

Dear 340B Covered Entities:

Sobi is updating its 340B policy to support greater transparency, audit readiness, and program integrity within the 340B program. This update expands on Sobi's existing 340B Contract Pharmacy Policy, which took effect on July 1, 2024.

Sobi currently operates, and will continue to operate, under a limited distribution model for its in-scope products.

What is changing?

Effective **July 1, 2026**, Sobi will require covered entities to submit 340B claims data through the 340B ESP™ platform for all utilization associated with products purchased at the 340B price.

For purposes of this policy, in-scope products include **Doptelet®**, **Kineret®**, and **Vonjo®**.

All 340B pharmacy and medical claims must be submitted through the 340B ESP™ platform within **45 days** of the dispense date to the covered entity's patient.

Failure to provide complete, timely, and accurate claims data may result in suspension of access to 340B pricing for the applicable products until the required data is received and validated.

For covered entities with an approved contract pharmacy designation under Sobi's policy, compliance with the universal claims data submission requirement is also a condition of maintaining the covered entity's contract pharmacy designation. Failure to provide complete, timely, and accurate claims data may result in suspension of the covered entity's contract pharmacy designation until the required data is received and validated.

What is not changing?

Sobi will continue to operate under its limited distribution model.

Sobi will continue to ship products purchased at the 340B price exclusively to locations registered with HRSA as a 340B covered entity location or child site location affiliated with that covered entity.

Sobi's existing contract pharmacy framework, first effectuated on July 1, 2024, will continue to apply.

Contract Pharmacy Policy: Effective July 1, 2024

To support access for covered entities that do not have an in-house pharmacy capable of dispensing 340B-purchased products to their patients, Sobi permits qualifying covered entities to designate one contract pharmacy location, subject to Sobi's policy requirements.

Covered entities that do not have an in-house pharmacy capable of dispensing 340B-purchased products to their patients may designate a single contract pharmacy location within 40 miles of the covered entity parent site, subject to Sobi's limited distribution requirements.

Sobi uses the 340B ESP™ platform to support contract pharmacy designations. Covered entities that have not already registered an account with 340B ESP™ may make their designation by visiting

www.340besp.com/designations. Users with an existing 340B ESP™ account can designate a contract pharmacy by navigating to the Entity Profile tab. If you have questions regarding the change in our 340B distribution model, please contact us at support@340Besp.com.

Why is Sobi making this change?

Sobi is implementing this updated policy to support transparency, audit readiness, and program integrity within the 340B program.

The universal claims data submission requirement is intended to validate that products purchased at the 340B price are dispensed or administered consistent with 340B program requirements.

The requested data includes routine claims information already collected by covered entities, pharmacies, and third-party administrators to support replenishment, eligibility validation, and 340B program operations.

How to Submit Claims Data

Covered entities can submit claims data under Sobi's policy by registering an account at www.340Besp.com. Users with an existing 340B ESP™ account can begin submitting Sobi claims by navigating to the Claims Data Submission tab.

The 340B ESP™ platform is the only platform for covered entities to submit claims data under Sobi's policy.

State Law Exceptions

Sobi's 340B contract pharmacy limitations do not apply where prohibited by state law. Sobi's claims data submission requirement also does not apply where prohibited by state law.

These exceptions notwithstanding, Sobi will continue to operate under a limited distribution model, which allows only IDN-owned pharmacies to serve as contract pharmacy locations eligible to receive and dispense 340B-priced, in-scope products.

If you have questions regarding this policy, please contact support@340Besp.com.

Best regards,

Steven Pieri

Steven Pieri, Vice President, Head of Market Access

Q: What specifically is Sobi changing, effective July 1, 2026?

A: Effective July 1, 2026, Sobi is requiring all covered entities to submit claims data for all 340B pharmacy dispenses and medical claims through the 340B ESP™ platform within 45 days of product dispense. Failure to provide claims data under Sobi's policy may result in loss of access to 340B pricing.

Q: How does Sobi define "in-house pharmacy"?

A: An in-house pharmacy is one owned by the 340B covered entity and identified by HRSA OPAIS under either "Street Address" or "Shipping Addresses".

Q: My covered entity dispenses 340B products through an in-house pharmacy. Is my entity required to submit 340B claims data?

A: Yes. Under Sobi's policy, covered entities who use an in-house pharmacy to obtain Sobi products at the 340B price are required to submit claims data for dispenses at the in-house pharmacy. Failure to provide claims data under Sobi's policy may result in loss of access to 340B pricing.

Q: My covered entity does not have an in-house pharmacy and has designated a single contract pharmacy location under Sobi's policy. Is my entity required to submit 340B claims data?

A: Yes. Under Sobi's policy, covered entities who do not have an in-house pharmacy and have designated a single contract pharmacy location are required to submit claims data for dispenses at the designated contract pharmacy. Failure to provide claims data under Sobi's policy may result in loss of access to 340B pricing through the designated contract pharmacy until the required data is submitted.

Q: Which products are subject to Sobi's policy?

A: Sobi's policy applies to all NDCs of Doptelet, Kineret, and Vonjo.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Sobi's policy?

A: Any covered entity may elect to designate a contract pharmacy location registered on the HRSA OPAIS database located within 40 miles of the covered entity parent site, regardless of ownership interest, as its single contract pharmacy location.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing Sobi drugs, but my entity doesn't use it to dispense Sobi drugs. Can my entity designate one contract pharmacy instead?

A: No, under Sobi's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B purchased products to eligible patients then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q: My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A: No. Sobi's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location within 40 miles of the covered entity parent site. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q: How often can my covered entity change its contract pharmacy designation?

A: Covered entities may change their contract pharmacy designation once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

Q: How does my covered entity change its contract pharmacy designation?

A: 340B covered entities can elect a single contract pharmacy every twelve (12) months. Changes to the single contract pharmacy can only be made by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q: Is Sobi requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A: Yes, a contract pharmacy must have a HIN assigned to it for a covered entity to designate it as its single contract pharmacy. This information is important for Sobi to manage its process with its wholesalers.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: Sobi will not register a HIN on your behalf, however if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340Besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q. How does my covered entity ensure that its eligible contract pharmacy locations take effect on July 1, 2024?

A. For a covered entity's eligible contract pharmacy locations to take effect on July 1, 2024, the entity must designate by June 21, 2024. After July 1, 2024, please allow 10 business days for the eligible contract pharmacy locations to take effect.

Q. How long does it take for my covered entity's eligible contract pharmacy locations to take effect after July 1, 2024?

A. Covered entities can take action to comply with Sobi's policy after it goes into effect on July 1, 2024. After July 1, 2024, please allow 10 business days for the eligible contract pharmacy locations to take effect.

Q: My entity is in a state that has passed legislation prohibiting 340B contracting restrictions. Does Sobi's 340B contract pharmacy policy still apply to us?

A: Sobi's 340B contract pharmacy policy does not apply in any state where prohibited by law; at the time of this document's publication this includes Arkansas, Colorado, Hawaii, Kansas, Louisiana, Maine, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Utah, Vermont, Washington, and West Virginia. Sobi continues to operate under a limited distribution model under which only IDN-owned pharmacies may be utilized as contract pharmacy locations to receive and dispense in-scope products purchased at the 340B price.

Q: My entity is in a state that has passed legislation prohibiting 340B claims collection requirements. Does Sobi's claims submission requirement still apply to us?

A: Sobi's claims submission requirement does not apply in any state where claims collection requirements are prohibited by law. At the time of this document's publication, this includes Colorado, Connecticut, Georgia, Maine, Nebraska, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, and West Virginia.

Where permitted by law, covered entities are required to submit dispense-level claims data through 340B ESP™ in accordance with Sobi's policy. Sobi will continue to recognize and comply with applicable state-law exemptions while maintaining its broader 340B policy requirements in states where claims collection is permitted.

Q: How do I submit 340B claims data?

A: 340B covered entities can submit claims under Sobi's policy by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for Sobi by navigating to the Claims Data Submission tab. 340B claims must be submitted within 45 days of product dispense to remain eligible to receive 340B purchased drugs.