



June 1, 2026

Dear Covered Entity:

Sanofi is updating its 340B integrity initiative policy. This June 1, 2026 update revises the September 3, 2025 340B integrity initiative, as amended, to:

- (i) introduce and expand the 340B integrity initiative to the collection of claims data¹ for entity-owned (“in-house”) pharmacies, beginning June 15, 2026;
- (ii) expand the 340B integrity initiative to Children’s Hospitals and Free Standing Cancer Hospitals, beginning June 15, 2026; and
- (iii) update state-specific policy information found in [Attachment B](#).

A clarification to WAYRILZ® (Rilzabrutinib™)’s limited distribution network (LDN) can also be found in [Attachment D](#).

Sanofi continues to support 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 updates reflect prevailing business practices that support the integrity of the 340B Program.

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)

As of June 15, 2026, Sanofi’s 340B Integrity Initiative will also be applied to the following covered entity types:

- Children’s Hospitals (PED)
- Free Standing Cancer Hospitals (CAN)

¹ Claims data includes pharmacy and medical claims.



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

Effective June 15, 2026, the policy for the six hospital types (CAH, DSH, RRC, SCH, PED, CAN) 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 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.
- **As of June 15, 2026, all in-house pharmacies will now be required to submit claim-level data² elements for all 340B utilization for covered outpatient drugs.** Entities must submit claims data through the 340B ESP™ platform to access 340B pricing. Claims data must be submitted within 45 days of the eligible claim's date of dispense.
- Covered entities without an in-house 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.** Claims data must be submitted within 45 days of the eligible claim's date of dispense.
- 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.

There is no change to the policy for covered entities within the Consolidated Health Center Program (CH) which will remain as follows:

- Covered entities will continue to be able to purchase Sanofi products at the 340B ceiling price when shipped to an in-house 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. **Entity-owned pharmacies will not be required to submit claims-level data elements.**
- Covered entities without an in-house 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.**

² Claims data includes pharmacy and medical claims.



- 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 Sites³.

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 WAYRILZ®⁴.

State-specific policy information can be found in [Attachment B](#).

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

Information on WAYRILZ®'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.

- 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

³ <https://www.hrsa.gov/about/faqs/what-associated-site-community-health-centers-federally-qualified-health-centers-fqhcs>

⁴ WAYRILZ® is a product subject to a limited distribution network (LDN) as outlined further in [Attachment D](#).



As reflected above, Children's Hospitals (PED) and Free Standing Cancer Hospitals (CAN) have been added to Sanofi's integrity initiative as of June 15, 2026.

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

A: Yes. As of June 15, 2026, all entity-owned pharmacies of the six hospital types (CAH, DSH, RRC, SCH, PED, and CAN) will now be required to submit claim-level data elements for all 340B utilization for certain covered outpatient drugs. Entities must submit claims data through the 340B ESP™ platform to access 340B pricing. Claims data must be submitted within 45 days of the eligible claim's date of dispense. Consolidated Health Centers (CH) are not required to submit claim-level data elements.

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, SCH, PED, and CAN covered entities 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.

For Children's Hospitals and Free-standing Cancer Hospitals added to Sanofi's 340B Integrity Initiative Policy as of June 15, 2026, designations need to be added through the 340B ESP platform™ and will be collected June 1, 2026 through June 12, 2026. Any designations made on or after June 13, 2026 will take ten (10) business days to become effective. Other covered entities already subject to Sanofi's 340B Integrity Initiative Policy do not need to redesignate.

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 six hospital types (CAH, DSH, RRC, SCH, PED, and CAN). As of June 15, 2026, all entity-owned pharmacies of these hospital covered entities (CAH, DSH, RRC, SCH, PED, and CAN) will also now be required to submit claim-level data elements for all 340B utilization for certain covered outpatient drugs. Eligible covered entities are similarly required to submit claims data through the 340B ESP™ platform for access to purchases at the 340B price for their WAYRILZ® limited distribution network (LDN) designated contract pharmacy.



Q: What are the requirements for submitting claims data?

A: For in-house pharmacies and contract pharmacy designations for the six hospital types (CAH, DSH, RRC, SCH, PED, and CAN), claims data must be submitted within 45 days of the eligible claim's date of dispense. The same data elements are requested for submissions for both in-house pharmacies and contract pharmacies. 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 the relevant in-house or contract pharmacy locations.

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

A: Data uploaded by CAH, DSH, RRC, SCH, PED, and CAN covered entity types for in-house pharmacies and designated contract pharmacies will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: I am a covered entity required to submit claims data under Sanofi's Integrity Initiative. What if I fail to submit the relevant claims data within 45 days?

A: A covered entity that does not accurately and timely submit the required claims data will be considered non-compliant with Sanofi's Integrity Initiative. Failure to meet these requirements may result in loss of access to 340B pricing at the relevant in-house or contract pharmacy locations.

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](#). State-specific information, including states exempt from the claim data element requirements for entity-owned pharmacies are outlined in [Attachment B](#).

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 A⁵

Admelog™

Ambien™

Apidra™

Arava™ (Leflunomide™)

Avalide™

Avapro™ (Ibesartan™)

Dupixent

Enoxaparin Sodium™

Insulin Glargine™

Kevzara™

Lantus™

Lovenox™

Multaq™

Plavix™

Priftin™

Primaquine™

Renvela™

WAYRILZ® (Rilzabrutinib™)⁶

Sevelamer™

Soliqua™

Toujeo™

Zolpidem™

⁵ Renagel™ has been discontinued as of January 31, 2024, Adlyxin™ has been discontinued as of September 30, 2023, Amaryl™ has been discontinued as of August 31, 2023, Doxercalciferol™ has been discontinued as of December 31, 2022, and Flomax™ has been discontinued as of October 31, 2025. For clarity these products have been removed from [Attachment A](#).

⁶ WAYRILZ® 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, SCH, PED and CAN): 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. Sanofi's newly announced claims collection requirement for in-house pharmacies will not apply to relevant Arkansas covered entities.
- 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. Sanofi's newly announced claims collection requirement for in-house pharmacies will not apply to relevant Colorado covered entities.
- Kansas:** Effective February 1, 2025, these arrangements are subject to Sanofi's national contract pharmacy and claims data submission policy.
- Louisiana:** Contract pharmacy arrangements between covered entities and Louisiana-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective June 1, 2026. As of June 1, 2026, Louisiana-based covered entities may utilize any "ship-to" location for their contract pharmacy arrangements. Sanofi's newly announced claims collection requirement for in-house pharmacies will not apply to relevant Louisiana covered entities.
- Maryland:** Effective August 1, 2024, 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.
- Mississippi:** Effective August 1, 2024, 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.
- Missouri:** Effective August 28, 2024, 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.
- New Mexico:** Contract pharmacy arrangements between Federally Qualified Health Centers (FQHCs) and New Mexico-based contract pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective January 1, 2026. Federally Qualified Health Center Look-Alikes are already exempt from Sanofi's 340B Integrity Initiative.



- 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:** Effective November 24, 2025, covered entities are subject to Sanofi's national contract pharmacy and claims data submission policy.
- 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. Sanofi's newly announced claims collection requirement for in-house pharmacies will not apply to relevant South Dakota covered entities.
- Tennessee:** Sanofi's newly announced claims collection requirement for in-house pharmacies will not apply to relevant Tennessee covered entities.
- Vermont:** Contract pharmacy arrangements between covered entities and Vermont-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective June 11, 2025. Sanofi's newly announced claims collection requirement for in-house pharmacies will not apply to relevant Vermont covered entities.
- Washington:** Contract pharmacy arrangements between covered entities and Washington-based pharmacies are exempt from Sanofi's 340B Integrity Initiative, effective June 11, 2026. As of June 11, 2026, Washington-based covered entities may utilize any "ship-to" location for their contract pharmacy arrangements. Sanofi's newly announced claims collection requirement for in-house pharmacies will not apply to relevant Washington covered entities.
- West Virginia:** Effective February 1, 2025, covered entities are subject to Sanofi's national contract pharmacy and claims data submission policy.



ATTACHMENT C

Sanofi Contract Pharmacy Anti-Diversion Policy

This policy applies to contract pharmacy arrangements between hospital covered entity types (CAH, DSH, RRC, SCH, PED and CAN) 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 WAYRILZ® (Rilzabrutinib™), specifically:

NDC Number	Pack Description
58468-0251-06	WAYRILZ® 400MG Tablet – 60 Tablets/Bottle
58468-0251-05 ⁷	WAYRILZ® 400MG Tablet - 56 Tablets per Dose Pack

Sanofi has implemented a limited distribution network for WAYRILZ®.

WAYRILZ® is available for purchase through the following specialty distributors:

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

The U.S. Food and Drug Administration (FDA) has officially granted Orphan Drug Designation to WAYRILZ®. Under 42 U.S.C. § 256b(e), certain covered entities (specifically ACA expansion entities: Critical Access Hospitals, Sole Community Hospitals, Rural Referral Centers, Free-standing Cancer Hospitals⁸) are not obligated to receive 340B pricing on orphan designated drugs. 340B pricing eligibility for Disproportionate Share Hospitals (DSH), Children's Hospitals (PED), Federally Qualified Health Centers (FQHC), Ryan White HIV/AIDS Grantees (RW), and other Specialized Clinics (STD, TB, Family Planning) is not impacted by orphan drug status. It is Sanofi's corporate policy to align its drug distribution and pricing models with federal eligibility parameters and does not extend 340B discounts for WAYRILZ® to entities impacted by the Orphan Drug exception.

For DSH, PED, and CH covered entities:

Consistent with Sanofi's integrity initiative, eligible covered entities can access 340B pricing for WAYRILZ® through their in-house pharmacies.

These covered entities subject to Sanofi's integrity initiative that do not operate an in-house pharmacy can access WAYRILZ® through a contract pharmacy arrangement with **one (1)** of the specialty pharmacies within WAYRILZ®'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.

⁷ This new NDC and package configuration for WAYRILZ® is anticipated to begin shipment on June 1, 2026.

⁸ These entities are newly added to Sanofi's Integrity Initiative as of June 15, 2026.



This LDN consists of:

- Biologics; and
- Onco360.

The WAYRILZ® designation needs to be added through the 340B ESP™ platform. Any change in designation will take ten (10) business days to become effective. For Children's Hospitals added to Sanofi's 340B Integrity Initiative Policy as of June 15, 2026, designations need to be added through the 340B ESP platform™ and will be collected June 1, 2026 through June 12, 2026. Any designations made by Children's Hospitals on or after June 13, 2026 will take ten (10) business days to become effective.

Consistent with Sanofi's integrity initiative, eligible covered entities will also be required to submit claims data through the 340B ESP™ platform to access 340B pricing at their designated WAYRILZ® 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 WAYRILZ® 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 WAYRILZ® at the 340B ceiling price through contract pharmacy arrangements with all of the specialty pharmacies within WAYRILZ®'s limited distribution network (LDN) listed above.

This list of specialty pharmacies within WAYRILZ®'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 WAYRILZ®.

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

Frequently Asked Questions (Updated as of June 1, 2026):

Q: I am an ACA expansion entity (Critical Access Hospital (CAH), Sole Community Hospitals (SCH), Rural Referral Centers (RRC), Free-standing Cancer Hospitals (CAN)). May I purchase WAYRILZ® at the 340B price?

A: The FDA has officially granted Orphan Drug Designation to WAYRILZ®. It is Sanofi's corporate policy to align its drug distribution and pricing models with federal eligibility parameters and does not extend 340B discounts for WAYRILZ® to entities impacted by the Orphan Drug exception.

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

A: Yes. All eligible covered entities in the 340B Program will be able to purchase WAYRILZ® at the 340B ceiling price when shipped to an in-house pharmacy. However, given WAYRILZ®'s Orphan Drug Designation (see FAQ #1, above), not every covered entity is eligible for 340B pricing.



Q: If I designate one contract pharmacy location to receive orders of WAYRILZ® 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 WAYRILZ®, covered entities that are subject to Sanofi's Integrity Initiative and that are not an ACA expansion entity are permitted to designate a single LDN contract pharmacy for WAYRILZ®. 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 WAYRILZ® LDN. Will I lose my retail designation?

A: No. For covered entities that are subject to Sanofi's Integrity Initiative and that are not an ACA expansion entity, designations for contract pharmacies within the WAYRILZ® 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 WAYRILZ®. Am I required to submit claims data to the 340B ESP™ Platform?

A: Yes. Under Sanofi's current Integrity Initiative, only DSH and PED covered entities are required to submit claims data through the 340B ESP™ platform for access to purchases at the 340B price for the WAYRILZ® 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 Programs (CH) without an in-house retail pharmacy must designate a contract pharmacy within the WAYRILZ® 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 WAYRILZ® through their in-house pharmacy and through contract pharmacy arrangements with any specialty pharmacy within WAYRILZ®'s LDN.

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

A: For covered entities that are subject to Sanofi's Integrity Initiative and that are not an ACA expansion entities, contract pharmacies that are within the LDN 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 for WAYRILZ®. To be more specific: wholly owned contract pharmacy designations must be within the LDN (Biologics or Onco360). If the wholly owned contract pharmacy is not one of these two pharmacies, covered entities are unable to use their wholly owned contract pharmacy to access 340B pricing for WAYRILZ®. Certain entities are also required to submit claims data for their designated contract pharmacy.