



Boehringer Ingelheim Approved 340B Rebate Model Pilot Plan

A. General 340B Rebate Model Pilot Plan Requirements

1. Costs for data submission

As noted above, the IT platform will be BRG's Beacon platform. Boehringer confirms that all costs for the Beacon platform will be borne by Boehringer.

2. Notice

Boehringer confirms that it will provide 90 calendar days' notice to covered entities and other impacted stakeholders before implementing its rebate model. Boehringer confirms that when it provides this notice, it will also provide instructions to covered entities for registering on the Beacon platform. Boehringer will provide a copy of its final approved plan for public posting on HRSA's website. Boehringer understands that changes to its approved plan will require HRSA review and approval prior to implementation.

3. Existing infrastructure

Boehringer confirms that its rebate model will comply with the Notice's requirements by allowing covered entities to order its active selected drugs for the initial price applicability years 2026 or 2027 under existing distribution mechanisms (e.g., 340B wholesaler accounts with WAC prices loaded) to ensure purchases flow through existing infrastructure.

4. Technical assistance / customer service

Boehringer confirms that its rebate model will comply with the Notice's requirements by providing technical assistance and a customer service component to ensure that covered entities have an opportunity to engage with Boehringer in good faith regarding questions or concerns. Technical assistance and customer service will be made available to covered entities through both the Beacon platform and the following Boehringer point of contact and email address will also be made available for covered entities.

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5. Data security

Boehringer confirms that the Beacon platform will comply with the Notice's requirements by incorporating mechanisms to ensure that data submitted to the platform is secure and protected and that collection of the data is limited to the elements listed below that are necessary for providing 340B rebates pursuant to section 340B(a)(1) of the Public Health Service Act. Beacon provides resources on cm.beaconchannelmanagement.com under [Trust Center\[1\]](#) and [Support Center\[2\]](#).

6. Protected Health Information or Patient Identifying Information

Boehringer confirms that Boehringer and the Beacon platform will incorporate mechanisms to protect the privacy and security of protected health information or other patient identifying information, which is required to be safeguarded in a manner consistent with any applicable federal privacy and data security laws, including the Health Insurance Portability and Accountability Act. We understand that the Beacon platform will provide security and privacy protection in line with industry best practices.

7. Exception

Boehringer confirms that an exception that would not apply broadly to all covered entities will be communicated to both HRSA and affected covered entities.

B. Reporting Requirements

1. Submission and reporting of data

Boehringer confirms that covered entities will be allowed to submit and report data for up to 45 days from the date of dispense, with allowances for extenuating circumstances and other exceptions, including adjustments when a 340B status change occurs on a claim.

2. Use of data

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Boehringer confirms that the Beacon platform will have the capacity to receive data that will filter and use only the data required under the pilot. If covered entities or others submit data for products other than active selected drugs for the initial price applicability years 2026 or 2027, the platform will be able to identify and discard unneeded data.

Boehringer confirms that, as requested by HRSA and unless otherwise authorized, covered entity data received under the rebate pilot program will not be used, collected, aggregated, shared, or licensed for any purpose beyond the pilot. Boehringer has also confirmed with BRG, the designated IT platform vendor operating the Beacon platform, that, as requested by HRSA and unless otherwise authorized, any covered entity data for Boehringer products received under the rebate pilot program will not be used, collected, aggregated, shared, or licensed for any purpose beyond the pilot.

3. Reconciliation reports

Boehringer confirms that the Beacon platform will comply with the Notice's requirements by incorporating the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.

4. Quarterly 340B price file

Boehringer confirms that a quarterly 340B price file for each of Boehringer's 11-digit NDCs will be made available to covered entities, so that covered entities may use the price file in conjunction with pharmacy billing systems to appropriately account for actual acquisition cost (i.e., post rebate price) for Medicaid billing and also to assist with sliding fee scales or cost sharing with patients.

5. Provision of reports

Boehringer agrees to provide HRSA/OPA with periodic reports consistent with the information outlined in HRSA's Notice. Boehringer also intends to provide that information in any reasonable and lawful format and manner that may in the future be specified by HRSA/OPA. Those reports will detail data on purchases provided through rebates, information related to claim denials, and other information that may facilitate evaluation of the rebate model's effectiveness.

C. Rebates

1. Rebate calculation

Boehringer confirms that the rebate calculation will equal WAC less the 340B ceiling price on the day of dispense.

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2. Level for payment

Under Boehringer's rebate model, rebates will be paid at the unit level.

3. Implementation phase

Boehringer will accommodate up to 2 unreplenished accumulated packages during the implementation phase. Covered entities shall have a 15-calendar day grace period, in which they may submit rebate requests for up to 2 unreplenished accumulated packages prior to the Pilot's effective date. The request for such rebates must still be made within 45 days of dispense.

4. Timing for rebates

Boehringer confirms that rebates will be paid or denied (with supporting documentation) within 10 calendar days of data submission, as provided in the Notice. If the submission is returned for incomplete data, the 10-day clock for rebate payment will restart when all necessary data is submitted.

5. Diversion / duplicate discounting

Boehringer confirms that it will ensure that 340B rebates are not denied based on eligibility or compliance concerns with diversion or Medicaid duplicate discounts, and that it will provide a rationale and specific documentation explaining the reasons why claims are denied. Boehringer understands that rebates may not be denied for perceived lack of WAC purchases.

6. Scope of rebates

Boehringer confirms that its rebate model will comply with the Notice by ensuring that 340B rebates are paid only on sales of active selected drugs for the initial price applicability years 2026 or 2027, as included on the CMS Medicare Drug Price Negotiation Selected Drug List, regardless of payer, or indication, and only during the selected drug's effective dates of negotiated prices. Boehringer understands that the NDC-11s of the selected drug are included in the Pilot only to the extent they are on the List, and the selected drug is in its price applicability period in the "Medicare Drug Price Negotiation Program."

D. Data

1. Data requested

Boehringer confirms that the data requested under its rebate model will be limited to the claims fields identified in the Notice. See Attachment D for Data Field Definitions.

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Covered entities will be permitted to resubmit data if a rebate request is deemed incomplete or missing data.

As to wasted or undispensed units, Boehringer does not believe there should be any issues relating to wasted or undispensed units.

With respect to waste, there should not be any waste for Jardiance®, Ofev®, and Tradjenta®. Boehringer understands that waste in the 340B context primarily occurs when the correct dose of a product must be extracted from a vial and any unused portion is discarded. Since Jardiance®, Ofev®, and Tradjenta® are in tablet form, covered entities should not encounter any waste of the products.

With respect to undispensed units, Boehringer has in place a return procedure for such units. Boehringer believes that this established return procedure should be utilized for covered entities to obtain refunds regarding Jardiance®, Ofev®, and Tradjenta®. Undispensed units are not eligible for a rebate as only dispensed units are effectuated through the rebate model.

As to how cash or uninsured patients should be characterized during the claims submission process, cash or uninsured patient status will be characterized under the RX BIN and RX PCN data fields submitted with pharmacy claims data. Those data fields include an option for specific values to indicate uninsured/cash claims. For RX PCN and Health Plan Name, for a cash patient, the covered entity would populate the fields with “CASH” for claim submission. For RX BIN, for a cash patient, the covered entity would populate the field with “999999” as this field only allows numeric digits.

Attachment D**Pharmacy Claims Data Fields**

Field	Description	Data Type
Date Of Service	Date on which the pharmacy filled the prescription.	Date
Date Prescribed	Date the healthcare provider wrote the prescription.	Date
Rx Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy.	Numeric
Fill Number	Indicates the number of times the prescription has been filled as of the current fill. For example, a value of "0" indicates that the prescription has not been filled previously and the current fill is the first one. The first refill would have a value of "1".	Numeric (0-99)
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)
Quantity	Number of units dispensed to the patient. Appropriate Units of Measure for each product will be provided within Beacon's NDC list.	Numeric
Prescriber ID	National provider identifier (NPI) of the healthcare provider that wrote the prescription.	Numeric (10 Digits)
Service Provider ID	NPI of the pharmacy that filled the prescription	Numeric (10 Digits)
340B ID	HRSA assigned identifier of the 340B covered entity that designated the dispense as 340B.	Alpha/Numeric
BIN Number	Prescription Drug Bank Identification Number for the primary payer. Enables pharmacies to electronically transmit data to the appropriate PBM for processing and reimbursement. If a patient is uninsured or a cash payer, mark "999999" in this field.	Numeric (6 Digits)
PCN Number	Processor Control Number for the primary payer. Identifier used to determine which processor will handle a prescription drug claim. If a patient is uninsured or a cash payer, mark "CASH" in this field. If there is no PCN, mark "NONE" in this field.	Alpha/Numeric

Attachment D**Medical Claims Data Fields**

Field	Description	Data Type
Health Plan Name	Name of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric
Health Plan ID	The identifier code of the patient's primary health insurance plan. If the patient is uninsured or a cash payer, mark "CASH" in this field. If no health plan information is recorded, mark "NONE" in this field.	Alpha/Numeric
Health Plan ID Qualifier	The qualifier for the patient's health insurance plan ID.	Alpha/Numeric
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.	Numeric (10 Digits)
NDC-11	The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.	Numeric (11 Digits)
Quantity	The quantity of medication administered to the patient. Quantity must reflect standardized billing units as defined by NCPDP for the NDC-11.	Numeric
Unit of Measure	UOM must be consistent with the standardized billing unit as defined by NCPDP for the NDC-11.	Alpha/Numeric
Date of Service	Date on which the medication was administered to the patient.	Date
Physician ID	The NPI of the healthcare provider who rendered or supervised the care reported on the claim.	Numeric (10 Digits)
Claim Number	A unique identifier for a prescription and claim processor. This value should align with the Patient Control Number or Claim Submission ID, as set within provider systems and included on EDI 837 transmissions to payers (Form 1500 Box 26 or Claim 1450 Box 3).	Alpha/Numeric
Claim Line Number	Identifies an individual line number on a claim. Line numbers distinguish services that are submitted on the same claim. Wastage Claims or undispensed units submitted should include a separate claim line number from the dispensed units.	Numeric
340B ID	HRSA assigned identifier of the 340B covered entity that designated the administration as 340B.	Alpha/Numeric