

April 20, 2026

## Notice Regarding Stemline Therapeutics' 340B Contract Pharmacy Policy

Dear Covered Entity,

I am writing to inform you that Stemline Therapeutics ("Stemline") is updating its policy for offering ORSERDU<sup>®</sup> (elacestrant) at the 340B price. Effective May 18, 2026, Stemline is implementing a policy affecting covered entities' ability to purchase ORSERDU at the 340B price for dispense at a contract pharmacy.

All covered entities can continue to purchase ORSERDU at the 340B price for use at their own in-house pharmacy through one of Stemline's in-network Specialty Distributors. These Specialty Distributors include McKesson Specialty, McKesson Plasma & Biologics, ASD/Oncology Supply, and Cardinal Specialty.

Under our new policy, Stemline will no longer facilitate "Bill To/Ship To" orders for covered entities for contract pharmacies, other than for the exceptions listed below:

- Stemline will permit covered entities that do not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients to designate a single contract pharmacy that is within the Limited Distribution Network for ORSERDU.
- Stemline will also require the submission of limited claims data on 340B utilization filled at contract pharmacies for covered entities. All specified claims data must be submitted on the 340B ESP<sup>™</sup> platform within 45 days of the date of dispense.

Stemline may choose to exempt from this policy covered entities in certain states in response to state law developments. To ensure transparency and program integrity at designated contract pharmacies, Stemline expects that all dispensing to 340B-eligible patients will occur by the properly designated contract pharmacy, and that 340B drugs will be shipped directly to that location by an authorized distributor.

Stemline is utilizing the 340B ESP<sup>™</sup> platform to support contract pharmacy designations and 340B claims data submission. 340B covered entities that haven't already registered an account with 340B ESP<sup>™</sup> can make their designations by visiting <https://340besp.com/designations>. Users that have registered an account with 340B ESP<sup>™</sup> 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](mailto:support@340Besp.com).

In support of a smooth transition to our new distribution model, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To/Ship To replenishment orders in advance of the May 18, 2026, effective date. PHS contracts administered by our wholesalers will no longer support distribution of 340B purchased drugs to 340B contract pharmacies after May 18, 2026, except as stated in this notice.

Best regards,



Jayson Levy  
Vice President, Head of US Market Access

## Frequently Asked Questions

**Q: Which products are subject to Stemline's policy?**

A: Stemline's contract pharmacy policy applies to NDCs included in Addendum A. Stemline will notify covered entities if/when additional products are added and of other changes to the product list.

**Q: What are the national specialty pharmacies within ORSERDU's Limited Distribution Network?**

A: The national specialty pharmacies in the Limited Distribution Network for ORSERDU are Onco360 and Biologics.

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

A: Yes, under Stemline's 340B contract pharmacy policy, contract pharmacies that are wholly owned by the covered entity or share common ownership with a health system are subject to the same policy requirements as other contract pharmacies. A wholly owned or common ownership pharmacy can be designated as a covered entity's single contract pharmacy.

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

A: No, under Stemline'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. three different Onco360 pharmacy locations). Can my entity designate all locations of the same pharmacy?**

A: No. Stemline's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location. 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](http://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 Stemline 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 in order for a covered entity to designate it as its single contract pharmacy. This information is important for Stemline 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: Stemline 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](mailto: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 May 18, 2026?**

A: For a covered entity's eligible contract pharmacy locations to take effect on May 18, 2026, the entity must designate its contract pharmacy by April 30, 2026. After April 30, 2026, 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 May 18, 2026?**

A: Covered entities can take action to comply with Stemline's policy after it goes into effect on May 18, 2026. After May 18, 2026, please allow 10 business days for the eligible contract pharmacy locations to take effect.

**Q: How do I submit 340B claims data originating from my single contract pharmacy location designation?**

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

**Q: What happens if my organization does not provide 340B claims by the required date?**

A: Failure to provide claims data under Stemline's policy may result in the designated contract pharmacy losing eligibility to receive products at the 340B price. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with any questions. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient.

**Addendum A**  
**In-Scope NDC List**

- Orserdu 86mg: 72187-0101-03
- Orserdu 345mg: 72187-0102-03