



By Electronic Submission to paperwork@hrsa.gov

September 5, 2025

HRSA Information Collection Clearance Officer
5600 Fishers Lane, Room 14NWH04
Rockville, MD 20857

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

Dear HRSA Information Collection Clearance Officer,

The **HIV+Hepatitis Policy Institute** is a national, non-profit organization whose mission is to promote quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. The HIV+Hepatitis Policy Institute submits this comment in support of HRSA's proposed documentation and registration updates for Sexually Transmitted Disease (STD) grantees and subgrantees participating in the 340B Drug Pricing Program. STI clinics are a key setting for HIV testing and prevention services, including PrEP and PEP, as well as for testing and treatment for viral hepatitis, especially hepatitis C.

As longstanding advocates for the 340B program, we believe strong oversight and clear documentation are critical to preserving its integrity and ensuring it continues to serve its core mission: supporting safety net providers and expanding access to care for low-income and underserved populations, including people with or at risk of HIV and hepatitis.

Participation by STD and subgrantees has grown considerably in recent years. As the program expands, it is reasonable to require consistent and verifiable documentation during enrollment and recertification, especially considering the growth in clinics qualifying through in-kind donations paid for by section 318 grant funds. The proposed updates are modest, administratively feasible, and consistent with standards already applied to other covered entities.

Given the significant 340B-related revenue many of these providers receive, they are well positioned to meet these requirements. Increased transparency will help HRSA validate eligibility, deter misuse, and ensure the program's benefits are directed toward patient care. We appreciate HRSA's continued leadership and encourage the agency to finalize these updates while providing technical assistance and a practical implementation timeline.

HIV+HEPATITIS POLICY INSTITUTE

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If you have any questions or need any additional information, please do not hesitate to reach out to our Government Affairs Manager, Zach Lynkiewicz, at zlynkiewicz@hivhep.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "Carl E. Schmid II". The signature is fluid and cursive, with a large, stylized "C" and "S".

Carl E. Schmid II
Executive Director