



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 contact 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 Sites<sup>1</sup>.

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.

<sup>1</sup> <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](mailto: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.
- Kansas:** Contract pharmacy arrangements between covered entities and Kansas based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective July 1, 2024.
- 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.
- West Virginia:** Contract pharmacy arrangements between covered entities and West Virginia based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective June 6, 2024.