

Notice Regarding Implementation of 340B Rebate Model Pilot Program for FIASP® and NOVOLOG® IPAY 2026 Selected Drugs

December 30, 2025, Update: By Order dated December 29, 2025, The United States District Court for the District of Maine preliminarily enjoined the Health Resources and Services Administration from implementing its 340B Rebate Model Pilot Program pending further court order. As of January 1, 2026, Novo Nordisk is suspending implementation of its HRSA-approved 340B Rebate Model Pilot Program plan pending ongoing litigation and will provide updates accordingly.

October 31, 2025

On January 1, 2026, Novo Nordisk Inc. (labeler code 00169), and Novo Nordisk Pharma, Inc. (labeler code 73070), collectively referred to herein as "Novo Nordisk," will begin participating in the Health Resources and Services Administration's (HRSA's) 340B Rebate Model Pilot Program (Rebate Model) for all NDCs associated with Fiasp® and NovoLog® branded and unbranded biologic products included on CMS's Initial Price Applicability Year (IPAY) 2026 Medicare Drug Price Negotiation Program Selected Drug list (Rebate Model Products).

The following table lists all Rebate Model Product NDCs:

NDC	Product Name
00169750111	NOVOLOG 10ML
00169210011	NOVOLOG 10ML RELION
00169330312	NOVOLOG PENFILL 3ML
00169633910	NOVOLOG FLEXPEN 5X3ML
00169210125	NOVOLOG FLEXPEN 5X3ML RELION
00169210112	NOVOLOG FLEXPEN 5X3ML RELION INNER
00169320111	FIASP VIAL 100U/ML 10ML
00169320415	FIASP FLEXTOUCH U100 5x3 ML
00169320511	FIASP PENFILL 3ML INNER
00169320515	FIASP PENFILL 100U/ML 5X3ML
00169320611	FIASP PUMPCART 100U/ML 5X1.6ML INNER
00169320615	FIASP PUMPCART 100U/ML 5X1.6ML
73070010011	INS ASPART INJECTION 1X10ML
73070010215	INS ASPART INJECT PENFILL 5X3ML
73070010210	INS ASPART INJECT PENFILL 3ML INNER
73070010315	INS ASPART INJECT 5X3ML FP
73070010310	INS ASPART INJECT 5x3ML FP INNER

This Notice describes the process by which 340B Covered Entities (CEs) may access the 340B ceiling price for Rebate Model Product units that are both purchased and dispensed throughout

the duration of the Rebate Model (subject to the limited exception set forth in Section 8), regardless of payer.

The Rebate Model Period begins on January 1, 2026, and will have a duration of at least one (1) year. For avoidance of doubt, this Notice applies to all CEs.

The Rebate Model, as authorized by HRSA, prevails over any State law that prohibits the use of rebates to offer the 340B ceiling price, bars the submission to manufacturers of 340B claims data, or otherwise conflicts with the Rebate Model. Accordingly, the process set forth in this Notice is applicable throughout the Rebate Model Period to all CEs irrespective of the U.S. State or territory in which a Rebate Model Product purchase or dispense occurs.

Beginning January 1, 2026, the 340B ceiling price for Rebate Model Products will no longer be made available to CEs at the time of purchase. Instead, pursuant to the Rebate Model, CEs will be required to purchase Rebate Model Products at Wholesale Acquisition Cost (WAC). Upon presentation of a valid claim (as described below), Novo Nordisk will extend the 340B ceiling price through payment of a rebate (340B Rebate). The required data elements and the CE submission process are described within this Notice.

CEs may order Rebate Model Products for furnishment to patients under the 340B program through their 340B wholesaler account at WAC.

1. Submission of Claims Data

Novo Nordisk will utilize the Beacon 340B technology platform operated by Second Sight Solutions (Beacon 340B Platform) to collect all relevant data elements from CEs, apply rebate eligibility criteria, and facilitate 340B Rebate payments to CEs.

Beginning January 1, 2026, CEs are required to submit all applicable data elements, as described below in Section 2 (Data Element Submission), via the Beacon 340B Platform to access 340B Rebates for any Rebate Model Product.

CEs are permitted to submit the required data elements via the Beacon 340B Platform for up to forty-five (45) calendar days from the date of the 340B eligible dispense.

Allowances for extenuating circumstances and other exceptions, including adjustments when a claim status changes to 340B outside of the 45-day window, will be considered according to Novo Nordisk's standard business practices.

CE registration instructions for the Beacon 340B Platform are provided in Attachment 1. Access to and use of the Beacon 340B Platform is provided to CEs free of charge.

2. Data Element Submission

To facilitate payment of 340B Rebates, CEs are required to submit the following specified pharmacy or medical benefit claim data elements (other than the data elements noted as

“(optional)”), as applicable, for each unit of Rebate Model Product for which a 340B Rebate is requested:

- Claims data elements required for pharmacy benefit claim submissions:
 - a. Date of Service
 - b. Date Prescribed
 - c. Rx number (original/unencrypted/native/unmodified)
 - d. Fill Number
 - e. 11 Digit National Drug Code (NDC-11)
 - f. Quantity Dispensed
 - g. Prescriber ID
 - h. Service Provider ID
 - i. 340B ID
 - j. Rx Bank Identification Number (Rx BIN)
 - k. Rx Processor Control Number (Rx PCN)
 - l. Group Number ID (optional)
- Claims data elements required for medical benefit claim submissions:
 - a. Date of Service
 - b. Claim Line Number
 - c. Claim Number
 - d. Unit of Measure
 - e. NDC-11
 - f. Quantity
 - g. Rendering Physician ID
 - h. Service Provider ID
 - i. 340B ID
 - j. Health Plan Name
 - k. Health Plan ID
 - l. HCPCS Code (optional)
 - m. HCPCS Modifiers (Up to 4) (optional)

Data definition tables are provided for your reference in Attachment 2.

3. Eligibility

A 340B claim submission will be eligible for a 340B Rebate payment only when the following criteria are met:

- 1) The NDC on the 340B claim is an NDC for a Rebate Model Product.
- 2) The date of dispense occurs during the Rebate Model Period (unreplenished partially accumulated units meeting the criteria set forth in Section 8 of this Notice are exempt from this requirement).

- 3) The dispensing pharmacy or site of administration is registered with HRSA as an eligible CE location and is eligible under Novo Nordisk's Contract Pharmacy Policy, as defined below in Section 7 (Applicability of Novo Nordisk's Contract Pharmacy Policy).
- 4) The unit amount on the 340B claim does not exceed WAC purchases made during the Rebate Model Period and shipped to the CE or its eligible contract pharmacy (unreplenished partially accumulated units meeting the criteria set forth in Section 8 of this Notice are exempt from this requirement).
- 5) The 340B claim has not already been submitted by another CE.
- 6) The CE purchased the Rebate Model Product directly from Novo Nordisk or a wholesaler at WAC during the Rebate Model Period (unreplenished partially accumulated units meeting the criteria set forth in Section 8 of this Notice are not required to have a purchase price of WAC).

A 340B claim submission will be rejected if any of the required data elements in the submission are invalid or incomplete. A CE will be permitted to resubmit a 340B claim submission previously rejected for invalid or incomplete data elements by submitting valid and complete data elements.

4. Payment of 340B Rebates and Reversal

Novo Nordisk will pay to the CE 340B Rebates on eligible 340B claims via the Beacon 340B Platform by Automated Clearing House (ACH) transfer (or deny with supporting documentation) within ten (10) calendar days of claims data submission by the CE.

340B Rebates will be paid per unit of 340B eligible Rebate Model Product and will be calculated as the difference between WAC for the unit on the date of dispense and the 340B ceiling price, as defined at section 340B(a)(1) of the Public Health Service Act, in effect during the calendar quarter in which the unit was dispensed.

340B claims paid in error will be reversed and credits for such reversals will be used to offset future 340B Rebate payments. This process will be transparent to CEs in the Beacon 340B Platform, and the Beacon customer support team will be available to address CE inquiries.

5. Customer Support

Novo Nordisk will provide technical assistance, customer service, educational resources, and a free CE-user platform enabling search functionality and reconciliation reporting through the Beacon 340B Platform. CEs are encouraged first to engage in good faith regarding questions directly through Beacon customer support. The Beacon customer support team will be available to CEs Monday through Friday, 9 am to 9 pm ET by phone: (878) 788-8907; chat; or email: support@beaconchannelmanagement.com. If needed, the issue can be escalated to Novo Nordisk through 340binfo@novonordisk.com.

6. Process for Deduplication of Maximum Fair Price (MFP) Refunds and 340B Rebates

Novo Nordisk will use 340B and MFP claims data elements to identify 340B claims submissions for MFP-eligible dispenses. When a match is identified between 340B and MFP claims data, a 340B Rebate will be paid on the unit and, if necessary, an adjustment will be made to the MFP refund for the unit via the Beacon MFP technology platform operated by Second Sight Solutions (Beacon MFP Platform) to effectuate provision of the lesser of the MFP or 340B ceiling price without duplication. CEs will be able to access MFP refund history and status in the Beacon MFP Platform and 340B Rebate payment history and status in the Beacon 340B Platform. CEs will be able to address any questions regarding deduplication with the Beacon customer support team.

7. Applicability of Novo Nordisk's Contract Pharmacy Policy

With the exception of the new requirement that CEs submit claims data for Rebate Model Products on the Beacon 340B Platform, all criteria set forth in Novo Nordisk's May 1, 2024 "Notice Regarding Revised Limitation on Hospital and Grantee 340B Contract Pharmacy Distribution" for contract pharmacy bill to/ship to arrangements (Contract Pharmacy Policy), shall apply in determining whether a contract pharmacy dispense is eligible for a 340B Rebate under the Rebate Model. This includes requirements relating to designation of contract pharmacies on the 340B ESP™ Second Sight Solutions platform (340B ESP). The Contract Pharmacy Policy is available on the 340B ESP website at <https://www.340besp.com/resources>.

Beginning January 1, 2026, CEs should submit all claims for Rebate Model Products, inclusive of contract pharmacy claims compliant with the Contract Pharmacy Policy, on the Beacon 340B Platform. Contract pharmacy claims for Rebate Model Products will no longer be accepted on 340B ESP as of January 1, 2026. CEs should continue to submit contract pharmacy claims for all drugs other than the Rebate Model Products to 340B ESP in accordance with the Contract Pharmacy Policy.

8. Rebate Eligibility for Unreplenished Partial Accumulations Dispensed Prior to January 1, 2026

HRSA has advised Novo Nordisk that CEs employing virtual replenishment models potentially may accrue partial package accumulations for 340B eligible dispenses from neutral inventory prior to January 1, 2026.

Novo Nordisk encourages CEs to replenish all fully accumulated packages of Rebate Model Products at the 340B ceiling price prior to January 1, 2026. However, Novo Nordisk will accept 340B claims submissions for up to one (1) full package size for unreplenished partial accumulations of Rebate Model Products with a date of dispense within 45 days prior to the January 1, 2026 start of the Rebate Model Period. Any outliers will be addressed in good faith by Novo Nordisk on a case-by-case basis.

Novo Nordisk requests that CEs maintain auditable records of partial accumulations.

9. Availability of Supplemental 340B Pricing File

Novo Nordisk will make a quarterly supplemental 340B ceiling price file available to CEs at the Beacon 340B Platform website. This supplemental pricing file will be available in an Excel format that may be exported by CEs.

10. Rebate Model Updates

Novo Nordisk reserves the right to update information in this Notice. Updated information regarding Novo Nordisk's implementation of the Rebate Model will be posted from time to time on the following websites:

- Novo Nordisk's website: <https://www.novonordisk-us.com/partnering-and-innovation/340b-program-updates.html>
- The Beacon website: <https://cm.beaconchannelmanagement.com/pages/resources>

ATTACHMENT 1
Registration Instructions for the Beacon 340B Platform

CEs can navigate to <https://cm.beaconchannelmanagement.com/> to enroll and register with the Beacon 340B Platform. Once enrollment and registration are complete, CEs will be able to verify their banking information, invite users, register additional entities and create column mappings to support their data submission in preparation for the Beacon 340B Platform's full go live on January 1, 2026. Beginning January 1, 2026, CEs will be able to submit data to generate 340B rebate payments. A dedicated Product Support and Product Success team will be available to CEs via email at support@beaconchannelmanagement.com, through an in-platform messenger available on the Beacon 340B Platform, and by phone. The Beacon Support Center provides onboarding materials (Welcome Packet, FAQs, tutorials) and hosts webinars.

ATTACHMENT 2
Data Definition Tables

Pharmacy Claims Layout:

Field Name	Description
340B ID	The HRSA assigned parent 340B ID of the covered entity where the prescription originated.
Date Prescribed	Date the prescriber wrote the prescription.
Date of Service	Date on which the 340B eligible patient filled their prescription.
Rx Number	The original/unencrypted/native/unmodified prescription number for the prescription as generated by the pharmacy.
Fill Number	Indicates the number of times a prescription has been filled. A value of 2 would mean the current prescription claim is for the second refill of the prescription. (0 = original dispensing; 1-99 = refill number)
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and the commercial package size.
Quantity Dispensed	The number of units in the prescription.
Prescriber ID	National provider identifier (NPI) of the physician that wrote the prescription.
Service Provider ID	NPI of the pharmacy that filled the prescription.
Rx BIN	Prescription Drug Bank Identification Number. Enables pharmacies to electronically transmit data to the appropriate PBM for processing and reimbursement.
Rx PCN	Processor Control Number. Identifier used to determine which processor will handle a prescription drug claim.
Group Number ID (optional)	ID assigned to the cardholders or employers group.

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Medical Claims Layout:

Field Name	Description
340B ID	The HRSA assigned parent 340B ID of the entity that purchased the administered medication.
Claim Number	The claim number as assigned by the healthcare provider.
Claim Line Number	The line number of the claim.
Date of Service	Date on which the medication was administered to the patient.
HCPCS Code	The five digit HCPCS code for separately payable medications. This value may not exist for medications that are reimbursed as part of procedure (e.g. a blood thinner used as part of an outpatient procedure).
HCPCS Code Modifier	Modifier code associated with a separately payable medication with its own 5 digit HCPCS code.
Health Plan Name	Name of the patient's primary health insurance plan. Examples include Medicare Part B, MediCal, Aetna POS, etc.
Health Plan ID	The identifier code of the patient's primary health insurance plan as assigned by the health insurer.
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and the commercial package size.
Rendering Physician ID	The NPI of the physician that administered the medication to the patient.
Quantity	The quantity - as measured in billable units - of medication administered to the patient.
Unit of Measure	Either HCPCS code or UOM is required. If HCPCS code is not included, UOM is required and it should be consistent with NCPDP units.
Service Provider ID	The NPI of the healthcare entity where the patient received the medication administration. For example, this could be the NPI of a hospital outpatient surgery center or the NPI of an outpatient infusion center.