340B HEALTH
The affordable prescription for healthy communities

August 15, 2022

Via e-mail: paperwork@hrsa.gov

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

RE: Proposed Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (OMB No. 0915–0327—Revision), 87 Fed. Reg. 35983 (June 14, 2022)

Dear HRSA Information Collection Clearance Officer:

340B Health submits these comments in response to the notice published in the Federal Register on June 14, 2022 requesting comments on a proposed collection of information by the Health Resources and Services Administration (HRSA).[1] 340B Health represents more than 1,400 public and non-profit hospitals that participate in the federal 340B drug pricing program.

HRSA is requesting approval for existing information collections related to covered entity enrollment/registration/certification, outpatient facility and contract pharmacy registration, and change request forms. The notice says that the previously approved collections are mostly unchanged and that some form changes were made to increase program efficiency and integrity. Several changes proposed by HRSA are significant because they impact long-standing HRSA guidance, and in some cases, conflict with Federal Register notices that HRSA finalized after soliciting and responding to comments from program stakeholders. One of the proposed changes is inconsistent with the 340B statute. Some proposed changes need explanation or clarification. If finalized as proposed, these changes are likely to create confusion for covered entity stakeholders and could fail to advance HRSA's efforts to promote 340B program integrity and transparency.

Set forth below are our comments that address such proposed form changes. Our comments propose modifications that are consistent with existing guidance or to improve the clarity of the information collection.

[1] 87 Fed. Reg. 35983 (June 14, 2022).

I. The Proposed Changes for Health Care Service Delivery Sites as Covered Entity Shipping Addresses Conflict with the 340B Statute and Existing Guidance and Impose Operational and Financial Burdens on Hospitals

HRSA's covered entity registration, certification, and change request forms include proposed changes that address when entities can list certain locations as shipping addresses on the Office of Pharmacy Affairs Information System (OPAIS). Under the revised forms, covered entities will be asked to identify whether the location is a pharmacy, health care service delivery site, or a non-pharmacy/non-health care service delivery location.

HRSA proposes language in the forms stating that health care service delivery sites that provide medical services to patients, including administering or dispensing drugs directly to patients cannot be listed as shipping addresses in OPAIS if they are not eligible to register as child sites in OPAIS. Under this change, new locations of a hospital that are reimbursable under Medicare cost reporting rules cannot be listed as shipping addresses in OPAIS if the new locations have not yet appeared on a filed Medicare cost report.

It is arbitrary for HRSA to exclude hospital locations that are reimbursable under Medicare rules from being listed as shipping addresses in OPAIS. HRSA allows hospitals to use 340B drugs for patients in new provider-based locations that are not yet eligible to be registered as child sites in OPAIS.[2] However, most wholesalers will not establish shipping arrangements with hospitals for locations that are not listed in OPAIS. Accordingly, under the proposed change, to use 340B drugs in new locations, hospitals must arrange for the drugs to be shipped to the hospital and to be couriered to the new locations. These extra tasks impose unnecessary costs on hospitals and divert limited staff resources. Hospital pharmacy staff must unpack the shipment, which may contain hazardous products that require special handling, determine the products that are to be couriered and the location(s), repackage the product, complete an internal manifest to document the shipment, and hand off the shipment to the courier. Not allowing new provider-based locations to be listed as shipping addresses in OPAIS also results in unnecessary courier costs that hospitals report may exceed $1,000 per week.

HRSA's proposed revision unnecessarily expands upon guidelines that HRSA published in the Federal Register in 1994 on eligible outpatient facilities.[3] Those guidelines say that an outpatient facility is an integral part of the hospital and eligible to participate in 340B if it is included as reimbursable on the hospital's Medicare cost report.[4] Outpatient facilities that are included under a hospital's Medicare provider number are reimbursable under Medicare cost reporting rules.[5]

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[2] *See* Apexus FAQ # 4301 ("HRSA notes that for hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity)."
[3] 59 Fed. Reg. 47884 (Sept. 19, 1994).
[4] *Id.* at 47886.
[5] *See e.g.,* Medicare Provider Reimbursement Manual – Part 2 (CMS Pub.15-2), Section 112 (explaining that institutions that have multiple facilities but only one Medicare provider number "are required to submit one cost report under that principle provider number"); State Operations Manual (CMS Pub. 100-07, ch. 2, § 2779F (explaining that facilities that have merged and that operate as a single institution are required to submit one cost report, which necessitates a single provider number).

Notably, Medicare rules do not require that a facility first appear on a cost report of the hospital before billing under the hospital's provider number. Provider-based status for a facility is effective on the earliest date all Medicare requirements for provider-based status have been met.[6] Thus, a policy to exclude as shipping addresses new health care service delivery sites that are reimbursable locations of the hospital is contrary to both HRSA's guidelines on eligible outpatient facilities and Medicare cost reporting rules on which that guidance relies.

Moreover, if finalized, this change would conflict with the 340B statute, which includes Medicare subsection (d) hospitals as a type of "covered entity" that is eligible to receive 340B discounts.[7] Consistent with Medicare law, reimbursable hospital clinics are "integral parts" of the subsection (d) hospital comprising the eligible covered entity. These locations are eligible to receive and use 340B drugs for the hospital's patients per the statute. The 340B statute does not provide HRSA with authority to limit accessibility to 340B for eligible locations of the hospital.

We propose that HRSA allow health care service delivery sites that are new provider-based locations not yet appearing on the hospital's Medicare cost report to be shipping addresses for the hospital. Our recommended changes to the registration, certification, and change request forms are in bold:

2) If HEALTH CARE SERVICE DELIVERY SITE is selected, then "Is the health care service delivery site eligible to register as a child/grantee associated site in OPAIS?

a. If "Yes" is selected, then "An eligible healthcare service delivery site dispensing/administering 340B drugs as part of medical encounters must be registered as a child/grant associated site in OPAIS."

b. If "No" is selected, then does the Authorizing Official attest that the location is a provider-based location included under the hospital's Medicare provider number?

i. **If "Yes" is selected, then "the healthcare service delivery site may be listed as a shipping address."**

ii. If "No" is selected, then "an ineligible healthcare service delivery site may NOT be registered as a child/grant associated site and may NOT be listed as a shipping address."

We support HRSA's program transparency efforts that include making covered entity hospital and clinic registration information available to pharmaceutical manufacturers. Allowing new reimbursable hospital locations to be listed as shipping addresses will provide HRSA and pharmaceutical manufacturers with greater transparency into where 340B drugs are being used.

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[6] 42 C.F.R. § 413.65(o)(1). Hospitals are required to complete the CMS-855A form or use the online Medicare Provider Enrollment, Chain, and Ownership System (PECOS) when enrolling in Medicare and when adding additional practice locations that will be operating under the same Medicare provider number and same provider agreement. 42 C.F.R. §§ 424.500, 424.502, 424.505. New outpatient locations can be added before the location appears on the hospital's next cost report.

[7] 42 U.S.C. § 256b(a)(4)(L).

II. Medicaid Billing Information

HRSA's proposed registration and certification forms include a clarification to the Medicaid billing question stating that "[a] covered entity bills Medicaid fee-for-service for a 340B drug when it dispenses or administers a 340B drug to an outpatient at a pharmacy or as part of a medical encounter."

We are concerned that HRSA's proposed clarification creates new obligations for covered entities that bill state Medicaid agencies for 340B drugs at all-inclusive rates as part of bundled services. In final guidelines on duplicate discounts and Medicaid rebates published in the Federal Register in 1993, HRSA stated that entities that bill state Medicaid agencies at all-inclusive rates or do not submit outpatient drug claims to state Medicaid agencies for reimbursement "have no need to participate in the mechanism to prevent duplicate discounts" because Medicaid rebates are not generated.[8] HRSA restated this position seven years later in a Federal Register notice clarifying previous guidance related to the mechanism to prevent duplicate discounts.[9]

We are aware of an FAQ published on the Apexus website indicating that covered entities that bill Medicaid fee-for-service (FFS) for 340B drugs must answer "yes" to the Medicaid billing question, regardless of the rate at which they are reimbursed under Medicaid, even if the entity bills an all-inclusive rate and transmits no NDC information.[10] However, HRSA has not rescinded its prior notices in the Federal Register. If the proposed clarification is intended to inform entities that they must list their billing numbers on HRSA's Medicaid Exclusion File even when they bill state Medicaid agencies for 340B drugs at all-inclusive rates, such a change would conflict with HRSA's long-standing guidelines. Covered entities will not be properly informed of such a change in HRSA's position if it is articulated only through a proposal to renew existing information collections. If HRSA has a new position on the Medicaid billing question and duplicate discount prevention that differs from long-standing guidance, HRSA should issue a separate notice and request for stakeholder comments before imposing requirements on covered entities.

Moreover, it would appear arbitrary for HRSA to require hospitals that bill at all-inclusive rates to answer "yes" to the Medicaid billing question and register billing numbers on the Medicaid Exclusion File. When an entity billing a state Medicaid agency on a bundled basis does not report the drug it is billing for on a distinct line of the Medicaid claim, it does not transmit national drug code (NDC) information to the state. States cannot collect Medicaid rebates on drugs that are provided and reimbursed as part of another service and for which the provider does not submit NDC information.[11] Hospitals should not be required to provide information under HRSA's mechanism to prevent duplicate discounts for a scenario that does not create a risk for duplicate

[8] 58 Fed. Reg. 34058, 34059 (June 23, 1993).
[9] 65 Fed. Reg. 13983 (March 15, 2000).
[10] Apexus FAQ 2187, (last modified July 22, 2020).
[11] CMS, Bundled Rate Payment Methodology, https://www.medicaid.gov/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf (last accessed August 10, 2022).

discounts. An information collection requiring hospitals to provide such information imposes an unnecessary burden under the Paperwork Reduction Act.

We are also concerned that covered entities will misinterpret the proposed clarification to the Medicaid billing question as applying to situations where the entity dispenses or administers 340B drugs to Medicaid FFS patients, but does not submit a claim to the state Medicaid agency. Some 340B hospitals dispense or administer 340B drugs to out-of-state Medicaid beneficiaries without submitting a bill to the out-of-state Medicaid agency. HRSA's proposed clarification may cause hospitals to mistakenly believe that they must include billing numbers on HRSA's Medicaid Exclusion File for states that they do not bill at all.

At a minimum, the language should be modified to avoid this confusion. We propose modifying the statement as follows:

> A covered entity bills Medicaid fee-for-service for a 340B drug when it dispenses or administers a 340B drug to an outpatient at a pharmacy or as part of a medical encounter **and submits a claim for reimbursement of that drug to the state Medicaid program**.

III. Removal of Contract Pharmacy Attestation

To participate in 340B, covered entity authorizing officials must certify that the hospital will be bound by attestations regarding compliance with program requirements. HRSA proposes to remove the following attestation from covered entity registration and certification forms:

> (5) If the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines;

In the notice, HRSA did not provide an explanation for proposing to remove this attestation. It is not clear why HRSA is proposing this change, since HRSA does not propose changes to the following attestation in the contract pharmacy registration form:

> (2) The Covered Entity and the Pharmacy agree to be in compliance with the provisions of the Contract Pharmacy Services guidelines as set forth in the Federal Register, at 75 Fed. Reg. 10272 (March 5, 2010), which can be found at https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf.

Stakeholders cannot meaningfully comment on this aspect of the information collection without additional information from HRSA on the proposed change to remove the attestation referencing the 2010 contract pharmacy guidelines from some forms and not others.

IV. HRSA Should Solicit Feedback from Covered Entity Stakeholders Before Finalizing Form Changes that Impact Pharmacy Shipping Address Listings

HRSA proposes language in the forms stating that a pharmacy that is not "owned by the covered entity" may not be listed as a shipping address but instead must be registered as a contract

pharmacy. The language in the forms does not specifically address the situation where the pharmacy and the hospital are commonly owned by the same health system entity, nor does the language mention "in-house" pharmacies that may be owned by the hospital or the health system. The forms also do not address pharmacies that are partially owned by the covered entity. The Federal Register notice regarding the proposed information collection merely states that "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."[12]

Hospitals have reported that the treatment of "in-house" and "entity-owned" pharmacies as shipping addresses has been a source of confusion and has been inconsistent. The meaning of these terms when used in program materials has not been clear.[13] We are concerned that the changes in the forms on pharmacies as shipping addresses could reflect a change in program policy and that covered entities will not be properly informed of such a change if it is articulated only through a proposal to renew existing information collections. We think feedback from covered entities and other stakeholders on this issue would be useful in developing a transparent and well-reasoned policy on the treatment of pharmacies as shipping addresses. HRSA should issue a separate notice and request for stakeholder comments before imposing limitations on shipping addresses related to covered entities' in-house and commonly-owned pharmacies.

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Thank you for considering our comments. Should you have any questions, please feel free to contact us at amanda.nagrotsky@340bhealth.org.

Sincerely,

Maureen Testoni
President & Chief Executive Officer

Amanda Nagrotsky
Senior Counsel

[12] 87 Fed. Reg. 35983, 35984 (June 14, 2022).
[13] *See* Apexus 340B Glossary of Terms (using "entity-owned pharmacy" and "in-house pharmacy" interchangeably and defining both terms as "a pharmacy that is owned by, and is a ***legal part of the 340B entity***.") (emphasis added). *Cf.* Apexus FAQ # 1184, last modified on May 29, 2020 (stating that an in-house pharmacy can be listed as a shipping address, but "if the covered entity has a contract with the in-house pharmacy because it is a ***separate legal entity***", then it must be registered as a contract pharmacy) (emphasis added). Apexus FAQ # 1184 suggests that an "in-house pharmacy" can include pharmacies that are not "entity-owned", which is inconsistent with the definitions in the Apexus glossary. This FAQ also could be read as suggesting that a pharmacy that is a separate legal entity from the covered entity may nevertheless qualify as an in-house pharmacy that is eligible to be listed as a shipping address in OPAIS if the covered entity does not have a contract with the pharmacy.