on General Schedule (GS) level and the estimated percentage of time they spend on 340B activities. Annual salary is multiplied by 1.5 to account for overhead costs.

Description	Time	Salary x 1.5	Annual Cost
Pricing & Registration Database Maintenance/Enhancement Contract	Yearly	N/A	$4,000,000.00
Public Health Analyst (hospital registrations) - GS-13/1	75% of time	$180,868.50	$135,651.38
Public Health Analyst (hospital registrations) – GS-13/1	75% of time	$180,868.50	$135,651.38
Public Health Analyst (hospital registrations) – GS-13/1	75% of time	$180,868.50	$135,651.38
Public Health Analyst (non-hospital registrations) – GS-12/1	75% of time	$152,101.50	$114,076.13
Public Health Analyst (recertifications) – GS-13/1	75% of time	$180,868.50	$135,651.38
Program Management Officer (pricing) – GS-13/1	75% of time	$180,868.50	$135,651.38
Program Management Officer (pricing) – GS-13/1	75% of time	$180,868.50	$135,651.38
Branch Chief – GS-14/1	50% of time	$213,732.00	$106,866.00
Total per year:			$5,034,850.41

15. Explanation for Program Changes or Adjustments

Currently, there are 59,359 reporting and record keeping burden hours in the OMB inventory. HRSA is requesting 75,448 burden hours, an increase of 16,089 hours. This increase is due to an increase average burden hours per response for the "340B Registrations for STD/TB Clinics Form" and the "340B Registrations for Various Other Entity Types Form."

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

A three-year clearance is being requested for this recurring data collection. The information collected is used solely for program administration, compliance, eligibility determinations, and customer service, and is not intended to support statistical analysis or generalizable findings. Because the collection may include sensitive or identifiable information and is subject to applicable privacy and confidentiality requirements, respondents have an expectation that their confidential information will not be aggregated or published, and no tabulation, analysis, or publication is planned.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.