

## **Update to Lilly's Contract Pharmacy Limited Distribution System**

### **June 19, 2024**

Eli Lilly and Company (Lilly) is issuing this notice to announce an update to Lilly's 340B Distribution Program (labeler codes 00002, 00077, and 66733).

On November 16, 2023, Lilly reinstated its initial 340B contract pharmacy Limited Distribution System because of the immense amount of effort required to monitor and pursue corrective actions for the serious issues encountered with providing covered entities access to contract pharmacies. As described in our [earlier notice](#), these issues include, but are not limited to, thousands of duplicate Medicaid discounts with refusal to issue refunds for agreed-upon amounts, gaming of Lilly's Limited Distribution Program and general lack of accountability for vendors and third-party administrators used by covered entities.

Since that time, we have discovered through audits that covered entities have limited controls in place to prevent duplicate discounts with Medicaid managed care and that HRSA itself does not even audit for this utilization, despite comprising approximately 85% of all Medicaid utilization. Our audits have also reinforced the understanding that contract pharmacies and third-party administrators are not acting as agents for their purported covered entity clients.

As part of its ongoing efforts to curb abuses of the program, Lilly is updating its contract pharmacy program. Effective July 1, 2024, Lilly will implement the changes described below to its 340B Limited Distribution Program for all covered entity types:

- Lilly will allow distribution of 340B ceiling-priced product directly to covered entities and their child sites only. Wholly-owned and affiliated contract pharmacies will no longer be eligible recipients for distribution or Bill To/Ship To replenishment orders, except:
  - covered entities that lack an in-house retail pharmacy may designate a single contract pharmacy where the covered entity agrees to provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders to 340B ESP™; and
  - 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) to 340B ESP™ demonstrating satisfaction of these terms and conditions.

### **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](http://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 policy.

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 of the Parent and Child Sites, or Grantee sites as listed on the HRSA OPAIS database.

Covered entities that do not currently have an existing “No In-House” exception will need to access 340B ESP™ and designate one contract pharmacy location per Lilly’s policy. Please complete your single contract pharmacy designation and data submission by June 25, 2024, to be effective by July 1, 2024.

For covered entities that designate a contract pharmacy after June 25, 2024, 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](mailto:340B@lilly.com). Communications related to HRSA’s 340B ADR process should be directed to [340B ADR Support@lilly.com](mailto:340B_ADR_Support@lilly.com).

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## Frequently Asked Questions

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

1. Go to [www.340BESP.com](http://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](http://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 340 ESP has already approved a single contract pharmacy exception for my covered entity, do I need to take any action?**

A2: If your covered entity is currently submitting claims-level data associated with such contract pharmacy orders to 340B ESP™ on a voluntary basis, no action is required. If your covered entity is not currently submitting claims-level data, please contact 340B ESP to begin the claims submission process. Covered entities with an approved single contract pharmacy exception must begin submitting claims-level data to 340B ESP™ by July 15, 2024, in order to maintain access to 340B pricing.

### **Q3: If 340B ESP has already approved a "penny priced" insulin exception, do I need to take any action?**

A3: No.

**Q4: What will be the effective date for my single contract pharmacy designation?**

A4: For covered entities that designate a contract pharmacy after June 25, 2024, please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your designation with 340B ESP™.

**Q5: How will Lilly use the 340B claims data that we provide through 340B ESP™?**

A5: 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.

**Q6: 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?**

A6: Yes. Contract pharmacies that are wholly owned by the covered entity are no longer exempted by Lilly's 340B Limited Distribution Program. Covered entities may elect a single wholly owned contract pharmacy if they do not have an in-house retail pharmacy under Lilly's policy change. Contact [www.340BESP.com](http://www.340BESP.com) to register for a new contract pharmacy exception and to set up the claims submission process, if not currently submitting data.

**Q7: I do not have an in-house retail 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?**

A7: No. The Lilly exception for covered entities without an in-house retail pharmacy allows covered entities to designate only a single contract pharmacy location. Claims data submission to 340B ESP™ must be submitted for this exception.

**Q8: My covered entity utilizes a central-fill pharmacy. Will the central-fill pharmacy be deemed an eligible contract pharmacy when it is utilized to acquire or distribute covered outpatient drugs to a 340B eligible contract pharmacy?**

A8: Centralized pharmacy replenishment facilities or "central-fill pharmacies" are not eligible as designated retail pharmacy locations. Lilly will only facilitate shipment or replenishment to the contract pharmacy for product dispensed directly by that contract pharmacy at their own physical location.

**Q9: Where do I direct communications related to Lilly's 340B program?**

A9: Communications related to Lilly's contract pharmacy policy should be sent to [340B@lilly.com](mailto:340B@lilly.com). Communications related to HRSA's 340B ADR process should be sent to [340B ADR Support@lilly.com](mailto:340B ADR Support@lilly.com).