



## Notice Regarding Revised Limitation on Hospital and Grantee 340B Contract Pharmacy Distribution

May 1, 2024

Beginning July 1, 2024, Novo Nordisk Inc. (labeler codes 00169 and 71090), and Novo Nordisk Pharma Inc. (labeler code 73070)<sup>1</sup>, herein referred to as Novo Nordisk, will revise its policy regarding bill to/ship to distribution of 340B product under a contract pharmacy (CP) arrangement for **all** Covered Entity (CE) types as described below. This policy supersedes previous Novo Nordisk policies.<sup>2</sup>

Novo Nordisk's policy 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.** The changes announced in this notice solely impact Novo Nordisk-facilitated shipment of its products to CPs (which are not themselves CEs and have no statutory right to receive the products). Novo Nordisk's policy limits when it will accept requests to provide services that go beyond the federal statutory requirements and facilitate CE requests that drugs be transferred to third party locations. Nothing in this policy precludes Novo Nordisk from making further changes to its 340B policy and/or asserting any rights it may have.

As of July 1, 2024, Novo Nordisk's criteria for CP bill to/ship to arrangements will be as follows:

- **Hospital CEs and Grantee CEs:** Novo Nordisk will allow a maximum of two CP designations for *hospital and grantee CEs*.
- **Hospital CEs:** Novo Nordisk will continue to facilitate bill to/ship to orders to 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 made by those wholly owned CPs.
- **Grantee CEs:** Novo Nordisk will facilitate bill to/ship to orders to an unlimited number of CPs where the grantee CE provides claims level data associated with 340B dispenses made by those CPs.

These conditions will apply whether a hospital or grantee CE has an in-house pharmacy or does not.

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 sufficient to allow Novo Nordisk to identify potential ineligible discounts, thereby enhancing program integrity.

### **Designating Any Two CPs (Hospital CEs & Grantee CEs):**

All CEs may designate any two CPs consistent with Novo Nordisk's policy on the ESP™ platform. All applications will be reviewed by Novo Nordisk prior to approval. Contract pharmacy designations shall apply to the CE parent and all related child sites of the CE.

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<sup>1</sup> 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).

<sup>2</sup> Novo Nordisk's previous policies were communicated on December 1, 2020, February 1, 2022, December 2, 2022, and June 1, 2023.

Novo Nordisk will allow hospital CEs to make changes to CP designations based on this policy change, and designate any two CPs (whether retail or specialty) on a one-time basis. Any change requests must be submitted by June 1, 2024. No action is required for hospital CEs that have already registered up to two CPs, and that do not wish to make changes to their CP designations.

For a grantee CP designation to be effective on July 1, 2024, a grantee CE designation must be submitted to the ESP™ platform by June 23, 2024.

Below is additional information on the process for designating any two CPs 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.
- CEs that have registered an account on the ESP platform may designate two CPs by navigating to the Entity Profile tab.
- CEs that wish to register a new account on the ESP platform can create a new account at <https://www.340besp.com/> and may designate two CPs by navigating to the Entity Profile tab.
- CEs that elect not to register an account on the ESP platform can make their two CP designations by visiting <https://www.340besp.com/designations>.

#### **Hospital CEs: Additional CP Designations for Wholly Owned CPs:**

Novo Nordisk's policy for CP bill to/ship to arrangements for hospital CEs designating wholly owned CPs beyond the two permitted CP designations remains unchanged. Novo Nordisk will allow bill to/ship to orders to 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 made by those wholly owned CPs.

Consistent with Novo Nordisk's previous policy, additional hospital wholly owned CP designations approved beyond the permitted two CP designations must register at <https://www.340besp.com> and provide 340B claims level data for those wholly owned CP designations within 30 days from the date of the initial 340B purchase on or after July 1, 2024, and within 45 days of the date of dispense for a CP to remain eligible to receive shipments of 340B-priced covered outpatient drugs. Refer to *Submitting CP Claims Level Data* for additional information on claim level data submission requirements.

#### **Grantee CEs: Additional CP Designations with Claims Submission:**

Novo Nordisk will also facilitate bill to/ship to orders to an unlimited number of CPs (both wholly owned, and non-wholly owned) beyond the two permitted CP designations for grantee CEs where the grantee CE provides claims level data associated with 340B dispenses made by those CPs. Grantee CEs seeking additional CP designations beyond the permitted two CP designations must provide timely CP claims level data for additional CP designations via the ESP platform.

Additional CP designations for grantee CEs beyond the permitted two CP designations must register at <https://www.340besp.com> and provide 340B claims level data within 30 days of the initial purchase on or after July 1, 2024, and within 45 days of the date of dispense for a CP to remain eligible to receive shipments of 340B-priced covered outpatient drugs. Dispenses occurring more than 45 days prior to July 1, 2024, will not be considered for any CE/CP arrangement. Refer to *Submitting CP Claims Level Data* for additional information on claim 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 data submitted via the ESP platform. If it is determined that claims data is not being timely submitted for any CP relationship, Novo Nordisk may terminate the bill to/ship to relationship for that CP. CEs may contact Second Sight Solutions at [support@340BESP.com](mailto:support@340BESP.com) with any questions on how to utilize the ESP platform for CP designations and/or claims level data submissions.

Please direct any questions about this revised policy to [340BInfo@novonordisk.com](mailto:340BInfo@novonordisk.com).

## FREQUENTLY ASKED QUESTIONS

In addition to reviewing the frequently asked questions below, please visit [www.340BESP.com/FAQs](http://www.340BESP.com/FAQs) to learn more about the ESP platform. For further help with the registration, account setup, and data submission processes, you may access a repository of webinars at [www.340BESP.com/resources/webinars](http://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: How do I make my two CP designations?**

CEs that wish to designate CPs consistent with Novo Nordisk's policy that have a registered account, or wish to register an account on the ESP platform, may do so at <https://www.340besp.com/designations> by selecting "Yes" under the contract pharmacy section. CEs that elect *not* to register an account on the ESP platform can make their designations by visiting [www.340besp.com/designations](http://www.340besp.com/designations).

### **Q: How often can my two CP designations change?**

CP designations can 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.

### **Q: How will Novo Nordisk use the 340B claims data that CEs provide through the ESP platform for approved additional CP designations?**

CP claims data uploaded by 340B CEs will be used for internal purposes only, such as to identify ineligible discounts, e.g., Medicaid rebates, Medicare Part D rebates, 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 Novo Nordisk products that have a defined distribution network. Refer to the ESP platform at [www.340BESP.com](http://www.340BESP.com) for a list of Novo Nordisk products subject to this policy.

### **Q: What is changing for hospital CEs?**

Under Novo Nordisk's revised 340B policy, all CEs—including hospital CEs—will continue to have the ability 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 to one retail and/or one specialty CP for hospital CEs, as determined by Novo Nordisk. Effective July 1, 2024, Novo Nordisk will facilitate bill to/ship to distribution of 340B product under a CP arrangement for a maximum of any two CP designations (e.g., two retail CPs, two specialty CPs, one retail CP and one specialty CP).

Novo Nordisk will continue to facilitate delivery to an unlimited number of wholly owned CPs where the hospital CE provides claims level data via 340B ESP associated with 340B dispenses made by those wholly owned CPs.

**Q: Are CP designations for hospital CEs approved by Novo Nordisk prior to July 1, 2024, subject to changes?**

Hospital CEs with Novo Nordisk approved CP exceptions for one retail and/or one specialty CP prior to July 1, 2024, will not see a change in the eligibility of their existing CP relationships unless a hospital CE wishes to change its CP designations based on Novo Nordisk's revised policy effective July 1, 2024. Hospital CEs that wish to make changes to their two CP designations must do so by June 1, 2024.

Hospital CEs with Novo Nordisk approved wholly owned CP exceptions prior to July 1, 2024, will need to continue to submit claims data for additional wholly owned CP elections being requested to maintain eligibility.

**Q: What is changing for grantee CEs?**

Under Novo Nordisk's revised 340B policy, all CEs—including grantee CEs—will continue to have the ability to purchase our products at the discounted 340B price for the benefit of their patients.

Novo Nordisk will facilitate bill to/ship to distribution of 340B product under a grantee CE-CP arrangement for a maximum of two CP designations (e.g., two retail CPs, two specialty CPs, one retail CP and one specialty CP) without the requirement to submit claims data.

Additional CP designations beyond the two designated CPs will now require claims data for grantee CEs. Novo Nordisk will allow an unlimited number of designated CPs where the grantee CE provides claims level data via 340B ESP associated with 340B dispenses made by those CPs.

**Q: Is Novo Nordisk requiring data for CE in-house pharmacies?**

No. CEs do not need to provide 340B claims data for utilization/dispenses at their own 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 1<sup>st</sup> and 16<sup>th</sup> of each month. Email reminders are automatically generated from 340B ESP™ and CEs can monitor claims submission status when logged in to the platform. Covered entities must submit 340B claims data 30 days after the first purchase that occurs on or after the effective date of this policy; thereafter within 45 days of the date of 340B dispense.

**Q: Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing for additional CP designations?**

340B claims level data must begin to be submitted within 30 days after the first purchase that occurs on or after the effective date of this policy; thereafter within 45 days of the date of 340B dispense.

**Q: If a grantee CE does not provide 340B claims data for additional CP designations by the required date, can it elect to do so later and gain access to 340B pricing for additional CPs?**

Yes. A grantee CE may elect to submit 340B claims data for additional CP designations at a later date, but must do so within 30 days of the first 340B purchase, and thereafter within 45 days of the date of 340B dispense. Otherwise, Novo Nordisk may suspend the facilitation of bill to/ship to CP replenishment orders until sufficient claims level data is submitted as required.

**Q: What happens if a CE who has already registered an additional CP on the platform misses a data submission date?**

If you miss a data submission date, please submit your data as soon as possible. If a CE does not provide required data in a timely manner, Novo Nordisk may no longer facilitate bill to/ship to CP replenishment orders on 340B claims for the CP locations for which data is not submitted. CEs can email [support@340BESP.com](mailto:support@340BESP.com) with any questions.

**Q: Will grantee CEs be able to register and begin submitting claims level data prior to July 1, 2024?**

The ESP platform will be configured to support 340B claims submissions and additional grantee CP designations for Novo Nordisk beginning July 1, 2024. Prior to July 1, 2024, grantee CEs may register on the ESP platform and familiarize themselves with the claims 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 [www.340besp.com/FAQs](http://www.340besp.com/FAQs). In addition, CEs can email [support@340BESP.com](mailto:support@340BESP.com) or [340BInfo@novonordisk.com](mailto:340BInfo@novonordisk.com) with any questions.