From:	Britton, Chantelle (HRSA)
To:	HRSA Paperwork
Cc:	Moore, Tierra (HRSA); Lim, Stephanie (HRSA)
Subject:	RE: Public Comment Request Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program : 87 FR 35983
Date:	Monday, August 15, 2022 4:08:03 PM
Attachments:	image002.png

Thank you. I know the comment period closed today. So far this is the second comment we've received. Please let us know if any other comments are received.

From: HRSA Paperwork <paperwork@hrsa.gov>
Sent: Monday, August 15, 2022 4:02 PM
To: Britton, Chantelle (HRSA) <CBritton@hrsa.gov>
Cc: Moore, Tierra (HRSA) <TMoore@hrsa.gov>
Subject: FW: Public Comment Request Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program : 87 FR 35983

Hello Chantelle,
A comment has been received regarding the 340B Drug Pricing Program. Thank you.

Tierra Moore (she/her)
Public Health Analyst , Division of Oversight, Reporting, and Regulatory Compliance
HRSA Office of Planning, Analysis, and Evaluation

From: Robert D. Bird <birdrd@mercyhealth.com>
Sent: Monday, August 15, 2022 10:58 AM
To: HRSA Paperwork <paperwork@hrsa.gov>
Subject: [EXTERNAL] Public Comment Request Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program : 87 FR 35983

Thank you for the opportunity to provide feedback for this proposed change to HRSA's information collection procedures / policies.
Below are descriptions of each of the forms and any resulting revisions that are captured in both the registration and pricing component of OPAIS with my comments.

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 to 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. No less than on an annual basis, covered entities need to certify the accuracy of the information provided and continued maintenance of their eligibility and to comply with statutory mandates of the Program.
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 Program Registrations & Recertifications for Hospitals (applies to all hospital types):* In September 2017, HRSA launched 340B OPAIS, which among other things, removed the attestation requirement from the Government Official for the classification of a parent hospital, but it was still required for the covered entity to enter the Government Official contact information. As covered entities are no longer required to obtain this attestation, HRSA is removing the requirement for the covered entity to enter the Government Official contact information in 340B OPAIS. This will not change the burden on the entities.
   - *I Agree with and support this proposed change*

2. *340B Registrations & Recertifications for Ryan White Entities:* Previously, HRSA requested that any Ryan White entity provide its Notice of Funding Opportunity (NOFO) number at the time of registration and recertification. After reevaluation, HRSA has determined that the NOFO number is an unnecessary component to determine the eligibility of a Ryan White entity's registration. Since the NOFO number correlates to the Ryan White entity's Federal Grant Number, which is already required to be entered in 340B OPAIS during registration, the NOFO number is not needed. This will not change the burden on the covered entities.
   - *I definitely agree with this proposed change. The NOFO number is difficult to find.*

3. *340B Registration, Recertification & Change Requests for Shipping Address:* HRSA is providing additional clarification for covered entities to complete the shipping address section in 340B OPAIS to assist in determining the exact shipping address location and relationship to the covered entity. This clarification will not change burden on entities.
   - *I support this proposed change*

4. *340B Program Registrations, Recertifications & Change Requests for Hospitals (applies to rural referral centers and sole community hospital entity types):* HRSA is revising the 340B OPAIS registration for the rural referral centers and sole community hospital types, in an effort to provide guidance that determines the eligibility criteria. If applicable, 340B OPAIS will prompt the covered entity for documentation that supports eligibility, which will be attached as part of its registration, recertification or change request submission. Currently, the request for the supporting eligibility documentation is obtained during the submission review process; therefore, this requirement would not change the burden on the entities.
   - *This is a good change. Once submitted, less review questions would make the process easier for the CE as many AO's are very busy and do not always remember to check*

OPAIS for review generated questions.

5. *340B Program Change Requests for Hospitals:* HRSA will allow hospital qualification information such as, the Disproportionate Share Adjustment Percentage, control type, hospital classification, and contract start date, to be changed under a change request submission as well as during recertification. This requirement would not change the burden on the entities, as this is an option to change the information by the hospital.
   - *I have no comment on this change*

6. *340B Primary Contact and Authorizing Official Information:* HRSA removed the FAX number field. This does not change the burden on covered entities, as this was an optional field.
   - *I support this change*

7. *340B Program Recertifications & Change Requests for Hospitals:* HRSA is clarifying when the covered entity would initiate a name change in 340B OPAIS. If applicable, 340B OPAIS will prompt the covered entity for documentation that supports the name change, which will be attached as part of its recertification or change request submission. Currently, the request for the supporting name change documentation is obtained during the submission review process, therefore, this requirement would not change the burden on covered entities.
   - *This is a good change. Once submitted, less review questions would make the process easier for the CE as many AO's are very busy and do not always remember to check OPAIS for review generated questions.*

Contract Pharmacy Certification

In order 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 their contract pharmacy arrangements and certify that signed agreements are in place with those contract pharmacies. There is no change in burden on the entities. - *I am not understanding if there is no change or if the proposed change will not increase the burden on CE's. The note here is not clear.*

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 Pharmaceutical Pricing Agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") 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. - *again, I am not certain of the change being proposed*

Pricing Data Submission, Validation and Dissemination

In order 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, 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). The 340B OPAIS securely collects the following data from manufacturers on a quarterly basis: AMP, 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. 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. - *again, I am not certain of the change being proposed*

I wish that the proposed changes related to the final 3 categories had been clear. Absent the exact change proposed, I cannot provide feedback.

Bob Bird
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