

September 3, 2025

Via Electronic Mail

Notice to Covered Entities of Modification to Exelixis' 340B Program Integrity Initiative

Dear 340B Covered Entity:

Exelixis is modifying its 340B program integrity initiative with respect to “*bill to/ship to*” arrangements with affiliated contract pharmacies, and to require claims data for additional 340B dispenses.

What is changing?

Effective October 1, 2025, covered entities may no longer utilize contract pharmacy “*bill to/ship to*” arrangements that are with “*affiliated contract pharmacies*” of the covered entity. Exelixis defines “*affiliated contract pharmacies*” to mean wholly-owned contract pharmacies and contract pharmacies under common ownership with a covered entity. Exelixis will continue to offer its 340B covered outpatient drugs directly to all covered entities at the HRSA registered locations for those entities.¹ A covered entity that does not have an in-house pharmacy capable of dispensing 340B drugs to its patients may continue to designate one (1) contract pharmacy within the product’s authorized specialty pharmacy network for delivery of 340B priced drugs, but may no longer select an affiliated contract pharmacy to fulfill this purpose.

In addition, Exelixis is requiring claims data for all 340B dispenses, including 340B drugs dispensed at in-house pharmacies, with the exception of federal grantees. Specifically, Exelixis requires that covered entities provide the following limited data elements:

- a) Date of Service
- b) Date Prescribed
- c) RX number
- d) Fill Number
- e) 11 Digit National Drug Code (NDC)
- f) Quantity Dispensed
- g) Prescriber ID
- h) Service Provider ID
- i) 340B ID

We are further clarifying that covered entities may receive 340B drugs only through Exelixis-authorized distribution channels and only to the location of actual dispense of the 340B drug. Covered entities are prohibited from participating in alternative distribution models for any Exelixis product. Such alternative distributions models may include virtual inventory models, “banking” orders outside of the reasonable window, virtual return, consolidated replenishment, central fill, virtual credit, or other non-transparent arrangements affecting a 340B drug. Exelixis does not consider such models or arrangements to result in a qualified 340B drug dispense, which may lead to chargeback reversal or other actions.

Why is Exelixis modifying its 340B Integrity Initiative?

¹ Covered entity registered locations include both the HRSA registered parent and child site locations.

Since Exelixis' 340B program integrity initiative began in July of 2022, we continue to engage in good faith discussions with covered entities to address various program integrity issues such as duplicate discounts and instances where multiple covered entities sought replenishment on the same dispense of a 340B product.

While the engagements have been fruitful, we believe modifying our approach to affiliated "*bill to/ship to*" contract pharmacy arrangements and requiring claims data for additional 340B dispenses will further program integrity and compliance with 340B program requirements.

What is not changing?

The modification to Exelixis' 340B program integrity initiative will not impact patient access to COMETRIQ® and CABOMETYX®. Consistent with Exelixis' statutory obligations and its commitment to patient access, both drugs will continue to be available to all 340B covered entities at the statutory ceiling price for delivery to locations registered as part of the covered entity on the HRSA Office of Pharmacy Affairs Information System (OPAIS) database.

Federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K) are excluded from the Exelixis 340B program integrity initiative, and may continue to place "*bill to/ship to*" orders of 340B priced drugs for all of their contract pharmacies.

Next Steps

In support of a smooth transition, covered entities should work with their contract pharmacy administrators and distributor to process any outstanding "*bill to/ship to*" replenishment orders to affiliated contract pharmacies in advance of the October 1, 2025 effective date. PHS contracts administered by our distributors will no longer support the distribution of 340B purchased drugs to affiliated contract pharmacies as of October 1, 2025, except as permitted by this notice.

Covered entities that are not currently registered for 340B ESP™ must register an account at www.340BESP.com to begin submitting data for their in-house pharmacies and/or make other selections.

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Exelixis reserves all rights to modify its 340B program integrity initiative in a manner consistent with law in the future.

We look forward to working collaboratively with you to strengthen the 340B program. Please do not hesitate to contact Exelixis at 340B@exelixis.com if you have any questions.

Sincerely,



Darnell Turner
VP, Pricing, Contracting, & Market Access Operations
Exelixis, Inc.

cc: Lance Piccoro

Exelixis Contract Pharmacy Integrity Initiative FAQs

This FAQ document is a reference guide to answer questions regarding Exelixis' 340B program integrity initiative. Inquiries that cannot be answered based on the below scenarios may be addressed to BRG at support@340besp.com and/or the Exelixis 340B team at 340b@exelixis.com.

1. Which products are subject to Exelixis' policy?

Exelixis' policy applies to the following products: COMETRIQ® and CABOMETYX®.

2. Is the 340B ESP™ platform the only way a covered entity without an in-house pharmacy can request contract pharmacy access?

Yes. Exelixis is utilizing the 340B ESP™ platform to manage all contract pharmacy access.

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

No, under Exelixis' 340B program integrity initiative, if a covered entity has an in-house pharmacy that is capable of dispensing 340B purchased products to eligible patients, then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

4. Where do covered entities go to make a contract pharmacy designation?

340B hospital covered entities are only allowed to designate a single contract pharmacy from within the product's authorized specialty pharmacy network if they do not have an in-house pharmacy that is capable of dispensing the drug. The covered entity may make the designation at www.340besp.com/designations. Users that have registered an account with 340B ESP™ may designate a single contract pharmacy by navigating to the Entity Profile tab. For a covered entity's eligible contract pharmacy location to take effect on October 1, 2025, the entity must register to designate and submit claims data by September 19, 2025.

5. How can a 340B covered entity change its contract pharmacy designation?

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 registered with a 340B ESP™ account may navigate to the Entity Profile tab to make their contract pharmacy designation.

6. What does our entity need to do to begin submitting 340B claims?

340B covered entities may submit 340B claims after registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ may begin submitting 340B claims for Exelixis by navigating to the Claims Data Submission tab. 340B claims must be submitted within 45 days of the date of dispense in order for the contract pharmacy to remain eligible to receive 340B purchased drugs.

7. Is Exelixis requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its contract pharmacy. This information is important for Exelixis to manage its process with its wholesalers.