

September 3, 2025

Dear Covered Entity:

Sanofi is updating its policy related to our 340B integrity initiative. This September 3, 2025 update revises the July 1, 2024 340B integrity initiative, as amended, in order to affirmatively include information to covered entities on how to purchase the product Rilzabrutinib™.

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. However, Sanofi continues to encounter 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's 340B Integrity Initiative continues to apply 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 Sites<sup>1</sup>.

Sanofi's 340B Integrity Initiative only applies to the Sanofi products listed in Attachment A. This list of products has been updated as of September 3, 2025 to reflect the inclusion of Rilzabrutinib™<sup>2</sup>.

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

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

<sup>2</sup> Rilzabrutinib™ is a product subject to a limited distribution network (LDN) as outlined further in Attachment D.



Sanofi's Contract Pharmacy Anti-Diversion Policy can be found in [Attachment C](#).

Information on Rilzabrutinib™'s limited distribution network, including answers to frequently asked questions, can be found in [Attachment D](#).

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:** 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). As of September 3, 2025 CAH, DSH, RRC and SCH covered entities are similarly required to submit claims data through the 340B ESP™ platform for access to purchases at the 340B price for their Rilzabrutinib™ limited distribution network (LDN) designated contract pharmacy.

**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).

**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™  
Rilzabrutinib™<sup>3</sup>  
Sevelamer™  
Soliqua™  
Toujeo™  
Zolpidem™

<sup>3</sup> Rilzabrutinib™ is a product subject to a limited distribution network (LDN) as outlined further in [Attachment D](#).



## **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.
- Colorado:** Contract pharmacy arrangements between covered entities and Colorado-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective August 6, 2025.
- 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.

- North Dakota:** Contract pharmacy arrangements between covered entities and North-Dakota-based contract pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective August 1, 2025. As of August 1, 2025, North Dakota-based covered entities may utilize any "ship-to" location for their contract pharmacy arrangements.
- Oklahoma:** Contract pharmacy arrangements between covered entities and Oklahoma-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective November 1, 2025. Effective November 24, 2025, these arrangements are subject to Sanofi's national contract pharmacy and claims data submission policy. Sanofi encourages covered entities who had not previously made any Oklahoma-based contract pharmacy designations to do so through the 340B ESP™ platform by November 24, 2025 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.
- South Dakota:** Contract pharmacy arrangements between covered entities and South Dakota-based contract pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective July 1, 2025. As of July 1, 2025, South Dakota-based covered entities may utilize any "ship-to" location for their contract pharmacy arrangements.
- Vermont:** Contract pharmacy arrangements between covered entities and Vermont-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective June 11, 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.



**ATTACHMENT D**  
**Information on Rilzabrutinib™'s Limited Distribution Network (LDN)**

This notice provides information to 340B eligible covered entities seeking to purchase Rilzabrutinib™, specifically:

NDC Number	Pack Description
58468-0251-06	WAYRILZ 400MG Tablet – 60 Tablets/Bottle

Sanofi is implementing a limited distribution network for Rilzabrutinib™.

Rilzabrutinib™ is available for purchase through the following specialty distributors:

- ASD;
- McKesson Specialty;
- Morris and Dickson;
- McKesson Plasma and Biologics; and
- Cardinal Specialty.

**For CAH, DSH, RRC, SCH, and CH covered entities:**

Consistent with Sanofi's integrity initiative, these covered entities can access 340B pricing for Rilzabrutinib™ through their in-house pharmacies.

These covered entities subject to Sanofi's integrity initiative that do not operate an in-house pharmacy can access Rilzabrutinib™ through a contract pharmacy arrangement with **one (1)** of the specialty pharmacies within Rilzabrutinib™'s limited distribution network (LDN). This designation shall be in addition to the single contract pharmacy permitted under Sanofi's integrity initiative to other retail Sanofi products listed on Attachment A.

As of September 3, 2025, this LDN consists of:

- Biologics; and
- Onco360.

The Rilzabrutinib™ designation needs to be added through the 340B ESP™ platform. Initial designations will be collected 9/3/2025 through 9/7/2025. Designations should be visible on or around 9/10/2025 for effect back to 9/3/2025. After this time period, designations will take ten (10) business days to become effective.

Consistent with Sanofi's integrity initiative, CAH, DSH, RRC and SCH covered entities will also be required to submit claims data through the 340B ESP™ platform to access 340B pricing at their designated Rilzabrutinib™ LDN contract pharmacy. This requirement does not apply to CH covered entities.

**For All Other 340B covered entities not subject to Sanofi's Integrity Initiative** (not listed above), access to Rilzabrutinib™ at the 340B ceiling price can be made through the above distributors when shipped to an in-house pharmacy of the covered entity.

340B covered entities can also access Rilzabrutinib™ at the 340B ceiling price through contract pharmacy arrangements with all of the specialty pharmacies within Rilzabrutinib™'s limited distribution network (LDN) listed above.



This list of specialty pharmacies within Rilzabrutinib™'s limited distribution network (LDN) may be updated from time to time.

All State-Specific Policies outlined in [Attachment B](#) apply to the purchasing of Rilzabrutinib™.

Sanofi is committed to compliance with the 340B statute and to responsible distribution of its products.

### **Frequently Asked Questions (Updated as of November 1, 2025):**

**Q:** I currently have an in-house pharmacy capable of dispensing Sanofi retail products. Can I purchase Rilzabrutinib™ at the 340B price through my in-house pharmacy?

**A:** Yes. All covered entities in the 340B Program will be able to purchase Rilzabrutinib™ at the 340B ceiling price when shipped to an in-house pharmacy.

**Q:** If I designate one contract pharmacy location to receive orders of Rilzabrutinib™ subject to this policy, may I also make a separate designation for a contract pharmacy location to receive other Sanofi products listed on [Attachment A](#) that are not subject to a limited distribution network?

**A:** Yes. Due to the LDN associated with Rilzabrutinib™, covered entities that are subject to Sanofi's Integrity Initiative (CAH, DSH, RRC, SCH, CH) are permitted to designate a single LDN contract pharmacy for Rilzabrutinib™. This designation will be in addition to the contract pharmacy the covered entity has already selected for other Sanofi products listed on [Attachment A](#) for those entities that are subject to Sanofi's Integrity Initiative.

**Q:** I currently have a Sanofi retail contract pharmacy designation, and I would like to designate a contract pharmacy within the Rilzabrutinib™ LDN. Will I lose my retail designation?

**A:** No. For covered entities that are subject to Sanofi's Integrity Initiative (CAH, DSH, RRC, SCH, CH) designations for contract pharmacies within the Rilzabrutinib™ LDN shall be in addition to the single contract pharmacy permitted for other Sanofi products listed on [Attachment A](#) for those covered entities that do not maintain an in-house pharmacy.

**Q:** I have made designations for Rilzabrutinib™. Am I required to submit claims data to the 340B ESP™ Platform?

**A:** Yes. Under Sanofi's current Integrity Initiative, only CAH, DSH, RRC and SCH covered entities are required to submit claims data through the 340B ESP™ platform for access to purchases at the 340B price for the Rilzabrutinib™ LDN designated contract pharmacies.

**Q:** Is my grantee covered entity required to designate only one contract pharmacy location for Sanofi medicines subject to a limited distribution network?

**A:** Under Sanofi's current Integrity Initiative, Consolidated Health Center Program (CH) without an in-house retail pharmacy must designate a contract pharmacy within the Rilzabrutinib™ LDN for access to this product at the 340B price. Consolidated Health Center Programs (CH) will not be required to submit claims data through the 340B ESP™ platform to access 340B pricing at their designated LDN contract pharmacy. All other federal grantee entity types are exempt from Sanofi's Integrity Initiative at this time and will be able to access



Rilzabrutinib™ through their in-house pharmacy and through contract pharmacy arrangements with any specialty pharmacy within Rilzabrutinib™'s LDN.

**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.