

September 24, 2025

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

By email: paperwork@hrsa.gov

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

Dear Ms. Britton:

On behalf of the National Alliance of State and Territorial AIDS Directors (NASTAD), thank you for the opportunity to comment on the proposed Information Collection Request (ICR) regarding the registration and recertification of entities in the 340B Drug Pricing Program. NASTAD represents the public health officials who administer HIV and viral hepatitis programs in all 50 U.S. states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the U.S. Pacific Island Jurisdictions, including U.S. Centers for Disease Control and Prevention Division of HIV Prevention and Division of Viral Hepatitis grantees authorized under Section 318 of the Public Health Service Act.

NASTAD generally supports the proposed 340B registration and recertification requirements for Sexually Transmitted Disease (STD) recipients and their subrecipients. We particularly support the proposed provision that subrecipients provide a copy of an executed written agreement that clearly outlines the relationship with the recipient. Requiring the inclusion of the recipient's and subrecipient's name and address, the grant and notice of funding opportunity number, and the terms and conditions of support is a positive step toward enhanced program integrity and clarity.

These written agreements are critical tools that allow the primary recipient, such as a state health department, to effectively manage its subawards and ensure alignment with public health goals. Specifically, these agreements allow recipients to stipulate:

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Stephen Lee (ex-officio)

- **Period of performance.** This involves an exclusive timeframe during which the subrecipient is authorized to perform the specific performance measures, after which point an agreement may be subject to extension or renewal.
- **Specific performance measures** tied to the NOA that confers 340B eligibility. This can include crucial outcomes such as increased rates of HIV or viral hepatitis testing; referrals to or provision of HIV prevention services like pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP); provision of viral hepatitis immunizations; delivery of other STI services like treatment and Doxycycline PEP (DoxyPEP); and linkage to care for patients diagnosed with HIV and/or viral hepatitis.
- **Clear reporting requirements** on performance measures back to the recipient.
- **Stipulations** that the subrecipient will adhere to core 340B program integrity requirements, including maintaining auditable records, prohibiting duplicate discounts and diversion, and reinvesting all program-generated savings to expand access to care for low-income and uninsured populations.

However, the proposed ICR does not acknowledge a significant operational challenge that will impact implementation. Many STD subrecipient agencies do not currently have written agreements with the recipient agency that meet the proposed standards. Furthermore, many existing agreements do not contain the specific information that may be required by the Office of Pharmacy Affairs for registration and annual recertification.

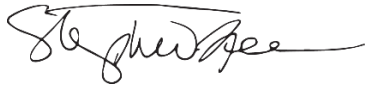
Due to stringent governmental public health agency procurement and contracting requirements, the process of establishing new written agreements or amending existing ones is often time-consuming and administratively complex. Recipient agencies will require ample time to draft, negotiate, and finalize these agreements, both internally and in collaboration with their existing and prospective subrecipient partners. To support this effort, we suggest that technical assistance be made available by the Office of Pharmacy Affairs and/or its prime vendor, Apexus, to help implement these new requirements. Such assistance is crucial to ensure recipients fully understand what must be included in agreements, thereby preventing scenarios where a recipient believes its agreement is compliant only to learn it is not, potentially resulting in a subrecipient's loss of 340B status or other adverse action from HRSA.

To ensure a smooth transition that does not jeopardize program access or continuity of care, NASTAD strongly recommends that HRSA provide a one-year implementation period after the new 340B registration and/or recertification process is finalized. A more rapid timeline may result in numerous 340B covered entities being unable to recertify because they cannot meet the new criteria in time. This would have a significant and detrimental impact on public health efforts to respond to STIs, HIV, and viral hepatitis. This is particularly true for local public health department STD clinics, which are often smaller, do not generate program income, and could not afford the Wholesale Acquisition Cost (WAC) for essential drugs like Bicillin L-A. During this

transition period, we also suggest HRSA accept letters from an STD recipient indicating they are in the process of executing a new agreement or amending an existing one to meet the new criteria. This grace period is essential to ensure that recipient agencies have the necessary time to develop compliant written agreements and support their subrecipient agencies in meeting these new requirements.

We appreciate HRSA's commitment to strengthening the 340B program and believe the proposed changes, coupled with a reasonable implementation timeline, will enhance accountability and effectiveness. Thank you for considering our comments. NASTAD stands ready to serve as a resource to you on this and other matters.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Lee", with a long horizontal flourish extending to the right.

Stephen Lee MD, MBA, DHSM

Executive Director

Pronouns: He/Him/His

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