October 6, 2025

Via e-mail: paperwork@hrsa.gov

HRSA Information Collection Clearance
Officer, Room 14NWH04
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, 90 Fed. Reg. 38167 (August 7, 2025)

Dear HRSA Information Collection Clearance Officer:

340B Health submits these comments in response to the notice published in the Federal Register on August 7, 2025 requesting comments on a proposed collection of information by the Health Resources and Services Administration (HRSA).[1] 340B Health represents more than 1,600 public and non-profit hospitals that participate in the federal 340B drug pricing program.

HRSA is requesting approval to revise previously approved information collections related to covered entity enrollment/registration/recertification, outpatient facility registration, and change request forms. HRSA notes that some form changes were made to increase program efficiency and integrity. While 340B Health agrees with several proposed changes and highlights others that require clarification (shipping address listings), we urge HRSA not to move forward with those that change long-standing policy and would impose a significant burden on many hospitals (new trial balance requirements).

I. HRSA Should Delay Implementation of New Hospital Change of Address Requirements Until It Provides Guidance as to the Purpose of the Change

The 340B change request form adds language to the street address section, directing hospitals to indicate whether the service will remain open at the old address. The form does not indicate the purpose of the question, nor how the answer would be used by HRSA when processing the change of address request. In the Federal Register notice for this ICR, HRSA states that the

[1] 90 Fed. Reg. 38167 (August 7, 2025)

answer to this question will "help determine the next appropriate action taken by the covered entity and HRSA."

HRSA should not implement this potentially significant change in policy until it clarifies its interpretation of the 340B statute that requires this change. As written, the language suggests that operating the same or similar service at the prior location could result in HRSA refusing to process the change of address. There are many reasons that a hospital would move a service location to another address and still operate that service at a smaller location. It could be used solely for outpatients, solely for infusions for a specific type of disease or patient, etc. There is no information as to what HRSA would be looking for or the legal basis for making its decision as to what the "next appropriate action" would be.

HRSA notes in the Federal Register notice that this change *"*will not increase the burden on covered entities because it provides increased transparency and facilitates a more efficient review with fewer exchanges between the covered entity and HRSA." We believe this change will decrease, not increase, the efficiency of review because HRSA does not explain what rules it is using to evaluate the request to change the address of an existing location.

II. HRSA Should Not Require Hospitals to List Unique Costs and Charges on the Trial Balance for Each Registered Child Site; Doing So Will Significantly Increase Administrative Burden on Many Hospitals

HRSA proposes adding a statement to its hospital outpatient facility registration form providing that hospitals are expected to be able to submit a trial balance that "clearly highlights the Cost and Revenue for each child site being registered. Cost and Revenue must be unique values for every child site." This is a significant change from the current language, which states that "the hospital may be required to provide…the associated trial balance," as that language does not say anything about what must be on the trial balance, leading the reader to understand that traditional Medicare rules apply.

It is also a significant change from HRSA's hospital registration instructions, which state that when costs and charges from more than one clinic…roll up to a single cost center, hospitals will need specific and unique costs and charges for each child site registered from the hospital's working trial balance.[2] Since Medicare does not require unique costs and charges for these locations, the reader would assume that HRSA is requesting the accounting or financial documentation that the hospital maintains to support the entries in its trial balance. There is nothing in this instruction requiring hospitals to change their trial balances, which are developed

[2] HRSA's 340B Hospital Registration Instructions, https://www.hrsa.gov/opa/registration/hospital-registration-instructions (last accessed October 6, 2025)

under Medicare policies, to a different and more complicated accounting process that could impact the hospital's entire system.

Moreover, we also understand that when hospitals have attempted to register a site and could not produce a trial balance with unique costs and charges for that particular site, HRSA routinely accepts supplemental financial documentation, such as financials, data from the electronic health record, or other materials.

We are very concerned about the burden this rule would place on hospitals. The Federal Register notice states that "this update will not change the burden on covered entities as there is no new or revised collection requirement." As discussed above, that statement is false with respect to existing documentation that HRSA requires. It is also false because it would require many hospitals to revise how they maintain their accounting, which is a significant and complicated issue for hospitals. Hospitals' current accounting complies with Medicare cost report requirements, thus these changes would impose additional burden on hospitals. We urge HRSA to continue its practice of reviewing supplemental financial documentation to support costs and charges. We describe below current Medicare rules and the types of entities and clinics this rule would significantly impact.

Under Medicare cost reporting rules, hospitals may choose to report multiple locations or services as one department/cost center on its general ledger. The trial balance is merely a snapshot at a specific period of time (i.e. fiscal year end). Requiring hospitals to break out reporting on the trial balance can significantly increase their accounting systems' complexity. Below are two examples of this how would work.

Many hospitals, especially rural providers, operate hospital-based primary care clinics. The clinics may operate in small communities that cannot support a physician practice five days a week, so the staff rotate to among communities (e.g., they are in one town on Mondays and Wednesdays and another on Tuesdays and Thursdays). Although there are two distinct locations, the clinic and its staff operate as one singular clinic, "Main Street Clinic," which is consistent with Medicare cost reporting rules. From an accounting perspective, the rural hospital has little incentive to track the separate physical locations on the general ledger as two departments, which would be unnecessarily burdensome to finance teams. Instead, the hospital records all personnel and capital costs on the general ledger in a single Main Street Clinic department/cost center number.

Another example of the misalignment between hospital operations and HRSA's proposed rule to maintain unique costs and charges on the trial balance applies to hospitals that treat the same disease state or offer the same services under multiple locations. In accordance with the

Medicare cost report's standard cost centers, the costs and charges for all the same service locations will feed into the same general ledger account. It is not uncommon for hospitals to have multiple locations for the same specialty (e.g., dermatology), but the locations have slightly different focuses (e.g., one location focuses more on issues like acne, eczema and the other location treats cancer and autoimmune disease). Because the same staff go between both locations, from an accounting perspective, it makes more sense to treat them as a single location. Additionally, hospitals may maintain multi-specialty clinics that involve the same clinical and administrative staff, but have different physicians that come at different times. Again, to maintain continuity, the costs and charges are put under one cost center.

In each of these cases, dividing up the costs and charges by location or specialty/service would be administratively challenging, create an opportunity for errors, and compromise the hospital's reporting and analytics. Please understand that hospitals can and do maintain separate financial statements that track the costs and charges associated with each geographic place or services of a cost center, but they do not have separate lines on their General Ledger, and corresponding Trial Balance, when that is not needed for Medicare cost report purposes. If HRSA will no longer accept those separate and supporting financial statements, as they traditionally have, hospitals will be forced to create additional cost centers by location and/or service, which could result in triple or quadruple their current number of cost centers.

III. Additional Clarification is Needed if HRSA Intends to Change its Policy on Listing Shipping Addresses

HRSA's covered entity registration, recertification, and change request forms include proposed changes that direct covered entities to list shipping addresses "under the 340B ID that purchases the drugs." Multiple hospital members reported that they could not determine HRSA's intent with this change.

HRSA's existing language allows hospitals to list shipping addresses under the main entity's registration or the offsite facility registration but notes that if a pharmacy serves multiple outpatient facilities, then the shipping address should be listed under the parent entity.[3] Under the new language, if the parent is purchasing all drugs for itself and child sites, then the hospital would list the shipping addresses under the parent, as is required under current policy. If the child site is actually purchasing drugs, then the shipping address would go under that child site. Thus, we cannot tell if this is effectively a change in policy, or just a rewording of the current policy.

[3] OPAIS User Guide for Covered Entity Users, https://340bpricing.hrsa.gov/Help/CoveredEntity/Resources/PDFUserGuides/340BCoveredEntityUserGuide.pdf (last accessed October 6, 2025)

If HRSA intends to follow its current policy, we recommend retaining the existing language. Based on the complexities and nuances with entities' drug ordering, distribution, and payment processes, use of the word "purchase" without more information will likely introduce confusion, and entities could misinterpret HRSA's expectations. Our members report that drugs are generally purchased by the parent, though through subsequent accounting, they may be allocated to other locations. However, they usually roll up to a single pharmacy cost center. Additionally, an invoice could list an offsite clinic as the billing address, but payment may be rolled up under the hospital's pharmacy cost center with pharmacy costs for all locations of the hospital. How this works can depend on various internal factors, processes, and budgeting.

340B Health would strongly oppose requiring a shipping address to be listed under each location that could be serviced by that shipping address. Such a rule would be incredibly burdensome, as entities cannot foresee all locations within a hospital that drugs may be used, and this could change over time. Hospitals would need to list all shipping locations under all registered sites, as they could not definitively say that registered sites would never use drugs shipped to a particular location. For example, if inventory is low in one child site, drugs from another hospital location could be sent to fill inventory for that child site. If the proposed change is intended to ensure entities list a shipping address under all the locations that are served by that address, we strongly oppose, as the change would impose significant burden and uncertainty on hospitals, without providing useful information to HRSA.

IV. HRSA Should Redefine the "Other" Category Under Shipping Address to Improve Clarity and Minimize Burden

HRSA's covered entity registration, recertification, and change request forms include proposed changes that address when entities can list certain locations as shipping addresses on OPAIS. Under the revised forms, covered entities will be asked to identify whether the location is a pharmacy, health care service delivery site, or an "other" receiving location. Within the "other" receiving location category, HRSA has proposed six types of locations for entities to select from and a free-form text field for locations that do not fit one of the options provided.

Our members have informed us that the types of locations listed under "other" overlap in terms of services provided at each location and they would not be sure which categories to check or whether they should check multiple locations. All of them have in common that they receive deliveries of prescription drugs and they do not dispense drugs directly to patients. Beyond that, however, the locations overlap. For example, "repackaging" is listed separately from warehouse and central distribution facilities, but repackaging is often considered a key part of central distribution and is often provided in warehouses. It is not uncommon for hospitals to have consolidated service centers that fulfill all the types of locations that are listed under "other."

We do not support including this language, as it will increase the burden of participating in 340B. These arrangements can change frequently, so that one location could merge into another location or add/remove services provided at that location. Requiring hospitals to update this information relating to their shipping addresses is burdensome and unnecessary. Instead of identifying the purpose of each location, especially when they overlap, we recommend that the form provide a check-box for the covered entity to confirm that the non-pharmacy shipping addresses represent locations where drugs are neither dispensed nor administered to patients, as this seems to be HRSA's primary goal of collecting this information.

If HRSA goes forward with this language, we recommend that HRSA permit entities to identify the type of receiving location based on which one the hospital considers to be the primary function (e.g., a central distribution and not repackager, because repackaging is part of central distribution). Alternatively, HRSA could allow hospitals to select more than one type of service per location. Based on what HRSA decides, there should be language that makes clear how entities should identify these locations to ensure consistency in how entities and HRSA understand this field.

V. We Support Updates to 340B Qualification Fields and Recommend Revisions to Published Information to Ensure Consistency

HRSA's hospital registration, recertification, and change request forms include two updates to qualification fields in the Office of Pharmacy Affairs Information System (OPAIS). We fully support the change from the language "Medicare Provider Number" to "CMS Certification Number (CCN)" to be consistent with CMS's language. Additionally, we support the change from the language "File Date" to "Date/Time Prepared." We are aware that hospitals have received audit findings when their OPAIS records have not reflected the Medicare Cost Report (MCR) preparation date and believe this update will help clarify the agency's expectations.

If HRSA finalizes the proposed revisions to these two qualification fields, we encourage the agency to revise published information to reflect the updated terminology. For example, HRSA's OPAIS User Guide for Covered Entity Users includes the term "Filing Date," defined as "the date when the Cost Center report was filed (required field for all hospital registrations)."[4] To provide consistency and help hospitals avoid confusion about which date they should use for registration (and recertification and making changes on a rolling basis), we recommend that HRSA revise this term in the User Guide to "Date/Time Prepared." Similarly, the term "Medicare

[4] OPAIS User Guide for Covered Entity Users, 340B Glossary, page 27 https://340bpricing.hrsa.gov/Help/CoveredEntity/Resources/PDFUserGuides/340BCoveredEntityUserGuide.pdf (last accessed October 6, 2025)

Provider Number (MPN)" appears in a few areas of the User Guide, including in the 340B glossary section, defined as "the identification number of an institutional provider certified by the Centers for Medicare and Medicaid Services (CMS) to provide services to beneficiaries."[5] We recommend that HRSA replace MPN with CCN.

We also note that HRSA's proposal to replace "File Date" with "Date/Time Prepared" is a substantive change. Hospitals usually prepare their MCR at least a few days before they actually submit it to Medicare (i.e., their e-Postmark date). This means that hospitals would be both eligible and ineligible a few days earlier than they would be if they used their "filed" date. If finalized, the updated language will help clarify the MCR date that hospitals must use to demonstrate initial and ongoing eligibility for 340B. It is not clear, however, whether HRSA expects hospitals to use the MCR preparation date to determine the effective date of lost eligibility. If that is HRSA's intention, we encourage the agency to review all published information for the term "file date" and replace it with "date/time prepared." For instance, we are aware of an FAQ published on the Apexus website indicating that a 340B hospital is no longer eligible to participate in 340B on the date it files its most recent Medicare cost report with a disproportionate share adjustment percentage below the 340B Program eligibility requirement. The covered entity is responsible for terminating its participation in the 340B Program and must cease purchasing and using 340B drugs on the filing date.[6]

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Thank you for considering our comments. Should you have any questions, please feel free to contact me at 202-552-5860 or Rebecca Swartz at 202-552-5852.

Sincerely,

Maureen Testoni
President & Chief Executive Office

[5] OPAIS User Guide for Covered Entity Users, 340B Glossary, page 29 https://340bpricing.hrsa.gov/Help/CoveredEntity/Resources/PDFUserGuides/340BCoveredEntityUserGuide.pdf (last accessed October 6, 2025)
[6] Apexus FAQ 1354 (last modified April 29, 2020)