American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

January 26. 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Dear Administrator Engels:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) writes to express our serious concerns with the recent announcement by Eli Lilly and Company (Lilly) to require 340B covered entities to submit claims data for *all* dispensations of *all* Lilly drugs, regardless of setting. **We urge the Health Resources and Services Administration (HRSA) to take immediate action to stop this policy from taking effect on February 1, including by assessing civil monetary penalties for intentionally overcharging 340B hospitals.**

On January 15, Lilly issued a notice to all 340B covered entities that it was updating its data requirements for its 340B distribution program. The notice states:

> All covered entity types will be required to provide claims level data (CLD) for pharmacy dispenses and medical claims for Lilly's entire portfolio of products […] Failure to provide timely, complete, and accurate data for all products dispensed at 340B ceiling prices may result in loss of access to pricing until such time as the outstanding data is provided.

As you know, Lilly first began imposing costly and burdensome claims-data submission requirements on 340B hospitals with its unprecedented contract pharmacy restrictions in 2021. As bad as those restrictions are, Lilly's new policy will vastly increase the costs and burdens on 340B hospitals. If allowed to take effect, Lilly's policy would now reach in-house hospital pharmacies and apply to drugs directly administered to patients. It also would include both pharmacy *and* medical claims.

Our members inform us that this sweeping expansion of claims data demands will inflict a range of onerous costs and burdens on them:

- *First*, the best sign of how onerous Lilly's new policy will be on covered entities is how onerous its old one has been. Setting up the data feeds that are required to comply with the contract pharmacy portion of Lilly's requirements take hospitals weeks, if not months, of work in coordination with their 340B third-party administrator (TPA). But that is only the beginning. Lilly now demands several additional categories of claims data. The labor and vendor expenses required to comply with these expanded demands will exceed anything 340B hospitals have faced to date — and the burdens imposed to date already have been unnecessarily costly. To take just one example, unlike the data used to comply with Lilly's contract-pharmacy restrictions, data for in-house dispenses are often spread across multiple recordkeeping systems. Reconciling and aligning those systems would add significant complexity and cost to covered entities.

- *Second*, 340B hospitals do not currently provide medical claims data to 340B ESP or any other vendor. Providing this data with the specific claim elements required by Lilly would be especially burdensome, if not impossible. Unlike with pharmacy claims where the data is readily available, 340B TPAs do not have the information necessary to submit medical claims to 340B ESP, as that would require direct interface with a hospital's electronic medical record. Without those data connections, which not only take time and resources to establish but also carry serious data security and privacy risks, hospitals would need to *manually* provide that information to their TPA. This, too, would require hospitals to divert significant staff time and resources to ensure compliance with Lilly's new policy.

- *Third*, Lilly's announcement states that the "340B ESP platform is the only way a covered entity can submit CLD under Lilly's policy." But hospitals that currently provide other data through 340B ESP tell us that the platform is rife with problems. Pricing is often loaded incorrectly, and claims are often wrongly denied for unknown reasons. As a result, hospitals must devote significant staff time to resolving such problems, ensuring that accurate 340B pricing is provided, and challenging false denials. Now imagine what will happen when *all* 340B covered entities are required to use this flawed 340B ESP platform. If problems already occur with a limited number of users, the bugs and blunders are certain to increase as more and more covered entities are required to use it. Those added mistakes, in turn, will increase costs for 340B covered entities because they must carefully monitor and fix inaccurate processing by 340B ESP.

At best, Lilly's new requirements will be prohibitively costly for 340B hospitals. At worst, they will be unworkable. Either way, they will prevent hospitals from obtaining the 340B discounts they are owed by statute.

By dramatically increasing the costs and burdens on 340B hospitals, Lilly's new policy is unlawful. The 340B statute requires drug companies to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such

drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). As the United States Court of Appeals for the District of Columbia Circuit has held, "some conditions may be onerous enough to effectively increase the contract 'price,' thus perhaps nudging it above the statutory ceiling." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 462 (D.C. Cir. 2024).[1] Here, Lilly's policy is far more than a "nudge." The cost of complying Lilly's expansive claims data requirements shoves the real-world price of any one of Lilly's drugs well above the statutory ceiling. It is precisely the type of "onerous condition" that the D.C. Circuit contemplated when leaving open the possibility that certain drug company requirements could violate the 340B statute's "must offer" provision. *Id*. at 464.[2]

Lilly tries to escape this conclusion by asserting that submitting this wide range of data is "standard business practice across the industry." But HRSA cannot take that assertion seriously. Even if the submission of *some* claims data qualified as a "standard business practice" — and it does not[3] — the forced submission of this massive amount and novel type of claims data is far from "standard."

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[1] A later district court decision, *Eli Lilly and Company v. Kennedy*, 2025 WL 1423630 (D.D.C. 2025), correctly described *Novartis*' narrow holding. In one part of the opinion, it described the holding as: "where conditions such as carrying costs are 'onerous enough to effectively increase the contract price, those conditions may violate the 340B ceiling price." *Id*. at *12. In another place, it described the holding as: "manufacturers must make a **'**bona fide**'** offer of sale, which may include *reasonable conditions on delivery*." *Id*. at *1 (emphasis added). And in a third place, the opinion described *Novartis*' holding as: "authorizing manufacturers to condition drug *delivery* on the provision of *certain* claims data." *Id*. at *10 (emphasis added). Thus, not only is *Novartis* properly understood to address only limited claims-data requirements, but it applies only to conditions affecting drug delivery — a subject on which the 340B statute was held to be silent. *See Novartis*, 102 F.4th at 460 ("Section 340B is thus silent about delivery conditions, which HRSA itself once acknowledged. As explained below, we think that this silence preserves — rather than abrogates — the ability of sellers to impose *at least some delivery conditions*." (emphasis added)).

[2] Given the sheer unworkability of many of Lilly's claims data demands, Lilly's policy falls into another recognized category of conditions that violate the 340B statute — those where a covered entity "could not supply the claims information demanded by" a drug company. *Id*.

[3] In describing its massive new claims data demands as seeking "standard" business information, Lilly is presumably trying to take advantage of the following statement in *Novartis*: "As for United Therapeutics' further requirement that contract pharmacies provide claims data for contract-pharmacy orders, the 1994 Guidance itself opined that drug manufacturers may require "standard information" from covered entities." 102 F.4th at 463. But *Novartis* did not fully analyze the 1994 Guidance, and the entire text of the Guidance contradicts the D.C. Circuit's superficial reading. Although that Guidance allowed manufacturers to request "standard information," Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25,113-114, the rest of HRSA's Guidance contains important clues about how to best understand that term. For example, the 1994 Guidance explicitly barred manufacturer demands for "drug acquisition" and "purchase" information — the exact kind of information Lilly demands here. *Id*. at 25,113-114. By explicitly barring demands for that information, the term "standard information" cannot include the kind of claims (or "purchase") data that

Likewise, when Lilly calls claims-data submission a "standard business practice," it is important to pay attention to the crafty move it makes. As Lilly's notice explains, any requirements to submit claims data did not become "standard," in its view, until after 2021 when Lilly and other drug companies began demanding such data in exchange for honoring contract pharmacy relationships. Their announcement states: "Since December 2021, Lilly has received claims-level data (CLD) from covered entities for dispenses made through contract pharmacies.… In the intervening years, the claims-level data submission process has become standard business practice across the industry." Thus, claims-data submission became "standard" on Lilly's telling *only because* it and other drug companies made it that way — notably, over the first Trump Administration's strong objections. A four-year history of compelled claims-data submissions does not make it "standard." HRSA must not allow Lilly to manufacture its own definition of "standard business practice" by imposing ever-expanding data demands as a condition of hospitals receiving the 340B discounts guaranteed by statute.

Lilly's asserted need for this tremendous amount of claims data further discredits its new policy. The company states that it will use this data to identify duplicate discounts and support requests for audits. Yet Lilly nowhere justifies its assertion that claims data has allowed it to undercover "countless instances of Medicaid duplicate discounts." Nor does it identify any audit requests it has made since 2021, let alone requests that were made possible by claims data submissions. If Lilly has such evidence — which we strongly doubt based on a factual analysis of the government's own program integrity data[4] — then Lilly should present that specific evidence to covered entities and HRSA. But Lilly has not done that here. Instead, Lilly has made only conclusory allegations of "countless" duplicate discounts. Consequently, Lilly's unsubstantiated assertions about program integrity do not justify its onerous claims data requirements.[5]

Lilly requires. What's more, another portion of the 1994 Guidance equates "standard information" with "routine information necessary to set up and maintain an account." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25,112. Needless to say, the vast amount of claims data required under Lilly's new policy is neither routine nor necessary to set up an account. **We urge HRSA to take this opportunity to reiterate what it has long viewed as "standard information" so that Lilly and other drug companies cannot continue to push the envelope by demanding more and more claims data from 340B hospitals and other covered entities.**

[4] American Hospital Association, *More Drug Company Oversight Needed to Maintain Compliance with 340B Program Rules*, *at* https://www.aha.org/guidesreports/2025-06-16-more-drug-company-oversight-needed-maintain-compliance-340b-program-rules.

[5] Lilly also does not explain why certain categories of data would be useful for identifying duplicate discounts. For example, there is virtually no risk of duplicate discounts in mixed-use settings that would warrant the need for medical claims data. After all, a patient being seen in a 340B hospital's emergency department is not at risk of being claimed as a patient of another covered entity.

More fundamentally, as the AHA has explained in numerous legal filings, Lilly cannot take the law into its own hands to enforce 340B program integrity. *See, e.g.*, Br. of the American Hospital Association, et al., *Novartis Pharmaceuticals Corporation, et al., v. Kennedy*, Nos. 25-5177, 25-5179, 25-5220, 25-5221, 255236 (D.C. Cir. Aug. 5, 2025), *at* https://www.aha.org/amicus-brief/2025-08-05-aha-others-defend-hhs-decision-reject-340b-rebate-models-drug-companies. The AHA need not repeat those points here. It is enough to underscore that Congress did not intend for participants in the 340B Program to engage in self-enforcement. Instead, Congress created specific audit and Administrative Dispute Resolution processes to ensure program integrity. Given this statutory scheme, HRSA must step in (yet again) to prevent a drug company from circumventing those processes with their own policies.[6]

All told, Lilly's draconian new policy is a case of "déjà vu all over again."[7] Once more, we have a drug company taking unilateral action against 340B hospitals based on flawed legal and policy reasoning, testing the limits of the law and challenging HRSA's authority over the 340B Program. Much like its 2021 contract pharmacy restrictions and its 2024 unilateral rebate policy, Lilly seeks to boost its bottom line at the expense of 340B hospitals and the vulnerable patients they serve. Lilly's policy — especially when it is inevitably adopted by other drug companies — will force hospitals to reduce or altogether eliminate services supported by the 340B Program and allocate more funds toward costly and unnecessary administrative compliance. And because Lilly's new policy applies to *all* of its drugs (many of which are used to treat cancer and other chronic conditions), patients will be at risk of losing access to life-saving medication. It is all depressingly familiar.

For these reasons, the AHA respectfully asks HRSA to take any and all available enforcement action (including imposing civil monetary penalties) to stop Lilly's unlawful and misguided policy from going into effect on February 1.[8]

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[6] *See e.g.*, Letter from Diana Espinosa Acting Administrator, Health Resources and Services Administration to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly and Company (May 17, 2021) ("The 340B statute provides a mechanism by which a manufacturer can address [program integrity] concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.").

[7] *See* Robert Knapel, *Yogi Berra: 'It's Deja Vu All Over Again' and His 25 Greatest Quotes*, BLEACHER REPORT (Apr. 7, 2011), *at* https://bleacherreport.com/articles/657044-yogi-berra-its-deja-vu-all-over-again-and-his-25-greatest-quotes.

[8] *See, e.g.*, Letter from Diana Espinosa Acting Administrator, Health Resources and Services Administration to Derek L. Asay Senior Director, Government Strategy, Eli Lilly and Company (May 17, 2021) ("Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs.… The Department of Health and Human Services will determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.").

We appreciate your attention to this important matter and ask that you please contact me directly or have a member of your team contact AHA's director of pharmaceutical policy, Bharath Krishnamurthy, at bkrishnamurthy@aha.org.

Sincerely,

/s/

Chad Golder
General Counsel & Secretary