

HRSA ISSUES 340B PROGRAM ORPHAN DRUG FINAL RULE AND REGULATIONS

EXECUTIVE SUMMARY

On July 23, 2013, the Health Resources and Services Administration ("HRSA") released a long-awaited final rule clarifying the scope of the 340B Program's "Orphan Drug" exclusion, which was established as part of final reconciliation under the Patient Protection and Affordable Care Act. 340B Program participating hospitals subject to this Final Rule include free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals ("Orphan Excluded Hospitals"). Orphan Drugs are drugs used for a rare disease or condition and granted orphan drug status by the FDA.

Among other important positions, the Orphan Drug Final Rule confirms that access to 340B Program pricing for an Orphan Drug is not available where such Orphan Drug is used by an Orphan Excluded Hospital for the rare disease or condition for which orphan status was granted. This means that drugs with an FDA orphan designation may be purchased by an Orphan Excluded Covered Entity using a 340B Program discount if the use is not related to the disease or condition for which orphan status was granted.

Although the Orphan Drug Final Rule presents some implementation challenges for Orphan Excluded Hospitals with large 340B Program volumes, it provides some much needed clarity for affected hospitals. This final rule becomes effective October 1, 2013.

DISCUSSION

The Orphan Drug Final Rule represents something of a milestone for the 340B Program since it establishes the first ever regulations governing 340B Program participating entities. Although the Orphan Drug Final Rule did not address a number of long-standing questions related to 340B Program standards such as a definition of what constitutes 340B-eligible drugs (commonly referred to as "covered outpatient drugs") or individuals eligible to receive such a drug (commonly referred to as "eligible patients"), the establishment of formally promulgated regulations provides much needed clarity for Orphan Excluded Hospitals.

Responding to a number of comments, HRSA states clearly that "a covered outpatient drug does not include orphan drugs that are transferred, prescribed, sold, or otherwise used *for the rare condition or disease for which that orphan drug was designated...*" (emphasis added). HRSA also confirms that the exclusion only applies to the drug manufactured by the sponsor of the drug's orphan indication.

Although helpful, Orphan Excluded Hospitals are left to determine how best to comply with this requirement since HRSA states that these entities are responsible for: (1) ensuring that Orphan Drugs purchased through the 340B Program are not used for the orphan-designated condition; and (2) maintaining auditable records sufficient to evidence compliance with this standard in the event of an audit. To the extent an Orphan Excluded Hospital does not want to track the usage of each drug to confirm compliance with these new regulations, HRSA states that compliance may also be achieved by developing an "alternative system to tracking each discounted drug through the purchasing and dispensing process." Any such alternative must be approved by HRSA, which will consider these requests on a case by case basis.

To the extent a covered entity is unwilling or unable to track compliance with this requirement, HRSA indicates that the entity must notify HRSA and purchase all Orphan Drugs outside of the 340B Program. This notification is described as an election that can be changed on a quarterly basis.

From a policy perspective, some of HRSA's comments are notable in light of recent 340B Program scrutiny from various Congressmen, Senators and pharmaceutical industry representatives. In describing its decision to clarify that the Orphan Drug exclusion does not apply unless the drug is used for the rare disease or condition for which orphan status is granted, HRSA states, "Interpreting the statutory language to exclude all uses of drugs with an orphan designation, including indications for other diseases and conditions, would nullify the benefits of the expansion of the 340B Program for those entities." This affirmative support of clear 340B Program goals is encouraging.

PRACTICAL TAKEAWAYS

Orphan Excluded Hospitals now have additional certainty regarding use of Orphan Drugs in the 340B Program setting. In order to help engender compliance with these new standards, these entities should:

1. Implement effective tracking/monitoring systems capable of producing auditable records confirming that Orphan Drugs were used

appropriately;

2. Carve out Orphan Drugs from 340B Program participation if such tracking is not feasible; or
3. Approach HRSA with alternatives to detailed Orphan Drug tracking.

If you have any questions, would like additional information about this topic or need help preparing and submitting comments, please contact Todd Nova at 414-721-0464 or tnova@hallrender.com.

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