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Federal Court Vacates 340B Rule Regarding Orphan Drugs

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On May 23, 2014, the U.S. District Court for the District of Columbia issued a Memorandum Opinion in ***Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services****, et al*. (the May 23rd Opinion), a case involving the federal government's authority to implement regulations affecting the 340B Federal Drug Pricing Program (the 340B Program). At issue in the case was a final rule (the Orphan Drug Rule) published by the Department of Health and Human Services (HHS) on July 23, 2013, regarding the purchase, pursuant to the 340B Program, of certain drugs designated by the Food and Drug Administration (FDA) as "orphan drugs." In the end, the court vacated the Orphan Drug Rule, holding that HHS did not possess the requisite statutory authority to implement such a rule.

The **340B Program** allows certain providers (Covered Entities) to purchase "covered outpatient drugs" from manufacturers at discounted prices. The Affordable Care Act (ACA) expanded the definition of Covered Entity to include four additional types of hospitals (critical access hospitals, sole community hospitals, rural referral centers and cancer hospitals, collectively, Newly Eligible Providers). The caveat to this expansion, however, was that the ACA specifically excluded orphan drugs from the definition of covered outpatient drugs for these types of hospitals. For example, as the May 23rd Opinion points out, Prozac is designated as an orphan drug for autism and certain dysmorphic disorders. It is also, however, commonly prescribed for depression, a non-orphan designated condition. If a Newly Eligible Provider wanted to purchase Prozac to treat patients for depression, it would not be able to do so at the discounted 340B price. These hospitals were required to purchase all orphan drugs at non-340B prices, regardless of the purpose for which they were being prescribed. With the Orphan Drug Rule, HHS was attempting to implement a pathway by which Newly Eligible Providers could in fact purchase an orphan drug at the 340B price. The Orphan Drug Rule permitted these hospitals to purchase orphan drugs so long as the drug was being prescribed to treat a non-orphan designated condition.

On September 27, 2013, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit against HHS challenging the Orphan Drug Rule. PhRMA argued that (1) the Orphan Drug Rule was contrary to the plain meaning of the ACA and (2) that HHS did not have the authority to implement it. In the end, the court found in favor of PhRMA and held that Congress had not delegated such broad authority to HHS. Because HHS had gone beyond the scope of its authority, the court vacated the Orphan Drug Rule. The court, in its opinion, discussed the important

differences between a rule, such as the Orphan Drug Rule, which it determined to be “legislative,” as opposed to one that is “interpretive.” While the court seemed to leave open an opportunity for HHS to re-characterize the rule as interpretive (which the court indicated HHS has the authority to promulgate), it appeared skeptical of the likelihood of HHS's success in pursuing this option.

As a result of the court’s decision, there is a risk that any drug with an FDA orphan designation may not be considered a covered outpatient drug with respect to Newly Eligible Providers. Thus, manufacturers may cease offering orphan drugs to these hospitals at the discounted 340B prices. Importantly, if orphan drugs used for a non-orphan condition are excluded from the definition of covered outpatient drug, cancer hospitals, which are prohibited from purchasing covered outpatient drugs through a group purchasing organization (GPO), may be able to purchase orphan drugs for use in treating any condition through their GPO.

In the wake of the May 23rd decision, it is a “wait and see” scenario for HHS. The agency may opt to pursue one of several courses of action: (1) provide an additional briefing on the interpretive guidance issue (as discussed above), (2) appeal the decision or (3) choose to issue new, non-regulatory guidance related to orphan drug purchases. HHS has not yet commented on the course of action it will pursue.

An interesting issue to ponder is whether Newly Eligible Providers may use the orphan drugs that they previously purchased at 340B prices without first paying the respective manufacturer the difference between the 340B price and the non-340B price. Alternatively, there is a question as to whether manufacturers may seek retroactive payments from Newly Eligible Providers for any orphan drugs purchased at 340B prices.

Finally, the May 23rd decision raises an important question as to whether the Health Resources and Services Administration, the HHS agency that administers the 340B Program, will move forward with plans to release its long-awaited, comprehensive proposed rule related to the 340B Program in June 2014, as it has previously stated. The proposed rule was expected to provide much-needed clarity regarding a number of issues, including 340B patient eligibility, the participation of off-site outpatient facilities and contract pharmacy participation. What is clear from the Orphan Drug Rule litigation is that any future attempt at rulemaking in the 340B space will be highly scrutinized.

Joseph Parise, an associate in McDermott’s New York office, also contributed to this newsletter.

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