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Health Resources and Services Administration (HRSA) Clarifies 340B Orphan Drug Exception But 340B Audit Enforcement Remains Murky

Article By:

Ellyn L. Sternfield

Recently, HRSA publicly announced the issuance of a final rule clarifying when 340B covered entities can purchase and distribute orphan drugs through the 340B Drug Pricing Program. Separately, HRSA quietly posted a report on its completed audits of 340B covered entities through July 12, 2013. While the new rule does shed light on when 340B entities can purchase orphan drugs at 340B discounted prices, the new audit report keeps 340B entities in the dark on HRSA enforcement of established regulatory violations.

Orphan Drugs

The Orphan Drug Act specifies that drugs used to treat a specific rare condition or disease, such as ALS or Huntington's disease, qualify as orphan drugs, and provides incentives for manufacturers of such drugs. The FDA designates which drugs qualify as orphan drugs.

The Affordable Care Act excludes orphan drugs from 340B pricing, but does not provide specifics on the breadth of the exclusion. The new 340B rule, which will go into effect October 1, 2013, specifies that the orphan drug exclusion only applies to three types of qualified 340B covered entities:

- Free standing cancer hospitals
- Critical access hospitals, and
- Rural referral and sole community hospitals.

Other types of covered entities can still purchase orphan drugs at 340B prices, as long as the entity is in compliance with other conditions of the 340B program.

Under the final rule, the orphan drug exception is only applicable to the three types of entities if the drug at issue is designated as orphan by the FDA and is being transferred, prescribed or sold for the rare condition or disease for which it was designated as orphan by the FDA. So, for example, if drug

X is designated as orphan for treatment of ALS, but is also FDA-approved to treat anorexia, it may be purchased at 340B discounts to dispense to anorexia patients.

A word of warning – providers can potentially qualify as a 340B covered entity under more than one of the eligibility classifications. Going forward, HRSA will require that each covered entity designate itself as a single type of covered entity and abide by all governing regulations specific to that type of entity. Providers will want to consider the applicability of the orphan drug exception when deciding which type of entity they will be for 340B purposes.

Audit Update

HRSA did not announce that it posted a report on completed FFY 2012 program audits through July 12, 2013. While there is some interesting information in the report, the report is more striking for what it doesn't say.

The report reflects:

- HRSA completed a total of 34 FFY 2012 audits.
- HRSA conducted audits of 340B covered entities in 20 different states: 5 audits in Texas, 3 in Georgia and Illinois, and 2 in California, Florida, Kentucky, Washington and Wisconsin, and multiple states had only 1 reported audit.
- Half of the audits had no adverse findings and half had 1 or more adverse findings.
- The most common adverse finding was dispensing drugs to ineligible patients, this included situations involving ineligible sites and or use of ineligible providers.
- The second most common finding was a violation of the duplicate discount prohibition through Medicaid billings.
- The third most common adverse finding was inaccurate record entries, involving incorrect addresses, listing of closed facilities, or use of an unlisted contract pharmacy.

The report does not reflect the total number of entities audited during FFY 2012 or how many audits are yet to be completed.

In several audits where the only listed violation involved an incorrect record regarding a site or contact, no sanction was imposed and corrective action was either limited to correction of the database or is pending. But where the inaccurate record included use of an unlisted contract pharmacy, or where there were other findings regarding ineligible patients or duplicate discounts, sanctions are reported as "to be determined" and corrective action remains "pending."

So we know HRSA is actively auditing 340B entities and the activities it finds problematic, but we still don't know what they are going do about those activities.

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