February 4, 2026

[Submitted electronically to TEngels@hrsa.gov]
Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Administrator Engels,

On behalf of our more than 65,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies, I am writing to respectfully request a meeting with you and your staff to discuss the importance of protecting and strengthening the 340B Drug Pricing Program, including the need for HRSA to take enforcement action to address recent manufacturer policies that conflict with the 340B statute.

Specifically, we urge HRSA to take the following steps:

- **Require Manufacturers to End Claims-Level Data Reporting Requirements**: We are deeply concerned by Eli Lilly's new policy, which took effect February 1, 2026, that conditions access to 340B pricing on the submission of claims-level data from covered entities' in-house pharmacies, including data from medical claims. This is yet another example of pharmaceutical manufacturers attempting to unilaterally impose extra-statutory changes to the 340B program. Eli Lilly's policy conflicts with the plain language of the 340B statute, which requires manufacturers to offer certain outpatient drugs to covered entities at or below the statutory ceiling price and does not permit manufacturers to impose conditions on purchases of drugs dispensed directly by covered entities to their patients. We are also concerned that Lilly's policy follows a similar announcement by another manufacturer, Exelixis, signaling a broader trend that, if left unchecked, could erode the 340B program nationwide.

  We urge HRSA to take all available enforcement actions to ensure that the covered entities and the patients they serve are not harmed by the administrative and financial burdens created by these unilateral manufacturer requirements. These burdens effectively raise the cost of 340B drugs above the ceiling price, undermining the statute and diverting scarce resources away from patient care.

- **Maintain Prospective Discounts for the 340B Program**: Although we appreciate that the 340B rebate pilot program did not take effect as scheduled, we urge HRSA not to re-promulgate the proposed rule. In addition to the burden the rebate pilot would impose

covered entities, we continue to believe that manufacturers are using the implementation of the Inflation Reduction Act (IRA) negotiated drug pricing framework as an improper justification for seeking 340B rebates. As we have previously detailed to both HRSA and the Centers for Medicare & Medicaid Services (CMS), clear legal authority exists for implementing a prospective payment for IRA negotiated price drugs, negating manufacturer arguments for 340B rebates.

We urge HRSA to work with CMS to ensure continued upfront pricing in the IRA negotiated drug framework for Part B drugs, protecting the program from manufacturer efforts to erode it. We are happy to accommodate your schedule and can meet virtually or in person at your convenience. Thank you for your continued leadership and for your commitment to ensuring the 340B program operates as Congress intended.

Sincerely,

Tom Kraus, J.D.
Vice President, Government Relations