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October 2, 2026

## GSK 340B Rebate Model Pilot Program Policy

GlaxoSmithKline (GSK) has been selected to participate in the Health Resources and Services Administration (HRSA) 340B Rebate Model Pilot Program (Pilot Program), as outlined in the Federal Register Notice, published August 3, 2026. Effective January 1, 2027, GSK will make the 340B ceiling price on eligible National Drug Codes (NDCs) available to 340B covered entities through the Pilot Program.

The rebate model will apply to all covered entities (CE) except AIDS Drug Assistance Program (ADAP) currently receiving 340B discounts in the form of a rebate. In addition, the rebate model will apply only for the GSK NDC-11s approved by HRSA for participation in the Pilot Program and included on the CMS Medicare Drug Price Negotiation Program Selected Drug List for Initial Price Applicability Year (IPAY) 2027. Covered entities will continue to purchase in-scope products through existing distribution mechanisms, including 340B wholesaler accounts with WAC prices loaded. ADAP Covered Entities currently receiving 340B discounts in the form of a rebate may continue operating within existing rebate processes.

GSK has engaged Second Sight Solutions to administer the Pilot Program through its Beacon platform (Beacon). 340B Covered Entities can access the Beacon platform at <https://cm.beaconchannelmanagement.com>.

### In-scope NDCs

| NDC-11      | Product         | Product Description                                       |
|-------------|-----------------|-----------------------------------------------------------|
| 00173085910 | BREO ELLIPTA    | BREO ELLIPTA 100/25 MCG INHPWDR 30 DS NDPI TRD PACK X 1   |
| 00173085914 | BREO ELLIPTA    | BREO ELLIPTA 100/25 MCG INHPWDR 14 DOSE NDPI INST PAC X 1 |
| 00173088210 | BREO ELLIPTA    | BREO ELLIPTA 200/25 MCG INHPWDR 1X 30D                    |
| 00173088214 | BREO ELLIPTA    | BREO ELLIPTA 200/25 MCG INHPWDR 1X 14D INST               |
| 00173091610 | BREO ELLIPTA    | BREO ELLIPTA 50/25 MCG INH PWDR 30 DS NDPI TRD PACK X 1   |
| 00173088710 | TRELEGY ELLIPTA | TRELEGY ELLIPTA 1X30D TRD 100/62.5/25MCG PK/CA            |
| 00173088714 | TRELEGY ELLIPTA | TRELEGY ELLIPTA 1X14D INST 100/62.5/25MCG PK/CA           |
| 00173089310 | TRELEGY ELLIPTA | TRELEGY ELLIPTA 200/62.5/25MCG 1X30D TRADE PACK           |
| 00173089314 | TRELEGY ELLIPTA | TRELEGY ELLIPTA 200/62.5/25MCG 1X14D INST PACK            |

### Program scope and affected covered entities

- **Applicable entities.** The rebate model applies to all covered entities except ADAP covered entities currently receiving 340B discounts in the form of a rebate. ADAP covered entities may continue within existing rebate processes.
- **Effective date.** The effective date for the GSK 340B Rebate Model Pilot Program is January 1, 2027.
- **Selected drugs.** In-scope products are limited to GSK NDC-11s for BREO ELLIPTA and TRELEGY ELLIPTA approved for the Pilot Program and included on the CMS Medicare Drug Price Negotiation Selected Drug List for IPAY 2027.
- **Ordering flow.** Covered entities should continue ordering through existing 340B wholesaler accounts for products to be purchased at WAC.
- Identification of a potential non-WAC purchase will not result in the denial of a rebate request. GSK will not deny a rebate solely on the basis of a suspected or perceived non-WAC purchase. GSK will continually monitor instances where non-WAC purchases were used for 340B rebate submission and will immediately raise such deviations with the appropriate covered entity. If a resolution is not obtained, GSK will escalate using the dispute resolution process.

### Beacon registration, payment setup, and support

- **Notice and registration.** GSK will provide no fewer than 90 calendar days' notice before implementation of the Pilot Program, including rebate plan information and Beacon registration instructions, through public posting and email communications.
- **Covered entity registration.** 340B covered entities that elect to submit 340B claims must first register with Beacon by navigating to <http://cm.beaconchannelmanagement.com/> and completing the registration process. Registration with and use of Beacon by 340B covered entities is free of charge. Use of Beacon is governed by the Terms of Use and Privacy Policy which are available at <http://cm.beaconchannelmanagement.com>. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant. CEs that have previously registered on Beacon may need to re-confirm documentation to ensure



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no information has changed. Additionally, to ensure payment can be made in a timely manner, Beacon may require CEs to submit an updated bank letter (to permit new micro-deposits for verification).

- **ACH payment setup.** Users must also submit bank account information for ACH payments which will be verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.
- **Support channels.** Beacon's Support Center will provide technical assistance, customer service, educational resources, webinars, recorded platform demonstrations, FAQ documents and escalation support  
<https://cm.beaconchannelmanagement.com/pages/support-center>. 340B CEs can also register to participate in live webinars. Information on how Beacon protects financial and healthcare related information is available online in the Trust Center tab of the Beacon website. Support is available by phone at (878) 788-8907, by chat through Beacon, or by email at [support@beaconchannelmanagement.com](mailto:support@beaconchannelmanagement.com).
- **Good faith engagement.** GSK is currently awaiting more information from HRSA regarding tooling to support a dispute resolution workflow for the Rebate Model. GSK requests that covered entities engage with Beacon Customer Support as an initial step in challenging denied claims before reporting denied rebates through HRSA's dispute process. This will ensure documentation to support the dispute resolution and provide a mechanism to resolve issues quickly. GSK and Beacon will coordinate to provide timely responses and additional information as required to assist in the resolution.

#### Submission timing, rebate calculation, payments, reconciliation data, and transition accommodation

- Starting January 1, 2027, Covered Entities should submit all claims for BREO ELLIPTA and TRELEGY ELLIPTA to Beacon, in accordance with GSK's 340B Rebate Model Pilot Plan. 340B Rebates will be paid only for claims occurring at eligible locations in compliance with GSK's 340B Rebate Model Pilot Plan. Contract Pharmacy & In-House claims for BREO ELLIPTA and TRELEGY ELLIPTA will no longer be accepted through 340B ESP. Contract Pharmacy & In-House claims for all other GSK products will continue to be submitted to 340B ESP in accordance with GSK's 340B Policy. Please visit <https://340besp.com/resources> for further details.
- **45-day submission window.** Covered entities may submit required pharmacy and/or medical claims data through Beacon within 45 calendar days from the date of dispense or administration. Covered Entities seeking an exception to this deadline for extenuating circumstances may request the exception via Beacon's Customer Support Team. Exceptions will be considered on a case-by-case basis in accordance with GSK's standard business practices.
- **Rebate calculation.** Rebates will be calculated as WAC less the 340B price on the date of dispense or administration and paid at the unit level via ACH.
- **Rebate Payments and Reconciliation Data.** Following the successful validation of 340B claim submissions according to the eligibility criteria approved by HRSA, Beacon initiates the rebate payment process. Rebates are priced based on the WAC price loaded to the 340B account and 340B Ceiling price as of the claim date of dispense. Rebate payments are transmitted to the 340B covered entity via an ACH payment within the time period approved by HRSA. The transaction ID of the rebate payment is appended to the 340B rebate record maintained in Beacon giving the 340B covered entity real-time access to reconciliation data in Beacon. Rebates that are determined to be ineligible are accessible in Beacon by the 340B covered entity and include details on the eligibility determination. In addition to accessing information online in Beacon, 340B covered entities can also download 340B rebate data for inclusion in their proprietary systems. Because 340B claims are de-identified prior to submission to the Beacon platform, a unique ID is appended to the data submission and made available to 340B covered entities immediately following the initial 340B claims submission. This unique ID allows 340B covered entities to link de-identified data maintained in Beacon with the identifiable data maintained in 340B covered entities' proprietary systems for reconciliation purposes.
- **10-day processing.** Rebates will be paid or denied with validation documentation within 10 calendar days after receipt of complete and validated data. If a submission is returned for incomplete data, the 10-day clock restarts when complete data is received.
- **Reconciliation Reports.** CEs will have access to real-time rebate status for submitted claims and payments made by Beacon. CEs must reverse any 340B claims submitted in error immediately. Reversal credits will be used to offset future 340B rebate payments. This process will be transparent to CEs in Beacon, and Beacon's Customer Support Team will be available to resolve inquiries.
- **Unreplenished accumulated packages.** GSK will allow for the payment of rebates based upon the collection of limited BREO ELLIPTA and TRELEGY ELLIPTA dispenses, dispensed within 15 days prior to the Rebate Model Pilot Program Effective Date and not otherwise used for 340B purchasing through a 340B chargeback, up to the amount of two packages per NDC-11 as unreplenished accumulated packages. Dispense information for unreplenished accumulated packages may be submitted for up to 45 days after the date of dispense.

#### Data collection, data use, and privacy/security

- **Data Collection.** Beacon will limit data collection to HRSA-approved fields needed to effectuate rebates. GSK will not request purchasing data, encounter data, invoice-level documentation, or patient-level clinical documentation unless HRSA separately approves a change and the change is implemented consistent with HRSA requirements.
- **Data filtering.** Beacon uses filtering and validation controls so data submissions are limited to eligible BREO ELLIPTA and TRELEGY ELLIPTA NDCs. Online submissions are filtered before submission, and server-side validations are designed to prevent Beacon from possessing ineligible data.  
**Permitted use.** Covered entity data that is handled by technology platforms and received by GSK as a part of this Pilot Program will not be used for any purpose other than those explicitly identified in this Pilot Program. GSK and Beacon will not use the data beyond the purpose of the Pilot Program and will not share data. This limitation extends to any collecting, aggregating, sharing, or licensing of Pilot Program data by GSK or technology platforms. GSK will only use information from this Pilot Program to support compliance with statutory requirements across federal drug pricing programs, e.g., Maximum Fair Price (MFP) deduplication.



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Neither GSK nor Second Sight Solutions/Beacon may collect, aggregate, share, or license Pilot Program data, except as necessary to administer the Pilot Program, consistent with the Notice and HRSA's requirements. To the extent the Beacon Terms of Use permit broader collection, aggregation, sharing or licensing of data, such provisions shall not apply to data submitted to GSK in connection with the HRSA 340B Rebate Model Pilot Program.

- **Privacy controls.** All data elements protected under HIPAA are de-identified through a HIPAA compliant hashing process known as SHA-3 hashing. An additional layer of security called a "salt" is applied prior to the hashing process and before any data is uploaded to Beacon. This process was granted an Expert Determination and meets the definition of a De-Identified Data Set under HIPAA. This means that Beacon does not collect or maintain identifiable PHI.
- **Security controls.** GSK and its partner, Second Sight Solutions/Beacon, will provide comprehensive and robust data security to support the Rebate Model Pilot. Beacon has implemented a robust data security framework. Beacon provides resources on [cm.beaconchannelmanagement.com](https://cm.beaconchannelmanagement.com) under Trust Center[1] and Support Center[2].
  - [1] <https://cm.beaconchannelmanagement.com/pages/trust-center>
  - [2] <https://cm.beaconchannelmanagement.com/pages/support-center>

### Validation, denials, and monitoring

- **No denial based on diversion or Medicaid duplicate discount concerns.** 340B rebate requests will not be denied based on diversion allegations or Medicaid duplicate discount concerns. Denials will include rationale and supporting documentation.
- **Validation.** Beacon applies a comprehensive set of front-end and back-end validations, including product eligibility, covered entity eligibility, provider validation, quantity validation, duplicate detection, orphan drug restrictions (where applicable), and other approved validation controls.
  - **Front-end validation.** Beacon validations include ineligible product, invalid field format, policy exception, and registered-user validations.
  - **Back-end validation.** Beacon validations include claim expired, pharmacy eligibility, CE Eligibility - Date, CE Eligibility - Orphan Drug, aberrant quantity, NDC expiration, prescriber ID - provider, prescriber ID – active, network eligibility if applicable, pre-policy claim, duplicate - one entity, and duplicate - multiple entities.
- **Duplicate checks.** Duplicate checks are performed for duplicate submissions by the same covered entity and for duplicate claims submitted by multiple covered entities. When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid.
- **MFP-340B deduplication.** GSK will initially address MFP-340B duplication through adjustment or rejection of MFP rebates under GSK's MFP Effectuation Plan and reserves the right to address MFP-340B deduplication through rejection of 340B rebates after an initial observability period.
- **Data integrity and WAC monitoring.** The integrity of the data submitted as part of the Rebate Model Pilot is crucial to achieving the pilot's intended goal of minimizing duplication between 340B and MFP discounts. As such GSK will regularly monitor rebate submissions to ensure that key data elements (Prescription Number, Pharmacy ID, Dispense Date, etc.) are not altered from their native values. Evidence of data integrity concerns will be raised immediately with covered entities and/or HRSA.

### Program Requirements

- GSK will use the Beacon platform operated by Second Sight Solutions to administer 340B rebate submissions and payments, with platform access provided at no cost to covered entities.
- GSK, through this notice, provides covered entities and other impacted stakeholders no fewer than 90 calendar days' notice of the planned implementation.
- Covered entities can purchase in-scope GSK products at WAC through its existing 340B wholesaler account. This will ensure purchases flow through existing infrastructure. Existing 340B wholesaler accounts will be loaded with WAC pricing for BREO ELLIPTA and TRELEGY ELLIPTA. 340B Pricing for all NDCs of BREO ELLIPTA and TRELEGY ELLIPTA will be available via Beacon.
- Covered entities can get technical assistance / customer service components through the Beacon Platform. A triage and escalation plan is in place to address covered entity questions and concerns. Questions regarding this notice may be submitted to GSK at [US.340B@gsk.com](mailto:US.340B@gsk.com).
- The Beacon platform has mechanisms in place to ensure that its data is secure, protected, and collection of data is limited to the elements necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA.
- The Beacon platform has mechanisms in place to protect the privacy and security of PHI or other PII, which is required to be safeguarded in a manner consistent with applicable federal privacy and data security laws, including HIPAA.

### Reporting Requirements

- Covered entities may submit required pharmacy and/or medical claims data through Beacon within 45 calendar days of the date of dispense, with allowances for documented extenuating circumstances and applicable 340B status changes.
- The Beacon Platform has the capacity to receive, filter, and use only the data required to effectuate the rebate.
- Beacon will provide real-time or near real-time reconciliation/status reporting so covered entities can monitor claim receipt, validation, payment, denial, and dispute status.
- GSK will make available on the platform to covered entities a quarterly 340B price file for each NDC-11 of GSK's eligible product.



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- GSK will work with HRSA's Office of Pharmacy Affairs (OPA) to provide periodic reports as specified by the agency.

## Rebates Requirements

- Rebates will be paid at the unit level.
- GSK will implement the transition accommodation required by HRSA for unreplenished accumulations. Covered entities may, during the fifteen (15) calendar day period following the Pilot effective date, submit rebate requests for up to two (2) unreplenished accumulated packages prior to January 1, 2027 and were not replenished before implementation of the rebate model. Any rebate request submitted under this transition accommodation must be submitted within forty-five (45) calendar days of the applicable dispense date and will be processed in accordance with the terms of the GSK 340B Rebate Model Pilot Program
- Rebates will be paid or denied with appropriate validation documentation within 10 calendar days of submission. If the submission is returned for incomplete data, the 10-day clock for rebate payment will restart when all necessary data is submitted.
- Rebates will not be denied based on diversion allegations, Medicaid duplicate discount concerns, pursuant to section 340B(a)(5)(A) and (B) of the Public Health Service Act. For any claims that are denied, GSK will provide rationale and specific documentation explaining the denial.
- Rebates will be limited to the active selected drugs for the initial price applicability years 2027 (Breo and Trelegy), 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. The NDC-11s of the selected drug(s) are included in the Pilot Program only to the extent the selected drug is in its price applicability period.

## Data Requirements

### Pharmacy Claims

| Field                      | Description                                                                                                                                                                                                                                                          | Data Type           | Required |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------|
| <b>Date Of Service</b>     | Date on which the pharmacy filled the prescription.                                                                                                                                                                                                                  | Date                | Y        |
| <b>Date Prescribed</b>     | Date the healthcare provider wrote the prescription.                                                                                                                                                                                                                 | Date                | Y        |
| <b>Rx Number</b>           | The native (unmodified) prescription number for the prescription as generated by the pharmacy.                                                                                                                                                                       | Numeric             | Y        |
| <b>Fill Number</b>         | 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)      | Y        |
| <b>NDC-11</b>              | The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.                                                                                                                                                              | Numeric (11 Digits) | Y        |
| <b>Quantity</b>            | Number of units dispensed to the patient. Appropriate Units of Measure for each product will be provided within Beacon's NDC list.                                                                                                                                   | Numeric             | Y        |
| <b>Prescriber ID</b>       | National provider identifier (NPI) of the healthcare provider that wrote the prescription.                                                                                                                                                                           | Numeric (10 Digits) | Y        |
| <b>Service Provider ID</b> | NPI of the pharmacy that filled the prescription                                                                                                                                                                                                                     | Numeric (10 Digits) | Y        |
| <b>340B ID</b>             | HRSA assigned identifier of the 340B covered entity that designated the dispense as 340B.                                                                                                                                                                            | Alpha/Numeric       | Y        |
| <b>BIN Number</b>          | 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)  | Y        |
| <b>PCN Number</b>          | 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       | Y        |



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## Medical Claims

| Field                    | Description                                                                                                                                                                                                                                                        | Data Type           | Required |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------|
| 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       | Y        |
| 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       | Y        |
| 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) | Y        |
| NDC-11                   | The 11-digit National Drug Code which indicates the manufacturer, product, and commercial package size.                                                                                                                                                            | Numeric (11 Digits) | Y        |
| Quantity                 | The quantity of medication administered to the patient. Quantity must reflect standardized billing units as defined by NCPDP for the NDC-11.                                                                                                                       | Numeric             | Y        |
| Unit of Measure          | UOM must be consistent with the standardized billing unit as defined by NCPDP for the NDC-11.                                                                                                                                                                      | Alpha/Numeric       | Y        |
| Date of Service          | Date on which the medication was administered to the patient.                                                                                                                                                                                                      | Date                | Y        |
| Physician ID             | The NPI of the healthcare provider who rendered or supervised the care reported on the claim.                                                                                                                                                                      | Numeric (10 Digits) | Y        |
| 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       | Y        |
| 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             | Y        |
| 340B ID                  | HRSA assigned identifier of the 340B covered entity that designated the administration as 340B.                                                                                                                                                                    | Alpha/Numeric       | Y        |

### Transition, Support, and Data Protection

- Covered entities are encouraged to reconcile and replenish existing eligible 340B accumulations before the January 1, 2027 implementation date. GSK will apply the implementation grace-period requirements established by HRSA for eligible unreplenished accumulated packages.
- Beacon support resources, templates, registration instructions, and technical assistance will be available through the Beacon Support Center. Covered entities may contact Beacon by phone at (878) 788-8907, by chat through the platform, or by email at [support@beaconchannelmanagement.com](mailto:support@beaconchannelmanagement.com).
- Beacon will limit data collection to the HRSA-approved claims fields needed to effectuate the rebate and will maintain mechanisms to protect privacy and data security consistent with HIPAA and other applicable federal requirements.
- Questions regarding this notice may be submitted to [US.340B@gsk.com](mailto:US.340B@gsk.com).

GSK will continue working with HRSA, covered entities, Beacon, and other stakeholders to support a smooth implementation of the HRSA 340B Rebate Model Pilot Program.

Note: A printed copy of the Beacon Terms of Use and Privacy Policy will be provided upon request. These documents are also available at <http://cm.beaconchannelmanagement.com>.