



**Eli Lilly and Company**

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Dear 340B Covered Entity:

Eli Lilly and Company (Lilly) is issuing this notice to announce a prospective expansion of Lilly's 340B Distribution Program (labeler codes 00002, 00077, and 66733), which has been in effect since September 1, 2020.

Lilly supports participation in the 340B program and has from its inception. At the same time, Lilly is committed to compliance with the 340B statute, responsible distribution of its products, and the transparency and accountability needed to safeguard the program from fraud, abuse, and diversion. Lilly hopes to work with all stakeholders to craft solutions that balance these important considerations, because—as one federal judge recently observed—the 340B program in its current state “can no longer be held together and implemented fairly for all concerned.”

In the meantime, and pending finality of the ongoing litigation over contract pharmacy arrangements, Lilly has elected to expand its 340B Distribution Program. Since September 2020, Lilly has limited distribution of all 340B ceiling-priced product directly to covered entities and their child sites only, plus their wholly owned and affiliated contract pharmacies, with the exception of (1) covered entities that lack an in-house retail pharmacy (who may designate a single contract pharmacy); and (2) certain insulins, if the covered entity agrees to pass on the 340B discounted price to 340B eligible patients at the point of sale.<sup>1</sup>

Going forward, and in addition to these existing criteria for delivering 340B medicines to contract pharmacies, Lilly will also permit 340B purchases by, and distribution through, an unlimited number of contract pharmacies, where the covered entity agrees to provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders. Lilly will be utilizing the 340B ESP™ Second Sight Solutions platform for this purpose, and Lilly will voluntarily honor contract pharmacy purchases for prescriptions dispensed to eligible 340B patients on or after October 29, 2021.<sup>2</sup> 340B ESP™ will collect minimal, de-identified claims data sufficient to allow Lilly to monitor diversion and duplicate discounts and promote program integrity. Please see the attached FAQs for additional information. Any covered entity that wishes to dispense 340B-discounted medicines through more than one contract pharmacy arrangement should contact Second Sight Solutions at [www.340BESP.com](http://www.340BESP.com).

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).

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<sup>1</sup> As set forth in Lilly's August 19, 2020 Notice, Lilly's 340B insulin policy also requires that (i) neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin; (ii) no insurer or payer is billed for the Lilly insulin dispensed; and (iii) the covered entity provides claim-level detail demonstrating satisfaction of these terms and conditions.

<sup>2</sup> Lilly will voluntarily honor claims retroactive to October 29, 2021, provided they are submitted through Second Sight Solutions no later than March 15, 2022.

## Frequently Asked Questions

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three 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.
3. We anticipate that the Second Sight Solutions' 340B ESP™ platform will be ready for you to submit Lilly-specific data in the coming weeks. Lilly will provide an update when the system is available for you to login to 340B ESP™ and submit your Lilly 340B contract pharmacy claims data on a bi-weekly basis. 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 ESP multiple contract pharmacy exception?**

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

### **Q2: Does the 340B ESP exception replace or change Lilly's other contract pharmacy exceptions?**

A2: No. The 340B ESP exception is in addition to Lilly's other exceptions related to the distribution of 340B ceiling-priced product directly to covered entities and their child sites, plus their wholly owned and affiliated contract pharmacies. Lilly also offers exceptions for (1) covered entities that lack an in-house retail pharmacy (who may designate a single contract pharmacy) (2) penny-priced insulins, if the covered entity agrees to certain conditions, including that the 340B discounted price is passed on to the patient. Contact [340B@lilly.com](mailto:340B@lilly.com) to request exceptions other than the 340B ESP exception. Contact [www.340BESP.com](http://www.340BESP.com) to register for the 340B ESP platform.

**Q3: If Lilly has already approved a contract pharmacy exception, do I need to take any action?**

A3: Your approved exception will remain effective without any additional actions. If you wish to expand your current exception to include multiple contract pharmacies, you must contact [support@340besp.com](mailto:support@340besp.com) to register and submit data.

**Q4: What will be the effective date for my contract pharmacies through Lilly's 340B ESP exception?**

A4: For newly registered covered entities, all prescriptions dispensed after the initial submission date are eligible for 340B replenishment purchases. Please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your initial Lilly claims submission to 340B ESP™.

Starting on March 16, 2022, registered covered entities shall have 45 days after product is dispensed to an eligible patient to upload into the 340B ESP system claims data for contract pharmacy orders. Replenishment orders associated with these claims must also be placed within the same 45-day period.

For 340B covered entities that registered and provided data for Lilly's NDCs via 340B ESP™ on or before March 15, 2022, Lilly honored contract pharmacy replenishment purchases for prescriptions dispensed to eligible 340B patients on or after October 29, 2021. Replenishment orders for prescriptions dispensed prior to October 29, 2021 will not be honored.

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

A6: Lilly is conditioning unlimited contract pharmacy distribution on a 340B covered entities willingness to register with 340B ESP™ and to provide 340B claims data. 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](mailto:340B@lilly.com) to request information on these exceptions.

**Q7: Is Lilly requesting data for pharmacies that are registered with HRSA as a covered entity?**

A7: No. Lilly is only requesting data for 340B claims that originate from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

**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 ESP exception?**

A8: No. Contract pharmacies that are wholly owned by the covered entity are not subject to Lilly's 340B ESP exception. Covered entities may continue using all of their wholly owned contract pharmacies if they have a wholly owned contract pharmacy exception in place by contacting [340B@lilly.com](mailto:340B@lilly.com).

**Q9. My 340B covered entity has contract pharmacy arrangements with multiple locations of a pharmacy (e.g. six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?**

A9. Each pharmacy location is considered a separate pharmacy, in this example there are six pharmacies. 340B covered entities can register with 340B ESP™ and provide 340B claims data to qualify for Lilly's 340B ESP multiple contract pharmacy exception. The Lilly exception for covered entities without an in-house pharmacy allows covered entities to designate only a single contract pharmacy location.

**Q10. 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?**

A10. 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.

**Q11. What happens if a covered entity that is registered on the 340B ESP™ platform misses a data submission date?**

A11. If a covered entity misses a data submission date it should submit its data as soon as possible. If a covered entity is unable to provide required data in a timely manner, Lilly may no longer facilitate bill to/ship to contract pharmacy replenishment orders on 340B claims for the CP locations for which data is not submitted.

