AMERICA'S ESSENTIAL HOSPITALS

June 18, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration (HRSA)
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Response to Lilly's Unlawful 340B Drug Pricing Program Activities

Dear Administrator Engels:

On behalf of America's Essential Hospitals, we write to urgently request that the Health Resources and Services Administration (HRSA) take immediate action to address Eli Lilly and Company's unlawful denial of 340B drug discounts—whether through in-house or contract pharmacies—to certain covered entities that have not complied with its unilateral and extralegal reporting requirements. Eli Lilly's illegal policy to deny 340B pricing implicates at least one member of America's Essential Hospitals and threatens every 340B covered entity. **We urge HRSA to expeditiously restore access to 340B pricing for these covered entities through its available enforcement authorities.**

America's Essential Hospitals is the leading association and champion for hospitals dedicated to high-quality care for all, including those who face social and financial barriers to care. Since 1981, America's Essential Hospitals has advanced policies and programs that promote health and access to health care. We support our more than 400 members with advocacy, policy development, research, education, and leadership development. Communities depend on essential hospitals for care across the continuum, health care workforce training, research, public health, and other services. Supported by Essential Hospitals Institute, the association's research and education arm, essential hospitals innovate and adapt to lead all of health care toward better outcomes and value.

Eli Lilly on June 1 provided public notice of its intent to unilaterally withhold statutorily mandated 340B discounts from covered entities that decline to participate in its proprietary data-reporting framework.[1] This extra-statutory mandate was issued without prior approval from HRSA, despite severe concerns raised repeatedly by America's Essential Hospitals and other stakeholder groups.[2] We are deeply disappointed that, despite our January

[1] O'Harra J. Letter to Thomas Engels on June 1, 2026. https://340breport.com/wp-content/uploads/2026/06/Lilly_In-House_Claims_Data_Requirement-Upcoming_Action.pdf. Accessed June 18, 2026.
[2] DeCubellis J. Letter to Thomas Engels on Jan. 29, 2026. https://essentialhospitals.org/wp content/uploads/2026/01/Lilly-Claims-Data-Submission-obligations-letter.pdf. Accessed June 18, 2026.

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correspondence detailing these impending violations, a major manufacturer is moving forward with a policy that threatens immediate disruption to the safety net.

As of June 18, we have been informed that Eli Lilly is now preventing covered entities from accessing drugs at 340B-discounted prices through their wholesalers. HRSA, not Eli Lilly, should set program rules; otherwise, covered entities will see substantial increases in the costs of providing drugs to their patients. Hospitals with resources to oppose Eli Lilly's policy even briefly will be forced to acquiesce to survive while they undergo the lengthy process required to challenge these illegal restrictions. **HRSA should use its enforcement authorities against Lilly and avoid needless harm to covered entities and their patients over this latest manufacturer action.**

Covered Entities are Not Required to Comply with These Unilateral, Extra-Legal Manufacturer Restrictions to Access Statutory Discounts

Eli Lilly's decision to deny 340B ceiling prices to covered entities that decline to submit in-house 340B claims data to its designated third-party platform (340B ESP) violates the plain language of the 340B statute in multiple ways. It is far beyond court rulings regarding manufacturer conditions on access to 340B drugs and would in fact require onerous new efforts and administrative costs by covered entities.

Congress established a clear requirement for manufacturers participating in Medicaid and Medicare Part B: manufacturers must offer covered outpatient drugs to eligible 340B covered entities at or below the applicable ceiling price. Rather than utilizing the statutory pathways established by Congress—requesting an audit with HRSA approval or pursuing a dispute resolution process—Eli Lilly has elected to impose its own enforcement framework and deny statutorily mandated discounts to covered entities that decline to participate in their scheme. Eli Lilly's conduct threatens to replace federal oversight with a varying patchwork of manufacturer-imposed requirements.

Eli Lilly appears to justify its policy by relying on recent appellate court decisions related to HRSA enforcement against manufacturer-imposed reporting and other restrictions on covered entities' use of contract pharmacies. But these narrow decisions simply discuss delivery of 340B drugs and relate only to contract pharmacy settings. **These courts did not bless the requirements at issue now or their extension to in-house pharmacies**.

In fact, those courts explicitly recognized that manufacturer-imposed conditions may be unlawful when they conflict with the requirements and structure of the 340B statute. The D.C. Circuit stated that, "some conditions might be onerous enough to effectively increase the contract 'price,' thus perhaps nudging it above the statutory ceiling."[3] As America's Essential Hospitals explained in our January correspondence, the claims submission requirements imposed through 340B ESP create significant operational and administrative burdens for covered entities.[4] Participation requires investments in personnel, technology, and compliance resources that extend well beyond any obligations imposed by federal law. The extension of these requirements to ***any and all*** purchases of a covered outpatient drug by a covered entity raises these costs to the point that it increases the effective cost of the drugs above the statutory ceiling price. As such, the policy goes beyond manufacturer conditions on

[3] *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 462 (D.C. Cir. 2024).
[4] DeCubellis J. Letter to Thomas Engels on Jan. 29, 2026. https://essentialhospitals.org/wp content/uploads/2026/01/Lilly-Claims-Data-Submission-obligations-letter.pdf. Accessed June 18, 2026.

delivery to effectively strike at the core function of the 340B statute: pricing. **Eli Lilly's policy is so onerous that it directly conditions and restricts covered entities' basic ability to access the statutory price itself.**

Moreover, by preventing a covered entity from purchasing and dispensing 340B discounted drugs at all, the policy is analogous to a situation explicitly identified by the Third Circuit. The court outlined a scenario where, if a drug maker were to bar all use of contract pharmacies, it would arguably have not "presented" discounted drugs "for acceptance" to covered entities with no in-house pharmacy because they would in turn have no way in practice to "accept" them.[5] The same concern is present where a drug maker bars access in *all* of a covered entities' pharmacies unless the entity reports.

Some covered entities have, under duress, complied with Lilly's absurd data demands to preserve access to lawful 340B discounts. **Coerced compliance under the threat of complete exclusion from statutory discounts does not legitimize an extra-statutory mandate.** For those entities that have complied, it has come at the cost of capacity and resources to support patient outcomes. Covered entities cannot be forced to choose between participation in a private manufacturer reporting platform and access to statutory discounts that Congress intended them to receive.

HRSA Must Act Immediately to Protect 340B Covered Entities

Eli Lilly's actions are now causing immediate and demonstrable financial harm to at least one of our member hospitals and the patients it serves. When covered entities purchase drugs at exponentially higher wholesale prices, the resulting overcharges directly reduce the resources available to support patient care. Essential hospitals rely on 340B savings to sustain services that are often inadequately reimbursed or uncompensated, including outpatient pharmacy programs, behavioral health services, specialty care, care coordination activities, and other critical services for low-income and medically underserved populations. Every dollar unlawfully withheld from covered entities is a dollar that cannot be invested in patient care and community health benefits that the 340B program was designed to support.

Several 340B hospitals joined litigation in 2025 challenging Eli Lilly's unilateral and improper implementation of a rebate model that threatened access to upfront 340B discounts. In a sworn declaration submitted in that litigation, a representative from our association member testified to a court that denied access to 340B pricing by Eli Lilly would cost the covered entity an additional $17.8 million annually. Loss of 340B pricing will negatively affect significant services this hospital provides in its community, including free care to low-income patients, a mobile care clinic providing free health and dental services to underserved patients, and a separate mobile care addiction team. **Denying statutorily mandated 340B discounts will substantially harm community programs and will erode access to health care services for patients essential hospitals serve.**

HRSA must act immediately to restore compliance with federal law and protect the integrity of the 340B program. We respectfully urge HRSA to direct Eli Lilly to immediately restore access to 340B ceiling prices for all affected covered entities and require the manufacturer to refund all overcharges incurred because of these unlawful restrictions. Covered entities should be made whole for every purchase made at prices above those permitted under federal law. In addition, HRSA should utilize all available enforcement

[5] *Sanofi-Aventis U.S. v. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703-704 (3d Cir. 2023).

authorities to address Eli Lilly's noncompliance, including civil monetary penalties described in the 340B statute.

Finally, **HRSA should affirm that manufacturers may not condition access to 340B pricing in all of a covered entity's pharmacies on compliance with manufacturer-created reporting requirements**. A clear statement from the agency is necessary to prevent future attempts to impose extra-statutory conditions on covered entities and to preserve HRSA's role as the administrator of the 340B program.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Robert Nelb, at 202-585-0127 or rnelb@essentialhospitals.org.

Sincerely,

Jennifer DeCubellis
President and CEO