

Mirga Inquiry 07072020

1. Has HRSA/OPA approved Lilly's 340B limited distribution plan for Cialis?

HRSA reviewed the plan in accordance with a 2012 Policy Notice that outlines expectations for manufacturers on limited distribution plans. (See:

<https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf>).

2. Is Lilly obligated to provide 340B-priced product to contract pharmacies? Are all manufacturers that have signed a Pharmaceutical Pricing Agreement with HRSA obligated to do so?

Contract pharmacies are a mode for dispensing 340B drugs and serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Manufacturers that refuse to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions. HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.

3. What is the status of HRSA's March 5, 2010 Final Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services?

The 2010 guidance is still in effect.

4. Does HRSA continue to believe, as stated in the March 5, 2010 final notice, that its contract pharmacy guidance "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law"? Does it now believe that its guidance established new substantive rulemaking?

The 2010 guidance is still in effect. However, guidance is not legally enforceable. Regarding the 340B Program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.

5. Could you please provide me with copies of Lilly's correspondence with HRSA/OPA about the design and implementation of its 340B limited distribution plan for Cialis and Lilly's position on compliance with the statute?

Please submit a Freedom of Information Act (FOIA) through the HRSA FOIA Office to determine the appropriateness of releasing this information.

6. In HRSA's Aug. 23, 1996 340B program guidance, HRSA agreed that "As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients." Does HRSA still agree that covered entity contract pharmacy rights are a matter of state law, rather than a right provided under the 340B statute?

Yes.

- 7. If HRSA's position is that Lilly is obligated to provide 340B priced product to contract pharmacies, will HRSA take action against Lilly's? What action will it take?**

As previously stated, HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.

- 8. Does HRSA wish to make any additional statement about 340B contract pharmacy and/or the enforceability of its 340B program guidance?**

No.