

Notice of Reinstatement of Lilly's Prior Contract Pharmacy Limited Distribution System

November 6, 2023

On December 16, 2021, Eli Lilly and Company (Lilly) updated its 340B contract pharmacy limited distribution system to permit an unlimited number of contract pharmacies provided that certain claim-level data was submitted by covered entities to 340BESP.com.

Since that time, Lilly has encountered various issues with the program, such as the following:

- Identification of thousands of duplicate Medicaid discounts, inconsistent with the 340B statute;
- Identification of hundreds of instances where multiple covered entities sought replenishment on the same unit of 340B product;
- Covered entity refusal to investigate Medicaid duplicate discount data;
- Covered entity refusal to issue refunds for agreed-upon Medicaid duplicate discount amounts;
- Underreporting of claim-level data by covered entities, leading to discrepancies between the claims data submitted and the 340B replenishment purchases being requested;
- Covered entity gaming of Lilly's Limited Distribution Program (e.g., misrepresentation of "bill to"/"ship to" relationships);
- Lack of covered entity accountability for vendors and third-party administrators;
- Covered entity threats of retaliation, litigation, or administrative disputes in response to required "good faith" dispute resolution requests pertaining to contract pharmacy utilization; and
- Unprofessional communications from and conduct by covered entity vendors and third-party administrators.

It is no longer feasible for Lilly to monitor and pursue corrective action for the issues identified above. Therefore, effective November 16, 2023, Lilly is reinstating its previous 340B Contract Pharmacy Limited Distribution System. That program limits distribution of all 340B ceiling priced product:

- To covered entities and their child sites;
- To contract pharmacies wholly owned by the covered entity;
- To unlimited contract pharmacies for "penny priced" insulin products, provided that:
 - The covered entity extends the 340B "penny prices" to eligible patients at the point-of-sale;
 - Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;
 - No insurer or payer is billed for the Lilly insulin dispensed; and,
 - The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

A covered entity without an in-house outpatient pharmacy may designate one contract pharmacy location. Lilly will facilitate bill to / ship orders of 340B priced medicines to that location only. Lilly considers all sites together as one Covered Entity, inclusive on the Parent and Child Sites, or Grantee sites as listed on the HRSA database. Lilly encourages 340B covered entities designating a single contract pharmacy to voluntarily submit limited claims data for their single contract pharmacy transactions for purposes of 340B Program integrity and transparency.

Single Contract Pharmacy Designation

Covered entities that are eligible to designate a single contract pharmacy can do so by registering an account at www.340BESP.com and navigating to the Entity Profile tab. The 340B ESP™ platform is the only way a covered entity can designate its single contract pharmacy location under Lilly's updated policy.

Covered entities that currently have an existing "No In-House" exception with Lilly will need to access 340B ESP™ and designate one contract pharmacy location per Lilly's updated policy. Please complete your single contract pharmacy designation and voluntary data submission by November 13, 2023 to be effective by November 16, 2023.

For covered entities that designate a contract pharmacy after November 13, 2023, please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your designation with 340B ESP™.

Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. Lilly will continue to offer all covered entities its 340B medicines at or below the 340B ceiling price, consistent with the 340B statute. Lilly will also continue to work with all stakeholders to improve program integrity and ensure that the 340B program can be properly and fairly administered going forward.

If you have any questions regarding this notice, please contact Lilly at 340B@lilly.com.

Frequently Asked Questions

To get started with Second Sight Solutions' 340B ESP™ platform, follow these simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes about 15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities. Once your account is set up, the claims upload process takes about 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process, please call Second Sight Solutions at 888-398-5520.

Q1: Which products are subject to Lilly's 340B Distribution Program?

A1: Lilly's 340B program applies to all products (Labeler codes 00002, 00777, 66733).

Q2: If Lilly has already approved a single contract pharmacy exception, do I need to take any action?

A2: Yes. Covered entities that are eligible to designate a single contract pharmacy must register for an account at www.340BESP.com no later than November 13, 2023, to have pricing available by November 16, 2023. Data submission is voluntary.

Q3: If Lilly has already approved an insulin exception, do I need to take any action?

A3: No. Covered entities that have filed, and received approval for, an exception with Lilly as it relates to extending "penny pricing" to eligible patients at the point of sale may continue using unlimited contract pharmacies for "penny priced" insulin products. There is no action required if a covered entity currently has an existing exception in place with Lilly. Contact www.340BESP.com to register for a new insulin exception.

Q4: If Lilly has already approved a wholly owned contract pharmacy exception, do I need to take any action?

A4: No. Contract pharmacies that are wholly owned by the covered entity are not subject to Lilly's 340B Limited Distribution Program. Covered entities may continue using all of their wholly owned contract pharmacies if they have a wholly owned contract pharmacy exception in place. There is no action required if a covered entity currently has an existing wholly owned exception in place with Lilly. Contact www.340BESP.com to register for a new wholly owned exception.

Q5: What will be the effective date for my single contract pharmacy designation?

A5: For covered entities that designate a contract pharmacy after November 13, 2023, please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your designation with 340B ESP™.

Q6: How will Lilly use the 340B claims data that we provide through 340B ESP™?

A6: Data uploaded by 340B covered entities will be used to monitor for and avoid duplicate discounts and to ensure the eligibility of certain contract pharmacy replenishment orders.

Q7: What happens if my organization does not want to provide 340B contract pharmacy claims data?

A7: Submission of claims data is voluntary. All participating 340B covered entities will continue to be able to purchase Lilly medicines at the 340B price when (1) shipped to an address registered on the 340B covered entity database as a parent or child site, or (2) contract pharmacy delivery meets one of the other exceptions recognized in Lilly's Limited Distribution Program. Contact 340B@lilly.com to request information on these exceptions.

Q8: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Lilly's 340B program?

A8: No. Contract pharmacies that are wholly owned by the covered entity are not subject to Lilly's 340B Limited Distribution Program. Covered entities may continue using all of their wholly owned contract pharmacies if they have a wholly owned contract pharmacy exception in place. There is no action required if a covered entity currently has an existing wholly owned exception in place with Lilly. Contact www.340BESP.com to register for a new wholly owned exception.

Q9. I do not have an in-house pharmacy and my 340B covered entity has contract pharmacy arrangements with multiple locations of a pharmacy (e.g. six different CVS pharmacy locations). Can my entity designate all locations of the same pharmacy?

A9. No. The Lilly exception for covered entities without an in-house pharmacy allows covered entities to designate only a single contract pharmacy location. Claims data submission to 340B ESP™ is voluntary for this exception.