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FAQs/Verbatims on Cialis Limited Distribution Program

1. Why is Lilly limiting distribution to exclude contract pharmacy shipments of Cialis?

Lilly has concerns regarding contract pharmacy compliance and expansion and seeks to minimize the risk of certain penalties and repayment obligations associated with its participation in the 340B program. To address these concerns, Lilly is seeking to limit the number of 340B transactions to only those that are required by statute.

2. Why Cialis? Or, why these package sizes of Cialis?

These formulations of Cialis are approved exclusively for use in patients with erectile dysfunction. Since October 2018, generic versions of Cialis have been widely available, and currently more than a dozen generic manufacturers offer low-priced versions of these medicines.

3. We think Lilly is required to provide 340B prices to contract pharmacies.

There is no statutory obligation to provide 340B priced product to contract pharmacies. The statute requires that manufacturers must offer 340B ceiling prices to covered entities, which Lilly is continuing to do. And, while HRSA has provided sub-regulatory guidance that, in HRSA's view, permits contract pharmacies to acquire product at 340B prices, this guidance is inconsistent with the statute and not legally binding.

4. Is Lilly planning to exclude contract pharmacy orders for other products?

At this time, Lilly has not made any decisions regarding other products.

5. We believe Lilly is in violation of program requirements and we plan to inform HRSA of our concerns.

Lilly has been open and transparent with HRSA regarding the design and implementation of this limited distribution plan and its position on compliance with the statute.

6. We plan to institute proceedings against Lilly for violation of program rules.

Please direct any correspondence 340BLegal@lilly.com.

7. We are a covered entity the lacks an in-house pharmacy, is there an alternative mechanism that would allow us to receive 340B ceiling priced product?

Yes. Covered Entities that do not have an in-house pharmacy within their system should contact Lilly via email regarding the exception process to designate one contract pharmacy location. (340B@Lilly.com)

8. We are a covered entity that operates several owned/affiliated contract pharmacies, are these owned/affiliated contract pharmacies able to acquire 340B priced product?

Contract pharmacies, including owned/affiliated contract pharmacies, will not be eligible to receive these formulations of Cialis at the 340B ceiling price as of July 1, 2020. Lilly is limiting distribution of 340B ceiling price product of these Cialis formulations directly to covered entities and their child sites only.

9. Can an eligible covered entity purchase at the 340B site and re-distribute the product to their contract pharmacy sites?

Lilly does not believe this would be permitted as the statute prohibits the resale or transfer of drugs to a person who is not a patient of the entity.