AMERICA'S ESSENTIAL HOSPITALS

March 6, 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 20857

Ref: March 2 Notice Regarding Update to Novo Nordisk's Hospital and Grantee 340B Distribution Policy

Dear Administrator Engels:

America's Essential Hospitals appreciates and supports the Health Resources and Services Administration (HRSA)'s efforts to preserve and protect the 340B Drug Pricing Program from unlawful actions by for-profit entities seeking to withhold access to statutorily required discounts. We are deeply concerned, however, by the notice Novo Nordisk published March 2 titled, "Notice Regarding Update to Novo Nordisk's Hospital and Grantee 340B Distribution Policy," which proposes to dramatically expand claims-level reporting requirements as a condition of accessing 340B pricing.[1] We previously asked HRSA to respond to a similar proposal by Eli Lilly and Company and to stop additional manufacturers from pursuing these policies. **We once again urge HRSA to act immediately to prohibit Novo Nordisk from implementing this policy, scheduled to take effect April 1, and impose all penalties authorized under the 340B statute for unlawfully withholding access to 340B discounts.**

The requirements at issue are not mere extensions of contract pharmacy requirements, but a vast new burden on all 340B hospital drug purchases and a significant new step in unilateral manufacturer actions to substitute their own rules for HRSA's. We believe Lilly and now Novo Nordisk are acting beyond the limits of the 340B statute, even under the standards of recent court decisions. **If, however, HRSA will not take enforcement action, we respectively request that the agency respond to our letter and those from other 340B providers and explain why these new policies are lawful under the 340B statute.**

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

[1] Novo Nordisk Inc. Notice Regarding Update to Novo Nordisk's Hospital and Grantee 340B Distribution Policy. March 2, 2026. https://340besp.com/resources/novo_nordisk/policy.pdf. Accessed March 5, 2026.

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and access to health care. We support our nearly 400 members with advocacy, policy development, research, education, and leadership development.

Our members provide a disproportionate share of the nation's uncompensated care, and more than three-quarters of their inpatient payer mix consists of Medicare, Medicaid, dually eligible, or uninsured patients. Essential hospitals depend on the 340B Drug Pricing Program to sustain access to care, and 97% of essential health systems participate in and rely on the program. Essential hospitals were able to provide more than $22 billion in unpaid care in 2023 because of 340B savings. This represents 29% of the nation's charity care, despite making up only 6% of hospitals nationwide.[2]

Congress created the 340B Drug Pricing Program with a clear and simple goal: "to help covered entities stretch scarce federal resources as far as possible, allowing them to reach more eligible patients and provide a wider range of services." Section 340B of the Public Health Service Act is explicit that the ceiling price established under the statute is "the maximum price that covered entities may permissibly be required to pay" and that manufacturers must offer covered outpatient drugs at or below that ceiling price whenever the drug is made available to any other purchaser.[3]

Through its March 2 notice, Novo Nordisk seeks to deny covered entities access to lawfully required 340B pricing nationwide by unilaterally imposing new conditions that are inconsistent with the statute and HRSA's long-standing guidance in the following ways:

- Illegally withholding access to discounts from lawfully obligated covered entities
- Failing to properly provide notice for a change
- Using claims-level data in conflict with existing HRSA guidance
- Creating additional administrative burden for 340B covered entities

Illegally and Harmfully Withholding Access to Discounts

Novo Nordisk's March 2 notice states that "Failure to submit complete and accurate data according to the timeline set forth in this notice may result in suspension of access to 340B pricing until the required data is submitted."[4] This approach directly conflicts with the manufacturer's obligations under the Pharmaceutical Pricing Agreement (PPA). As HRSA has noted, "a manufacturer may not condition the offer of 340B discounts upon a covered entity's assurance of compliance with section 340B Program requirements."[5]

There is no dispute that in-house pharmacies operated by 340B covered entities are entitled to access 340B pricing, and no manufacturer has challenged that entitlement. Novo Nordisk's policy goes beyond prior disputes regarding delivery locations or contract pharmacy arrangements. Instead, it seeks to cut off access to discounted pricing altogether based on a manufacturer-defined data submission regime. This represents a fundamentally different and

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[2] Miu R, Kelly K, Nelb R. *Essential Data 2025: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. November 2025. essentialdata.info. Accessed March 5, 2026.
[3] Public Health Service Act § 340B, 42 U.S.C. § 256b (2024).
[4] Novo Nordisk Inc. Notice Regarding Update to Novo Nordisk's Hospital and Grantee 340B Distribution Policy. March 2, 2026. Page 1. https://340besp.com/resources/novo_nordisk/policy.pdf. Accessed March 5, 2026.
[5] 340B Drug Pricing Program Manufacturer Resources. Health Resources and Services Administration. https://www.hrsa.gov/opa/manufacturers. Accessed March 5, 2026

more severe form of restriction—one that directly contravenes the statutory requirement that manufacturers offer covered outpatient drugs at or below the ceiling price.[6]

Even further, Novo Nordisk intends to create a heightened risk for 340B covered entities with multiple contract pharmacies. Novo Nordisk's notice states: [7]

> "Failure of a hospital CE with an in-house pharmacy to submit complete and accurate claims level data associated with any wholly owned CP according to the timeline set forth in this notice will result in suspension of the distribution of drugs purchased at the 340B price to all wholly owned CPs, and may result in suspension of access to 340B pricing by the CE's in-house pharmacy locations, until the required data is submitted.[8]

The more contract pharmacies with which a covered entity contracts, the higher the risk that at least one third party contract pharmacy will not comply with Novo Nordisk's policy. If even one contract pharmacy fails to comply, covered entities—which have little to no influence over contract pharmacy operations—could face disrupted access to the 340B price at *all* of *their* pharmacies and for all of their patients. This result would be detrimental for hospitals and patients.

This new policy not only increases burden on covered entities that have already expanded contract pharmacy relationships to benefit rural and remote patients, it also will disincentivize covered entities seeking to expand their contract pharmacy offerings moving forward. Covered entities should not be punished for expanding pharmacy access to those who need it most.

Moreover, Novo Nordisk's requirement that covered entities submit claims-level data for all dispensations far exceeds HRSA's long-standing interpretation of the statute, which limits manufacturers to requesting routine, standard information necessary to establish and maintain a 340B account. Conditioning access to pricing on expansive claims submissions is neither authorized by statute nor supported by HRSA guidance.

Even the courts that have authorized manufacturers to impose certain delivery conditions have recognized limits that Novo Nordisk's policy exceeds. For instance, the D.C. Circuit has indicated that "onerous" manufacturer conditions may violate the 340B statute on its face.[9] As detailed below, we expect Novo Nordisk's much more expansive reporting requirements to impose costly burdens on our members, "effectively increas[ing] the contract 'price'" beyond that permitted by the 340B statute.[10]

This policy is additionally troubling because Novo Nordisk would require submission of sensitive claims-level information—including medical claims data—through a manufacturer-selected platform. Before rollout of the 340B Rebate Pilot Program, the participating data vendor declined to complete security questionnaires needed to validate data protections. Essential hospitals must be able to verify that appropriate safeguards are in place before transmitting highly sensitive patient data.

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[6] 42 U.S.C. § 256b(a)(1) (2024).
[7] Novo Nordisk Inc. Notice Regarding Update to Novo Nordisk's Hospital and Grantee 340B Distribution Policy. March 2, 2026. Page 2. https://340besp.com/resources/novo_nordisk/policy.pdf. Accessed March 5, 2026.
[8] Ibid.
[9] *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 464 (D.C. Cir. 2024).
[10] Ibid.

Failing to Provide Proper Notice of a Change

Notwithstanding our contention that the proposed changes to the 340B program are contrary to statute, Novo Nordisk has provided covered entities with less than one month to comply with a sweeping new reporting regime before the policy's April 1 implementation date. This abbreviated timeline is particularly problematic given the operational complexity of claims-level reporting and the substantial systems changes required for compliance.

Good-faith engagement and reasonable notice are core principles reflected throughout HRSA's administration of the 340B program, including in the Administrative Dispute Resolution (ADR) process, which explicitly requires documentation of good-faith efforts by parties raising compliance concerns. Novo Nordisk's unilateral action—implemented without meaningful engagement, transition time, or opportunity for clarification—stands in stark contrast to these principles and effectively sets covered entities up for failure, followed by loss of access to discounted pricing.

We have heard from members of America's Essential Hospitals that developing an in-house pharmacy claims reporting process can take several weeks—making prompt claims submission impossible on April 1. **The timeline of this policy creates a de facto denial of access to 340B discounts by Novo Nordisk.**

Novo Nordisk Intends to Use Data Collected in Conflict with HRSA Guidance

In its notice, Novo Nordisk states that the expanded reporting requirements will be "used to identify ineligible duplicate discounts," and "to determine eligibility for certain replenishment orders under the policy."[11] This justification conflicts with HRSA's guidance and undermines HRSA's role in overseeing the 340B program.

HRSA's guidance does not permit manufacturers to collect broad claims-level data for the purpose of making their own compliance determinations or policing covered entities. Audit authority and program integrity oversight rest with HRSA, not with manufacturers acting unilaterally. Novo Nordisk's stated intent to use submitted data to identify alleged abuses and support audit activity effectively substitutes manufacturer judgment for HRSA oversight and mirrors prior attempts by manufacturers to impose unapproved rebate-based models on the 340B program.

New Claims Submission Adds Unauthorized Administrative Burden for 340B Covered Entities

Essential hospitals have extensive experience managing the operational complexity of claims data reporting for contract pharmacy arrangements. Novo Nordisk's proposed policy would dramatically expand those obligations by requiring submission of detailed claims data for both pharmacy and medical claims across in-house and contract pharmacy dispensing. In addition, the lack of alignment between the data requested by Novo Nordisk and Lilly magnifies the administrative costs of complying with these unauthorized requests.

[11] Novo Nordisk Inc. Notice Regarding Update to Novo Nordisk's Hospital and Grantee 340B Distribution Policy. March 2, 2026. Page 6. https://340besp.com/resources/novo_nordisk/policy.pdf. Accessed March 5, 2026.

Essential hospitals had an average operating margin of -7.1% in 2023, more than three times lower than the aggregate operating margins of all other hospitals.[12] Covered entities do not currently submit medical claims data as part of routine 340B compliance, and doing so would require costly integration with electronic medical record systems, new data governance processes, and additional vendor relationships. These requirements would impose significant new administrative and financial burdens on hospitals already operating on extremely thin margins.

Forcing covered entities to expend additional resources on unneeded 340B program compliance may amount to effective denial of 340B discounts by covered entities. Manufacturers' purchasing agreements prohibit denying access to 340B discounts and provide a mechanism for HRSA to levy civil monetary penalties in such an event. **HRSA should consider using civil monetary penalties if 340B pricing is denied to covered entities because of this policy.**

Novo Nordisk's policy clearly attempts to condition access to 340B discounts on unilateral manufacturer compliance determinations, introduces significant new reporting obligations with limited notice, and substantially increases administrative burdens beyond what courts have previously considered. Thus, **we urge HRSA to act swiftly to prohibit the policy from taking effect before April 1**. Implementation of this policy will erode the 340B program, threaten patient access to care supported by 340B savings, and undermine HRSA's statutory authority to oversee the 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

[12] Miu R, Kelly K, Nelb R. *Essential Data 2025: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. November 2025. essentialdata.info. Accessed March 5, 2026.