Billing Code 4165-15

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

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has 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.

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

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to

202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations.

OMB No. 0915-0327 – Revision

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act; ''Limitation on Prices of Drugs Purchased by Covered Entities''), provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula (''ceiling price'').

A manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed in the 340B Program database. Manufacturers rely on the information in the 340B database to determine if a covered entity is participating in the 340B Program or for any notifications of changes to eligibility that may occur within a quarter. By

signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements, including any changes that occur after execution of the PPA.

Covered entities which 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) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, Section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

Need and Proposed Use of the Information: 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, which shall include the following:

> (I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.
>
> (II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.
>
> (III) Performing spot checks of sales transactions by covered entities.
>
> (IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

HRSA's Office of Pharmacy Affairs (OPA) has previously obtained approval for information collections in support of 340B covered entity recertification and registration, as well as registration of contract pharmacy arrangements and the PPA itself. OPA is requesting comments on an additional information collection in response to the above pricing verification requirements, as well as the routine renewal of approval for the existing information collections. The previously approved collections are substantially unchanged, except that HRSA has transitioned completely to online versus hardcopy forms.

Pricing data submission, validation and dissemination:

In order to implement Section 340B(d)(1)(B)(i)(II), HRSA has already developed a system to calculate 340B ceiling prices prospectively from data obtained from the Centers for Medicare & Medicaid Services as well as OPA-identified commercial databases. However, in order to conduct the comparison required under the statute, manufacturers must submit the quarterly pricing data as required by section 340B(d)(1)(B)(i)(II).

HRSA is developing a mechanism for secure manufacturer submissions. This notice proposes collecting Average Manufacturer Price, Unit Rebate Amount, Package Sizes, National Drug Code (NDC), period of sale (year and quarter), and manufacturer-determined 340B ceiling price for each NDC produced by a manufacturer subject to a PPA. Once any discrepancies between the manufacturer and OPA-calculated prices have been resolved, the validated prices will be made available to registered covered entities via a secure Internet-accessible platform as required by Section 340B(d)(1)(B)(iii).

Accurate and timely pricing data submissions are critical to successful implementation of the 340B Program, ensuring that covered entities have confidence that the amounts being charged are in accordance with statutorily-defined ceiling prices. The burden imposed on manufacturers by this requirement is low because the information requested is readily available.

Likely Respondents: Drug 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	Hours per Respondent	Total Burden Hours
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Hospitals	194	1	194	2	388

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Respondent	Total Burden Hours
Certifications to Enroll Hospital Outpatient Facilities	697	8	5576	0.5	2788
Hospital Annual Recertifications	2134	6	12804	0.25	3201
Registrations and Recertifications for Entities Other Than Hospitals					
340B Registrations for Community Health Centers	427	3	1281	1	1281
340B Registrations for STD/TB Clinics	647	1	647	1	647
340B Registrations for Various Other Eligible Entity Types	405	1	405	1	405
Community Health Center Annual Recertifications	1204	5	6020	0.25	1505
STD & TB Annual Recertifications	3123	1	3123	0.25	780.75
Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics	4899	1	4899	0.25	1224.75
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	1758	5	8790	1	8790
Other Information Collections					
Submission of Administrative Changes for any Covered Entity	9396	1	9396	0.5	4698
Submission of Administrative Changes for any Manufacturer	350	1	350	0.5	175
Manufacturer Data Required to Verify 340B Ceiling Price Calculations	600	4	2400	0.5	1200
Pharmaceutical Pricing	200	1	200	1	200

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Respondent	Total Burden Hours
Agreement					
Total	26,034	--	--	--	27283.5

Jackie Painter,

Director, Division of the Executive Secretariat.

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