



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327 – Revision

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 projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327 – Revision.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service (PHS) Act, which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are also 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. 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 statutorily defined 340B ceiling prices. 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) of the PHS Act prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity.

Need and Proposed Use of the Information: To ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency, and integrity, HRSA developed a process of registration for covered entities to enable it to address specific statutory mandates. Specifically, 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) 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.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except some forms have been revised to increase program efficiency and integrity. Below are descriptions of each form and any resulting revisions that are captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (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:

- (1) 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.
- (2) 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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

Likely Respondents: Drug manufacturers and covered entities.

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****
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
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	177
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

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours****
PPA and Addendum	73	1	73	1.00	73
Total	46,183		133,251		74,204

*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.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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