

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.

## Exelixis' 340B Program Integrity Initiative Frequently Asked Questions

June 9, 2023

### 1. Which covered entity types are subject to Exelixis' 340B program integrity initiative?

Exelixis is requesting that hospital covered entities (including their child sites) provide claims level data for COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> dispensed by contract pharmacies and wholly-owned pharmacies. Until further notice, covered entities that are registered as eligible for the 340B program based on receipt of federal grants (as defined under 42 U.S.C. § 256b(a)(4)(A)-(K)) may continue to use contract pharmacies and wholly-owned pharmacies that are within the product's specialty pharmacy network without submitting claims data.<sup>2</sup>

### 2. How does a covered entity register with 340B ESP<sup>™</sup>?

Exelixis requests that covered entities register with 340B ESP<sup>™</sup> platform by visiting <https://www.340besp.com/register>. The initial registration includes an onboarding module that guides users through each step of the registration process. The registration process takes approximately 15 minutes, and will be operational beginning June 10, 2022. Registration and utilization of the 340B ESP<sup>™</sup> platform is free of charge for covered entities.

### 3. How does a covered entity upload data?

Once a covered entity's 340B ESP<sup>™</sup> account is activated, the entity will be able to upload claims-level data by visiting the "Claims Data Submission" tab. Covered entities that elect to participate and provide the requested data elements will be able to continue using bill to/ship to arrangements for COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> with contract pharmacy locations that are within the product's specialty pharmacy network.

Exelixis requests that covered entities begin submitting data starting June 10, 2022, but no later than June 20, 2022, in order for a covered entity's eligible contract pharmacy locations to take effect on July 6, 2022. Subsequent submissions should be uploaded twice per month. Covered entities will receive periodic notifications from 340B ESP<sup>™</sup> of upcoming data submission deadlines.

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<sup>2</sup> Further information regarding the authorized specialty pharmacy network for COMETRIQ<sup>®</sup> is available at <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/updated-notice-distribution-model-cometriq.pdf> and further information regarding the authorized specialty pharmacy network for CABOMETYX<sup>®</sup> is available at <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/notice-distribution-model-cabometryx.pdf>.

With the update, Exelixis requests that covered entities begin submitting data starting June 9, 2023 for a covered entity's wholly owned contract pharmacy(ies). Covered entities that previously enrolled with wholly owned contract pharmacy exemptions (prior to June 9, 2023) are requested to submit claims no later than June 26, 2023.

**4. -What happens if a covered entity does not provide 340B claims data by the required date? May a covered entity elect to do so at a later date and gain access to 340B pricing for contract pharmacies and wholly-owned pharmacies?**

Subject to the exceptions noted herein, covered entities that elect not to provide claims data will no longer be eligible for ship to/bill to orders for their contract pharmacies and wholly-owned pharmacies on or after July 6, 2022.

A covered entity can elect to provide claims data after July 6, 2022. After July 6, 2022, covered entities should allow up to 10 business days for their eligible contract pharmacy locations to take effect.

With the update, covered entities that elect not to provide claims data will no longer be eligible for ship to/bill to orders for their contract pharmacies and wholly-owned pharmacies on or after June 26, 2023.

**5. Which data elements are requested?**

Exelixis is requesting the following limited data elements: Rx Number, prescribed date, fill date, NDC, quantity, pharmacy ID, prescriber ID, wholesaler invoice number and 340B covered entity ID.

**6. Are there any privacy protections for the submitted claims data?**

Claims data is deidentified through a HIPAA-compliant process before it is uploaded to 340B ESP™. 340B ESP™ does not collect any protected health information (PHI).

The administrator of 340B ESP™, Second Sight Solutions, makes a standard Business Associate Agreement (BAA) available to 340B covered entities that require a BAA be in place prior to submitting data. To request a BAA, email [baarequest@340besp.com](mailto:baarequest@340besp.com) or complete the BAA request form at <https://340besp.com/baa>.

**7. How will Exelixis use the 340B claims data that covered entities provide through 340B ESP™?**

Exelixis will use claims data solely to identify and resolve duplicate discounts and ineligible rebates under Medicaid and under Medicare Part D and commercial agreements.

**8. Does Exelixis provide 340B pricing on COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> to rural referral centers, sole community hospitals, critical access hospitals, or free-standing cancer hospitals that participate in Exelixis' 340B contract pharmacy program integrity initiative?**

No. COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> are designated as orphan drugs by the U.S. Food and Drug Administration. Notwithstanding Exelixis' 340B program integrity initiative and consistent with 42 U.S.C. § 256b(e), Exelixis does not provide voluntary 340B discounts on COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup> to covered entities registered in 340B Office of Pharmacy Affairs Information System as rural referral centers, sole community hospitals, critical access hospitals, or free-standing cancer hospitals.

**9. Are wholly-owned contract pharmacies and wholly-owned pharmacies subject to Exelixis' policy?**

Contract pharmacies and wholly-owned pharmacies that are wholly-owned by, or under common ownership with, a covered entity and that dispense products only to patients of the covered entity are subject to this policy.

**10. If a covered entity is eligible to designate a single contract pharmacy, how does the covered entity make its designation?**

A covered entity that does not provide claims data and that does not have an in-house pharmacy may designate a single contract pharmacy location within the product's authorized specialty pharmacy network for the shipment of COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup>. The covered entity cannot designate multiple locations of the same pharmacy chain.

If the covered entity has an in-house pharmacy that is capable of dispensing COMETRIQ<sup>®</sup> and CABOMETYX<sup>®</sup>, but does not use it, the covered entity cannot designate a contract pharmacy location.

Covered entities may designate a single contract pharmacy location by visiting <https://www.340besp.com/designations>. A covered entity may change its contract pharmacy designation once every 12 months from the date of first designation.

**11. Who should I contact if I have any other questions about Exelixis' 340B contract pharmacy program integrity initiative?**



1851 Harbor Bay Parkway  
Alameda, CA 94502

650.837.7000 MAIN  
650.837.8205 FAX  
[www.exelixis.com](http://www.exelixis.com)

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