



Notice Regarding Revised Limitation on Hospital Contract Pharmacy Distribution

June 1, 2023

Beginning July 1, 2023, Novo Nordisk Inc. (labeler codes 00169 and 71090), and Novo Nordisk Pharma Inc. (labeler code 73070)¹, 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 any of the six “hospital” Covered Entity (CE) types as described below. This policy supersedes previous Novo Nordisk policies communicated on December 1, 2020, February 1, 2022, and December 2, 2022.

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) that will be revised as of July 1, 2023. 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, 2023, Novo Nordisk’s criteria for CP bill to/ship to arrangements at hospital CEs will be as follows:

- Novo Nordisk will allow a maximum of two CP designations (one retail and/or one specialty, as determined by Novo Nordisk) for all hospital CEs.
- 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.
- These conditions will apply whether the hospital 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. Hospital CEs seeking to designate two CPs (i.e., one retail and/or one specialty) shall utilize the ESP platform to submit CP designation applications. Hospital CEs shall utilize the ESP platform to provide claims level data associated with 340B purchases for distribution to additional wholly owned CPs beyond the one retail and/or one specialty CPs referenced above. Hospital 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.

None of the “grantee” CE types are impacted by this change in policy. Novo Nordisk will continue at its discretion to facilitate CP bill to/ship to arrangements at “grantee” CEs.

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).

HOSPITAL CEs

Consistent with the classification regime set out in Health Resources and Services Administration's ("HRSA") Office of Pharmacy Affairs ("OPA") 340B Office of Public Affairs and Information Services ("OPAIS") database, Novo Nordisk considers the following CE types as hospital CEs:

Entity Type Description	Entity Type
Children's Hospital	PED
Disproportionate Share Hospital	DSH
Critical Access Hospital	CAH
Free Standing Cancer Hospital	CAN
Rural Referral Center	RRC
Sole Community Hospital	SCH

Hospital CEs that wish to designate CPs consistent with Novo Nordisk's policy that have registered an account on the ESP platform may designate CPs by navigating to the Entity Profile tab by June 17, 2023 for CP designations to be effective on July 1, 2023. Hospital CEs that elect not to register an account on the ESP platform can make their designations by visiting www.340bosp.com/designations. 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. No action is required for hospital CEs that have already registered up to two CPs.

Hospital CEs seeking additional CP designations for wholly owned CPs beyond the permitted designations (i.e., one retail and one specialty pharmacy) must submit CP designation requests and provide timely CP claims level data for wholly owned CPs via the ESP platform. Hospital CEs electing this option must register at <https://www.340bosp.com/>. All wholly owned CP exceptions currently approved by Novo Nordisk on the 340B ESP platform will continue to be eligible for bill-to/ship-to arrangements contingent upon submission of 340B claims level data. 340B claims level data must be submitted within 30 days from the purchase date and within 45 days of the date of dispense for a wholly owned CP to remain eligible to receive shipments of 340B-priced covered outpatient drugs. 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 will terminate the bill to/ship to relationship for that CP.

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

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FREQUENTLY ASKED QUESTIONS

In addition to reviewing the frequently asked questions below, please visit 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 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 www.340BESP.com.

Q: How will Novo Nordisk use the 340B claims data that CEs provide through the ESP platform for wholly owned CPs?

CP claims uploaded by 340B CEs will be used to identify and resolve ineligible Medicaid, Medicare Part D, and commercial rebates and to determine eligibility for certain replenishment orders under the policy.

Q: Are all Novo Nordisk products subject to its CP policy?

Yes.

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.

However, Novo Nordisk will only facilitate bill to/ship to distribution of 340B product under a CP arrangement for a maximum of two CP designations (one retail and/or one specialty, as determined by Novo Nordisk). Additional wholly owned CPs beyond the two designated CPs will now require claims data.

Importantly, Novo Nordisk will allow 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 designations approved by Novo Nordisk prior to July 1, 2023 subject to changes?

CEs with a Novo Nordisk approved exception for one retail and/or one specialty CP prior to the revised policy effective on July 1, 2023, will not see a change in the eligibility of their existing CP relationships.

CEs with a Novo Nordisk approved wholly owned CP exception prior to the revised policy effective date of July 1, 2023 will now need to submit claims data for additional wholly owned CP elections being requested to maintain eligibility. Wholly owned CPs that are designated as the CE's one retail and/or

specialty CP within 30 days from the purchase date are not required to submit claims data.

Q: Are designations approved by Novo Nordisk prior to July 1, 2023 for wholly owned CPs subject to claims reporting?

Yes. Novo Nordisk requires claims data submission for all wholly owned CPs that are in addition to any wholly owned CPs that are designated as a CE's one retail and/or specialty.

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 sites.

Q: How often will I need to upload 340B wholly owned CP claims data to the ESP platform?

The ESP platform supports an unlimited number of 340B claims uploads, and hospital CEs are encouraged to submit 340B claims uploads on the 1st and 16th 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 within 45 days of the date of dispense.

Q: Will I be able to register and begin submitting data prior to July 1, 2023?

The ESP platform will be configured to support 340B claims submissions and CP designations for Novo Nordisk beginning June 1, 2023.

Q: What training and resources will be provided to CEs to help with this transition?

The claims data submission process is not difficult. Detailed information and tutorials on how to use the ESP platform can be found at www.340BESP.com/FAQS. Hospital CEs can email support@340BESP.com with any questions.

Q: If my CE has chosen not to submit claims data for a wholly owned CP and is eligible to designate two CP relationships, how does our hospital CE make its designations?

Hospital CEs that wish to designate CPs consistent with Novo Nordisk's policy that have a registered account on the ESP platform may designate CPs at <https://www.340besp.com/designations> by selecting "Yes" under the single retail contract pharmacy and/or single specialty contract pharmacy sections. Hospital

CEs that elect not to register an account on the ESP platform can make their designations by visiting www.340bsp.com/designations.