Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: **Proposed Collection: Comment Request**

Action: Notice

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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 Information Collection Request must 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 mail the HRSA Information Collection Clearance Officer, Room 10C-03, Parklawn Building, 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 the HRSA Information Collection Clearance Officer at (301) 443-1984.

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

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 Pub. L. 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. The manufacturer shall

rely on the information in the 340B database to determine if the 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.

Pricing data submission, validation and dissemination:

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

HRSA has developed a mechanism for secure manufacturer submissions; the Agency currently proposes collecting Average Manufacturer Price, Unit Rebate Amount, Package Sizes, National Drug Code and manufacturer-determined 340B ceiling price for each product 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 Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Reporting Requirement	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
HOSPITAL ENROLLMENT, ADDITIONS & RECERTIFICATIONS					
340B Program Registrations & Certifications for Hospitals	546	1	546	2.00	1092
Certifications to Enroll Hospital Outpatient Facilities	606	1	606	.50	303
Hospital Annual Recertifications	4842	1	4842	.50	2421
REGISTRATIONS AND RECERTIFICATIONS FOR ENTITIES OTHER THAN HOSPITALS					
340B Registrations for Community Health Centers	253	1	253	1.0	253
340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types	353	1	353	1.0	353
Community Health Center Annual Recertifications	4507	1	4507	.50	2253.5
Family Planning Annual Recertifications	3879	1	3879	.50	1939.5
STD & TB Annual Recertifications	2754	1	2754	.50	1377
Annual Recertification for entities other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics	1174	1	1174	.50	587
OTHER INFORMATION COLLECTIONS					
Submission of Administrative Changes for any Covered Entity	2500	1	2500	.50	1250
Submission of Administrative Changes for any Manufacturer	350	1	350	.50	175
Manufacturer Data Required to Verify 340B Ceiling Price Calculations	600	4	2400	.50	1200
CONTRACTED PHARMACY SERVICES REGISTRATION & RECERTIFICATIONS					
Contracted Pharmacy Services Registration	2500	1	2500	1.0	2500
TOTAL	24,664		26,464		15,704

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.

Dated: September 23, 2014

Jackie Painter

Acting Director, Division of Policy and Information Coordination

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