VIA ELECTRONIC FILING TO: paperwork@hrsa.gov

October 6, 2025

Chantelle Britton
Director
Office of Pharmacy Affairs
c/o HRSA Information Collection Clearance Officer,
Room 14NWH04
5600 Fishers Lane, Rockville, MD 20857

Re: Proposed Collection: Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327-Revision

Dear Director Britton:

Gilead Sciences, Inc. ("Gilead" or "the Company") appreciates the opportunity to provide feedback on the Health Resources and Services Administration's ("HRSA's") information collection request regarding Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (the "ICR"), particularly for Section 317 (tuberculosis or TB) and Section 318 (sexually transmitted disease or STD) grantees.[1] Headquartered in Foster City, California, Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines in areas of unmet medical need. Gilead's therapeutic areas of focus include human immunodeficiency virus/acquired immunodeficiency syndrome ("HIV/AIDS"), liver diseases, respiratory diseases, and cancer. For more than 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing, linkage to care, and cure research. We are actively working to ensure patient outcomes are optimized for all individuals impacted by HIV through antiretroviral regimens that achieve long-term viral suppression and prevention therapies. Most recently, Gilead received approval for YEZTUGO® (lenacapavir), a twice-yearly long-acting injectable for HIV pre-exposure prophylaxis.

Gilead supports HRSA's 340B Drug Pricing Program (the "340B Program") as one way to ensure broader access to medicines for uninsured and underinsured patients. At the same time, we are concerned that oversight of the 340B Program has not kept pace with its explosive growth. We appreciate HRSA recognizing in the ICR the need for compliance, greater program efficiency, and

[1] HRSA, *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*, 90 Fed. Reg. 38,167 (Aug. 7, 2025).

integrity in the 340B program. Additionally, while HRSA is requesting that certain grantees report additional information about their eligibility for the 340B program, such reporting requirements are not meaningful without clear standards for eligibility based on the type of data being submitted. We believe that, by adding these standards to the ICR, HRSA could take an important step toward improving program integrity.

Summary of Gilead's Recommendations to Better Improve Program Integrity for Grantees

1. ***Set forth defined, transparent criteria for grantees and subgrantee eligibility for the 340B program*:** To increase program integrity in the annual process for certifying and recertifying grantees, Gilead urges HRSA to clarify how effective dates of 340B eligibility are based on a particular qualifying grant and clarify that in-kind donations do not suffice for eligibility. After clarifying the above, HRSA should further revise the ICR to collect individual data elements on grant period funding, funding amount, and/or value of monetary contributions received, and ensure such information is made available to the public through OPAIS.

2. ***Require that grantees and subgrantees use 340B program income consistently with the goals of the relevant qualifying grant.*** Additionally, HRSA should require information in writing from grantees and subgrantees demonstrating compliance with this requirement.

3. ***Establish policies and procedures for maintaining current records in OPAIS and enforcement measures when timely updates are not provided.*** HRSA states that the ICR's proposed new documentation requirement "streamlines the verification process and enhances program integrity for STD and TB entity types."[2] It is imperative that HRSA make clear descriptions of the processes to administer verification and ensure program integrity available to stakeholders, so they can understand how HRSA intends to use the information it proposes to collect.

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1. **<u>Set forth defined, transparent criteria for grantees and subgrantee eligibility for the 340B program</u>**

HRSA has yet to define in guidance or regulation many critical aspects for determining 340B eligibility for grantees. Even less guidance has been issued on subgrantee qualification for 340B program eligibility, which is not provided for under the 340B statute. For example, HRSA has yet to define criteria for considering whether and how monetary or in-kind donations are sufficient to confer 340B program eligibility.

[2] *Ibid.*

This lack of clarity has had significant consequences for program growth as certain types of grantees have exploited HRSA's ambiguous requirements. For example, STD clinics have grown dramatically as a proportion of the 340B program and there is no evidence that oversight has kept pace with this growth. In 2015, STD clinics were the 14th largest covered entity type by size of 340B purchases. By 2023, STD clinics were the 6th largest covered entity type by size of 340B purchases, now exceeding $1.66 billion annually.[3] STD clinics' purchases have grown at an average rate of 68% each year, as compared to 22% for covered entities overall.[4] Prior analyses have shown that 340B program growth was roughly equal for grantees (14.8%) and hospitals (15.7%) from 2020 and 2021.[5] Similarly, CBO recently found that anti-infective drugs account for the majority of spending at FQHCs (59%), Ryan White HIV/AIDS clinics (98%) and specialized clinics (75%) and that 340B spending growth was roughly double the overall growth in prescription drug spending for those drugs from 2010 to 2021.[6]

Eligibility criteria for grantees

HRSA is requesting that Section 317 and 318 grantees provide "a copy of the federal grant notice of award that identifies the grantor, grant number, period of funding, and recipient information." Collecting data about these clinics' eligibility is important, so that copies of federal grant notices of award can be used to verify eligibility appropriately. Such reporting would be more useful if HRSA defines clear eligibility standards based on the terms and conditions of a grant or its period of funding.

HRSA must also establish policies regarding these grantees' eligibility, in particular:

a. If 340B eligibility is determined based on the period of grant funding *or* on whether the grant funds have been expended; and

b. How 340B eligibility will be terminated in cases where a qualifying grant has been non-renewed, cancelled, paused, or revoked.

As part of the ICR, HRSA should require Section 317 and 318 grantees to separately report information needed to verify eligibility in new fields and ensure that such information is also made available to the public through OPAIS.

Eligibility criteria for subgrantees

Via subregulatory program guidance, HRSA has interpreted 340B eligibility to extend to entities that receive financial or "in-kind" donations tied to an STD or TB grant award. As a result

[3] Source: Analysis of 340B Prime Vendor Program Data.
[4] *Ibid*.
[5] E. Blalock. Federal Grantee Clinics and the 340B Drug Discount Program. BRG. April 2023.
[6] Congressional Budget Office. Growth in the 340B Drug Pricing Program. September 2025.

of HRSA's guidance on these "subgrantees," which are not provided for under the 340B statute, there are a growing number of physician groups and other entities that are qualifying for participation in the 340B program because they receive (often small) subgrants, including monetary or in-kind donations, from grantee clinics. In turn, such subgrantees are using their 340B eligibility status to dramatically expand the footprint of the 340B program, all based on unspecified and non-transparent monetary donations or "in-kind" support provided to subgrantees. Furthermore, HRSA has not provided any limits to the number of "levels" of subgrantees in a chain of monetary or "in-kind" donations that can be certified for eligibility in the 340B program. As the number of subgrantees continues to grow, improved transparency and accountability become critical to maintaining program integrity.

To address this, HRSA should establish policies for making eligibility determinations based on parameters of agreements between grantees and their subrecipients. However, HRSA proposes reporting without establishing these necessary standards. HRSA states that "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."

Gilead recommends that HRSA also issue guidance on the following points:

The minimum value of original grant funds that must be provided to a sub-recipient in order to establish subgrantee eligibility.

HRSA should determine thresholds of value for the purposes of conferring 340B eligibility via monetary contributions. Section 340B(a)(4)(K) of the Public Health Service Act (PHSA) defines a covered entity to include certain entities that receive "funds" under various Federal grant programs. While the statute does not define the term "funds," HRSA can clarify that grant funds awarded under PHSA Section 318 clearly contemplate "funds" as "monetary assistance."

An in-kind donation is insufficient to establish eligibility for the 340B program.

Furthermore, HRSA should withdraw its current guidance and FAQs regarding in-kind support. Instead, HRSA should clarify that funding must be provided to subrecipients in the form of monetary contributions from the original underlying federal grant and may not be represented by donations of other types of materials or services. This will help establish a clearer tie to the original grant and accountability for the subgrantee to adhere to its rules.

2. Require that grantees and subgrantees use 340B program income consistently with the goals of the relevant qualifying grant.

In addition to program-specific requirements specified in the original grantmaking authority and terms and conditions of the grant award, the Office of Management and Budget

(OMB) has promulgated generally applicable regulations for grantees known as the "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (Uniform Guidance).[7] In the context of the 340B program, the Uniform Guidance's broad definition of "program income" and how it may be used can be read to include 340B profit (defined for this letter's purpose as the difference between a third-party's reimbursement rate and the 340B acquisition price) and require that such profit be used for a purpose that is consistent with the underlying federal grant. HRSA has expressly adopted this position in subregulatory guidance with respect to Ryan White HIV/AIDS Program (RWHAP) grantees and Hemophilia Treatment Center (HTC) grantees.

Generally speaking, 340B-eligible Section 317 and 318 grantees, as well as their subgrantees, are parties to a "grant agreement" because they receive federal financial assistance from HHS. As such, they must comply with a range of different requirements under the Uniform Guidance including, among other things, the appropriate calculation and use of "program income." To improve transparency, accountability, and ensure consistency across 340B program administration across all types of covered entities, HRSA should establish comparable rules regarding appropriate use of 340B program income for Section 317 and 318 grantees – as well as all 340B covered entities. In particular, as it has done for RWHAP and HTC grantees, HRSA should require STD clinic grantees and subgrantees to demonstrate in writing or with other supplemental documentation how these covered entity types are complying with the Uniform Guidance by using 340B program income consistently with the purposes of the underlying Federal grant.

3. **Establish policies and procedures for maintaining current records in OPAIS and enforcement measures when timely updates are not provided.**

HRSA asserts that the ICR's proposed new requirements for supporting documentation "streamlines the verification process and enhances program integrity for STD and TB entity types." Gilead encourages HRSA to explain how the new requirements will translate into enhanced program integrity, since oversight protocols and enforcement plans and procedures are not defined. For example, regarding shipping addresses, HRSA states "The information collected will also help determine if the location should be listed as a shipping address or potentially registered separately in OPAIS as a contract pharmacy or covered entity." To make this data collection more meaningful, HRSA should *also* establish in guidance or rulemaking its policies for when it is appropriate for a covered entity to register a location as a shipping address versus a contract pharmacy.

HRSA's request for updated shipping addresses, street addresses, and contact information for the primary point of contact should also require covered entities to updates this information within 30 days of a change. The agency should also describe its procedures for ensuring compliance. For example, Gilead is aware of instances where a point of contact listed for a covered

[7] 79 Fed. Reg. 75867 (Dec. 19, 2014).

entity is an individual who has been deceased for more than one year. HRSA should be explicit about terminating 340B eligibility under such unacceptable circumstances.

Additionally, after including data fields in the ICR reflecting new policies for grantee and subgrantee eligibility, HRSA should establish protocols for reporting relevant metrics and data transparently in OPAIS. This would help to reinforce the agency's policies for conducting oversight and enforcement and increase transparency to other 340B stakeholders.

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Thank you again for the opportunity to comment on the ICR, including the ways in which HRSA can ensure more efficient program processes and greater program integrity under the 340B Program. We look forward to further dialogue on these issues. If you have any questions regarding Gilead's comments, or if we can provide any additional information, please contact Michelle Drozd at michelle.drozd2@gilead.com.

Sincerely,

Rekha Ramesh
Vice President, U.S. Policy
Government Affairs

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