

May 31, 2024

***Via Electronic Mail***

**Notice to Covered Entities of Modification to Exelixis' 340B Program Integrity Initiative – Use of Contract Pharmacies**

Dear 340B Covered Entity:

Exelixis is modifying its 340B program integrity initiative with respect to “*bill to/ship to*” arrangements with contract pharmacies.

**What is changing?**

Effective July 1, 2024, covered entities may only 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. Except for federal grantees, Exelixis will require claims for all contract pharmacy dispenses.

**Why is Exelixis modifying its 340B Integrity Initiative?**

Since Exelixis' 340B program integrity initiative began in July of 2022 and was subsequently updated in June of 2023, 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 unaffiliated “*bill to/ship to*” contract pharmacy arrangements 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.

A covered entity that does not have an in-house pharmacy or an affiliated contract pharmacy capable of dispensing 340B drugs to its patients may designate one (1) contract pharmacy for delivery of 340B priced drugs.

Covered entities must submit 340B claims through 340B ESP™ for all utilization dispensed through contract pharmacies and be consistent with Exelixis' replenishment policy.

Federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K) will continue to be eligible 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 in advance of the July 1, 2024 effective date. PHS contracts administered by our distributors will no longer support the distribution of 340B purchased drugs to 340B contract pharmacies as of July 1, 2024, except as permitted by this notice.

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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](mailto:340B@exelixis.com) if you have any questions.

Sincerely,



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

cc: Lance Picoro

## Exelixis Contract Pharmacy Integrity Initiative FAQs

This FAQ document is a reference guide to answer questions regarding Exelixis' 340B Contract Pharmacy Integrity Initiative. Inquiries that cannot be answered based on the below scenarios may be addressed to BRG at [support@340besp.com](mailto:support@340besp.com) and/or the Exelixis 340B team at [340b@exelixis.com](mailto:340b@exelixis.com).

### 1. Which products are subject to Exelixis' policy?

Exelixis' policy applies to the following products: COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup>.

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

Yes. Exelixis is utilizing the 340B ESP<sup>™</sup> 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 Integrity Initiative, if a covered entity has an in-house pharmacy, wholly owned contract pharmacy, or a pharmacy under common ownership with the covered entity 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 drug's limited distribution network if they do not have an in-house pharmacy, wholly owned contract pharmacy, or a contract pharmacy under common ownership with the covered entity that is capable of dispensing the drug. The covered entity may make the designation at [www.340besp.com/designations](http://www.340besp.com/designations). Users that have registered an account with 340B ESP<sup>™</sup> may designate a single contract pharmacy by navigating to the Entity Profile tab. For a covered entity's eligible contract pharmacy locations to take effect on July 1, 2024 the entity must designate or submit claims data by June 21, 2024.

### 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](http://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. Where do covered entities go to apply for a wholly owned contract pharmacy exemption?**

The 340B ESP™ platform provides a “Wholly owned contract pharmacy exemption” application that may be used to request exemptions to the drug’s limited distribution network. This application may be used by 340B covered entities to request access for their wholly owned contract pharmacies, and contract pharmacies that are under common ownership with the covered entity. Exelixis does not allow exemptions for claims data, so all approved contract pharmacy exemptions will still need to provide claims data. Entities may begin the exemption application process at [www.340besp.com/wholly\\_owned\\_application](http://www.340besp.com/wholly_owned_application).

**7. 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](http://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.

**8. 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 single contract pharmacy. This information is important for Exelixis to manage its process with its wholesalers.