VIA Electronic Delivery
October 6, 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 Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on HRSA's Information Collection Request (ICR) on Enrollment and Re-Certification of Sexually Transmitted Disease (STD) grantees and subgrantees participating in the 340B Drug Pricing Program.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

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

The 340B Program, originally created in 1992 to support vulnerable patients' access to more affordable prescription medicines, has since grown well beyond its intended scope. Broad and over-expansive interpretations of clear statutory language, combined with profit-driven business models and lax oversight, have created significant abuses and program integrity risks. For years, numerous entities purporting to be STD subgrantees have been certified, despite not meeting the statutory criteria of 340B participation. This has resulted in millions of dollars being funneled to statutorily ineligible entities.[1] Considering this significant degree of abuse, it is evident that the certification and recertification of ineligible entities in the 340B Program is a major problem that requires prompt action and enforcement.

[1] See Amgen Inc., Eli Lilly & Co., & UCB Inc. v. Xavier Becerra, Secretary, U.S. Dep't of Health & Human Services, et al., No. 1:24-cv-3571 (D.D.C. filed Dec. 20, 2024).

Criteria for Certification

BIO urges HRSA to establish the statutorily required certification process described under subsection (a)(7) of the 340B statute, which directs HHS to establish a process for the certification of STD subgrantees and to make "criteria for certification" available to manufacturers under which information concerning past purchases of covered outpatient drugs must be submitted to determine eligibility for subsequent purchases of such drugs at 340B prices. It is discouraging that HRSA has not included any mention of this statutory mandate within the enrollment and recertification documents for this ICR, given the numerous documented program integrity concerns and abuses within the 340B Program.

Continued 340B Program Integrity Concerns

There are special statutory requirements for these grantees and HRSA has statutory obligations specific to them. While BIO appreciates HRSA's intent to enhance the oversight of grantees and subgrantees during enrollment and recertification, the proposed documentation and registration updates in this ICR fall short of HRSA's statutory obligations. Namely, the ICR does not resolve underlying core issues regarding the review and rescinding of certification of entities that are not eligible to participate in the 340B program.

To uphold 340B program integrity, HRSA must issue clear program requirements and take appropriate enforcement actions based on a consistent standard. An entity may only participate in the 340B program as a covered entity if all statutory eligibility criteria are met and may only purchase 340B-priced drugs for purposes consistent with the underlying federal grant. Accordingly, BIO urges HRSA to clearly state that entities under the Section 318 STD grant program are ineligible to be certified as a covered entity under section 340B(a)(4)(K) when they:

I. Use drugs acquired at 340B prices for other than STD prevention and treatment for their patients.
II. Receive federal grant funds only from subgrantees, rather than "through a State or unit of local government."
III. Receive in-kind contributions (e.g. pamphlets or condoms), not grant "funds" (i.e., cash).

Enforcement of these standards is necessary to prevent erroneous certifications and recertifications of STD covered entities and uphold the integrity in the 340B Program.

Patient Definition

In addition to the erroneous certification of ineligible entities that do not provide STD prevention or treatment services, HRSA has also erroneously certified entities that divert 340B-priced medicines to non-patients. Under 42 U.S.C. § 256b(a)(5), there is a clear requirement that "a covered entity shall not resell or otherwise transfer [any covered outpatient] drug to a person who is not a patient of the entity." Under longstanding guidance, HRSA considers an individual a patient of a 340B entity "only if . . . the individual receives a health care service or range of services from the covered entity which is

consistent with the service or range of services for which grant funding . . . has been provided to the entity."[2] Under subsection (a)(4)(K) of the 340B statute, an STD covered entity must receive eligible grant funding for the "treatment of sexually transmitted diseases." Moreover, HRSA's own guidance states that STD clinics participating in the 340B Program "may purchase and dispense any 340B drugs associated with a service for which the covered entity is responsible, including contraceptives, to that patient, *to the extent it aligns with patient definition and is consistent with the scope of the grant.*"[3]

Thus, it is evident the statute requires that STD covered entities may use 340B drugs for their patients if those drugs are for the treatment of sexually transmitted diseases. To strengthen 340B program integrity, HRSA must consistently apply and enforce a patient definition that conforms to the statute and furthers the intent and purpose of the 340B program.

Ineligible Receipt of STD Grant Funds

340B subgrantees have erroneously sought to confer 340B eligibility by transferring a portion of their own grant funds to other entities, contrary to the 340B statute. Under 42 U.S.C. § 256b(a)(4)(K), a covered entity gains 340B qualification by its receipt of STD grant funds only if it is "receiving funds . . . through a State or unit of local government." The statute does not authorize subgrantees to attempt to confer 340B eligibility on other entities by transferring STD grant funds to an indefinite number of other recipients, termed sub-subgrantees. Thus, HRSA must enforce existing statute and clearly state that entities receiving contributions only from other section 318 subgrantees (and not through a state or local government) are ineligible to participate in the 340B program as an STD entity under subsection (a)(4)(K).

In-Kind Contributions

HRSA's guidance[4] allowing the mere receipt of in-kind contributions to qualify an entity as a 340B-eligible STD clinic conflicts with plain language and the intent of the 340B statute. The plain meaning of "funds" as well as existing law demonstrates that grant funds are distinct from in-kind contributions such as supplies or equipment.[5] The current practices have led to various abuses of the 340B Program. For example, 340B eligibility has been documented for apparently for-profit physician offices based on their receipt of small quantities of condoms and marketing materials.

Accordingly, the ongoing certification of entities that only receive in-kind contributions weakens 340B program integrity by creating opportunities for entities to obtain 340B pricing

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[2] 61 *Federal Register* 55157-58

[3] HRSA, https://www.hrsa.gov/about/faqs/are-318-grantees-std-grantees-participate-340b-program-permitted-purchase-contraceptives-other-340b

[4] HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs.

[5] See Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/grant ("an amount of money given especially by the government to a person or organization for a special purpose") and 42 U.S.C. § 247c(e)(4): Authorizes Secretary to "reduce [a] grant by the fair market value of any supplies or equipment furnished to such recipient.

based on in-kind" items instead of "funds" required under the statute. This undermines efforts designed to ensure that the 340B program is used to the benefit of vulnerable and underserved patients as Congress intended. We urge HRSA to enforce existing law that an entity that receives only in-kind contributions is ineligible to be certified as a 340B covered entity.

HRSA must also provide manufacturers with transparent criteria for certification under subsection (a)(7). Implementation and enforcement of rigorous certification criteria would help curb abuses, reinforce accountability, and ensure that the 340B Program returns to its original intent, to provide discounted drugs to disadvantaged patients.

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We thank you for the opportunity to register our concerns on this topic and look forward to future discussions. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Regards,

/s/
Jack Geisser
Vice President
Health Policy

/s/
Melody Calkins
Director
Health Policy