District Court in D.C. Vacates HHS' Interpretive Rule Regarding Orphan Drug Exclusion from 340B Discount Pricing

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In what amounts to a victory for the pharmaceutical industry, on October 14, 2015, the U.S. District Court for the District of Columbia vacated the interpretive rule issued by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) regarding the exclusion of orphan drugs from 340B discount pricing for certain covered entities, as provided under section 340B(e) of the Public Health Service Act (PHSA). This court ruling is the latest and possibly last event in a long-running fight between HHS and Pharmaceutical Research & Manufacturers of America (PhRMA) over the scope of orphan drug exclusion from 340B discount pricing.

The heart of this controversy is the Orphan Drug Exclusion Rule. The Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA), revised the 340B statute to add the following provider types as 340B covered entities: children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. But all of these newly eligible covered entities, except children's hospitals, were excluded from access to discount pricing under the 340B program for orphan drugs used to treat rare diseases or conditions. As amended by HCERA and section 204 of the Medicare and Medicaid Extenders Act of 2010, section 340B(e) of the PHSA sets forth this orphan drug exclusion as follows:

> EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES—For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.[1]

Covered entities and pharmaceutical manufacturers hold opposing views on the scope of orphan drug exclusion. Covered entities have argued that the exclusion only applies when an orphan drug is used for an orphan indication. Pharmaceutical manufacturers have argued that, based on the statutory text, the exclusion applies regardless of the indications for which orphan drugs are used.[2] HHS, however, took the position favored by the covered entities in its proposed rule issued in May 2011 and its final rule issued in July 2013. Thus, under HHS' final rule, critical access hospitals, sole community hospitals, rural referral centers, and free-standing cancer hospitals could purchase orphan drugs at discounted pricing under the 340B program only if the drugs were used to treat non-orphan conditions.

In September 2013, PhRMA brought an action against HHS challenging the validity of the Orphan Drug Exclusion Rule as set forth in HHS' final rule, claiming that HHS lacked legislative authority to promulgate the rule and that the rule contradicted the underlying statutory language. On May 23, 2014, the Court in *PhRMA v. HHS*, found in favor of PhRMA by vacating the Orphan Drug Exclusion Rule.[3] The Court agreed with PhRMA that HHS had exceeded the scope of its legislative authority. The Court noted that Congress only specifically authorized the agency to implement rules under

1 Codified at 42 U.S.C. § 256b(e).
2 Travis Jackson, *Orphan Drug Decision Clouds HRSA's Ability to Provide 340B Program Clarity*. American Health Lawyers Weekly (June 6, 2014).
3 *See* F.N. 4, *supra*.

PHSA section 340B in three areas: (1) establishing an administrative dispute-resolution process, (2) regulating the methodology used for calculating ceiling prices, and (3) imposing monetary civil sanctions.

HRSA responded to this ruling by implementing its orphan drug exclusion policy as an interpretive rule (effective July 21, 2014) rather than as a final regulation that must be subject to the notice-and-comment rulemaking process. PhRMA, in turn, argued that HHS' interpretive rule is materially the same as the final rule that the Court vacated and thus should likewise be struck down. The Court, however, held that PhRMA's complaint only challenged the final rule promulgated by HRSA[4] and, accordingly, that PhRMA's challenge to the new interpretive rule was beyond the scope of the present law suit.

On October 9, 2014, PhRMA responded by filing with the U.S. District Court in D.C. an action specifically targeting HRSA's July 2014 interpretive rule. In its complaint,[5] PhRMA argued that the statutory text of the 340B orphan drug exclusion is self-executing and emphasized that the exclusion is based on the designation of the orphan drug, rather than on how it is used. Roughly one year later, on October 14, 2015, the district court sided with PhRMA by granting PhRMA's motion for summary judgment. In arriving at this decision, the court found that HHS' interpretive rule constitutes a final agency action that is subject to review under the Administrative Procedure Act and that it contravenes the plain language of the underlying statute. The court also stated that HHS' interpretation deserved no deference due to the agency's lack of authority to issue regulations in this area that carry the force of law.

This ruling could mark the end of this matter, but that may not be a safe bet. HHS has 60 days to appeal, and, based on the history of this dispute and the stakes involved, this may be the likely next step in an ongoing controversy.

4 No. 13-1501 (D.D.C. Aug. 27, 2014).
5 *PhRMA v. HHS*, Complaint, Civil Action No. 14-1685 (D.D.C. Oct. 9, 2014).

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