

Merck 340B Rebate Model Pilot Program Plan

If approved by the Health Resources and Services Administration (“HRSA”), Merck Sharp & Dohme LLC (“Merck”) will implement a 340B rebate model (“Rebate Model”) under the federal 340B Rebate Model Pilot Program (“Pilot”). This Rebate Model Plan (“Plan”) describes Merck’s approach to participating in the Pilot. Merck intends for the Plan to satisfy all criteria identified by HRSA in its Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48,883 (Aug. 3, 2026) (“Pilot Notice”).

Under the Rebate Model, covered entities (“CEs”) may purchase JANUVIA, JANUMET, and JANUMET XR (collectively, the “Products”) at their wholesale acquisition cost (“WAC”), and subsequently receive the applicable 340B discount in the form of a rebate following validation of required data submitted to Merck. Merck’s Rebate Model will be available on a nationwide basis and will be administered uniformly across all participating CEs and U.S. jurisdictions.

Merck respectfully requests HRSA’s approval of this Plan. Merck welcomes HRSA’s feedback to finalize this Plan and looks forward to participating in the Pilot.

A. General 340B Rebate Model Pilot Plan Requirements

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1. Plan must identify the IT platform to be used for covered entity data submission and include assurances that all costs for IT platform used for data submission, be borne by the manufacturer.	Merck will operate its Rebate Model using the Beacon Rebate Model platform (“Beacon”), a web-based technology platform developed by Second Sight Solutions (“Second Sight”) that supports the implementation and operation of 340B rebate models. Beacon collects 340B claims data from CEs, validates eligibility of submitted data, facilitates payment of 340B rebates to CEs, provides data and reporting, and provides real-time access to 340B rebate status to CEs and manufacturers. Effective January 1, 2027, CEs seeking 340B pricing on Products can submit data through Beacon for rebate processing. Merck will make Beacon available to participating CEs at no cost. CEs will not be charged registration, access, transaction, or other administrative fees to participate in the Rebate Model or submit claims through the platform.
2. Plan must allow for 90 calendar days’ notice to covered entities and other impacted stakeholders before implementing an approved rebate pilot plan, with instructions for registering for any IT platforms. Changes to approved plans must be	On or before October 3, 2026, Merck will issue a notice to CEs and other impacted stakeholders before implementing its approved Plan, with instructions for registering for Beacon. This timeline will allow for at least 90 calendar days’ notice. Merck will submit any changes to its approved Plan to HRSA for review and approval prior to implementation. Merck will provide HRSA with a copy of its final approved Plan for public posting on HRSA’s website.

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submitted to OPA for review and approval prior to implementation, including the mechanism by which covered entities are to acquire drugs included in the rebate model pilot. OPA will determine if the changes can take effect immediately or if they require a notification period to covered entities. Manufacturers will be expected to provide HRSA with a copy of their final approved plan for public posting on HRSA's website to ensure consistency with what HRSA approved.	
3. Plan must allow for covered entities to order the selected drugs under existing distribution mechanisms (e.g., 340B wholesaler accounts with WAC prices loaded) to ensure purchases flow through existing infrastructure.	Upon launch of its Rebate Model, CEs may continue to access the Products at WAC through existing distribution channels, such as through existing 340B wholesaler accounts. Merck will update its wholesaler pricing files to reflect WAC in 340B accounts. Merck will not pay rebates based upon purchases made from non-340B wholesaler accounts.
4. Plan must provide technical assistance/customer service component and ensure that opportunities to engage directly with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and provide a point of contact at the manufacturer.	Beacon will provide technical assistance, customer support, and educational resources to CEs engaging with Merck's Rebate Model. Beacon's customer support team will assist CEs with and address questions regarding registration, data submission, rebate requests, claim status, denied claims, and other aspects of the Rebate Model. Customer support is available by phone, web chat, and email Monday through Friday, from 9:00 a.m. to 9:00 p.m. ET. Beacon also provides proactive educational and training resources, including online reference materials, prerecorded webinars, and live training sessions. Additional information regarding Beacon support resources is available through the Beacon Support Center, found at https://cm.beaconchannelmanagement.com/pages/support-center. Merck encourages CEs to engage in good faith through Beacon as an initial step in addressing questions, concerns, or potential issues related to rebate submissions and payments, including denied rebate claims. Merck requests that CEs first seek resolution through Beacon before engaging HRSA's dispute resolution process. This approach promotes efficient issue resolution, ensures Beacon has access to all

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	documentation or information necessary to inform dispute resolution, and may help resolve concerns without unnecessarily utilizing government resources. Beacon is committed to responding to CE inquiries within 24 hours of receipt and will work to resolve inquiries as promptly as practicable. To facilitate resolution, Beacon may request additional information necessary to understand and evaluate a CE inquiry. While CEs are encouraged to work directly through Beacon for efficient issue resolution, CEs can contact Merck through the following e-mail address: 340Brebate@merck.com.
5. Plan must ensure that the IT platform has assurances in place to ensure that the data is secure and protected and 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 PHSA. 6. Plan must ensure that the manufacturer and the IT platform have 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 any applicable federal privacy and data security laws, including HIPAA.	Beacon has implemented a data security framework for Beacon that is designed to ensure that data is secure and protected. Beacon also incorporates safeguards to protect the privacy and security of all data submitted to the Rebate Model in a manner consistent with applicable federal privacy and data security laws, including HIPAA. Beacon is designed to operate without the use of protected health information (“PHI”) as defined by HIPAA. Specifically, Second Sight has received an expert determination from Dr. Brad Malin that the data collected through Beacon meets the definition of a De-Identified Dataset under HIPAA. Consistent with HRSA guidance, this de-identification occurs through automated processes prior to data ingestion by the platform such that Beacon does not receive, process, or retain PHI. Appendix I contains additional technical information regarding the platform’s security architecture, privacy controls, and operational functionality. Additional information regarding Beacon’s security program and privacy controls is also available through the Beacon Trust Center¹ and Support Center.² Merck would be pleased to provide HRSA with any additional information regarding the privacy and data security protections incorporated into its Rebate Model upon request.
7. Plan must describe whether an exception that would not apply broadly to all covered entities, and if any, will be communicated to both HRSA and affected covered entities (e.g., covered entities without access to a third-party	Merck intends for its Rebate Model to apply uniformly across all covered entity types and does not currently anticipate any exceptions that would apply to only a subset of CEs.

¹ <https://cm.beaconchannelmanagement.com/pages/trust-center>.

² <https://cm.beaconchannelmanagement.com/pages/support-center>.

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administrator or rural hospitals or health centers).	

B. Reporting Requirements

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1. Plan must ensure that covered entities are allowed to submit and report data (as detailed below), at a minimum, up to 45 calendar days from date of dispense, with allowances for extenuating circumstances and other exceptions, including adjustments when a 340B status change occurs on a claim.	Beacon will allow CEs to submit required data for eligible rebate claims for up to 45 calendar days from the date of dispense, either directly or through a participating third-party administrator (“TPA”). CEs experiencing extenuating circumstances may request an exception through Beacon's Customer Support Team. Merck will evaluate such requests on a case-by-case basis and may grant appropriate accommodations where warranted by the circumstances.
2. Plan must ensure that the IT platform will have the capacity to receive data from all applicable covered entities and to filter and use only the data required to effectuate the rebate (e.g., if drugs other than a selected drug for initial price applicability year 2026 or 2027 during its price applicability period under the MDPNP are submitted, the platform will be able to identify and discard unneeded data).	Data collected through Beacon for the Products will be proactively limited to the HRSA-approved data elements necessary to support the Rebate Model. Regardless of the method of data submission, the same filtering, security, and privacy protocols described in Appendix I will apply. Beacon employs client-side controls that exclude records associated with non-Product submissions before data is transmitted to the platform. Beacon also applies server-side validation controls to verify that submitted data satisfies applicable eligibility requirements and to prevent the processing of ineligible data. Consistent with these controls, Beacon is designed to limit data collection to information necessary to administer the Rebate Model and process eligible rebate requests.
3. Plan must ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.	Beacon will provide real-time reconciliation reports to inform CEs of rebate status. Reconciliation processes will be transparent to CEs, with rationales and appeal processes for any denials, as well as customer support to resolve inquiries. CEs will be provided with an opportunity to resubmit data if denied for incomplete or missing data elements. To the extent a CE submits a rebate claim in error, the CE must promptly reverse the claim through Beacon. Any resulting reversal credits will be used to offset future 340B rebate payments. Beacon will provide CEs with visibility into claim reversals, credits, and

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	related reconciliation activities, and Beacon's Customer Support Team will be available to respond to inquiries and facilitate resolution of any related issues.
4. Plan must ensure that a quarterly 340B price file for each of the manufacturer's 11-digit NDCs is 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.	Through Beacon, Merck will provide participating CEs with access to a quarterly pricing file containing 340B package-level pricing for Products at the NDC-11 level. The pricing file will be available for download through the Beacon platform.
5. Plan must require the manufacturer to provide HRSA/OPA with periodic reports consistent with the information outlined in this Notice, in a format and manner specified by HRSA/OPA (instructions forthcoming). Such data should detail data on purchases provided through rebates, information related to claim denials, and other information that may evaluate the effectiveness of the rebate model.	Merck will provide HRSA/OPA with periodic reports in the format, manner, and frequency specified by HRSA/OPA, including information regarding rebate transactions, claim denials, and other data necessary to evaluate the effectiveness of the Pilot. Merck is committed to supporting HRSA's evaluation of the Pilot and would welcome the opportunity to work collaboratively with HRSA/OPA to develop reporting metrics and report formats that are most useful to the Agency.

C. Rebates

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1. Plan must include the rebate calculation equal to the wholesale acquisition cost (WAC) less the 340B ceiling price on the day of dispense.	Merck will calculate rebate amounts for validated claims as the WAC less the 340B ceiling price for the NDC-11 on the date of dispense.

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2. Plan must specify that rebates are paid at the unit level.	Merck will pay rebates on validated claims at the unit level.
3. Plan must include details to 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. For example, a covered entity may request a rebate for up to 2 packages of a product dispensed from its neutral inventory on December 16, even though the effective date for the product's participation in the pilot is January 1. The request for such rebates should still be made within 45 days of dispense.	Merck will accommodate up to two unreplenished accumulated packages per NDC-11 during implementation of the Rebate Model for validated dispenses occurring during the 15-calendar-day period preceding the Pilot effective date. Specifically, for units dispensed between December 16, 2026 and December 31, 2026, CEs may submit rebate requests provided that such dispenses have not otherwise been used to obtain 340B pricing through a 340B chargeback or other 340B replenishment mechanism. Rebate requests for these unreplenished accumulated packages may be submitted for up to 45 calendar days from the date of dispense and will be processed in the same manner as other eligible rebate requests submitted through Beacon.
4. Plan must ensure that all rebates are paid to the covered entity (or denied, with documentation to support) within 10 calendar days of completed data 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 be paid to the applicable CE by automated clearing house transfer through Beacon, or denied with supporting documentation, within 10 calendar days of receipt of a complete data submission. If Beacon determines that a submission is incomplete, the CE will be notified of the deficiency and provided an opportunity to submit the missing information. In such cases, the 10-calendar-day period for payment or denial will commence upon receipt of a complete data submission. If a denied claim is subsequently corrected and resubmitted with all required information, Beacon will process the claim and either issue payment or provide a denial with supporting documentation within 10 calendar days of the completed resubmission.
5. Plan must ensure that 340B rebates are not denied based on eligibility or compliance concerns with diversion or	Merck will not deny rebate claims based on eligibility, diversion or Medicaid duplicate discount concerns. Consistent with the purposes of the Pilot, Merck will use covered entity claims data to identify and prevent both 340B/MFP duplication and Medicaid

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Medicaid duplicate discounts, pursuant to section 340B(a)(5)(A) and (B) of the Public Health Service Act and should provide for rationale and specific documentation for reasons claims are denied (e.g., nonduplication of discounts for a selected drug for which the MFP is required under the MDPNP or 340B rebate provided to another covered entity on the same claim). Rebates may not be denied for perceived lack of WAC purchases. If a manufacturer has concerns regarding Medicaid duplicate discounts, diversion, eligibility, or insufficient WAC purchases to support rebate requests, the manufacturer must raise those concerns directly with HRSA/OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution, for addressing such issues. Covered entities are also afforded opportunities to raise concerns with HRSA/OPA if there are issues with rebate denials through reporting tools sent to 340Bpricing@hrsa.gov.	duplicate discounts. Merck would not deny a covered entity’s rebate request upon identification of a duplicate discount. Instead, Merck would take appropriate steps to prevent payment of the duplicative Medicaid rebate. Covered entity data received through the Pilot will not be used, collected, aggregated, shared, or licensed for any purpose beyond the Pilot, by either Merck or Second Sight. For a complete list of Beacon’s validations, please see Appendix II. Merck will evaluate submitted claims for potential duplication with Maximum Fair Price (“MFP”) refund requests using data received by Merck from the Medicare Transaction Facilitator Data Module (“MTF-DM”) under the Inflation Reduction Act Medicare Drug Price Negotiation Program. At this time, Merck intends to address identified MFP-340B duplication through adjustment, offset, or rejection of MFP refund payments, including through use of the MTF credit/debit ledger processes as applicable, in accordance with CMS guidance, and 340B rebates will not be denied or adjusted based on duplication with the MFP. Consistent with Merck’s 340B Program Integrity Initiative (available for review and download on the 340B ESP resources webpage at 340B ESP), which limits access to 340B-priced purchases of Merck products to covered entities that satisfy the requirements of that initiative, eligibility for rebates under this Rebate Model is strictly limited to covered entities and transactions that fully qualify under Merck’s 340B Program Integrity Initiative. Accordingly, Merck will accept rebate requests only for claims associated with purchases that are eligible for 340B pricing under Merck’s 340B Program Integrity Initiative, as such policy may be amended from time to time in accordance with applicable law. Any claim associated with a contract pharmacy arrangement that does not comply with the terms, designation requirements, or data-submission mandates of Merck’s 340B Program Integrity Initiative shall be ineligible for 340B pricing and, consequently, ineligible for rebates under this Rebate Model. Additionally, in situations where multiple CEs submit a rebate request for the same utilization, Merck will honor the first submitted request only. If Merck identifies concerns regarding Medicaid duplicate discounts, diversion, insufficient WAC purchases to support rebate requests, data integrity, or other potential compliance issues, Merck will raise such concerns directly with HRSA/OPA and/or utilize the mechanisms available under section 340B and applicable

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	regulations, including audits and the administrative dispute resolution process, as appropriate.		
6. Plan must ensure that its implementation of the Pilot is limited to using the 340B rebates model 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 (“List”), ⁴¹ regardless of payer, or indication, and only during the selected drug’s effective dates of negotiated prices. 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 MDPNP.	Rebates will be available for all salable, non-expired NDC-11s of Products, regardless of payer. The following NDC-11s are eligible for rebates under the Rebate Model.		
	IPAY Applicability Period	Selected Drug Name	Selected NDC-11s
	2026-2027	JANUVIA 50MG TABLET 100UU 1 UNIT OF USE BOTTLE OF 100	00006-0112-28
	2026-2027	JANUVIA 50MG TABLETS 30UU 1 UNIT OF USE BOTTLE OF 30	00006-0112-31
	2026-2027	JANUVIA 50MG TABLETS 90UU 1 UNIT OF USE BOTTLE OF 90	00006-0112-54
	2026-2027	JANUVIA 25MG TABLET 100UU 1 UNIT OF USE BOTTLE OF 100	00006-0221-28
	2026-2027	JANUVIA 25MG TABLETS 30UU 1 UNIT OF USE BOTTLE OF 30	00006-0221-31
	2026-2027	JANUVIA 25MG TABLETS 90UU 1 UNIT OF USE BOTTLE OF 90	00006-0221-54
	2026-2027	JANUVIA 100MG TAB 100UD 1 UNIT OF DOSE BOTTLE OF 100	00006-0277-28
	2026-2027	JANUVIA 100MG TABLET 30UU 1 UNIT OF USE BOTTLE OF 30	00006-0277-31
	2026-2027	JANUVIA 100MG TABLET 90UU 1 UNIT OF USE BOTTLE OF 90	00006-0277-54
	2026-2027	JANUVIA 100MG TAB 1000UD 1 BOTTLE OF 1000	00006-0277-82
	2027	JANUMET 50/500MG TAB 60CT	00006-0575-61
	2027	JANUMET 50/500MG 180 CT	00006-0575-62
	2027	JANUMET 50/500MG TAB 1000	00006-0575-82
	2027	JANUMET 50/1000MG 60 CT	00006-0577-61
	2027	JANUMET 50/1000MG 180 CT	00006-0577-62
	2027	JANUMET 50/1000MG TAB	00006-0577-82
	2027	JANUMET XR 50/500MG 60	00006-0078-61
	2027	JANUMET XR 50/500MG 180	00006-0078-62
	2027	JANUMET XR 50/500MG 1000	00006-0078-82
	2027	JANUMET XR 50/1000MG 60	00006-0080-61
	2027	JANUMET XR 50/1000MG 180	00006-0080-62
	2027	JANUMET XR 50/1000MG 1000	00006-0080-82
	2027	JANUMET XR 100/1000MG 30	00006-0081-31
	2027	JANUMET XR 100/1000MG 90	00006-0081-54
	2027	JANUMET XR 100/1000MG 1000	00006-0081-82

D. Data

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1. All data requested as part of the Plan should be limited to only the following claim fields: <u>Pharmacy claims data fields</u> Date of Service Date Prescribed Rx number Fill number NDC-11 Quantity Dispensed Prescriber ID Service Provider ID 340B ID Rx BIN Rx PCN <u>Medical claims data fields</u> Date of Service Claim Line Number Claim Number Unit of Measure NDC-11 Quantity Rendering Physician ID Service Provider ID 340B ID Health Plan Name Health Plan ID Health Plan ID Qualifier (if available) • Data definitions for each field must be submitted with the plan for HRSA's approval to ensure consistency and make it available for covered entities. Purchasing data and encounter data requests should not be requested as part of the pilot at this time. • For BIN, PCN, and Health Plan fields for uninsured or	Please see Appendix II for a complete list of the data elements that the Rebate Model will collect, together with the applicable data definitions. Consistent with HRSA's requirements, requested data is limited to approved pharmacy and medical claims data necessary to administer the Rebate Model. No purchasing (invoice-level) data or encounter-level data is collected as part of the Pilot. The Pilot Notice contemplates that to accommodate BIN, PCN, and Health Plan fields for uninsured or cash-paying patients, Rebate Models should accept "CASH" in lieu of insurance-based reimbursement information. However, because BIN represents a numeric field, the Beacon platform will accept "999999" instead of "CASH". As discussed above in response to "Rebates" criteria 4, if Beacon determines that a submission is incomplete, the CE will be notified of the deficiency and provided an opportunity to submit the missing information. Consistent with the Pilot Notice criteria, Beacon will accept submissions for up to 45 calendar days following the date of dispense. Regarding wasted or undispensed units, rebate requests for such units should be submitted as a secondary medical claim, with a separate "Claim Line Number" from the dispensed units. Dispensed and undispensed units associated with the same patient encounter should utilize the same "Claim Number" as defined in Appendix II.

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cash paying patients, please allow the submission in the fields to be marked “CASH”. • Covered entities must be permitted to resubmit data if a rebate request is deemed incomplete or missing data. • Instructions for providing data regarding wasted or undispensed units must be provided as part of the manufacturer’s plan and communicated to covered entities. Covered entity data that is handled by technology platforms and received by manufacturers as a part of this Pilot should not be used for any purpose other than those explicitly identified in this Pilot. This limitation extends to any collecting, aggregating, sharing, or licensing of Pilot data by manufacturers or technology platforms.	

Appendix I: Beacon Functionality Overview

As Provided by Second Sight

Beacon Overview

Beacon is a web-based technology platform that supports the effectuation of a 340B rebate model. Beacon is used to collect 340B claims from 340B covered entities, validate eligibility of submitted data, facilitate payment of 340B rebates to 340B covered entities, and provide real-time access to 340B rebate status to 340B covered entities and pharmaceutical manufacturers. Beacon is also utilized to provide reporting to HRSA. The information provided in this document is applicable to any pharmaceutical manufacturer that selects Beacon for its 340B rebate model effectuation.

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>. To comply with federal law and financial institution requirements, Second Sight requires that new users complete a Know Your Business (KYB) verification process which includes the submission of certain legal documents such as Articles of Incorporation and IRS letter CP 575. Once a new account has been verified, additional users may be given access to the Beacon account by the initial registrant or subsequent assigned administrators.

Users must also submit bank account information for ACH payments which is verified according to financial institution requirements. Verification includes the submission of a bank letter and performance of a standard penny test.

Data Submission

340B covered entities can submit data online through Beacon or via a direct data submission process with participating third-party administrators (TPAs). Data submissions are proactively limited to only those data elements that have been approved by HRSA and 340B covered entities cannot inadvertently submit additional data elements that fall outside the scope of the 340B rebate model pilot. Regardless of whether data is submitted online or through a TPA, the same filtering, security and privacy protocols apply.

Data Filtering

Beacon collects data for only those NDCs for which a 340B rebate model pilot has been approved. For online data submissions, client-side JavaScript functions exclude from data submissions any records that include an NDC that has not been approved for a 340B rebate model pilot by HRSA. Client-side JavaScript functions ensure that the data is filtered prior to submission to Beacon and server-side validations ensure that Beacon is never in possession of the ineligible data. For direct data submissions by a TPA, the filtering process is executed by the TPA utilizing similar client-side technology provided by Second Sight, again ensuring that data filtering occurs prior to submission to Beacon.

Data Security

Beacon is hosted on Microsoft Azure, a premier cloud computing platform known for its reliability, scalability, and security. Beacon is distributed across multiple Azure Availability Zones, each a unique physical location comprising of one or more data centers within an Azure region. By distributing applications across multiple Availability Zones, Beacon can achieve high availability and fault tolerance for its service.

At the core of the Beacon platform is a strong commitment to data security. Second Sight builds and maintains the Beacon systems in alignment with industry-recognized frameworks such as the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) and Open Web Application Security Project (OWASP) best practices. Security is embedded throughout the software development lifecycle—from design and code reviews to deployment and monitoring. Second Sight follows secure coding standards and performs regular threat modeling, vulnerability scanning, and automated testing to ensure a robust security posture.

All data in Beacon is encrypted at rest and in transit using industry-standard protocols supporting the use of Transport Layer Security (TLS) 1.2+ or higher. Beacon services enforce mandatory Multi-Factor Authentication (MFA) to ensure a high level of security for end-users, providing email, SMS, and application-based authentication methods.

Second Sight engages established third-party risk and cybersecurity firms to perform annual internal, external, and web application penetration tests, along with comprehensive security assessments across all platforms and infrastructure.

In addition, Beacon has achieved SOC 1 and SOC 2 certification, demonstrating compliance with rigorous standards for security, availability and confidentiality.

To ensure the security of the Beacon Rebate Model Platform engagement from synthetic traffic, including but not limited to AI agents, bots, or emulated users, is prohibited platform behavior. Specific monitoring devices are in place to detect and stop this behavior to protect platform security for all users.

Data Privacy

Beacon is designed to operate without the use of any protected health information (PHI) as defined by the Health Information Portability and Accountability Act (HIPAA). Second Sight has received an expert determination from Dr. Brad Malin that the data collected through Beacon meets the definition of a De-Identified Dataset under HIPAA. As described in Dr. Malin's expert determination, the de-identification process occurs prior to the submission of data to Beacon. Furthermore, Second Sight does not reidentify this data and personnel with access to identifiable data do not also have access to de-identified data. De-identified datasets can be linked to other de-identified datasets but, as discussed in Dr. Malin's expert determination, this does not constitute a reidentification of data and no PHI is exposed through this linking process. Second Sight has utilized this deidentification process with 340B claims data submitted through 340B ESP since 2020 and has successfully ensured that no HIPAA violations have occurred.

Beacon also collects personally identifiable information (PII) including user's names and email addresses. This information is stored securely, and Second Sight complies with all applicable privacy laws. Additional information on how we collect, maintain and use PII is available in our Privacy Policy.

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 detail 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.

Finally, Second Sight has communicated its willingness and has already begun to integrate directly with TPAs to simplify the reconciliation process. Second Sight will not charge TPAs for this integration service though 340B covered entities will have to approve any integrations with TPAs for their specific data.

Beacon Customer Support

Beacon's customer support team is trained to engage with 340B covered entities and address questions or concerns arising from their use of Beacon for 340B rebate payments. Support topics may range from technical (How do I use Beacon?) to policy (Why was my 340B rebate determined to be ineligible?) to financial (Was my 340B rebate payment made?) in nature. Beacon will work in coordination with manufacturers to provide accurate and timely responses. Customer support information is provided proactively through online resources, pre-recorded training webinars and live training sessions as well as reactively through responses to inbound calls, emails, and chats. For additional information, please visit <https://cm.beaonchannelmanagement.com/pages/support-center>.

Beacon is committed to responding to 340B covered entity inquiries within 24 hours of receipt and the Beacon customer support team will work to resolve inquiries as quickly as possible. As Beacon interacts with Covered Entities, the Customer Support Team may request additional information from the entity in order to properly understand and evaluate the concern. Data on 340B covered entity inquiries is analyzed to identify themes and trends and may result in process or technology updates intended to address common questions raised by 340B covered entities.

Appendix II: Data Submission Field Definitions and Validations

As Provided by Second Sight

Pharmacy Claims Data Field Definitions

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

Medical Claims Data Field Definitions

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

Pharmacy Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted
Registered User	Submission must be for 340B ID registered to User
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPPES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing guidelines, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Prescriber ID - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID - Active	Prescriber ID must be active in the NPI registry at Date of Service.
Network Eligibility	Service Provider ID must be included in the dispensed drug's Limited Distribution Network, if applicable to the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Rx Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.

Medical Claim Validations

Validation	Description
<i>Front End Validations</i>	
Ineligible Product	NDC submitted must be subject to manufacturer policy.
Invalid [Field]	Entry must meet field requirements, e.g., NPI must be 10 digits.
Policy Exception	If an entity has a policy exception and is not eligible for rebates via Beacon, no submissions will be accepted where entity has been exempted
Registered User	Submission must be for 340B ID registered to User
<i>Back End Validations</i>	
Claim Expired	Claim submission date must be within X days after the Date of Service where X is determined by manufacturer policy.
Pharmacy Eligibility	The Service Provider ID must meet the following conditions as of the Date of Service: 1. Active and included within the NCPDP and NPDES databases, 2. A valid Covered Entity site, shipping address, or contract pharmacy according to HRSA OPA enrollment data, or 3. Eligible to dispense 340B-priced drugs according to the manufacturer's contract pharmacy policy.
Prescriber ID - Provider	Prescriber ID must be in the NPI registry as a provider.
Prescriber ID - Active	Prescriber ID must be active in the NPI registry at Date of Service.
CE Eligibility - Date	Covered Entity is active in HRSA OPAIS at Date of Service.
CE Eligibility - Orphan Drug	If an NDC is identified as an orphan drug, and the manufacturer does not voluntarily offer 340B pricing for certain hospital types (e.g., SCH, CAN, CAH, RRC), claims from these hospital types will not be accepted.
Aberrant Quantity	Quantity submitted must align with standard dispensing practices, consistent with manufacturer commercial business practices. Aberrant Ceiling: Claim quantity cannot be equal to or greater than the maximum aberrant quantity for the NDC. Aberrant Partial: Claim quantity cannot be a partial number listed for the NDC, e.g. Per NDC, the submitted quantities must be multiples of expected quantities.
NDC Expiration	Claim Date of Service must be prior to the final product expiration date for the NDC.
Pre-Policy Claim	Claim must have Date of Service on or after policy start, exempting specifically permitted pre-policy claims.
Duplicate - One Entity	Duplicate check is performed on distinct claim fields against past conforming claims submitted to the platform by that covered entity. Distinct claim: Date of Service, Service Provider ID, NDC, Claim Number.
Duplicate - Multiple Entities	When the same claim is submitted by multiple covered entities, the first conforming claim submitted in Beacon will be considered valid. Subsequent submissions will be considered invalid.