



January 19, 2024

Notice to Arkansas Hospital Covered Entities Regarding Revisions to the Novo Nordisk Limitation on Hospital Contract Pharmacies (See Page 8)



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

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).

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.

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.340besp.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.340besp.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?

This policy applies to all Novo Nordisk products, with the exception of Rivfloza®, which has its own designated distribution network.

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.340besp.com/designations.



Notice of Revised Limited Contract Pharmacy Distribution Policy for Arkansas Covered Entities

January 19, 2024

Dear Valued Partner:

By this letter, Novo Nordisk Inc. and Novo Nordisk Pharma Inc. respectfully inform all 340B hospital covered entities operating within the state of Arkansas of certain Novo Nordisk contract pharmacy distribution policy revisions specific to 340B eligible hospital covered entities located within the state of Arkansas. This notification applies to 340B eligible hospital covered entities (CEs) and contract pharmacies (CPs) within Arkansas **only**, and is governed by the executed agreement in place between Novo Nordisk and the Arkansas Insurance Department (AID).

Effective **February 1, 2024**, Novo Nordisk will implement the following criteria for CP bill to/ship to arrangements for hospital CEs physically operating within the state of Arkansas:

- Consistent with Novo Nordisk's nationwide policy, Novo Nordisk will allow up to two CP designations (**one retail and/or one specialty**) for all hospital CEs for which claims level data will not have to be provided by the CE.
- Novo Nordisk will also facilitate bill to/ship to orders to an unlimited number of CPs (**both wholly owned, & non-wholly owned CPs**) located within the state of Arkansas where the hospital CE provides claims level data associated with 340B dispenses made by those CPs.
- No CE that is contracting with an "outside" CP (i.e., non-wholly owned) under an "inventory replenishment model" will be entitled to demand the delivery of drugs purchased at the 340B price to such a CP in replenishment for drugs dispensed to a person who is not an **active patient of the covered entity**. **An active patient of a covered entity must have received his or her prescription, which must have been generated from an outpatient visit with a provider at the covered entity, within six months of the dispense date to be eligible for replenishment.** CEs must maintain auditable medical

records and provide claims level data, as may be requested by Novo Nordisk, sufficient to demonstrate compliance with this requirement. CEs may be audited by Novo Nordisk once every six months for compliance with this requirement. If it is determined by Novo Nordisk that a CE is diverting to non-active patients of the covered entity, Novo Nordisk may reinstitute its 340B restrictions upon providing twenty days' notice to both AID and the covered entity. In addition, AID may report such diversions or illegal transfers to the Health Resources and Services Administration ("HRSA").

- In all states except Arkansas, Novo Nordisk will continue to apply its policy as announced to all other covered entities on June 1, 2023, with an effective date of July 1, 2023. Please refer to our letter dated June 1, 2023, or to our Frequently Asked Questions document, for information regarding that policy.
- These conditions will apply regardless of whether the hospital CE has an in-house pharmacy or does not.
- This policy will not apply to "grantee" CEs.

Novo Nordisk will utilize the 340B ESP™ Second Sight Solutions platform (ESP platform) to collect (i) wholly owned and non-wholly owned CP designation applications and (ii) 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**) where data is not required, must utilize the ESP platform to submit CP designation applications. Hospital CEs must utilize the ESP platform to provide claims level data associated with 340B purchases for distribution to 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 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 the request of "grantee" CEs.

Hospital CEs that wish to designate CPs and provide claims level data consistent with Novo Nordisk's policy may do so by navigating to and registering on the ESP platform

(www.340besp.com). All applications will be reviewed by Novo Nordisk prior to approval. Contract pharmacy designations will apply to the CE parent and all related child sites of the CE (that is, if a CP is approved for a parent, it will be available to all child sites of that parent). No action is required for hospital CEs that have already registered up to two CPs that are physically located within the state of Arkansas.

Hospital CEs seeking additional (in-state) CP designations beyond the two 'non-data' designations permitted (**i.e., one retail and/or one specialty pharmacy**) must provide timely CP claims level data via the ESP platform. Hospital CEs electing this option must register at <https://www.340besp.com>. All CP exceptions meeting the policy parameters outlined above and 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. For continued approval for such existing CP exceptions, 340B claims level data must be submitted within 30 days of the effective date of this Arkansas specific policy.

Arkansas hospital CEs with unlimited in-state 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 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 February 1, 2024, will not be considered for any CE/CP arrangement. 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, & support@340besp.com.

FREQUENTLY ASKED QUESTIONS -- January 2024 Arkansas Supplement

1. What is changing with respect to Novo Nordisk's 340B contract pharmacy (CP) distribution policy beginning February 1, 2024?

A. The changes noted are to Novo Nordisk's current CP distribution policy (effective as of July 1, 2023), and only apply to hospital CEs within the state of Arkansas and their OPAIS-registered CPs within the state of Arkansas:

A. Effective February 1, 2024, Novo Nordisk will apply the following policy:

- Consistent with Novo Nordisk's nationwide policy, Novo Nordisk will allow up to two CP designations (one retail and/or one specialty) for all hospital CEs for which claims level data will not have to be provided by the CE.
- Novo Nordisk will also facilitate bill to/ship to orders to an unlimited number of CPs (both wholly owned, & non-wholly owned CPs) located within the state of Arkansas where the Arkansas-based hospital CE provides claims level data associated with 340B dispenses made by those CPs.
- Grantee CEs are still permitted unlimited use of CPs both within Arkansas and nationwide.

2. Who should I contact if I have questions about the updates to Novo Nordisk's policy in Arkansas that goes into effect on February 1, 2024?

A. Please contact Novo Nordisk (340BInfo@novonordisk.com) and/or Second Sight Solutions (support@340BESP.com), if you have questions.

3. Does Novo Nordisk's updated policy apply to contract pharmacies that are wholly owned by an Arkansas-based hospital CE or are under common ownership of an Arkansas-based hospital CE?

A. Yes, Novo Nordisk's 340B CP distribution policy for the State of Arkansas will apply to all CP arrangements (both wholly owned and non-wholly owned).

4. Is Novo Nordisk requiring the submission of claims level data for claims originating from Arkansas-based contract pharmacies?

A. Yes, for hospital CEs in the state of Arkansas wishing to designate additional in-state CP relationships beyond the two permitted under Novo Nordisk's national policy, claims level data will be required to establish and maintain approval for each designated CP relationship.

- Novo Nordisk will utilize the 340B ESP™ Second Sight Solutions platform (ESP platform) to collect (i) wholly owned and non-wholly owned CP designation applications, and (ii) de-identified claims data sufficient to allow Novo Nordisk to identify ineligible discounts, thereby enhancing program integrity. Hospital CEs seeking to designate two CPs (i.e., one retail and/or one specialty) where data is not required, and more CPs for which data is required, must utilize the ESP platform to submit CP designation applications. Hospital CEs must also utilize the ESP platform to provide claims level data associated with 340B purchases for distribution to CPs beyond the one retail and/or one specialty CPs referenced above.
- 340B claims level data must be submitted within 30 days of the effective date of this Arkansas specific policy; thereafter 340B claims level data must be submitted 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 February 1, 2024, will not be considered for any CE/CP arrangement. 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.

5. Why has Novo Nordisk changed its policy applicable for Arkansas but not for other states?

- A. Consistent with its discretion under the 340B statute, Novo Nordisk has decided to permit expanded access to CP distribution within Arkansas, subject to the terms and conditions of the agreement reached with the Arkansas Insurance Department (AID). The AID agreement is only binding until the Court of Appeals for the 8th Circuit publishes a decision regarding the constitutionality of the Arkansas contract pharmacy statute.

6. Does Novo Nordisk’s CP distribution policy apply to all of Novo Nordisk’s products?

- A. This policy applies to all Novo Nordisk products, with the exception of Rivfloza®, which has its own defined distribution network.

7. How can an Arkansas hospital 340B covered entity change a contract pharmacy designation?

- A. Changes to a contract pharmacy designation can be made by visiting www.340Besp.com.

8. Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing?

- A. Yes, dispenses occurring more than 45 days prior to February 1, 2024, will not be considered for any CE/CP arrangement. 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.

9. What is an “active patient” of an Arkansas-based hospital CE, and what does that definition have to do with my right to seek replenishment?

- A. An active patient of a CE must have received his or her prescription, which must have been generated from an outpatient visit with a provider at the CE, within six months of the dispense date to be eligible for replenishment. Hospital CEs must maintain auditable records and provide sufficient claims level data, as requested by Novo Nordisk, sufficient to demonstrate compliance with this requirement. Hospital CEs may be audited by Novo Nordisk once every six months for compliance with this requirement.

Only CP dispenses to active patients of an Arkansas-based hospital CE are subject to replenishment. If a hospital CE seeks replenishment for a unit of Novo Nordisk product dispensed to an individual who is not an active patient, Novo Nordisk and the AID will consider that to be a violation of the 340B diversion prohibition. Such diversion can result in referral to HRSA and/or cancellation of the hospital CE's right to unlimited Arkansas CPs.