340B HEALTH

March 6, 2026

Via E-Mail: TEngels@hrsa.gov

Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Parklawn Building Room 13N188
Rockville, MD 20857

RE: Update to Novo Nordisk's 340B Distribution Program for In-House Pharmacies (March 2, 2026)

Dear Administrator Engels:

On behalf of 340B Health, we write to express our serious concerns regarding Novo Nordisk Inc.'s and Novo Nordisk Pharma Inc.'s (collectively, "Novo Nordisk"), new policy to bar access to 340B pricing for drugs unless the covered entity shares claims-level data from in-house pharmacies, including data from medical claims, effective April 1, 2026. (see Attachment A). Novo Nordisk's policy conflicts with the 340B statute and would impose severe administrative and financial burdens on 340B covered entities, which are essential to our nation's health care safety net. We urge HRSA to use all available enforcement options under the 340B statute to prevent Novo Nordisk from implementing this unlawful policy.

Novo Nordisk's new policy requires all covered entities to submit claims data for all 340B dispenses from in-house pharmacies, including both retail and mixed-use, as a condition of accessing the statutory 340B price. This policy violates the 340B statute, which requires manufacturers to offer covered entities covered outpatient drugs for purchase at or below the applicable ceiling price. There are no provisions in the 340B statute permitting conditions to be placed on purchases of drugs that will be dispensed directly by the covered entity to its patients. Imposing such provisions would significantly raise the costs of participating in 340B, as the data being requested covers millions of claims, requiring more staff and extensive IT work to develop, monitor, and review for inaccurate processing and use by Novo Nordisk or its vendors.

Failure to comply with this illegal requirement would bar access to 340B pricing for covered entities for Novo Nordisk's drugs. This puts covered entities in the position of trying to comply with this illegal condition under duress for the sole reason of maintaining access to 340B pricing for these drugs for their patients

Novo Nordisk's notice attempts to couch this new and burdensome policy change as "minimal, standard business information". That is simply false. Novo Nordisk is requesting data that far exceeds data previously requested by ESP. Many hospitals report that they do not have access to all of the required data for medical claims. The data largely mirrors fields that were required under HRSA's rebate program. As we previously shared with HRSA, we were informed by many 340B hospitals shortly before the Rebate Program was slated to go into effect that the hospitals would not be able to meet some of the program's data sharing requirements. Further, hospitals continue to report to us significant issues with the 340B ESP platform, including the loss of 340B pricing despite consistent and compliant submission of claims data, as well as requiring hospitals to divert limited staff resources away from direct patient care.

To date, this is the third manufacturer attempting to require claims data from inhouse pharmacies, in addition to Exelixis and Eli Lilly and Company ("Lilly"). We urge HRSA to use all enforcement options under the 340B statute to prevent Novo Nordisk, Lilly, and Exelixis from implementing these unlawful policies. The labor and expense placed on covered entities would effectively raise the cost of 340B drugs above the 340B ceiling price, in violation of the 340B statute. If HRSA does not take enforcement action, there is nothing preventing all manufacturers from adopting this policy, further elevating the cost of 340B drugs, and limiting safety-net hospitals' ability to stretch scarce resources to care for vulnerable patients.

Thank you for your attention to this matter. Please feel free to contact me at maureen.testoni@340bhealth.org if you have questions or would like to discuss.

Sincerely,

Maureen Testoni
President & CEO
340B Health

cc: Krista M. Pedley, PharmD, MS, Director, Office of Special Health Initiatives, Health Resources and Services Administration, KPedley@hrsa.gov

Chantelle Britton, Director, Office of Pharmacy Affairs, Health Resources and Services Administration, CBritton@hrsa.gov

Vicky Gormanly, Assistant General Counsel, Novo Nordisk Inc., VCGA@NOVONORDISK.COM

Notice Regarding Update to Novo Nordisk's
Hospital and Grantee 340B Distribution Policy

March 2, 2026

As of April 1, 2026, Novo Nordisk Inc. (labeler codes 00169 and 71090) and Novo Nordisk Pharma Inc. (labeler code 73070)[1] (collectively, Novo Nordisk), will revise its policy regarding distribution of 340B-priced products for **all** Covered Entity (CE) types as described below. This policy supersedes previous Novo Nordisk policies[2] and will be effective on April 1, 2026.

Since January 1, 2023, Novo Nordisk has collected claims level data from certain CEs. The data is of the type routinely compiled by CEs and their third-party administrators to identify and seek replenishment of previously dispensed products at the 340B price. This data has provided necessary transparency for 340B program integrity and is critical to Novo Nordisk's ability to remedy program noncompliance by exercising its right to initiate audits.

Claims level data also permits Novo Nordisk to accurately identify and de-duplicate discounts for product purchased at the 340B price and subsequently submitted for "maximum fair price" (MFP) refunds,[3] as required by law.[4] The Health Resources and Services Administration (HRSA) has acknowledged the importance of claims level data in the 340B/MFP deduplication process.

Given the above considerations, Novo Nordisk will require **all** CE types to submit claims level data for pharmacy and medical dispenses for **all** 340B dispenses including in-house pharmacy and contract pharmacy (CP) dispenses effective on April 1, 2026.

Novo Nordisk's collection of data from CEs will support the accurate identification of Medicaid and MFP duplicate 340B claims, provide information critical to the initiation of 340B audits, and promote 340B program integrity and transparency.

Novo Nordisk's policy complies with the 340B statute and does not deny access to 340B-priced covered outpatient drugs to any CE. **Novo Nordisk will continue to offer 340B prices to all 340B CEs, and each may purchase as much Novo Nordisk product at the 340B price that it wishes, provided that the CE submits the minimal, standard business information described in this notice.**

The following policy will apply effective April 1, 2026:

> **In-House Pharmacy Dispenses by All CE Types:** All CEs will be required to submit claims level data for all 340B dispenses by in-house pharmacies. 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.

---

[1] Novo Nordisk's policy also applies to the following NDCs: 80644-0012-01 (inner NDC 80644-0012-02) and 80644-0013-01 (inner NDC 80644-0013-02).

[2] Novo Nordisk's previous policies were communicated on December 1, 2020, February 1, 2022, December 2, 2022, June 1, 2023, and May 1, 2024.

[3] FIASP® and NOVOLOG® branded and unbranded biologic products are included on CMS's Initial Price Applicability Year (IPAY) 2026 Medicare Drug Price Negotiation Program (MDPNP) Selected Drug list and became subject to MFP on January 1, 2026. OZEMPIC®, RYBELSUS®, and WEGOVY® branded products are included on CMS's IPAY 2027 MDPNP Selected Drug list.

[4] 42 U.S.C. §1320f-2(d).

CEs that Do Not Have an In-House Pharmacy: A CE that does not have an in-house pharmacy may designate one CP to which Novo Nordisk will facilitate bill to/ship to distribution. The designated CP cannot be a central fill pharmacy. The CE will be required to submit claims level data for all 340B dispenses by its designated CP. Failure to submit complete and accurate data according to the timeline set forth in this notice may result in suspension of the distribution of drugs purchased at the 340B price to the one designated CP until the required data is submitted.

CPs for Hospital CEs: Novo Nordisk will facilitate bill to/ship to orders to an unlimited number of CPs that are wholly owned and operated by a hospital CE (irrespective of whether the CE has or does not have an in-house pharmacy) where the hospital CE provides claims level data associated with 340B dispenses by those wholly owned CPs.

- **Hospital CEs with Wholly Owned CPs and an In-House Pharmacy:**

  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.

- **Hospital CEs with Multiple CPs and No In-House Pharmacy:**

  If a hospital CE does not have an in-house pharmacy and has wholly owned CP relationships other than its one designated CP, failure to submit timely, complete and accurate claims level data associated with any CP other than the one designated CP:
  - will result in suspension of the distribution of drugs purchased at the 340B price to all CPs other than the one designated CP; and
  - may result in suspension of the distribution of drugs purchased at the 340B price to the one designated CP until the required data is submitted.

CPs for Grantee CEs: Novo Nordisk will facilitate bill to/ship to orders to an unlimited number of CPs (irrespective of whether the CE has or does not have an in-house pharmacy) where the grantee CE provides claims level data associated with 340B dispenses by those CPs.

- **Grantee CEs with CPs and an In-House Pharmacy:**

  Failure of a grantee CE with an in-house pharmacy to submit complete and accurate claims level data associated with any 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 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.

- **Grantee CEs with Multiple CPs and No In-House Pharmacy:**

  If a grantee CE does not have an in-house pharmacy and has CP relationships other than its one designated CP, failure to submit timely, complete and accurate claims level data associated with any CP other than the one designated CP:
  - will result in suspension of the distribution of drugs purchased at the 340B price to all CPs other than the one designated CP; and
  - may result in suspension of the distribution of drugs purchased at the 340B price to the one designated CP until the required data is submitted.

<u>Claims Level Data Submission Timeline</u>: Commencing on April 1, 2026, CEs must submit the required 340B claims level data for the relevant CP or CE in-house pharmacy location **within 45 days of the date of dispense**.

Novo Nordisk will continue to utilize the 340B ESP™ Second Sight Solutions platform (ESP™ platform) to collect CP designation applications and de-identified claims data.

Designation of One CP by a CE that Does Not Have an In-House Pharmacy (Hospital CEs & Grantee CEs):

A grantee or hospital CE that does not have an in-house pharmacy must designate one CP for bill to/ship to distribution and submit claims level data for 340B dispenses by the designated CP. The designated CP cannot be a central fill pharmacy.

For hospital CEs, the CP designation shall apply to the hospital CE parent and all related child sites of the hospital CE.

For a CP designation to be effective on April 1, 2026, the CE must submit its designation via the ESP™ platform by March 20, 2026.

Novo Nordisk will allow CEs that do not have an in-house pharmacy to make changes to their existing two CP designations (if applicable) based on this policy change by designating any one CP on a one-time basis. Any change requests must be submitted by March 20, 2026, to be effective on April 1, 2026. If such a CE fails to designate a single CP by March 20, 2026, the CE will be permitted to designate a single CP on a one-time basis. The single designated CP will become active within approximately ten (10) business days after the CE submits the designation via the ESP™ platform.

Below is additional information on the process for designating a single CP consistent with Novo Nordisk's policy:

- CP designations may be changed once every twelve (12) months from the date the designation was approved by Novo Nordisk. Novo Nordisk will permit changes to CP designations within the twelve-month period if a CE/CP relationship is terminated.
- Eligible CEs that have registered an account on the ESP™ platform may designate one CP by navigating to the Entity Profile tab.

Hospital CEs: Facilitation of Bill To/Ship To Orders for Wholly Owned CPs with Claims Level Data Submission

Novo Nordisk will continue to allow bill to/ship to orders for an unlimited number of CPs that are wholly owned and operated by a hospital CE where the hospital CE provides claims level data associated with 340B dispenses by those wholly owned CPs.

Consistent with Novo Nordisk's previous policy, CEs must register at https://www.340besp.com, submit the Wholly Owned CP form through the ESP™ platform, and provide 340B claims level data for wholly owned CPs within 45 days of the date of dispense. Refer to ***Hospital CEs and Grantee CEs: Submitting CP Claims Level Data*** below for additional information on claims level data submission requirements.

Grantee CEs: Facilitation of Bill To/Ship To Orders for CPs with Claims Level Data Submission

Novo Nordisk will continue to facilitate bill to/ship to orders for an unlimited number of CPs (both wholly owned and non-wholly owned) where the grantee CE provides claims level data associated with 340B dispenses by those CPs.

Consistent with Novo Nordisk's previous policy, CEs must register at https://www.340besp.com and provide 340B claims level data for CPs within 45 days of the date of dispense. Refer to ***Hospital CEs and Grantee CEs: Submitting CP Claims Level Data*** below for additional information on claims level data submission requirements.

Hospital CEs and Grantee CEs: Submitting CP Claims Level Data

Novo Nordisk will monitor the timing and completeness of the claims level data submitted via the ESP™ platform. CEs may contact Second Sight Solutions at support@340BESP.com with any questions on how to utilize the ESP™ platform for CP designations and/or claims level data submissions.

Nothing in this policy precludes Novo Nordisk from making further changes to its 340B policy and/or asserting any rights it may have.

Please direct any questions about this revised policy to 340BInfo@novonordisk.com.

FREQUENTLY ASKED QUESTIONS

In addition to reviewing the frequently asked questions below, please visit ESP™ platform FAQs to learn more about the ESP™ platform. For further help with registration, account setup, and data submission processes, you may access the repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 1-888-398-5520. Any changes to Novo Nordisk's policy will be available in the most up-to-date policy document at https://www.340besp.com/resources.

Q. What specifically is Novo Nordisk changing?

Effective April 1, 2026, Novo Nordisk is revising its policy regarding distribution of 340B products as follows:

1. CEs will be required to submit claims level data for all 340B dispenses by in-house pharmacies.
2. Only 340B CEs that do not have an in-house pharmacy will be permitted to designate a single CP that will be treated similarly to an in-house pharmacy for purposes of this policy.
3. CEs will be required to submit claims level data for all 340B dispenses by designated CPs.

Novo Nordisk will continue to facilitate bill to/ship to orders to an unlimited number of wholly owned CPs for hospital CEs that submit claims level data for 340B dispenses by such CPs via the ESP™ platform.

Novo Nordisk will continue to facilitate bill to/ship to orders to an unlimited number of CPs (wholly owned and not wholly owned) for grantee CEs that submit claims level data for 340B dispenses by such CPs via the ESP™ platform.

Q: How does Novo Nordisk define "in-house pharmacy"?

An "in-house pharmacy" is a pharmacy that is: (i) 100% owned by the CE, (ii) capable of purchasing and dispensing Novo Nordisk 340B covered outpatient drugs, (iii) licensed or authorized by the appropriate state regulatory body, and (iv) not listed on OPAIS as a contract pharmacy for the CE. Novo Nordisk will require CEs to certify annually via the ESP™ platform whether they operate an in-house pharmacy. Novo Nordisk may require submission of documentation, such as auditable records, to confirm 100% ownership by your CE.

Q: If my CE dispenses 340B product exclusively through in-house pharmacies and does not have any CP relationships, does this policy change impact my CE?

Yes. Effective April 1, 2026, all CEs are required to submit claims level data for all in-house pharmacy 340B dispenses. If not currently submitting data, CEs can navigate to www.340BESP.com or call Second Sight Solutions at 888-398-5520 to register for the ESP™ platform.

Q: How does a CE that does not have an in-house pharmacy make its one CP designation?

CEs that do not have an in-house pharmacy must register on the ESP™ platform and designate their one CP at https://www.340besp.com/designations by selecting "Yes" under the contract pharmacy section for Novo Nordisk. The designated CP cannot be a central fill pharmacy.

For a CP designation to be effective on April 1, 2026, the CE must submit its designation via the ESP™ platform by March 20, 2026.

Novo Nordisk will allow CEs that do not have an in-house pharmacy to make changes to their existing two CP designations (if applicable) based on this policy change by designating any one CP on a one-time basis. Any change requests must be submitted by March 20, 2026, to be effective on April 1, 2026. If such a CE fails to designate a single CP by March 20, 2026, the CE will be permitted to designate a single CP on a one-time basis. The single designated CP will become active within approximately ten (10) business days after the CE submits the designation via the ESP™ platform.

The CE will be required to submit claims level data for all 340B dispenses by the one designated CP according to the timeline set forth in this notice.

Q: How often can a CE that does not have an in-house pharmacy change its one CP designation?
A CP designation can be changed once every twelve (12) months from the date the designation was approved by Novo Nordisk. Novo Nordisk will permit changes to a CP designation within the twelve-month period if a CE/CP relationship is terminated.

Q: How will Novo Nordisk use the 340B claims level data that CEs provide through the ESP™ platform?
Claims level data uploaded by 340B CEs will be used to identify ineligible duplicate discounts, e.g., Medicaid rebates, Medicare Part D rebates, MFP, etc., and to determine eligibility for certain replenishment orders under the policy.

Q: Are all Novo Nordisk products subject to its CP policy?
This policy applies to all Novo Nordisk products, except for certain Novo Nordisk products that have a defined distribution network. Refer to the ESP™ platform at ESP™ platform Product List for a list of Novo Nordisk products subject to this policy.

Q: What is changing regarding CP arrangements under Novo Nordisk's revised Policy?
Under Novo Nordisk's revised 340B distribution policy, all CEs are still able to purchase our products at the discounted 340B price for the benefit of their patients.

Novo Nordisk's current policy facilitates bill to/ship to distribution of 340B product under a CP arrangement for two CP designations without submission of claims level data for 340B dispenses by those CPs.

Commencing April 1, 2026, however, Novo Nordisk will only facilitate bill to/ship to orders for CPs if the CE submits claims level data associated with all 340B dispenses by each CP. Novo Nordisk will no longer facilitate bill to/ship to orders without submission of claims level data for any CP, including CPs that were designated under Novo Nordisk's current policy.

Q: What is changing regarding CE in-house pharmacies under Novo Nordisk's revised policy?
Under Novo Nordisk's revised 340B distribution policy, all CEs are still able to purchase our products at the discounted 340B price for the benefit of their patients.

There is no requirement in Novo Nordisk's current policy that CEs submit claims level data for 340B dispenses by in-house pharmacies.

Commencing April 1, 2026, however, CEs with one or more in-house pharmacies will be required to submit claims level data via the ESP™ platform for all 340B dispenses by each of its in-house pharmacies.

Q: How often will I need to upload 340B claims data to the ESP™ platform?
The ESP™ platform supports an unlimited number of 340B claims uploads, and CEs are encouraged to submit 340B claims uploads on the 1st and 16th of each month. CEs must submit 340B claims level data within 45 days of the date of 340B dispense.

Q: Is my CE required to submit pharmacy and medical 340B claims level data under Novo Nordisk's updated policy?
Yes. CEs must submit all 340B claims level data under Novo Nordisk's updated 340B Distribution Policy, inclusive of pharmacy and medical claims. A list of required data elements can be viewed at the following links: Pharmacy Claims Data Table; Medical Claims Data Table.

Q: What happens if a CE with an in-house pharmacy fails to submit data associated with an in-house pharmacy 340B dispense within 45 days of the date of dispense?
Failure to submit timely, complete and accurate data associated with 340B dispenses at any CE in-house pharmacy may result in suspension of access to 340B pricing until the required data is submitted.

Q: Will CEs be able to register and begin submitting claims level data prior to April 1, 2026?
The ESP™ platform will be configured to support 340B claims level data submissions for in-house pharmacies and CPs beginning April 1, 2026. Prior to April 1, 2026, CEs may register on the ESP™ platform and familiarize themselves with the claims level data submission and CP designation processes. The registration process takes just a few minutes, and there is a dedicated support team available to assist.

Q: What training and resources will be provided to CEs to help with this transition?
Detailed information and tutorials on how to use the ESP™ platform can be found at ESP™ platform FAQs. In addition, CEs can email support@340BESP.com or 340BInfo@novonordisk.com with any questions.