



Notice Regarding Revised Limitation on Hospital Contract Pharmacy Distribution

December 2, 2022

Beginning January 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.

On January 1, 2023, Novo Nordisk’s criteria for CP bill to/ship to arrangements at hospital CEs will be as follows:

- If a hospital CE does not have a wholly owned CP, Novo Nordisk will allow a maximum of two CP designations (one retail and/or one specialty, as determined by Novo Nordisk).
- If a hospital owns and operates a wholly owned CP, Novo Nordisk will allow the hospital CE to designate multiple wholly owned CP relationships.
- Novo Nordisk will also allow an unlimited number of CPs where the hospital CE provides claims level data associated with 340B dispenses made by those CPs.

Novo Nordisk will 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. Beginning January 1, 2023, hospital CEs seeking to purchase Novo Nordisk 340B drugs shall utilize the ESP platform to designate a CP relationship and provide claims level data associated with 340B purchases. Hospital CEs should 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 in its discretion to facilitate CP bill to/ship to arrangements for these CEs. All approved and active grantees may continue to place orders for Novo Nordisk product and have such product shipped to their registered CPs, without limitation.

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

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).

Rural Referral Center	RRC
Sole Community Hospital	SCH

If a hospital CE does not have a wholly owned CP, the hospital CE may request to designate two CPs (one retail and/or one specialty, as determined by Novo Nordisk). If a hospital CE operates a wholly owned CP, the hospital CE may designate multiple wholly owned CPs. Approved locations will be permitted to accept bill to/ship to orders from the parent hospital CE and its child sites. Hospital CEs that have registered an account on the ESP platform can designate a CP by navigating to the Entity Profile tab. Hospital CEs that elect not to register an account on the ESP platform can make their designations by visiting www.340besp.com/designations. All exception applications will be reviewed by Novo Nordisk prior to approval.

Hospital CEs seeking additional CP designations beyond the permitted designations (i.e., one retail and one specialty pharmacy for hospital CEs without wholly owned CPs; and wholly owned CPs for the CEs that have them) must submit CP claims level data via the ESP platform. If a hospital CE elects to submit CP claims level data via the ESP platform, the hospital CE may gain access to Novo Nordisk products for all CP relationships for which claims data is submitted via the ESP platform. Hospital CEs electing this option must register at <https://www.340besp.com/>.

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 submitted for any CP relationship, Novo Nordisk will terminate the bill to/ship to relationship for the CP not included within the claims data submission.

Novo Nordisk's policy does not deny access to 340B-priced covered outpatient drugs to any CE. Novo Nordisk shall 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 January 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.

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

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FREQUENTLY ASKED QUESTIONS

In addition to 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 process, you may access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. Any changes to Novo Nordisk's policy will be available in the most up-to-date policy document on www.340BESP.com.

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

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. The policy will be applied across the Novo Nordisk product portfolio.

Q: Are designations approved by Novo Nordisk prior to January 1, 2023 subject to claims reporting?

CEs with a Novo Nordisk approved exception prior to the revised policy effective on January 1, 2023 will not see a change in the eligibility of their existing CP relationships. However, if any CE requests to add new designations to those approved prior to January 1, 2023, the CE will be required to submit claims data for the additional CP elections being requested.

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

No. Novo Nordisk requires the six 340B hospital CE types to provide 340B claims data on units dispensed by CPs. 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 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.

Q: If my organization does not provide 340B claims data by the required date, can it elect to do so later and gain access to 340B pricing for CPs?

Yes. A hospital CE may elect to submit 340B claims data at a later date. However, Novo Nordisk's policy requires that hospital CEs submit 340B claims data within 45 days of the date of dispense. Hospital CEs will not be eligible to make 340B purchases for prescriptions dispensed outside of the 45-day period. Once the required data submission has been made, Novo Nordisk will facilitate bill

to/ship to CP replenishment orders on product dispensed to eligible patients from and after the date of data submission as well as the prior 45-day period.

Q: What happens if a CE who is already registered on the platform misses a data submission date?

If you miss a data submission date, please submit your data as soon as you are able. If a CE is unable to 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.

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

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

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 or hospital CEs can email support@340BESP.com with any questions.

Q: My CE wholly owns an outpatient pharmacy that is registered with HRSA as a CP. Must my CE submit claims for the wholly owned CP?

No. If a CE wholly owns or has common ownership with an outpatient pharmacy that is registered as a CP for the CE, the CE need not submit claims level data for the wholly owned CP, provided it has submitted and received approval to designate the wholly owned CP as an exception.

Q: If my CE has wholly owned CPs, may it request to designate additional CPs that are not wholly owned?

Yes, but only if the CE provides claims level data associated with 340B dispenses made by the non-wholly owned CPs.

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

If a CE chooses not to submit CP level claims data, the CE may designate a total of two CP relationships (one retail and/or one specialty, as determined by Novo Nordisk). Hospital CEs that have registered an account on the ESP platform can designate a CP by navigating to the Entity Profile tab. Hospital CEs that elect not to register an account on the ESP platform can make their designations by visiting www.340besp.com/designations. The ESP platform will be the only way a CE can designate CPs under Novo Nordisk's policy effective January 1, 2023.