



October 6, 2025

HRSA Information Collection Clearance Officer
Room 14NWH04
5600 Fishers Lane
Rockville MD 20857
Email: paperwork@hrsa.gov

We are writing to share our comments on the proposed changes outlined in the notice, "[Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327-Revision](#)"; published in the Federal Register on 8/7/25.

The University of Wisconsin (UW) HIV Care and Prevention Program is eligible for the 340B Drug Pricing Program as a subrecipient of funds through Section 318 of the Public Health Service Act, which covers projects for the prevention and treatment of Sexually Transmitted Diseases (STDs). UW has been receiving these funds and enrolled in the 340B Drug Pricing Program as an STD covered entity, since 2018. The 340B program is essential to our work to offer HIV biomedical prevention services (PrEP) to low-income individuals at risk for HIV to support the national goal of ending the HIV epidemic. We are concerned that the proposed changes to the recertification process for Section 318 grantees could potentially prevent us from accessing the 340B program in the future. Loss of 340B eligibility would be deeply detrimental to our ability to provide care to low-income individuals and to our efforts to decrease HIV transmission rates.

We understand and support efforts to ensure that the 340B Drug Pricing Program is only accessed by those entities for which Congress intended the program. We support the improvements that the Office of Pharmacy Affairs has made in recent years to oversight of the 340B Drug Pricing Program and the registration and recertification process. We are providing comments on the 8/7/2025 notice with the intention to ensure that future changes don't prevent eligible entities from accessing the program appropriately.

Our comments are focused on the following wording from the Enrollment/Registration/Recertification section of the notice:

(2) 340B Registration and Recertification for Sexually Transmitted Disease (STD) and Tuberculosis (TB) Grantees: HRSA is requesting that STD and TB grantees provide supporting documentation to demonstrate 340B eligibility pursuant to section 340B(a)(4)(K) of the PHS Act during initial registration as well as during recertification if requested to ensure compliance. The requested documentation will include a copy of the federal grant notice of award that identifies the grantor, grant number, period of funding, and recipient information. If the entity is a subgrantee then they

will also need to provide a copy of the executed written subrecipient agreement that includes the name and address of the recipient and subrecipient, the grant and notice of funding opportunity number, and the terms and conditions of support.

The notice states that “this requirement will slightly increase the burden on covered entities since eligible covered entities should already have this documentation readily available prior to registering and recertifying for the 340B Program.” While well intentioned to align with the goals of program integrity, the structure and process by which Section 318 grants and sub-awards are awarded means that the new requirement represents a **significant increase in burden**.

If the documentation requirements as worded go into effect, it may prevent eligible entities like ours from being able to recertify by the due date – despite being eligible for the program. We respectfully ask for consideration of the below process constraints in the final proposal.

- **Potential Blocked Access to NOA.**

- As a sub-awardee, we don't currently receive a copy of the recipient's Notice of Award (NOA) for the STD funding. The recipient of the STD funding in our case is the State of Wisconsin. In response to this notice, we reached out to our current contact at the State of Wisconsin and after consulting with others at the State he confirmed that he could provide us with a copy of the State's NOA if we send an email request with a justification for why we need it. This process would mean that our 340B eligibility would be dependent on a staff member at the State of Wisconsin understanding the requirement, being available to help us, and agreeing to share this legal document with us within the recertification time period.

- **Award Timing Challenges.**

- In recent years, the STD 340B recertification process has taken place in May. Our STD subrecipient funding periods have varied greatly in recent years. Here are the last 4 funding periods for our STD subagreements:
 - 6/1/25-5/31/26
 - 8/1/24-5/31/25
 - 1/1/24-7/30/24
 - 1/1/23-12/31/23

Subagreements take time to be issued by the sponsoring institution and to be reviewed and signed by the recipient institution. Each year, we receive an email from the recipient notifying us that they will be subawarding us funding and are starting the contracting process. For the funding period that started on 8/1/24, the subagreement was fully executed by UW and the State on 11/4/24. This is a typical timeframe for finalizing a subagreement. So if the 340B recertification window was in August or September, and our grant year started 8/1 then we wouldn't have an executed subagreement ready to submit during the recertification period.

If the 340B STD recertification window stays in May, and our grant year continues to start on June 1, then we will likely have the fully executed subagreement well before May. However, if the grant year start date or the recertification date were to move then we might not have the fully executed subagreement available to submit.

- **Delays in Federal NOAs**

- Challenges with timing can also originate from the federal agency. In 2025, the CDC did not issue NOAs until 3 weeks after the grant funding year started on 6/1/25. While this was unusually late compared to previous years, federal agencies often don't issue NOAs until right before the grant funding year begins. This delays all aspects of the recipients and subrecipients work, including the development of the subagreement by the recipient.

We hereby request that HRSA add potential acceptable alternatives to a subagreement; for example, the agency could accept a draft subagreement or a letter/email expressing the intent to fund provided by the recipient to the subrecipient, along with the federal NOA. This type of letter/email plus the NOANOA may still be challenging for some entities to obtain, however this would be less burdensome than requiring a fully signed subagreement.

Sincerely,



Julie Yendrek
Administrative Manager
HIV Care and Prevention Program
jky@medicine.wisc.edu