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VIA EMAIL (paperwork@hrsa.gov)

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

Samantha Miller, Information Collection Clearance Officer
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 14WH04
Rockville, MD 20857

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

Dear Ms. Miller:

Eli Lilly and Company (Lilly) appreciates the opportunity to respond to the above captioned information collection request (ICR) that the Health Resources and Services Administration (HRSA) intends to submit to the Office of Management and Budget concerning covered entity enrollment and recertification in the 340B program.[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives. Relatedly, we remain committed to the 340B program as originally intended as a program to benefit low-income and uninsured patients.

We are encouraged to see HRSA attempting to impose additional rigor on the enrollment and recertification process for covered entities. According to the ICR, responses will be used "[t]o ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency and integrity" and to permit a "HRSA developed [ ] process of registration for covered entities to enable it to address specific statutory mandates."[2] However, as it relates to the proposals for Sexually Transmitted Disease (STD) and Tuberculosis (TB) grantees specifically, HRSA's proposal will, if adopted, further erode the transparency and accountability of the enrollment and certification processes for these grantees, as described in detail below.

As we have brought to the agency's attention previously, certain entities are using the STD and TB grantee certification process to illegally gain access to 340B pricing. These unlawful workarounds are largely possible due to HRSA's lax enforcement of certification of STD and TB grantees, and the minimal documentation proposals in this ICR will not fully address this ongoing exploitation. With this background in mind, it is interesting (and disappointing) to note that HRSA is only "requesting" STD and TB grantees provide extra documentation, when such documents must be "required" to ensure compliance with the 340B statute. Since the purpose of an ICR is to collect information that the agency may not possess and may wish to evaluate in determining whether certain program administration documents are too burdensome or not burdensome enough, Lilly is providing this detailed information to HRSA for consideration as it seeks to evaluate the need for clear accountability for STD and TB grantee enrollment and to aid the agency in coming into full compliance with its statutory certification duties.

[1] 90 Fed. Reg. 38167 (Aug. 7, 2025).
[2] *Id*.

I. HRSA's Proposal Fails to Address Extra Qualifications Congress Imposes for STD and TB Grantees

Congress recognized that STD and TB grantees pose a special risk of abusing the 340B program and therefore imposed additional requirements. For just these types of grantees, the Secretary is required to separately establish "a process for certification" and must make these "criteria for certification" available to manufacturers. 42 U.S.C. § 256b(a)(7). Despite this mandate, HRSA has **never** made its certification criteria available to manufacturers, and despite addressing the very topic in this ICR and even citing this particular statutory provision, the agency is still not proposing to meet this foundational statutory requirement.

Congress also provided specific directions to the Secretary on the certification process for STD and TB grantees. *Id*. These grantees must "submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices." *Id.* § 256b(a)(7)(B). States must "prepare and submit a report to the Secretary that contains a list of" STD and TB grantees that are in the state. *Id.* § 256b(a)(7)(D). And the annual recertification process for these grantees "shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities." *Id.* § 256b(a)(7)(E). Again, there is no evidence that any of these requirements have been met **ever**, and HRSA's proposal to receive minimal grant award information will not meet these statutory requirements either.

Beyond requiring that STD and TB grantees provide copies of grant materials, which HRSA has firsthand knowledge can be back dated and can involve the exchange of de minimis funds (if any funds at all), HRSA should comply with the 340B statute and holistically reform the entire certification and reenrollment process, including providing manufacturers with the enrollment criteria and requiring STD and TB grantees to submit annual information about their 340B purchases.

II. HRSA's Proposal Fails to Close Unlawful Loopholes for STD and TB Grantees

An entity qualifies as a covered entity based on its receipt of STD or TB grant funds only if it is "receiving funds . . . **through** a State or unit of local government." 42 U.S.C. § 256b(a)(4)(K) (emphasis added). Despite this clear language, HRSA has allowed grantees to pass on 340B eligibility even further down the chain, by transferring a portion of its own grant funds to create "sub-subgrantees" that HRSA unlawfully recognizes as valid covered entities. Allowing a subgrantee to pass on 340B eligibility by transferring grant funds to other entities also has no logical stopping point and violates the deliberate specification with which Congress identified and defined the list of eligible covered entities. HRSA's proposed ICR must make clear that a subgrantee must receive its funds directly from a State or unit of local government and cannot continue to confirm 340B status on ineligible sub-subgrantees.

Revisiting the statutory language above, an entity further only qualifies as a STD or TB grantee if it is "receiving **funds** . . . through a State or unit of local government." 42 U.S.C. § 256b(a)(4)(K) (emphasis added). The plain meaning of "funds" is "money, often money for a specific purpose."[3] Despite this clear requirement to receive funds, HRSA has a policy of allowing STD and TB grantees to qualify based on the receipt of in-kind contributions and many purported covered entities claim 340B eligibility through this means. Similar to the sub-subgrantee loophole described above, HRSA must revise its proposed guidance to make clear that STD and TB grantees must provide documentation of receipt of actual money to be an eligible covered entity.

[3] Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/funds.

Beyond in-kind contributions being inconsistent with the 340B statute, it appears that HRSA does not even do the most minimal amount of verification of these in-kind contributions in the certification process. A cursory check of OPAIS identifies active STD grantees listing things such as "State of NJ"[4] "office supplies"[5] "[w]e purchase medications at a discounted price"[6] "340B"[7] and "[i]n kind support was extended"[8] as evidence of their in-kind support, to name just a few examples that even a cursory review by HRSA should have caught. These examples show both how little effort it takes for entities to become covered entities and that HRSA's proposed ICR to the enrollment and certification process do not go nearly far enough to restoring transparency and integrity to the STD and TB grantee eligibility process.

Our experiences with abuse of the STD and TB grantee status shows that Congress's concerns about these entities were valid and demonstrates why HRSA must perform greater diligence in their certification. Many entities registered as STD and TB clinics hold themselves out as practicing in rheumatology, dermatology, or other fields unrelated to the underlying STD or TB grants, without any clear connection to serving STD or TB patients. They seek—and apparently obtain—covered entity status based on so-called "in-kind" contributions, like condoms and pamphlets, from other grantees. And these entities are purchasing 340B priced medicines from companies like Lilly that do not make a single product designed to treat STDs or TB. Such abuse of the 340B program only further sows distrust in the program and undermines HRSA's efforts at oversight.

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As HRSA considers in this ICR the compliance "burden" on STD and TB grantees in the enrollment and certification process, we hope it acknowledges and incorporates the information described above. As always, we would be happy to discuss these issues further.

Sincerely,

Derek L. Asay
Senior Vice President, Government Strategy and Federal Accounts

[4] 340B ID: STD08817
[5] 340B ID: STD126015
[6] 340B ID: STD14222
[7] 340B ID: STD28425
[8] 340B ID: STD79107