



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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