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D.C. District Court Vacates HRSA's Interpretative Rule on Orphan Drugs

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On Wednesday, October 14, 2015, the U.S. District Court for the District of Columbia (the "Court"), Judge Rudolph Contreras, vacated the Health Resources and Services Administration's ("HRSA") interpretive rule on Orphan Drugs ("the Interpretative Rule") as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[1] As a result of the ruling, pharmaceutical manufacturers are not required to provide 340B discounts to certain types of covered entities for Orphan Drugs, even when the drugs are prescribed for uses other than to treat the rare conditions for which the Orphan Drug designation was given.[2] This issue has been the subject of long and protracted litigation including a previous court ruling that invalidated HRSA's Final Rule on Orphan Drugs because HRSA lacked the authority to promulgate the rule.[3] [HRSA Issues Interpretive Rule on 340b Orphan Drug in Response to Court Vacating Final Rule]

By way of background, the Affordable Care Act ("ACA") amended the Public Health Service Act ("PHSA" or "the statute") and expanded access to 340B discounts by creating new categories of eligible covered entities including freestanding cancer hospitals, children's hospitals, critical access hospitals, rural referral centers and sole community hospitals.[4] For these categories of covered entities only, the amendment also excluded drugs "designated by the Secretary under section 360bb of Title 21 for a rare disease or condition" ("Orphan Drugs") from the definition of covered outpatient drugs subject to mandatory 340B pricing requirements ("the orphan drug exclusion").[5]

In the Interpretive Rule issued on July 24, 2014, HRSA narrowly interpreted the exclusion and required pharmaceutical manufacturers to provide 340B discounts to the new types of covered entities for Orphan Drugs when they are used to treat something other than the rare diseases and conditions they were developed to target.[6] In addition, HRSA sent letters to pharmaceutical manufacturers stating that failure to provide 340B discounts to eligible 340B covered entities for non-orphan uses would be deemed a violation of the statute.[7] The lawsuit challenged HRSA's interpretation, arguing that the orphan drug exclusion must apply to Orphan Drugs regardless of their particular use.[8] The Court denied HRSA's motion for summary judgment and granted PhRMA's motion for summary judgment because it determined HRSA's Interpretive Rule was contrary to the plain language of the statute.[9]

Analysis in the Court's Opinion

Initially, the Court recognized HRSA's authority to offer its interpretation of the statute and noted that PhRMA was not challenging HRSA's authority to issue the Interpretive Rule. Although the Court determined in the previous litigation that HRSA did not have authority under the statute to promulgate its Final Rule, the Court recognized that HRSA would need to provide interpretation of a pharmaceutical manufacturer's obligations under the 340B Program.[10]

The Court determined that the Interpretive Rule constituted "final agency action" under the Administrative Procedure Act ("APA").[11] The Court focused the majority of its analysis on whether HRSA's Interpretive Rule was "final."[12] Based on the two-part test set forth in *Bennett v. Spear*, the Court analyzed whether the action was the "consummation of the agency's decision-making process" and whether "the action must be one by which rights or obligations have been determined or from which legal consequences will flow."[13] Since HHS conceded that the Interpretive Rule met the first element, the Court focused on the second element and determined that even prior to enforcement action, there were significant practical and legal burdens for covered entities and pharmaceutical manufacturers in the Interpretive Rule that impacted their business practices. Additionally, since HRSA sent the manufacturers letters informing them that they were non-compliant with the statute unless the requirements in the Interpretive Rule were followed, potential penalties would accrue until HRSA pursued an enforcement action.[14] The Court stated that "[h]aving thus flexed its regulatory muscle, [HHS] cannot now evade judicial review."[15] The Court concluded that the Interpretive Rule met the second element of the *Bennett* test.[16]

When analyzing the merits, the Court held that the Interpretive Rule "conflicts with the statute's plain language."[17] Because of the conflict, the Court afforded the Interpretive Rule no deference.[18] The Court relied on how Congress used the Orphan Drug terminology in other parts of the U.S. Code.[19] Previously, in other contexts Congress included additional language to specify that the applicability was limited to occasions when the designated drug was used to treat the rare disease or condition, rather than the use of the Orphan Drug in general. The Court noted that if it adopted the narrow meaning HRSA intended under the Interpretive Rule, the identified phrases elsewhere in the Code would be rendered superfluous based on the principle of statutory construction to give effect to every word in the statute. Because of its conflict with the plain language of the statute, the Court held that the Interpretative Rule was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[20]

Implications from the Decision

This decision means that pharmaceutical manufacturers are not required to provide 340B discounts on Orphan Drugs, whatever their use, to the types of covered entities added by the ACA. The Court acknowledged concerns that the amount of lost savings for these drugs could impact a covered entity's decision to participate in the 340B Program.[21]

Additionally**,** this decision has implications for HRSA's proposed Omnibus Guidance published on August 28, 2015, the comment period for which is open until October 27, 2015. The Omnibus Guidance provides comprehensive guidance for the 340B Program. [HRSA Issues Proposed "Omnibus Guidance"]. While the Court recognized HRSA's ability to issue interpretive guidance,[22] such guidance could be vulnerable to challenge if HRSA, after consideration of the comments submitted, finalized an Omnibus Guidance that is not consistent with the 340B statute. Industry stakeholders should consider highlighting these types of inconsistences in the proposed Omnibus Guidance as they formulate comments for submission next week.

Finally, the recent decision might provide impetus for Congress to take legislative action. The Court noted that it "would not rewrite the statute," suggesting that Congress needs to take action if its intent was to limit the orphan drug exclusion.[23] Given Congress' recent focus on the 340B Program, it is possible that Congress could either amend the statute to clarify the orphan drug exclusion or to provide HRSA with additional rulemaking authority to allow it to address this issue and other oversight issues.

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[1] 5 U.S.C. § 706(2)(A). *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs*, No. 1:14-cv-01685-RC at 38 (D.D.C October 14, 2015) (hereinafter "PhRMA").

[2] PhRMA at 36-8. HRSA may appeal the District Court's decision within 60 days of the decision date.

[3] *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28 (D.D.C. 2014).

[4] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(a), 124 Stat. 119, 821–22 (codified as amended at 42 U.S.C. § 256b(a)(4)(M)–(O)).

[5] 42 U.S.C. § 256b(e). The orphan drug exclusion does not apply to disproportionate share hospitals.

[6] HHS HRSA, Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, (July 21, 2014), http://www.hrsa.gov/opa/programrequirements/interpretiverule/

[7] PhRMA at 10. Additionally, the HRSA website explained that manufacturers could be subject to statutory penalties, refunds of overcharges, or termination of their Pharmaceutical Pricing Agreements. Id.

[8] Id. at 1-2.

[9] Id. at 1-2.

[10] Id. at 12-13.

[11] The APA mandates that judicial review is permitted only when there is "final agency action."

[12] Id. at 14, 15-27.

[13] Id. at 14.

[14] Id. at 22-26.

[15] Id. at 27.

[16] Id. at 23-27.

[17] Id. at 2.

[18] Id. at 29. The Court explained that if the statute were ambiguous, the Interpretive Rule was entitled toSkidmore deference, which means the Court would only follow the Interpretive Rule to the extent it is persuasive. HRSA's Interpretive Rule would not receive Chevron deference because HRSA lacked the authority to promulgate regulations related to the orphan drug exclusion (as decided in the prior litigation). Id.

[19] Id. at 30.

[20] Id. at 38.

[21] Id. at 36-37.

[22] Id. at 12-13.

[23] Id. at 37.

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