



Update March 18, 2024: For state-specific policies, see Attachment B

May 15, 2023

Dear Covered Entity:

Sanofi is updating its policy related to our 340B integrity initiative effective June 1, 2023. 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. These updates will help strengthen the integrity of the 340B program by further reducing duplicate discounts that originate from 340B contract pharmacy utilization. This update will not affect patient access to Sanofi medicines.

This update does not include any changes for federal grantees, as discussed in greater detail below.

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

- Critical Access Hospitals (CAH)
- Disproportionate Share Hospitals (DSH)
- Rural Referral Centers (RRC)
- Sole Community Hospitals (SCH)

Effective June 1, 2023, the policy for these four hospital types will be:

- 340B covered entities will continue to be able to purchase Sanofi products at a 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site. These entities will no longer be able to place 340B replenishment orders for any contract pharmacies.
- For any 340B covered entities that do not have an in-house pharmacy, a single contract pharmacy location must be designated through the 340B ESP™ platform. No claims data is required for the designated single contract pharmacy location. If you currently have a designation in place through 340B ESP™, you do not need to re-designate.
- 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 the covered entity does not have an in-house pharmacy, and the wholly



owned pharmacy is designated as the single contract pharmacy through the 340B ESP™ platform.

Federal Grantees within the Consolidated Health Center Program (CHs) will have no change to the process that is in place today. For CH entity types, the current process is:

- All CH entities can purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.
- If a CH does not have an in-house pharmacy location registered on the covered entity database as a shipping address or child site of the covered entity, they may designate a single contract pharmacy for this purpose. A qualifying covered entity may choose a single contract pharmacy for the covered entity and its child sites and Sanofi will provide 340B pricing in this circumstance, irrespective of whether the covered entity provides the data Sanofi requests. If you already have a designation in place, you do not need to take any action at this time.
- In addition to the option for CHs that lack an in-house pharmacy to designate a single contact pharmacy at which to receive 340B pricing, CHs may also receive 340B pricing at an unlimited number of contract pharmacies by submitting claims data for 340B prescriptions of Sanofi products filled through those contract pharmacies.

All other hospital and grantee types not listed are excluded from this initiative.

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.



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: 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 the covered entity does not have an in-house pharmacy, and the wholly owned pharmacy is designated as the single contract pharmacy through the 340B ESP™ platform.

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: No. If you do not have an in-house pharmacy and have already designated a single contract pharmacy location, you do not need to re-designate.

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

A: No, you do not need to submit claims data for your designated contract pharmacy location.

Q: Which entities are required to submit 340B claims data?

A: Data is only required for covered entity type CH to access 340B pricing for contract pharmacies. All CH entities can purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site. If a CH does not have an in-house pharmacy location registered on the covered entity database as a shipping address or child site of the covered entity, they may designate a single contract pharmacy through 340B ESP™ for this purpose. No data is required for this single contract pharmacy designation. If a CH would like to access 340B pricing at additional contract pharmacies, it will need to upload its 340B claims data for these locations through the 340B ESP™ platform in order to access 340B pricing for these locations.

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

Data uploaded by 340B CHs 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: What are the requirements for submitting claims data?

A. CHs participating in the 340B Integrity Initiative must submit claims data 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: 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.



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: Contract pharmacy arrangements between covered entities and Arkansas-based community pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective March 18, 2024.