



Pharmacy Service Line
Chelsea Dolloff
340B Program Manager
Brown University Health

October 6, 2025

The Honorable Maria G. Button
Director, Executive Secretariat
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

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Re: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision

Dear Executive Secretariat Button:

Brown University Health (“BUH”), on behalf of its 340B Covered Entity affiliates: Rhode Island Hospital (RIH) (DSH410007), Morton Hospital (DSH220073), and Saint Anne’s Hospital (DSH220020), all safety net DSH hospitals, the Miriam Hospital’s Immunology Center operating a Sexually Transmitted Disease Clinic (STD02904), its Rise TB clinic, a Tuberculosis Clinic (TB02906), and its Ryan White Care Program, a Ryan White AIDS/HIV Part C grantee (HV00018) (collectively “BUH”), thanks you for the opportunity to comment on the referenced announcement in 90 Fed. Reg. 38167 (August 7, 2025), issued by the Health Resources and Services Administration (HRSA) and Department of Health and Human Services (HHS).

The purpose of this letter is to address the specific actions posed in the Federal Register and advise on any supplemental action or support necessary should HRSA follow through with the proposed changes.

Enrollment/Registration/Recertification

(1) 340B Registration, Recertification and Change Requests for Shipping Address:

Adding detail to the shipping addresses in OPAIS to clarify their classification as a pharmacy, health care delivery site, or other receiving location would be very helpful as manufacturers have continuously misinterpreted infusion clinic pharmacies as in-house pharmacies, causing chargeback denials, removal of 340B pricing on hospital based purchasing accounts, and removal of 340B pricing from the designated contract pharmacy listed in 340B ESP in accordance with the manufacturer’s restriction notices. This issue continues despite repeated attestations, clarifications, submission of state and DEA license information, and is being used by manufacturers like Sanofi to improperly claim that covered entities are intentionally misrepresenting the status on their system pharmacies to further their claims of non-compliance and justify their attacks on contract pharmacies.

(2) 340B Registration and Recertification for Sexually Transmitted Disease (STD) and Tuberculosis (TB) Grantees:

As a general practice, we already provide the HHS NOA during recertification, along with our state sub-contract. However, we have had some difficulty receiving an updated NOA from the State Department of Health. If this were to become required, we would ask that at least one month before the opening of the recertification period for STD and TB grantees, that a copy of the current HHS NOA be sent to the AO and PC listed in OPAIS for these entity types or that HRSA otherwise establish a process to ensure documents are available to the grantees, like including a downloadable pdf link to the HHS NOA via the current grant search function on <https://data.hrsa.gov/topics/grants/find-grant>.

(3) 340B Program Registrations, Recertifications, and Change Requests for Family Planning

No comment – we do not have an active covered entity of this type.

(4) 340B Recertification and Change Requests for Street Address

We generally feel this is another appropriate clarification as we have had this question posed by the HRSA reviewer in the past and there are situations where a service is being split to its own or multiple clinic sites to accommodate increased patient volume.

(5) 340B Program Registrations, Recertifications, and Change Requests for Urban Indian and Tribal Contract/ Compact with IHS (FQHC628) Covered Entities

No comment – we do not have an active covered entity of this type.

(6) 340B Program Registrations, Recertifications, and Change Requests for Hospitals

No concerns – this is an appreciated clarification.

(7) 340B Program Registrations, Recertifications, and Change Requests for Hospitals

No concerns – this is an appreciated clarification.

(8) 340B Program Registrations for Hospitals

No concerns – this is an appreciated clarification.

(9) 340B Program Registrations for Hospitals

The current instructions in OPAIS for registering off-site outpatient locations requires entry of the expense and revenue values “for the entire line”, meaning the summed values for all clinics reported on that MCR line, such as line 90. OPAIS then refers to the MCR line as the cost center, which is confusing, but generally understood to mean the cost center’s MCR line. We then need to report the same values “associated with the specific clinic, service or facility being registered”. A service line, like Dermatology, can have multiple locations with different addresses but all roll up to the same cost center. A facility can

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have multiple floors and suites with different services that report to different cost centers. A clinic can have the same address and multiple services within the same suite. Without additional clarification from HRSA on how clinic, service, or facility is defined, covered entities could continue to interpret this differently and structure their cost centers accordingly.

The assumption that this change will not add burden to covered entities is not entirely accurate. If the current formatting of data for the Trial Balance sheet does not include the redefined detail required, covered entities will need to update their data, potentially create new reporting builds to meet this criteria. This change could also require covered entities to create new cost centers in order to provide that level of detail, which would cause currently eligible child sites to become ineligible because the new cost center is not on the most recently filed MCR. More clarification is needed from HRSA to ensure eligibility gaps are not created and that a grace period of some kind will be offered to covered entities to make appropriate changes.

Thank you for considering our comments.

Sincerely,

A handwritten signature in cursive script that reads "Chelsea L Dolloff".

Chelsea Dolloff, CPhT, 340B ACE
Manager, 340B Program