July 5, 2019

Via First-Class Mail & Electronic Mail: paperwork@hrsa.gov

HRSA Information Collection Clearance Officer
Room 14N136B
5600 Fishers Lane
Rockville, MD 20857

Re: HRSA Proposed Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327-Revision, 84 Fed. Reg. 20373 (May 9, 2019)

Dear HRSA Information Collection Clearance Officer:

We are submitting comments on behalf of 340B Health in response to the notice published in the Federal Register on May 9, 2019 requesting comments on a proposed collection of information by the Health Resources and Services Administration (HRSA).[1] 340B Health represents nearly 1,400 public and nonprofit hospitals that participate in the federal 340B drug pricing program. The notice announces HRSA's plans to submit to the Office of Management and Budget (OMB) a proposed information collection request related to section 340B of the Public Health Service Act (the 340B program).

Specifically, HRSA is requesting approval for existing information collections related to covered entity registration and recertification, contract pharmacy registration, the pharmaceutical pricing agreement (PPA) and addendum, and drug manufacturer pricing information to help verify the accuracy of 340B ceiling prices. The notice says that the previously approved collections are mostly unchanged and that HRSA is proposing revisions to certain existing collections. Below we set forth our comments on HRSA's request for renewal of existing collections and proposed modifications.

I. 340B Program Registration Forms for Hospitals

A. Medicaid Billing Information

HRSA's proposed 340B program registration forms for hospitals include several changes, in sections titled "Medicaid Billing Information," that clarify the information that hospitals are required to submit if they bill fee-for-service (FFS) Medicaid for 340B drugs.[2] 340B Health applauds HRSA for specifying that the reporting requirements for state assigned Medicaid billing numbers and national provider identifiers (NPIs) apply to FFS, not Medicaid managed care (MCO) claims. We also appreciate HRSA clarifying its expectation that covered entities should list both their state assigned Medicaid billing number(s) and NPI if both are used to bill FFS Medicaid. These changes will significantly improve clarity for 340B hospitals related to numbers they should report on HRSA's Medicaid Exclusion File. We have additional clarification recommendations based on two concerns:

1. The Medicaid Billing Information section in HRSA's proposed registration forms directs covered entities to provide the state(s) and associated billing number(s) listed on the claims used to bill Medicaid FFS for a particular state. We understand HRSA expects covered entities to list the billing numbers for every state that they will bill Medicaid FFS for 340B drugs, including the state the hospital is located in and any out-of-state Medicaid agencies (i.e., states in which the hospital will carve-in). We believe that hospitals would find explicit language regarding out-of-state Medicaid billing numbers helpful.

2. The Medicaid Billing Information section in HRSA's proposed registration forms for hospitals also directs covered entities not to list a state for which the covered entity does not bill Medicaid FFS for 340B drugs. We presume this refers to states that the hospital carves-out or does not plan to bill Medicaid even if 340B drugs are provided to the state's Medicaid enrollees. We are concerned that the proposed language uses the wrong tense when discussing billing and will be confusing to hospitals registering for the 340B program.

---

[1] 84 Fed. Reg. 20373 (May 9, 2019).
[2] *See* Section III in the 340B program registration forms for rural referral centers, sole community, and critical access hospitals; *see also* Section IV in the 340B program registration forms for disproportionate share, children's, and free-standing cancer hospitals.

To make it clear that hospitals should list billing numbers for each state they plan to bill for 340B drugs (i.e., carve-in), including out-of-state Medicaid, and to avoid confusion regarding the carve-out billing language, we recommend the following changes to the proposed registration forms for hospitals (see Attachment A, Section III):

> At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices? □Yes □ No
>
> If the answer is yes, please provide the state(s) and associated billing number(s) listed on the claims ~~used~~ to bill Medicaid fee-for-service for ~~a~~each ~~-~~particular state that you plan to bill for 340B drugs in the space(s) below (this could include numbers for the state your hospital is located in and any out-of-state Medicaid agencies your hospital plans to bill for 340B drugs)**.** All numbers you plan to use~~d~~ to bill Medicaid fee-for-service should be provided and may include the billing provider's national provider number (NPI) only, state assigned Medicaid number only, or both the NPI and state assigned Medicaid number. Do not list a state for which the covered entity ~~does~~will not bill Medicaid fee-for-service for drugs purchased at 340B prices.
>
> HRSA exports the Medicaid billing information listed in this site's 340B OPAIS record to generate the quarterly Medicaid exclusion file (MEF). HRSA requires the information on the MEF be accurate and complete for every registered site in the 340B OPAIS, and that covered entities follow any additional state Medicaid requirements in order to prevent duplicate discounts.
>
> While this site may request a change to its 340B OPAIS record at any time, the Medicaid fee-for service billing practice at this site, must match the quarterly MEF.

B. Hospital Classifications

Section II of HRSA's proposed registration forms for hospitals indicate in Subsection C, titled "Hospital Classification", that hospitals will be asked during enrollment and recertification to provide documentation to support the hospital's chosen classification and directs hospitals to refer to OPA's hospital registration instructions for documentation options. 340B Health supports the guidance that HRSA's Office of Pharmacy Affairs (OPA) has provided to hospitals regarding acceptable documentation, as the guidance outlines several documentation options for governmental hospitals, non-profit hospitals, and options for hospitals formally granted governmental powers. We applaud HRSA for avoiding a one size fits all approach to acceptable documentation and instead providing hospitals with flexibility.

340B Health also supports HRSA's removal of the requirement that a government official certify to the hospital's eligibility within a short time frame, which had proven to be a prohibitively burdensome requirement for hospitals owned or operated by a state or local government and private non-profit hospitals with a contract with a state or local government to provide care to low-income patients.

C. Self-Disclosure of Program Violations

HRSA's proposed registration forms for hospitals, in sections titled "Signed Agreement", require covered entities to attest to the following: "…the covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing [program requirements]…" [3] 340B Health is concerned that hospitals interpret this as requiring them to disclose even minor compliance issues that arise, which places a significant and unrealistic burden on hospitals. In fact, we have received several questions from 340B hospitals about this language and whether they are required to disclose to OPA issues that are not material, such as an isolated instance of an improper accumulation on a hospital's 340B account for one drug.

Prior to 2016, HRSA's registration and recertification forms included the word "material" as a modifier of the types of breaches entities must self-disclose. HRSA's contractor, Apexus, maintains a tool on its website to help covered entities define what constitutes a "material breach" by providing different threshold examples that could trigger a self-disclosure to OPA.[4] We recommend that HRSA add the "material breach" language back into the registration and recertification

---

[3] *See* Section VI in the proposed registration forms for DSH, children's hospitals, critical access hospitals, rural referral centers and sole community hospitals; *see also* Section VII in the proposed registration form for free-standing cancer hospitals.

[4] Apexus, 340B University, Defining Material Breach Tool, (Mar. 9, 2016), https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

attestations to ensure that collections of self-disclosures from covered entities are efficient and to minimize the burden on program participants and to HRSA of responding to non-material disclosures.[5]

D. Orphan Drug Exclusion

Section IV of HRSA's proposed registration forms for rural referral centers, free-standing cancer, critical access and sole community hospitals require the hospitals to indicate whether or not they will purchase orphan drugs under the 340B program and maintain auditable records to demonstrate compliance with the orphan drug exclusion. The proposed forms, in a section titled "Orphan Drug Exclusion", state that 340B hospitals subject to the orphan drug exclusion must ensure that any orphan drug purchased through the 340B program is not used for the rare condition or disease for which the orphan drug is designated. We question whether this provision is necessary, as HRSA withdrew its prior regulation permitting rural and cancer hospitals to purchase orphan drugs through the 340B program when the drug was used for a purpose other than the rare condition or disease for which the drug is afforded orphan drug status. The 340B statute specifically excludes orphan drugs used for any purpose from the 340B program. As such, 340B hospitals have no legal obligations with respect to purchasing or using orphan drugs, even if purchased at a discount offered by a manufacturer. To avoid confusion and placing an unnecessary burden on rural and cancer hospitals, we recommend[6] that HRSA remove the section on the Orphan Drug Exclusion from its proposed information collections.

II. 340B Program Recertification Form for Hospitals

The Medicaid Billing Information section in HRSA's proposed recertification forms for hospitals[7] contains the same language as the section in HRSA's proposed registration forms for hospitals, for which we suggested additional language about out-of-state Medicaid and use of the wrong tense about billing. (See Section I.A. of this comment letter). We suggest HRSA address the Medicaid Billing Information section in the recertification forms slightly differently than what we recommend above for the registration forms, as hospitals that are recertifying are enrolled in the 340B program and have already chosen to bill or not bill Medicaid FFS for 340B drugs. We recommend the following changes to the proposed recertification forms (see Attachment B, section IV).

> At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices? □Yes □ No
>
> If the answer is yes, please provide the state(s) and associated billing number(s) listed on the claims used to bill Medicaid fee-for-service for each ~~a~~ particular state that you bill for 340B drugs in the space(s) below (this could include numbers for the state your hospital is located in and any out-of-state Medicaid agencies your hospital bills for 340B drugs)**.** All numbers used to bill Medicaid fee-for-service should be provided and may include the billing provider's national provider number (NPI) only, state assigned Medicaid number only, or both the NPI and state assigned Medicaid number. Do not list a state for which the covered entity does not bill Medicaid fee-for-service for drugs purchased at 340B prices.
>
> HRSA exports the Medicaid billing information listed in this site's 340B OPAIS record to generate the quarterly Medicaid exclusion file (MEF). HRSA requires the information on the MEF be accurate and complete for every registered site in the 340B OPAIS, and that covered entities follow any additional state Medicaid requirements in order to prevent duplicate discounts.
>
> While this site may request a change to its 340B OPAIS record at any time, the Medicaid fee-for service billing practice at this site, must match the quarterly MEF.

---

[5] Our recommended changes to the Signed Agreement section in HRSA's proposed registration forms for hospitals are included in Attachment A.

[6] Our recommended changes to the Orphan Drug Exclusion section in HRSA's proposed registration (and recertification) forms for rural referral centers, free-standing cancer, critical access, and sole community hospitals are included in in the Orphan Drug Exclusion Section in Attachment A.

[7] *See* Section III in the 340B program recertification forms for rural referral centers, sole community, and critical access hospitals; *see also* Section IV in the 340B program recertification forms for disproportionate share, children's, and free-standing cancer hospitals.

III. Contract Pharmacy Registration Form

HRSA's proposed contract pharmacy registration form contains a "Medicaid Billing" section. We appreciate HRSA's proposed changes to make clear that the reporting requirements apply to FFS, not Medicaid managed care (MCO) claims. Along these lines, we urge HRSA to clarify in this form, as they did in the proposed hospital registration forms, that the carve-in or carve-out determination applies only to FFS, not MCO. We recommend the following changes:[8] (see Attachment C)

□ The contract pharmacy will not dispense 340B drugs to Medicaid fee-for-service patients and subsequently bill Medicaid fee-for-service for those transactions.

□ The contract pharmacy will dispense 340B drugs to Medicaid fee-for-service patients and subsequently bill Medicaid fee-for-service for these transactions, and an established arrangement of the covered entity, the contract pharmacy and the State Medicaid agency has been reported by the covered entity to HRSA/OPA.

IV. Cost Center Information in 340B Program Registration Form for Outpatient Facilities

Section III of HRSA's proposed 340B Registration Form for Outpatient Facilities directs hospitals to "enter expenses associated with the specific clinic, service or facility being registered." We have heard from hospitals that HRSA's requirement that hospitals register and list in the 340B Office of Pharmacy Affairs Information System (OPAIS) every clinic located in an offsite building and individual services provided in offsite locations is extremely burdensome, as it can significantly increase the number of child sites hospitals must register and for which hospitals maintain database information. This requirement also places a burden on hospital authorizing officials who are required to verify the accuracy of potentially several hundred registrations each year.

OPA can streamline the process of registering offsite clinics and services in a way that would ensure the clinics are eligible to provide 340B drugs while minimizing the burden on hospitals. When every clinic located in an offsite building is listed on a reimbursable line of the hospital's Medicare cost report, OPA should allow the hospital to certify that every location in the building is 340B-eligible and register only the offsite building as a child site. A similar certification process could also help streamline the registration of offsite services by allowing a hospital to certify that every service in a clinic is listed on a reimbursable line of the hospital's cost report and is therefore 340B-eligible.

V. Manufacturer Information

A. 340B Quarterly Pricing Data

340B Health supports the collection of information from manufacturers for the 340B ceiling price database to allow covered entities to verify that they are not being overcharged for 340B drugs. In addition to the data points listed in HRSA's proposed 340B quarterly pricing data form, it would be helpful to hospitals if the Food & Drug Administration (FDA) "ingredient name" could also be listed in the ceiling price database, as this is how drugs are typically listed in hospital records. We have heard from hospitals that they are sometimes not familiar with the FDA "product name." For example, most hospital systems label the drug Oncaspar as Pegaspargase because drugs are commonly referred to by their ingredient name, not their brand name. Pegaspargase, however, is listed in the ceiling price database as Oncaspar. To find Pegaspargase in the ceiling price database, hospitals unaware that the brand name is Oncaspar would need to search their wholesaler catalogue or pharmacy information system to find the product name, the national drug code (NDC) or other data point that could then be used to search for the drug in the ceiling price database. If covered entities could search for products using the product's ingredient name, that would save them the additional step of having to consult another resource in this situation, which is not uncommon. It is not clear whether HRSA already has access to this information or if manufacturers would need to provide HRSA with ingredient names for HRSA to upload to the ceiling price database. 340B Health provides this comment for HRSA's consideration.

B. Manufacturer Recertification

HRSA should require manufacturers to complete an annual recertification process to verify the accuracy of manufacturer information in the OPAIS, including contact information for manufacturer authorizing officials and primary contacts and require manufacturers to attest to program compliance and their obligations under the 340B program. Given the history of manufacturer overcharges of 340B covered entities, it is important that manufacturers be reminded of program requirements

[8] Our recommended changes to HRSA's proposed 340B Contract Pharmacy Registration form are included in Attachment C.

and have accurate information in OPAIS to allow hospitals to contact manufacturers if they suspect an overcharge.[9] Accurate manufacturer information in OPAIS will also facilitate covered entity outreach to manufacturers to allow covered entities to disclose compliance errors and initiate repayments to manufacturers if appropriate.

C. Pharmaceutical Pricing Agreement Addendum

340B Health supports the collection of information from manufacturers in the addendum to the Pharmaceutical Pricing Agreement (PPA) that HRSA created to incorporate 340B program integrity provisions that were included in the Affordable Care Act. Under these requirements, a manufacturer (1) must provide the 340B ceiling prices of its covered outpatient drugs to the Secretary of Health and Human Services (HHS) on a quarterly basis and (2) must offer a covered entity a covered outpatient drug for purchase at or below the 340B ceiling price if the drug is made available to any other purchaser at any price.[10] HRSA's launch of the ceiling price database on April 1, 2019 represents an integral step in ensuring that manufacturers are complying with their statutory obligations. The PPA addendum proposed by OPA, however, does not reflect that the 340B ceiling price database is currently operational. Along these lines, we recommend that OPA update the PPA addendum to reflect this. We also suggest additional changes in bold to help clarify manufacturer obligations under the "must offer" provision.

> **General Instructions for Completing the 340B Drug Pricing Program Pharmaceutical Pricing Agreement – Addendum**
>
> Section 340B(d)(1)(B)(i) of the PHS Act, as amended by section 7102 of the Affordable Care Act, requires HRSA to develop a 340B ceiling price validation system to calculate and verify 340B ceiling prices for covered outpatient drugs as compared to the manufacturers' 340B prices offered to a covered entity. This system will enable HRSA to receive pricing information directly from manufacturers, which will allow HRSA to more efficiently identify discrepancies among the ceiling price variables and resolve them with minimal burden on the industry. As part of HRSA's oversight of the 340B Program, this Addendum to the Agreement will help to ensure that the requirements of the statute are met, including that manufacturers provide HRSA with their calculated prices for the pricing validation system, and the provision to offer covered entities drugs for purchase at or below the applicable ceiling price if such drugs are made available to any other purchaser at any price. **These requirements apply to all covered outpatient drugs, including specialty drugs that manufacturers place in limited distribution networks to comply with the Food and Drug Administration's Risk Evaluation and Mitigation Strategy (REMS) requirements so long as the covered entity can meet the REMS requirements.**

* * * *

Thank you for considering our comments. If you have any questions, please feel free to contact Maureen Testoni at 202-552-5860 or maureen.testoni@340bhealth.org or Amanda Nagrotsky at 202-552-5866 or amanda.nagrotsky@340bhealth.org.

Sincerely,

Maureen Testoni
President & Chief Executive Officer

Amanda Nagrotsky
Legal Counsel

[9] *See e.g.,* HHS OIG, Pharmaceutical Manufacturers Overcharged 340B-Covered Entities (Mar. 10, 2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf; HHS OIG, Review of 340B Prices (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf, HRSA OPA, Manufacturer Notices to Covered Entities, https://www.hrsa.gov/opa/manufacturer-notices/index.html.
[10] 42 U.S.C. § 256b(a).

Attachment A

OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM REGISTRATION FOR CRITICAL ACCESS HOSPITALS

To meet the eligibility requirements for a disproportionate share hospital to participate and be listed as an eligible covered entity under Section 340B(a)(4)(L) of the Public Health Service Act, this registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa).

A completed registration package must include:

(1) The following registration information and compliance certification, and the following documents if the hospital is alerted;

(2) A copy of Worksheet S that is signed and dated from the latest filed Medicare cost report;

(3) A copy of Worksheet S-2 to demonstrate ownership type, and depending upon the hospital type the additional documentation described in II, D, below); and

All documentation described in 1-3 above is required to constitute a complete registration package. The entire package must be submitted on the same day to be considered complete. Incomplete packages will not be processed.

I. Hospital Information:

Hospital Name: _____

Medicare Provider Number:_____

Employer Identification Number:_____

Hospital Street Address (PO Boxes are not allowed):_____

City:_____ State:_____ZIP:_____

Hospital Billing Address (if different): _____

City:_____ State:_____ZIP:_____

Hospital Shipping Address (if different; PO Boxes are not allowed): _____

City:_____ State:_____ZIP:_____

II. Eligibility Criteria

❒ **Entity is a Critical Access Hospital defined by section 1820(c)(2) of the Social Security Act, and this status is recognized by CMS.**

A. Medicare Cost Reporting Period:_____/ __ /_____–____/___/_____
Filing Date: __ / __ / _____

B. Type of Control (as filed on cost report Worksheet S-2, Line 21)

- ❒ 1 – Voluntary Nonprofit, Church
- ❒ 2 – Voluntary Nonprofit, Other
- ❒ 3 – Proprietary, Individual
- ❒ 4 – Proprietary, Corporation
- ❒ 5 – Proprietary, Partnership
- ❒ 6 – Proprietary, Other
- ❒ 7 – Government, Federal
- ❒ 8 – Governmental, City-County
- ❒ 9 – Governmental, County
- ❒ 10 – Governmental, State
- ❒ 11 – Governmental, Hospital District
- ❒ 12 – Governmental, City
- ❒ 13 – Governmental, Other

C. Hospital Classification

❒ Owned or Operated by State or Local Government

Official documentation must indicate that the hospital is owned or operated by a unit of State or Local government. More than one document may be necessary to demonstrate eligibility. Any documentation provided should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Private, Non-Profit Hospital with State/Local Government Contract

Hospitals must be able to demonstrate through official documentation that it is both private nonprofit and that it has a contract as set forth in the statute. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

Contract start date: MM / DD / YYYY Contract end date: MM / DD / YYYY

❒ Check here if the entity's contract is valid until cancelled.

❒ A public corporation which is formally granted governmental powers by a unit of State or local government or Private Non-Profit Hospital Formally Granted Governmental Powers

Please submit the following documentation:

1. *Documents that clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility;*
2. *Identity of the government entity granting the governmental powers;*
3. *A description of the governmental power that has been granted to the hospital and a brief explanation as to why the power is considered to be governmental; and*
4. *A copy of an official document issued by the government to the hospital that reflects the formal granting of governmental power.*

Please refer to the *hospital registration instructions on the* Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Ineligible for-profit institution – **for-profit institutions are ineligible for registration**

D. Government Official who can certify the hospital's classification

Name: _____ Title: _____

Government Organization: _____

Phone: _____ Ext.: _____

Email: _____

III. Medicaid Billing

At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?
Yes ❒ No ❒

If the answer is yes, please provide the state(s) and associated billing number(s) listed on the claims ~~used~~ to bill Medicaid fee-for-service for ~~a~~ each particular state that you plan to bill for 340B drugs in the space(s) below (this could include numbers for the state your hospital is located in and any out-of-state Medicaid agencies your hospital plans to bill for 340B drugs). All numbers you plan to use~~d~~ to bill Medicaid fee-for- service should be provided and may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both the NPI and state assigned Medicaid number. Do not list a state for which the covered entity ~~does~~will not bill Medicaid fee-for-service for drugs purchased at 340B prices.

HRSA exports the Medicaid billing information listed in this site's 340B OPAIS record to generate the quarterly Medicaid exclusion file (MEF). HRSA requires the information on the MEF be accurate and complete for every registered site in the 340B OPAIS, and that covered entities follow any additional state Medicaid requirements in order to prevent duplicate discounts.

While this site may request a change to its 340B OPAIS record at any time, the Medicaid fee-for service billing practice at this site, must match the quarterly MEF.

~~IV. Orphan Drug Exclusion~~

~~340B hospitals subject to the orphan drug exclusion (i.e., critical access hospitals, sole community hospitals, and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act.~~

~~Please choose one of the following:~~

~~❒ The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.~~

~~❒ The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drug exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used. Only Cancer Hospitals cannot use a GPO to purchase orphan drugs.~~

~~V.~~IV. 340B Primary Contact and Authorizing Official Information:

Covered Entity Primary Contact Name
(Must be someone employed by the Covered Entity): _____

Title: _____

Phone:_____Ext._____ Fax: _____

Email Address: _____

Covered Entity Authorizing Official
The Authorizing Official must be someone who can bind the organization into a contract, such as the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program Director. Forms that are signed by an individual that OPA determines is not an acceptable representative will not be processed. If you are in doubt regarding the acceptability of a signature, please contact the 340B Prime Vendor Program at 1-888-340-2787 or via email at ApexusAnswers@340bpvp.com prior to submission of your registration.

Covered Entity Authorizing Official Name:_____

Title: _____

Phone:_____Ext._____ Fax: _____

Email Address: _____

~~VI.~~V. Signed Agreement:

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity into a contract and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The undersigned further acknowledges the 340B covered entity's responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity and its outpatient facilities that:

(1) all information listed on the 340B Program database for the covered entity will be complete, accurate, and correct;
(2) the covered entity will meet all 340B Program eligibility requirements;
(3) the covered entity will comply with all requirements of Section 340B of the Public Health Service Act and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts/rebates and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act), and the exclusion of orphan drugs for critical access hospitals, free- standing cancer hospitals, sole community hospitals and rural referral centers.
(4) the covered entity will maintain auditable records pertaining to compliance with the requirements described in paragraph (3) above, pursuant to section 340B(a)(5)(C) of the Public Health Service Act;
(5) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines;
(6) the covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
(7) the covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to removal from the list of eligible 340B entities.

In addition, I have read all applicable registration instructions and I am aware that my registration will not be reviewed if the required supporting documents are not submitted today.

Please provide any additional information that may be helpful in reviewing this registration for 340B eligibility:

_____

_____

Signature of Authorizing Official Date:

Attachment B

OFFICE OF PHARMACY AFFAIRS (OPA)
340B PROGRAM RECERTIFICATION FOR DISPROPORTIONATE SHARE HOSPITALS

A completed recertification must include:
(1) This Basic recertification information, and the following documents if the hospital is alerted;
(2) A copy of Worksheet S that is signed and dated from the latest filed Medicare cost report;
(3) A copy of Worksheet E, Part A from the latest filed Medicare cost report (for the DSH adjustment percentage in II, A, below.);
(4) A copy of Worksheet S-2 to demonstrate ownership type, and depending upon the hospital type the additional documentation described in II, D, below); and

I. Hospital Information:

Hospital Name:_____

Medicare Provider Number:_____

Employer Identification Number:_____

Hospital Street Address (PO Boxes are not allowed):_____

City: _____ State: _____ Zip: _____

Hospital Billing Address (if different): _____

City: _____ State: _____ Zip: _____

Hospital Shipping Address (if different; PO Boxes are not allowed): _____

City: _____ State: _____ Zip:

II. Eligibility Criteria

❒ **Entity is a Disproportionate Share Hospital defined by section 1886(d)(1)(B) of the Social Security Act, and this status is recognized by CMS.**

A. Disproportionate Share Adjustment Percentage:_____% based on
Medicare Cost Reporting Period: MM / DD / YYYY – MM / DD / YYYY Filing
Date: MM / DD / YYYY

B. Control Type per HCRIS

- ❒ 0 – Undetermined
- ❒ 1 – Voluntary Nonprofit, Church
- ❒ 2 – Voluntary Nonprofit, Other
- ❒ 3 – Proprietary, Individual
- ❒ 4 – Proprietary, Corporation
- ❒ 5 – Proprietary, Partnership
- ❒ 6 – Proprietary, Other
- ❒ 7 – Government, Federal
- ❒ 8 – Governmental, City-County
- ❒ 9 – Governmental, County
- ❒ 10 – Governmental, State
- ❒ 11 – Governmental, Hospital District
- ❒ 12 – Governmental, City
- ❒ 13 – Governmental, Other

C. Hospital Classification

❒ Owned or Operated by State or Local Government

Official documentation must indicate that the hospital is owned or operated by a unit of State or Local government. More than one document may be necessary to demonstrate eligibility. Any documentation provided should clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Private, Non-Profit Hospital with State/Local Government Contract

Hospitals must be able to demonstrate through official documentation that it is both private nonprofit and that it has a contract as set forth in the statute. Please refer to the hospital registration instructions on the Office of Pharmacy Affairs website for a description of acceptable documentation.

Contract start date: MM / DD / YYYY Contract end date: MM / DD / YYYY

❒ Check here if the entity's contract is valid until cancelled.

❒ A public corporation which is formally granted governmental powers by a unit of State or local government or Private Non-Profit Hospital Formally Granted Governmental Powers

Please submit the following documentation:

1. *Documents that clearly state the hospital's ownership, the date the ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility;*
2. *Identity of the government entity granting the governmental powers;*
3. *A description of the governmental power that has been granted to the hospital and a brief explanation as to why the power is considered to be governmental; and*
4. *A copy of an official document issued by the government to the hospital that reflects the formal granting of governmental power.*

Please refer to the *hospital registration instructions on the* Office of Pharmacy Affairs website for a description of acceptable documentation.

❒ Ineligible for-profit institution – **for-profit institutions are ineligible for registration**

D. Government Official who can certify the hospital's classification

Name: _____ Title: _____

Government Organization: _____

Phone: _____ Ext.: _____

E-mail: _____

III. Statutory Prohibition on Group Purchasing Organization Participation

Section 340B(a)(4)(L)(iii) of the Public Health Service Act, which is reiterated in the Statutory Prohibition on Group Purchasing Organization Participation Policy Release (2013-1), requires that the hospital not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. This is a requirement for Disproportionate Share Hospitals, Children's Hospitals, and Free Standing Cancer Hospitals.

The authorizing official must certify that this hospital will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the OPA database. If drugs are purchased using a GPO for covered outpatient drugs while participating in the 340B Program, the covered entity understands that this violates program eligibility requirements and that the covered entity is obligated to

inform OPA and may be required to repay manufacturers for the 340B discount received.

❒ Yes, I Confirm

IV. Medicaid Billing Information

At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices? Yes ❒ No ❒

If the answer is yes, please provide the state(s) and associated billing number(s) listed on the claims used to bill Medicaid fee-for-service for ~~a~~each particular state that you bill for 340B drugs in the space(s) below (this could include numbers for the state your hospital is located in and any out-of-state Medicaid agencies your hospital bills for 340B drugs). All numbers used to bill Medicaid fee-for-service should be provided and may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both the NPI and state assigned Medicaid number. Do not list a state for which the covered entity does not bill Medicaid fee-for-service for drugs purchased at 340B prices.

HRSA exports the Medicaid billing information listed in this site's 340B OPAIS record to generate the quarterly Medicaid exclusion file (MEF). HRSA requires the information on the MEF be accurate and complete for every registered site in the 340B OPAIS, and that covered entities follow any additional state Medicaid requirements in order to prevent duplicate discounts.

While this site may request a change to its 340B OPAIS record at any time, the Medicaid fee-for service billing practice at this site, must match the quarterly MEF.

Attachment C

340B Contract Pharmacy Registration

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau
OMB No. 0915-03

Contract Details

The contract begin date is set in accordance to the registration period guidelines.

Contract Begin Date:

Covered Entity Details

340B ID:
Entity Name:
Entity Sub-Division Name:
Entity Type:
Grant Number:
StartDate:
Address:

Contract Pharmacy Details

Name:
Address:

CE Authorizing Official

Name:
Title:
Phone: **Ext:**

Pharmacy Representative

*** Name:**

(First name, Last name - ie., John Smith)

***Title:**

*** Phone:**

(xxx-xxx-xxxx

Medicaid Billing

☐ The contract pharmacy will not dispense 340B drugs to Medicaid fee-for-service patients and subsequently bill Medicaid fee-for-service for those transactions.

☐ The contract pharmacy will not dispense 340B drugs to Medicaid fee-for-service patients and subsequently bill Medicaid fee-for-service for those transactions.

Continue Cancel