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May 19, 2011

HRSA Releases Proposed Rule Implementing 340B Program Orphan Drug Exclusion

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On May 19, 2011, the Office of the Federal Register put on display a Notice of Proposed Rulemaking ("NPRM") implementing a provision of the Affordable Care Act ("ACA") that prohibits certain newly-eligible Covered Entities from receiving discounts on orphan drugs under the 340B Drug Discount Program.

The NPRM clarifies that the prohibition, informally called the "orphan drug exclusion," only applies to an orphan drug when used for the rare condition or disease for which it received orphan designation under Section 526 of the Federal Food Drug and Cosmetic Act (the "FDCA"). The prohibition *does not* apply when the drug is used for non-orphan indications or for any other lawful use (e.g. when it is used off-label).

The NPRM includes details about how the Health Resources and Services Administration ("HRSA") proposes to implement the orphan drug exclusion, including, among others, a proposed requirement that the affected Covered Entities will have to put in place "tracking and recordkeeping requirements to demonstrate compliance with the limits on the use of orphan drugs." According to the NPRM, affected Covered Entities will have to create separate purchasing accounts and improve inventory and auditing capacity.

The newly-eligible Covered Entities that are subject to the orphan drug exclusion are free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.

Comments are due 60 days after the NPRM is published in the Federal Register, which is scheduled for May 20, 2011. The NPRM is currently available here.

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