

June 9, 2023

***Via Electronic Mail***

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

Dear 340B Covered Entity:

After careful consideration, we are updating our 340B program integrity initiative for contract pharmacy orders, which we previously notified you about on June 7, 2022.

**What is changing?**

Effective June 26, 2023, covered entities may continue to utilize “ship to/bill to” arrangements with contract pharmacies that are wholly-owned or under common ownership with a covered entity, if the covered entity elects to provide limited claims-level data for COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> that the pharmacy dispenses to patients of the covered entity.

**Why is it changing?**

We are updating our 340B program integrity initiative to promote much-needed transparency that will help further program integrity and compliance with 340B program requirements. Since our 340B program integrity initiative went into effect on July 6, 2022, the claims data we have received has improved transparency and our ability to identify and resolve duplicate Medicaid rebates. We have not, however, been able to fully realize these benefits with respect to contract pharmacies that are wholly-owned or under common ownership with a covered entity.

**What is not changing?**

This update to the 340B program integrity initiative will not affect patient access to COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup>. Consistent with our statutory obligations and deep commitment to patient access, our covered outpatient drugs will continue to be available to all 340B covered entities at the applicable statutory ceiling price.

A covered entity that elects not to provide the limited claims data and that does not have an in-house pharmacy may designate a single contract pharmacy location — whether a contract pharmacy that is wholly-owned or under common ownership with the covered entity or a third-party contract pharmacy within the specialty pharmacy network — for the shipment of 340B product. Additionally, until further notice, covered entities that are registered as eligible for the 340B program based on receipt of federal grants may continue to use an unlimited number of contract pharmacies within the product's specialty pharmacy network without providing claims-level data for contract pharmacy utilization.<sup>1</sup>

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<sup>1</sup> Grantee covered entities are defined in 42 U.S.C. § 256b(a)(4)(A)-(K).

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

**Next Steps**

All wholly owned contract pharmacy exceptions currently approved by Exelixis on the 340B ESP platform will continue to be eligible for bill-to/ship-to arrangements, contingent upon the timely submission of limited claims-level data.

Covered entities that wish to begin using their wholly owned contract pharmacies should apply by navigating to [https://www.340besp.com/wholly owned application](https://www.340besp.com/wholly_owned_application) and begin submitting limited claims-level data in a timely manner via 340B ESP.

Covered entities that are not currently registered for 340B ESP™ must register an account at [www.340BESP.com](http://www.340BESP.com) to begin submitting data for their wholly owned contract pharmacies.

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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  
Executive Director, Government Pricing and Market Access Operations  
Exelixis, Inc.