



November 22, 2024

Dear Covered Entity:

Sanofi is updating its policy related to its 340B Integrity Initiative and the method through which Sanofi effectuates the 340B ceiling price for certain Covered Entities. As described in detail below and as part of Sanofi's 340B Integrity Initiative, Sanofi will be adopting a new model for 340B ceiling price effectuation (the "Credit Model"). Sanofi will continue to offer the 340B price to all covered entities, but for the covered entities listed below, Sanofi will effectuate the 340B price through a credit paid to the covered entities. In addition, for hospital covered entities, Sanofi will effectuate the 340B price when they dispense the drugs to their patients, as defined by HRSA's guidance, but not when the drugs are dispensed to others.

The 340B Drug Pricing Program today bears little resemblance to the safety net program established by Congress over 30 years ago. The 340B Program is now the nation's second largest federal prescription drug program with more than \$66 billion in annual sales at discounted prices.¹

340B's unchecked growth has not come with any meaningful increase in patient benefit. Government reports have found that most patients receive no discount on drugs dispensed by 340B covered entities.² And a recent analysis showed that patients receive a portion of 340B discount in only 1.4% of 340B contract pharmacy claims.³ 340B's financial incentives also skew prescribing decisions and increase patient out-of-pocket costs. According to multiple analyses, patients of 340B hospitals receive more drugs and more expensive drugs than patients of non-340B hospitals.⁴

Over the past few years Sanofi took multiple steps to address prohibited duplicate discounts and diversion in the 340B Program. But this waste and abuse has unfortunately persisted, in part because of the current model of 340B. Today, the various transactions and data points that establish 340B eligibility and effectuate the 340B price are disconnected from one another. That disconnect generates opacity, a primary driver of 340B waste and abuse.

¹ HRSA, "2022 Covered Entity Purchases," (September 2023), <https://www.hrsa.gov/opa/updates/2022-340b-covered-entity-purchases>.

² GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 30 (June 2018), <https://www.gao.gov/products/GAO-18-480>.

³ IQVIA, Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?, (September 27, 2022), <https://www.iqvia.com/locations/united-states/library/white-papers/are-discounts-in-the-340b-drug-discount-program>.

⁴ GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-422, at 2 (June, 2015), <https://www.gao.gov/products/gao-15-422>; Milliman, Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals (September, 2022), https://www.milliman.com/-/media/milliman/pdfs/2022-articles/9-13-22_phrma-340b-commercial-analysis.ashx.



Sanofi is implementing the 340B Credit Model to rein in the 340B waste and abuse we see today. Sanofi's 340B Credit Model will, for the first time, link the relevant data elements and transactions for every 340B dispense. This innovation will bring transparency to 340B. It will identify potential duplicate discounts and prevent instances of illegal diversion.

Sanofi's 340B Integrity Initiative, including the Credit Model, applies to the following covered entities:

- Hospital Covered Entities:
 - Critical Access Hospitals (CAH)
 - Disproportionate Share Hospitals (DSH)
 - Rural Referral Centers (RRC)
 - Sole Community Hospitals (SCH)
- Consolidated Health Centers (CH)

All covered entity types not listed are excluded from this initiative.

The 340B Integrity Initiative applies only to the products listed in Attachment A (the "Products").

Sanofi's Contract Pharmacy Policy is located in Attachment B.

State-specific policy information is located in Attachment C.

Sanofi's Contract Pharmacy Anti-Diversion Policy is located in Attachment D.

The requested data elements for the 340B Credit Model are located in Attachment E.

The 340B Credit Model

Sanofi will continue to offer the 340B price to all covered entities, but Sanofi will now effectuate the 340B price through a 340B Credit for certain covered entities.

Sanofi's Credit Model will be operationalized using the Beacon platform. Detailed instructions on covered entity registration, data submission, and other pertinent information regarding Beacon are available on the Beacon website at www.beaconchannelmanagement.com. Sanofi encourages covered entities to register an account on Beacon as soon as possible.

Under the Credit Model, the 340B ceiling price will be effectuated through a credit paid directly to the covered entity using the following 3-step process:

Step 1: The covered entity places an order for a Product through their wholesaler at the Product's Wholesale Acquisition Cost (WAC).

Step 2: The Product is dispensed to a patient of the covered entity.



Step 3: The covered entity submits purchase and claims data to Beacon for 340B eligible dispenses. Beacon confirms 340B eligibility and issues a credit payment to the covered entity representing the difference between the WAC and 340B price.

Covered entities will not be required to carry the cost of purchasing a Product at WAC as part of Sanofi's Credit Model. The Credit Model is designed to ensure that Sanofi will pay the 340B Credit within 30 days of a covered entity's WAC order — and thus before the wholesaler's bill becomes due under commercially prevalent terms — when the covered entity submits data within 22 days of the WAC order. As a result, a covered entity that promptly submits data should never carry the cost of the full WAC because it will receive a credit for the difference between the WAC and 340B price before it must pay the wholesaler at the WAC.

Credit Model Effective Dates

This update will go into effect on the dates listed below. As of the dates listed below, 340B pricing will no longer be available through wholesalers for the applicable covered entity types for the products listed on Attachment A. The 340B price will instead be available through a credit from Beacon.

- January 6, 2025 – CAH, DSH, RRC, SCH
- March 1, 2025 – CH

Claim Submission, Validation, and 340B Credit Payment Process

Within 30 days of the dispense of a Product, the covered entity must submit a claim for a 340B Credit from Sanofi by submitting the applicable data elements listed in Attachment E to the Beacon platform. These data elements consist of standard purchase and claims data that covered entities and their Third-Party Administrators ("TPAs") already collect, maintain, and use to establish 340B eligibility or submit to insurers for reimbursement in the ordinary course of business.

Through Beacon, Sanofi will review the data submitted and validate that a claim is eligible for a 340B Credit. Claims will be eligible for a 340B Credit if 1) the drug was ordered by a covered entity at WAC; 2) the drug was dispensed or administered at a covered entity location, in-house pharmacy, or contract pharmacy consistent with Sanofi's Contract Pharmacy Policy; 3) for Hospital Covered Entities, the drug was dispensed to a patient of the Covered Entity; and 4) the requested claims data was submitted within 30 days of the drug's dispense. Through the Beacon platform, Sanofi will validate claims on a rolling basis, as they are submitted.

To maintain consistency with current covered entity operations, 340B Credit payments will be calculated and paid at the NDC-11 level. The 340B Credit will equal the difference between (i) WAC and (ii) the 340B ceiling price of the Product.

For Hospital Covered Entities (CAH, DSH, RRC, SCH), payment for a 340B Credit will be transmitted within 7 days after the covered entity submits data sufficient to trigger a full package accumulation, which, for Products with single-unit package sizes, will be a single validated 340B dispense.



For CHs, Sanofi will presumptively transmit a 340B Credit upon submission and validation of only the Purchase Data Elements listed in Attachment E. Sanofi encourages CHs to submit Purchase Data Elements immediately upon placing an order at WAC with their wholesaler to receive the 340B Credit as soon as possible. CHs must still submit all remaining applicable data elements within 30 days of the drug's dispense. Sanofi will validate both the Purchase and Pharmacy or Medical Claim Data Elements, and 340B Credit payments will only be applied to valid data submissions. Credits presumptively transmitted on a claim that is not validated will be applied to subsequent claims for 340B Credits.

Sanofi encourages covered entities to submit data as quickly as possible to ensure faster payment of 340B Credits.

Payment details will be available on the Beacon platform, permitting covered entities to reconcile and verify 340B Credits claimed, validated, and paid.

Sanofi will continue to work together with covered entities in good faith, as it has always done, in the event a covered entity notifies the company that it should have received a 340B Credit in a particular case.

340B Patient Definition

This section is effective March 1, 2025, and shall apply to Hospital Covered Entities only. This section does not apply to CHs.

As part of the 340B claim submission for pharmacy claims, Hospital Covered Entities are required to append healthcare encounter data that establishes that the submitted claim is for a prescription dispensed to the covered entity's patient. The healthcare encounter data elements are listed in Attachment E.

Sanofi shall utilize the appended healthcare encounter data to validate that the patient to whom the drug was dispensed for the specific 340B pharmacy claim is a patient of the covered entity, as set forth in HRSA's 1996 guidance available at 61 Fed. Reg. 55156. HRSA's 1996 guidance states that:

An individual is a patient of the covered entity if:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.



An individual will not be considered a “patient” of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

To operationalize HRSA’s 1996 patient definition, Sanofi will use healthcare encounter data to determine if the individual receiving a dispense (1) is currently receiving medical care from the covered entity, and (2) receives the prescription in connection with health care services provided by the covered entity.

Sanofi will presume that a person who has received healthcare services from the covered entity within 24 months of the prescription being dispensed is currently receiving medical care from the covered entity; under this approach, a person who has not received healthcare services from the covered entity within that period of time is presumptively not a patient of that entity.

Sanofi will also presume that a prescription written by a health care professional who is employed by or similarly affiliated with the covered entity is being provided in connection with health care services provided by the covered entity. For prescriptions that arise from a referral following a patient encounter at the covered entity, where the prescriber is not employed by or similarly affiliated with the covered entity, Sanofi will analyze the data submitted to determine if the prescription relates to the health care services provided by the covered entity to the patient.

For prescriptions dispensed to individuals who do not satisfy HRSA’s patient definition, Sanofi will decline a 340B Credit to avoid statutorily prohibited diversion of 340B drugs. In the event of such a denial, a covered entity will have an opportunity to submit additional or alternative data for the same claim in order to demonstrate that the individual was the covered entity’s patient.

FREQUENTLY ASKED QUESTIONS

Q: What types of covered entities are NOT included in Sanofi’s 340B Integrity Initiative?

A: Sanofi’s 340B Integrity Initiative does not include the following categories of covered entities.

- Children’s Hospitals
- Free Standing Cancer Hospitals
- Hemophilia Treatment Centers
- Ryan White Clinics
- Tribal / Urban Indian Health Centers
- Federally Qualified Health Center Look-Alikes
- Sexually Transmitted Diseases Clinics
- Family Planning Clinics
- Tuberculosis Clinics
- Native Hawaiian Health Centers



Q: Will I continue to have access to 340B pricing through my wholesaler?

A: Upon the applicable Credit Model effective date, 340B pricing for Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) will no longer be available through wholesalers for in-scope products included in Attachment A. 340B covered entities will initially place an order for these products at WAC from their wholesaler and then the 340B ceiling price will be effectuated for that order through a 340B Credit payment.

Q: Does Sanofi's policy apply to all 340B utilization or just contract pharmacies?

A: Sanofi's policy applies to all 340B utilization for the covered entities described above, inclusive of utilization at in-house retail pharmacies and contract pharmacies, as well as utilization administered to eligible 340B patients in an outpatient setting.

Q: Can my wholly owned contract pharmacy receive 340B Credits?

A: Contract pharmacies that are wholly owned by the covered entity or have common ownership with the entity are subject to Sanofi's 340B Integrity Initiative, including Sanofi's Contract Pharmacy Policy.

Q: How do I designate a contract pharmacy?

A: The designation process is administered through 340B ESP™ which can be accessed at <https://www.340besp.com/>. The 340B ESP™ platform is currently the only method for a covered entity to designate a contract pharmacy location under Sanofi's policy. Please note that a contract pharmacy must have an assigned HIN for the wholesaler to process 340B transactions for Sanofi drug products. Covered entities may change their designated contract pharmacy twelve months after a designation occurs. Contract pharmacy designations can take up to 10 business days to process.

Q: I have already designated a contract pharmacy. Do I need to re-designate my contract pharmacy?

A: Covered entities that currently have a designation in place through 340B ESP™ do not need to re-designate.

Q: Does Sanofi's Integrity Initiative apply to all Sanofi products?

A: No, Sanofi's 340B Integrity Initiative only applies to the Sanofi products listed in Attachment A.

Q: Is Sanofi requiring data for my designated contract pharmacy if my covered entity does not have an in-house pharmacy?

A: Data is required for a designated contract pharmacy. Please see Attachment E for the required data elements.

Q: What are the requirements for submitting data?



A: Data must be submitted within 30 days of the claim's date of dispense or administration. If a claim is submitted more than 30 days after the claim's date of dispense or administration, the applicable drug dispense or administration will not be eligible for a 340B Credit. Sanofi will work in good faith with covered entities if they believe they were incorrectly denied a 340B Credit.

Q: Who can submit data to Beacon on behalf of a covered entity?

A: Beacon account administrators may submit data on behalf of a covered entity or may grant access to other covered entity employees or contractors to submit data via Beacon. Currently, TPAs are not able to submit data to Beacon via an API or other direct data submission method on behalf of a covered entity. Sanofi anticipates that Beacon will support direct submissions from TPAs in early 2025 and additional information will be made available to 340B covered entities as this functionality becomes available.

Q: How frequently should a covered entity submit data to Beacon?

A: There is no limitation on how frequently data may be submitted. Sanofi encourages covered entities to submit data as frequently and as early as practicable. Covered entities should endeavor to submit Purchase Data Elements immediately after placing a WAC order with their wholesaler. Covered entities should submit all other applicable data elements immediately following a 340B eligible dispense or administration of a Product.

Q: How will Sanofi use the data that covered entities provide through Beacon?

A: Data uploaded by covered entities will be used to confirm 340B eligibility of the dispense, and to identify and resolve duplicate Medicaid and commercial rebates. The Beacon platform will validate that:

- 1) the drug was ordered by a covered entity at WAC;
- 2) the drug was dispensed or administered at a covered entity location, in-house pharmacy, or contract pharmacy consistent with Sanofi's Contract Pharmacy Policy;
- 3) for Hospital Covered Entities, the drug was dispensed to a patient of the Covered Entity; and
- 4) the requested claims data was submitted within 30 days of the drug's dispense.

Through the Beacon platform, Sanofi will validate claims on a rolling basis, as they are submitted.

Q: How are claim reversals submitted and processed in Beacon?

A: Submission of a claim to Beacon is a request for payment of a 340B Credit, and 340B covered entities should only submit final claims. In the event that a previously submitted and validated claim must be reversed, the covered entity should submit the same claim detail with a negative unit amount. Claims associated with purchases for which no 340B Credit has been paid will be disassociated with the purchase. If the 340B credit has already been paid, a future 340B claim submission will replace the reversed claim.



Q. Can a covered entity dispute a claim submission that is not validated in Beacon?

A: Yes. Many aspects of the 340B eligibility and claims validation processes can be disputed by a 340B covered entity within the Beacon platform. Disputes are initiated in Beacon and may require the submission of additional documentation. Additional information on the dispute process is available in the Beacon Support Center.

Q. Is the Credit Model compatible with central fill pharmacy systems?

A: Yes. Sanofi recognizes that many covered entities operate a central fill pharmacy in which their drug purchases are shipped to a centralized pharmacy location but dispensed or administered through numerous locations operated by the 340B covered entity. The Credit Model supports this. Eligible claim submissions dispensed or administered at a location registered with HRSA as a parent or child site or shipping address of a parent or child site will be associated with any purchase shipped to a location registered with HRSA as a parent or child site or shipping address of a parent or child site.

Q: What is the amount of the 340B Credit payment?

A: The 340B Credit payment will always equal the difference between the (1) WAC and (2) the 340B ceiling price of the Product at the time the product was initially purchased as indicated in the Purchase Data Elements.

Q: Will 340B Credits be paid on an individual dispense of Products?

A: 340B Credits are calculated and paid on NDC-11 packages of Products to maintain consistency with how 340B pricing is effectuated today. Once the number of eligible 340B dispenses accumulated in Beacon equals the NDC-11 package size of Product, a 340B Credit will be paid. For Products with single-unit package sizes, a 340B Credit will be paid after a single validated 340B dispense.

Q: When will 340B Credits be paid?

A: The Credit Model is designed to ensure that Sanofi will pay the 340B Credit within 30 days of a covered entity's WAC order — and thus before the wholesaler's bill becomes due under commercially prevalent terms — when the covered entity submits data within 22 days of the WAC order. A 340B Credit payment will be transmitted within 7 days after a full package accumulation of 340B eligible dispenses for a given Product which, for Products with single-unit package sizes, will be after a single validated 340B dispense. Beacon validates claims for 340B Credits on a rolling basis. Sanofi encourages covered entities to submit data frequently and promptly to ensure timely payment of 340B Credits.

For CHs, Sanofi will presumptively transmit a 340B Credit upon submission and validation of only the Purchase Data Elements listed in Attachment E. CHs must still submit all remaining applicable data elements within 30 days of the drug's dispense.

Q: How should covered entities identify dispenses that are eligible for a 340B Credit?



A: Covered entities should continue to rely on their standard business practices, consistent with the 340B Statute and HRSA guidance, to identify dispenses eligible for a 340B Credit.

Q: Who can I contact if I need assistance?

A: Beacon's Support Center, available at www.beaconchannelmanagement.com, provides a variety of resources, including webinars, recorded platform demonstrations, and FAQ documents. 340B covered entities can also register to participate in live webinars and information on how Beacon protects financial and healthcare related information is available online in the Trust Center. Technical, data submission, registration, or contract pharmacy designation questions should be direct to the Beacon support team at support@beaconchannelmanagement.com or 1.878.788.8907. For other issues, customers can email Sanofi340BOperations@Sanofi.com.



ATTACHMENT A

Admelog™

Ambien™

Apidra™

Arava™

Avalide™

Avapro™

Doxercalciferol™

Dupixent™

Enoxaparin Sodium™

Flomax™

Insulin Glargine™

Ibesartan™

Kevzara™

Lantus™

Leflunomide™

Lovenox™

Multaq™

Plavix™

Priftin™

Primaquine™

Renvela™

Sevelamer™

Soliqua™

Toujeo™

Zolpidem™



ATTACHMENT B Contract Pharmacy Policy

Sanofi's Contract Pharmacy Policy remains in effect. As of the effective dates noted below, Sanofi's Contract Pharmacy Policy will be effectuated through the Beacon platform.

For Hospital Covered Entities effective January 6, 2025, the Contract Pharmacy Policy is as follows:

- Covered entities without an in-house retail pharmacy may designate a single contract pharmacy location at which to receive access to 340B pricing.
- Covered entities designating a single contract pharmacy must submit the requested data elements listed in Attachment E to access 340B pricing at their designated contract pharmacy.

For CHs effective March 1, 2025, the Contract Pharmacy Policy is as follows:

- CH covered entities may designate up to 3 contract pharmacy locations at which to receive access to 340B pricing.
- Covered entities designating contract pharmacies must submit the requested data elements listed in Attachment E through the Beacon platform to access 340B pricing at their designated contract pharmacies.

All data must be submitted through the Beacon platform. All contract pharmacy designations must be made in the 340B ESP™ platform, at <https://www.340besp.com/>. If the covered entity has already designated their contract pharmacy or pharmacies on the 340B ESP™ platform, no further action is required to be take on the 340B ESP™ platform.

Sanofi considers all sites together as one covered entity for purposes of Sanofi's 340B Integrity Initiative, inclusive of the covered entity's Parent Site, Child Sites, and Associated Sites⁵.

Contract pharmacies that are wholly owned by or have common ownership with the covered entity are subject to this Contract Pharmacy Policy.

State-specific policy information is located in Attachment C.

⁵ <https://www.hrsa.gov/about/faqs/what-associated-site-community-health-centers-federally-qualified-health-centers-fqhcs>



ATTACHMENT C STATE POLICIES

- Arkansas:** Arkansas-based pharmacies with which the covered entity has a contract pharmacy relationship are exempt from Sanofi's Contract Pharmacy Policy. Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) utilizing contract pharmacies in Arkansas must timely submit the applicable data elements listed in Attachment E to receive 340B Credits on drugs dispensed from those contract pharmacies. Hospital Covered Entities are also subject to the Sanofi Contract Pharmacy Anti-Diversion Policy. Please see Attachment D for additional information.
- Kansas:** Kansas-based pharmacies with which the covered entity has a contract pharmacy relationship are exempt from Sanofi's Contract Pharmacy Policy. Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) utilizing contract pharmacies in Kansas must timely submit the applicable data elements listed in Attachment E to receive 340B Credits on drugs dispensed from those contract pharmacies.
- Maryland:** Maryland-based pharmacies with which the covered entity has a contract pharmacy relationship are exempt from Sanofi's Contract Pharmacy Policy. Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) utilizing contract pharmacies in Maryland must timely submit the applicable data elements listed in Attachment E to receive 340B Credits on drugs dispensed from those contract pharmacies.
- Mississippi:** Mississippi-based pharmacies with which the covered entity has a contract pharmacy relationship are exempt from Sanofi's Contract Pharmacy Policy. Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) utilizing contract pharmacies in Mississippi must timely submit the applicable data elements listed in Attachment E to receive 340B Credits on drugs dispensed from those contract pharmacies.
- Missouri:** Missouri-based pharmacies with which the covered entity has a contract pharmacy relationship are exempt from Sanofi's Contract Pharmacy Policy. Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) utilizing contract pharmacies in Missouri must timely submit the applicable data elements listed in Attachment E to receive 340B Credits on drugs dispensed from those contract pharmacies.
- West Virginia:** West Virginia Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) must submit the Purchase Data Elements listed in Attachment E to receive 340B Credits from Sanofi. No claims data or utilization data is required to be submitted for payment of the 340B Credits.
- West Virginia-based pharmacies with which the covered entity has a contract pharmacy relationship are exempt from Sanofi's Contract Pharmacy Policy. Hospital Covered Entities (CAH, DSH, RRC and SCH) and Consolidated Health Centers (CH) utilizing contract pharmacies in West Virginia must submit the Purchase Data Elements listed in Attachment E to receive 340B Credits on drugs dispensed from those contract pharmacies.



ATTACHMENT D

Sanofi Contract Pharmacy Anti-Diversion Policy

This policy applies to contract pharmacy arrangements between hospital covered entity types (CAH, DSH, RRC and SCH) and pharmacies located in the following states:

- Arkansas: Effective 9/23/2024

As detailed in Attachment C, Sanofi has modified its 340B policies in certain states. Sanofi remains committed to 340B program integrity, including the avoidance of federally prohibited drug diversion.

To further that objective, Sanofi has adopted a Contract Pharmacy Anti-Diversion Policy. Under this policy, Sanofi will continue to offer 340B-priced drugs to covered entities consistent with Attachment C. However, Sanofi's offer includes a new term: a covered entity must provide evidence or, alternatively, attestation that it retains legal title to Sanofi 340B-priced drugs delivered to its contract pharmacies until the contract pharmacies dispense those drugs to 340B-eligible patients, consistent with federal law. "Sanofi 340B-priced drugs" shall refer to those drugs listed in Attachment A to this document. This term applies only with regard to contract pharmacies located in the state(s) listed above.

Covered entities will have 30 days from the effective date(s) noted above to log into the 340B ESP™ platform and complete the Contract Pharmacy Anti-Diversion process located on the righthand side of the 340B ESP™ Entity Profile. Covered entities must complete this process for every contract pharmacy located within the state(s) listed above at which the covered entity seeks to retain or obtain 340B pricing from Sanofi. Covered entities will lose access to 340B pricing at contract pharmacies located within the state(s) listed above for which the covered entity does not complete the Contract Pharmacy Anti-Diversion process. Covered entities may return to the Contract Pharmacy Anti-Diversion process at any time to add or remove contract pharmacies at which the covered entity seeks to have Sanofi 340B-priced drugs delivered.

For covered entities that previously completed the Contract Pharmacy Anti-Diversion process on 340B ESP™, no further action is required.

Covered entities that have designated a single contract pharmacy location at which to receive access to 340B pricing in any of the states listed above will have that contract pharmacy designation terminated 30 days from the applicable effective date.

Covered entities that have designated a single contract pharmacy location at which to receive access to 340B pricing in a state not listed above and subsequently secure access to 340B pricing at a contract pharmacy under this Contract Pharmacy Anti-Diversion Policy will have their single contract pharmacy designation canceled.

Proof of Title Requirements

Covered entities may secure access to Sanofi 340B-priced drugs at contract pharmacies located within the state(s) listed above only through the Contract Pharmacy Anti-Diversion process on the 340B ESP™ platform. Sanofi permits covered entities to submit one of two forms of proof of title for each contract pharmacy at which the covered entity seeks access to 340B pricing.

1. Contract Pharmacy Agreement



Covered entities may secure access to 340B pricing at contract pharmacies located within the state(s) listed above by submitting the applicable contract pharmacy agreement(s) demonstrating they retain title to Sanofi 340B-priced drugs until the contract pharmacy dispenses those drugs to 340B-eligible patients.

The agreement must be true, correct, and currently in effect.

The contract pharmacy shipping address must be stated in the agreement.

The agreement must state or otherwise demonstrate by its express terms that the covered entity retains legal title to Sanofi 340B-priced drugs at the contract pharmacy until those drugs are dispensed to 340B-eligible patients.

If the covered entity believes that any part of the contract pharmacy agreement is confidential, the covered entity may redact those confidential portions of the agreement. However, the covered entity must provide the relevant provisions evidencing legal title unredacted.

Sanofi will review and approve or deny any submitted contract pharmacy agreement in a timely manner.

2. Proof of Title Attestation

Covered entities may also secure access to 340B pricing at contract pharmacies located within the state(s) listed above by signing the Contract Pharmacy Anti-Diversion Attestation for those contract pharmacies at which the covered entity retains legal title to Sanofi 340B-priced drugs until such drugs are dispensed to 340B-eligible patients. Please note that the Contract Pharmacy Anti-Diversion Attestation is declared under penalty of perjury, pursuant to 28 U.S.C. § 1746.

Sanofi will review and approve or deny any submitted attestations in a timely manner.



ATTACHMENT E Required Data Elements

The tables below list the specific data elements collected as part of the purchase and 340B claim submissions process for the Credit Model. Submission template files with details on data validations are available in the Support Center at www.beaconchannelmanagement.com.

Purchase Data Elements

Field Name	Description
Invoice Date	Date the purchase was invoiced to the covered entity
Invoice Number	Wholesaler assigned invoice number for the purchase order
NDC-11	National Drug Code of the product that was purchased by the covered entity
Package Units	Number of packages of the product ordered
Purchase Account Number	Wholesaler assigned account number used to place the order
Wholesaler Name	Name of the wholesaler that processed the invoice and shipped the purchase
340B ID	HRSA assigned identifier of the 340B covered entity that made the purchase
Ship To Pharmacy ID (NPI)	NPI of the pharmacy that received the physical shipment of the product from the wholesaler

Pharmacy Claim Data Elements

Field Name	Description
Date Of Service	Date the prescription was filled at the pharmacy. Sometimes referred to as the Fill Date.
Date Prescribed	Date the physician wrote the prescription. Always comes on or before the Date of Service.
Rx Number	Identifier applied to the prescription by the pharmacy.
Fill Number	Indicates the number of times the prescription has been filled as of the current fill. For example, a value of 2 indicates that the prescription has been filled twice and the current fill is the second one.
NDC-11	National Drug Code which is a unique identifier of the drug dispensed to the patient.
Quantity	Number of units dispensed to the patient.
Prescriber ID	National provider identifier (NPI) of the physician that wrote the prescription.
Service Provider ID	NPI of the pharmacy that filled the prescription



340B ID	HRSA assigned identifier of the 340B covered entity that designated the prescription as 340B
BIN Number	Bank identification number of the primary payer on the claim
PCN Number	Processor control number assigned by the entity processing payment

Medical Claim Data Elements

Field Name	Description
Health Plan ID	ID assigned to identify the plan.
Health Plan	The name of the plan.
Service Provider ID	ID assigned to a pharmacy or provider.
NDC-11	ID of the product dispensed or service provided.
Quantity	Total quantity being submitted.
Date of Service	Identifies date the prescription was filled or professional service rendered.
Physician ID	ID assigned to the prescriber.
Claim Number	A unique identifier for a prescription and claim processor
340B ID	Code specifying the 340B covered entity

Healthcare Encounter Data Elements

These data elements are applicable to Hospital Covered Entities only. CHs are not required to submit these data elements.

Field Name	Description
Billing Service Provider ID	ID assigned to the entity billing for the healthcare services provided to the patient.
Date of Service	Identifies date the prescription was filled or professional service rendered.
Rendering Physician ID	ID assigned to the healthcare professional providing the healthcare services to the patient.
HCPCS Code	HCPCS Level II code set value assigned to the healthcare service provided to the patient.
Diagnosis Code	ICD-10 code indicating medical conditions evaluated as part of the healthcare encounter.
Place of Service Code	Code identifying the place where a product or service is administered.