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HEALTH CARE PROFESSIONALS



Recent Developments in the
340B Drug Pricing Program

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ELI LILLY NOTICE

- **Eli Lilly Notice**

- Eli Lilly issued a notice to 340B covered entities informing them that, effective July 1, it is limiting distribution of its drug Cialis to covered entities and their child sites only and that contract pharmacies will no longer be eligible to receive formulations of the drug at 340B prices
 - Eli Lilly's notice to covered entities challenges the Health Resources and Services Administration's (HRSA) contract pharmacy guidance that allows contract pharmacies to access drugs at 340B prices

- **HRSA's Response**

- HRSA issued a statement noting that, although its contract pharmacy guidance remains in effect, the guidance is not legally enforceable
- HRSA strongly encouraged manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements

MERCK NOTICE

■ Merck Notice

- Merck also recently sent a notice to covered entities requesting that they share contract pharmacy claims data for Merck products through Second Sight Solutions' 340B ESP™ platform beginning on August 14
- Merck indicated that the request is part of a new 340B integrity initiative and that the claims data uploaded to the 340B ESP™ platform will be used to identify and resolve duplicate Medicaid and commercial rebates
 - The 340B statute only prohibits duplicate discounts in Medicaid
- Although Merck has indicated that the use of 340B ESP™ is voluntary, its notice states that “absent significant cooperation from covered entities, Merck may take further action to address 340B Program integrity”

340B COALITION LETTER

- **340B Coalition Letter**
 - 340B Health, the National Rural Health Association, National Association of Community Health Centers, and the National Health Care for the Homeless Council are asking the Department of Health and Human Services (HHS) to:
 - Prohibit Merck from imposing substantially more burdensome requirements if covered entities do not voluntarily share contract pharmacy claims data through the 340B ESP™ platform
 - Intervene in regard to Eli Lilly's notice, arguing that Eli Lilly's decision to limit 340B pricing violates the 340B statute's requirement that manufacturers must offer 340B prices to eligible covered entities

340B LEGISLATIVE PROPOSAL

■ 340B Advocacy

- 340B hospitals have been advocating for HHS and HRSA to temporarily waive the Disproportionate Share Hospital (DSH) adjustment percentage 340B eligibility requirement given the impact of the COVID-19 pandemic
- HRSA recently stated its position in COVID-19 340B guidance that it is unable to waive statutory requirements, such as the DSH percentage

■ Attempts at a Statutory Fix

- Senator Ben Sasse (R-NE) made an attempt to incorporate a 340B amendment to the Coronavirus Aid, Relief, and Economic Security Act
- Senate Majority Whip John Thune (R-SD) introduced a 340B bill (S. 4160) that he hopes to incorporate into the next COVID-19 relief legislation

Today's Presenters



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