



June 5, 2024

Dear Covered Entity:

Sanofi is updating its policy related to our 340B integrity initiative effective July 1, 2024.

Sanofi supports the 340B Drug Pricing Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to strengthening the 340B Program's mission. Since Sanofi's prior update to its 340B Integrity Initiative on May 15, 2023, Sanofi has encountered multiple issues, including duplicate Medicaid discounts, exploitation of an unintended bypass to the Integrity Initiative, and misrepresentations by covered entities regarding their lack of in-house pharmacies.

Sanofi is implementing changes to its 340B Integrity Initiative for the following covered entity types:

- 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.

Effective July 1, 2024, the policy for the four hospital types (CAH, DSH, RRC and SCH) is as follows:

- Covered entities will continue to be able to purchase Sanofi products at the 340B ceiling price when shipped to an in-house retail pharmacy at an address registered on the 340B covered entity database as a parent or child site. These entities will not be able to place 340B orders at any contract pharmacies.
- Covered entities without an in-house retail pharmacy may designate a single contract pharmacy location through the 340B ESP™ platform at which to receive access to 340B pricing. **Covered entities designating a single contract pharmacy must submit claims data through the 340B ESP™ platform to access 340B pricing at their designated contract pharmacy.** Covered entities that currently have a designation in place through 340B ESP™ do not need to re-designate, but must begin submitting claims data to retain access to 340B pricing at their designated contract pharmacy.



- Contract pharmacies that are wholly owned by the covered entity (or have common ownership with the covered entity) will not be able to access 340B pricing unless: (i) the covered entity lacks an in-house pharmacy, (ii) the wholly owned pharmacy is designated as the single contract pharmacy through the 340B ESP™ platform, and (iii) claims data for this designated contract pharmacy are submitted through the 340B ESP™ platform.

Effective July 1, 2024, the policy for covered entities within the Consolidated Health Center Program (CH) is as follows:

- Covered entities will continue to be able to purchase Sanofi products at the 340B ceiling price when shipped to an in-house retail pharmacy at an address registered on the 340B covered entity database as a parent or child site. These covered entities will not be able to place 340B orders at any contract pharmacies.
- Covered entities without an in-house retail pharmacy may designate a single contract pharmacy location through the 340B ESP™ platform at which to receive 340B pricing. Covered entities are not required to submit claims data to access 340B pricing at their designated contract pharmacy. **Covered entities that currently have a designation in place through 340B ESP™ must re-designate their one contract pharmacy to continue receiving access to 340B pricing at that contract pharmacy.**
- Contract pharmacies that are wholly owned by the covered entity (or have common ownership with the covered entity) will not be able to access 340B pricing unless (i) the covered entity lacks an in-house pharmacy, and (ii) the wholly owned pharmacy is designated as the single contract pharmacy through the 340B ESP™ platform. Covered entities are not required to submit claims data to access 340B pricing at their designated contract pharmacy.

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 Sites¹.

Sanofi's 340B Integrity Initiative only applies to the Sanofi products listed in Attachment A.

State-specific policy information can be found in Attachment B.

We look forward to working collaboratively with you to further strengthen the 340B program.

¹ <https://www.hrsa.gov/about/faqs/what-associated-site-community-health-centers-federally-qualified-health-centers-fqhcs>



FREQUENTLY ASKED QUESTIONS

Q: What types of covered entities are NOT included in Sanofi's integrity initiative?

A: Our integrity initiative does not include the following categories of covered entities. The below covered entities do not have any conditions for accessing 340B pricing for Sanofi products.

- 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: Is Sanofi requesting data for pharmacies that are registered with HRSA as an in-house pharmacy of the covered entity?

A: No. Covered entities do not need to provide 340B claims for prescriptions filled at in-house pharmacies.

Q: Can my wholly owned contract pharmacy access 340B pricing?

A: For covered entities that fall within Sanofi's Integrity Initiative, contract pharmacies that are wholly owned by the covered entity (or have common ownership with the entity) will not be able to access 340B pricing unless (i) the covered entity lacks an in-house pharmacy, and (ii) the wholly owned pharmacy is designated as the single contract pharmacy through the 340B ESP™ platform. CAH, DSH, RRC and SCH are also required to submit claims data for their designated contract pharmacy.

Q: How do I designate a single 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 the only method for a covered entity to designate its single 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 single contract pharmacy. Do I need to re-designate my contract pharmacy?



A: Covered entities within the Consolidated Health Center Program (CH) that currently have a designation in place through 340B ESP™ must re-designate their one contract pharmacy to continue receiving access to 340B pricing at that contract pharmacy. Hospital covered entities (CAH, DSH, RRC and SCH) that currently have a designation in place through 340B ESP™ do not need to re-designate, but must begin submitting claims data to retain access to 340B pricing at their designated contract pharmacy.

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 for four hospital types (CAH, DSH, RRC and SCH).

Q: What are the requirements for submitting claims data?

A: For contract pharmacy designations for the four hospital types (CAH, DSH, RRC and SCH), claims data must be submitted within 45 days of the eligible claim's date of dispense. If a claim is submitted more than 45 days after the claim's date of dispense, the applicable drug dispense will not be eligible for 340B pricing. Where a particular drug requires longer than 45 days to trigger a replenishment order, the covered entity will still receive 340B pricing on the applicable drug dispense if the corresponding claims data is submitted within 45 days of the eligible claim's date of dispense. Failure to meet these requirements may result in loss of access to 340B pricing at contract pharmacy locations.

Q: How will Sanofi use the data that we provide through 340B ESP™?

Data uploaded by 340B CAH, DSH, RRC and SCH covered entity types for designated contract pharmacies will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: Is Sanofi requiring data for all Sanofi products?

A: No. 340B claims data submission, where applicable, is only required for the Sanofi products outlined in Attachment A.

Q: Who can I contact if I need assistance?

A: Technical, data, submission or contract pharmacy designation questions or issues can be addressed by the ESP team via phone or email located at <https://www.340besp.com/>. For other issues, customers can email Sanofi340BOperations@Sanofi.com.

Q: May a covered entity accept delivery of 340B-priced Sanofi products and reship them to another entity?

A: Sanofi products offered at the 340B price are exclusively for the covered entity's own use. Consistent with the statutory prohibition on diversion, covered entities are prohibited from reselling or transferring Sanofi products purchased at the 340B price to anyone who is not a patient of the covered entity, or to any other entity for resale or other purposes. Covered entities must retain ownership of Sanofi products purchased at the 340B price from acquisition until they are dispensed to a patient of the covered entity.



ATTACHMENT A

Adlyxin™
Admelog™
Amaryl™
Ambien™
Apidra™
Arava™
Avalide™
Avapro™
Doxercalciferol™
Dupixent
Enoxaparin Sodium™
Flomax™
Insulin Glargine™
Ibesartan™
Kevzara™
Lantus™
Leflunomide™
Lovenox™
Multaq™
Plavix™
Priftin™
Primaquine™
Renagel™
Renvela™
Sevelamer™
Soliqua™
Toujeo™
Zolpidem™



ATTACHMENT B STATE POLICIES

- Arkansas:** Hospital covered entity types (CAH, DSH, RRC and SCH): Contract pharmacy arrangements between hospital covered entities and Arkansas-based community pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective March 18, 2024. These arrangements are subject to the Sanofi Contract Pharmacy Anti-Diversion Policy, effective September 23, 2024. Please see Attachment C for additional information.
- Consolidated Health Center Program (CH): Contract pharmacy arrangements between CH covered entities and Arkansas-based community pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective March 18, 2024.
- Kansas:** From July 1, 2024, through January 31, 2025, contract pharmacy arrangements between covered entities and Kansas-based pharmacies are exempt from Sanofi's 340B Integrity Initiative. Effective February 1, 2025, these arrangements are subject to Sanofi's national contract pharmacy and claims data submission policy. Sanofi encourages covered entities to make any Kansas-based contract pharmacy designations through the 340B ESP™ platform by January 27th to avoid a lapse in access to 340B pricing at the designated contract pharmacy. For covered entities that previously designated a contract pharmacy, that designation will be automatically reinstated, and no further action is necessary to designate a contract pharmacy.
- Maryland:** Covered Entities may access 340B pricing at an unlimited number of Maryland-based contract pharmacies by submitting claims data through the 340B ESP™ platform for each of the Covered Entity's contract pharmacy arrangements in Maryland. Covered Entities that currently have a contract pharmacy designation in place through 340B ESP™ will have that designation canceled and must begin submitting claims data to have access to 340B pricing at their contract pharmacies. This policy is effective August 1, 2024.
- Mississippi:** Covered Entities may access 340B pricing at an unlimited number of Mississippi-based contract pharmacies by submitting claims data through the 340B ESP™ platform for each of the Covered Entity's contract pharmacy arrangements in Mississippi. Covered Entities that currently have a contract pharmacy designation in place through 340B ESP™ will have that designation canceled and must begin submitting claims data to have access to 340B pricing at their contract pharmacies. This policy is effective August 1, 2024.
- Missouri:** Covered Entities may access 340B pricing at an unlimited number of Missouri-based contract pharmacies by submitting claims data through the 340B ESP™ platform for each of the Covered Entity's contract pharmacy arrangements in Missouri. Covered Entities that currently have a contract pharmacy designation in place through 340B ESP™ will have that designation canceled and must begin submitting claims data to have access to 340B pricing at their contract pharmacies. This policy is effective August 28, 2024.



- South Dakota:** Contract pharmacy arrangements between covered entities and South Dakota-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective July 1, 2025.
- Vermont:** Contract pharmacy arrangements between covered entities and Vermont-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective July 1, 2025.
- West Virginia:** From June 6, 2024, through January 31, 2025, contract pharmacy arrangements between covered entities and West Virginia-based pharmacies are exempt from Sanofi's 340B Integrity Initiative. Effective February 1, 2025, these arrangements are subject to Sanofi's national contract pharmacy and claims data submission policy. Sanofi encourages covered entities to make any West Virginia-based contract pharmacy designations through the 340B ESP™ platform by January 27th to avoid a lapse in access to 340B pricing at the designated contract pharmacy. For covered entities that previously designated a contract pharmacy, that designation will be automatically reinstated, and no further action is necessary to designate a contract pharmacy.



ATTACHMENT C

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 B, Sanofi has modified its contract pharmacy policy 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 the contract pharmacy policies set forth in Attachment B. 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.

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.