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 Number 0915-0327 – Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA 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 ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

A 60-day notice was published in the Federal Register on May 9, 2019, vol. 84, No. 90; pp. 20373-75. There were four public comments received. Some comments addressed policy issues that are outside of the scope of this information collection request. HRSA responded to technical comments that pertain to the ICR and revised the draft instruments based on technical comments received.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, 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, 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 required by section 1927(a)(5)(A) of the Social Security Act to enter into

agreements with the Secretary of HHS 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 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) 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 that HRSA has transitioned completely to online versus hardcopy instruments. In doing so, some of the instruments have been revised to increase program efficiency and integrity. Below are descriptions of each of the instruments and any resulting revisions captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (OPAIS).

Enrollment/Registration

To enroll and certify the eligible federally funded grantees and other safety net health care providers, HRSA requires 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. The purpose of this registration information is to determine eligibility for the 340B Program. To maintain accurate records, HRSA requests entities to submit modifications to any administrative information that they submitted when initially enrolling into the Program. 340B covered entities

have an ongoing responsibility to immediately notify HRSA in the event of any change in eligibility for the 340B Program. No less than on an annual basis, entities must certify the accuracy of the information provided and continued maintenance of their eligibility and comply with statutory mandates of the Program.

Registration and annual recertification information is entered into the 340B OPAIS by entities and verified by HRSA staff according to 340B Program requirements. In response to the comments received, HRSA has made technical revisions to the draft instruments and explains the revisions below.

1. 340B Program Registrations & Certifications for Hospitals (applies to all hospital types): With the launch of 340B OPAIS in September 2017, HRSA removed the requirement for a Government Official to attest to the hospital classification of a parent hospital. HRSA would like to require parent hospitals to attach documents supporting the hospital classification that they select during registration. This is a more accurate and efficient way to determine the eligibility of parent hospital registrations, without increasing the burden, since the Government Official attestation has been removed. In response to comments, HRSA notes that the 340B Program Hospital Registration Instructions lists examples of the types of documentation that supports the hospital's classification. The instructions are located at https://www.hrsa.gov/sites/default/files/hrsa/opa/340b-hospital-registration-instructions.pdf.
2. 340B Program Registrations for STD/TB Clinics: HRSA is requesting that any STD and TB entity provide its Notice of Funding Opportunity (NOFO) number at the time of registration. HRSA is also requesting that an entity describe the type of in-kind funding

it receives, as well as the period of the funding. This will assist HRSA in accurately determining the eligibility of the covered entity registration. This requirement would impose minimal burden on the public, as the NOFO number correlates to the Federal Grant Number, which is already required during registration.

In response to comments submitted during the first public review of this ICR, HRSA continues to believe there will be no additional burden associated with providing what type of in-kind funding they receive as it is expected to be provided as part of an audit of a covered entity. The draft instruments explain that in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

3. 340B Registrations for Ryan White Entities: HRSA is requesting that any Ryan White entity provide its NOFO number at the time of registration. HRSA is also requesting that an entity provide the period of assistance. This will assist HRSA in accurately determining the eligibility of the registration. This requirement would impose minimal burden on the public, as the NOFO number correlates to the Federal Grant Number, which is already required during registration.
4. Medicaid Billing: HRSA is making a minor change to clarify the question about Medicaid billing. In response to comments received, HRSA has made general technical and editorial revisions to this instrument.

Accurate records are critical to the prevention of drug diversion to non-eligible individuals as well as duplicate discounts in the 340B Program. To maintain accurate records, HRSA also requires that covered entities recertify eligibility annually, and that they notify the program of

updates to any administrative information that they submitted when initially enrolling into the program. HRSA expects that the burden imposed these processes is low for recertification and minimal for submitting change requests.

Contract Pharmacy Self-Certification

To ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are required to submit general information about the arrangements and certify that signed agreements are in place with those contract pharmacies. In response to comments, HRSA has made several technical corrections to this instrument.

Pharmaceutical Pricing Agreement and Addendum

In accordance with the 340B Program guidance issued in the May 7, 1993, Federal Register, section 340B(a)(1) of the PHS Act provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a PPA with the Secretary of HHS in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage. In addition, section 340B(a)(1) of the PHS Act includes specific required components of the PPA with manufacturers of covered outpatient drugs. In particular, section 340B(a)(1) includes the following requirements:

I. "Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that

covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price") and

II. ". . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

The burden imposed on manufacturers by submission of the PPA and PPA Addendum is low as the information is readily available.

Pricing Data Submission, Validation and Dissemination

To implement section 340B(d)(1)(B)(i)(II) of the PHS Act, HRSA developed a system to calculate 340B ceiling prices prospectively from data obtained from the Centers for Medicare & Medicaid Services as well as a third party commercial database. However, 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). The 340B OPAIS securely collects the following data from manufacturers on a quarterly basis: average manufacturer price, unit rebate amount, package size, case pack size, unit type, national drug code, labeler code, product code, period of sale (year and quarter), FDA product name, labeler name, wholesale acquisition cost, and the manufacturer determined ceiling price for each covered outpatient drug produced by a manufacturer subject to a PPA. One commenter suggested that HRSA list FDA "ingredient names" in the 340B OPAIS to simplify the search process for covered entities. HRSA will

consider this for future collections due to system changes that would need to occur to operationalize this suggestion.

The burden imposed on manufacturers is low because the information requested is readily available and utilized by manufacturers in other areas.

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	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	6,202
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	1,008
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	0.50	1,200
Total	36,983		94,629		43,433

*Revised since last OMB submission, but burden was not affected.
**Burden changed from .50 to .25 due to the 340B OPAIS improvement.

During the first public review of the ICR, HRSA inadvertently omitted the burden estimate for the instrument pertaining to manufacturer data required to verify the 340B ceiling price. The estimate for that instrument has been included here and HRSA invites comments to be submitted to OMB for consideration during the review and approval period.

Maria G. Button,

Director, Division of the Executive Secretariat.

Billing Code 4165-15

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