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D.C. Court Strikes Down 340B Orphan Drug Rule Again: Will This Impact the "Mega Guidance"?

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A federal court vacated the Department of Health and Human Services' (HHS) Orphan Dug Rule that had allowed certain ***340B Drug Pricing Program*** (340B Program) hospital covered entities to receive discounted prices when purchasing orphan drugs for a non-orphan use. In addition to its significant financial impact on hospital covered entities subject to the rule, the decision's discussion of the limitations on HHS' rulemaking authority under the 340B Program could pave the way for future challenges to HHS' recently proposed Omnibus Guidance.

History of the Orphan Drug Rule Litigation

The D.C. District Court's decision on October 14, 2015 is the latest in an ongoing controversy between HHS and the Pharmaceutical Research and Manufacturers of America (PhRMA) over the scope of the orphan drug exclusion, and the second time HHS' orphan drug rule has been invalidated. In July 2013, the Health Resource and Services Administration (HRSA) within HHS published a final 340B Program rule (Final Rule) implementing the statutory exclusion of orphan drugs for certain covered entities from the 340B Program's definition of a "covered outpatient drug." Specifically, the Final Rule applied the statutory exclusion to orphan drugs purchased by free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals *only* when the drugs were transferred, prescribed, or sold for treating the rare disease or condition for which the drug was designated as an orphan drug. Under the Final Rule, 340B Program pricing could be available for drugs designated as orphan drugs when the drugs were dispensed or prescribed for a "non-orphan" condition. However, in May 2014, the D.C. District Court struck down the Final Rule, holding that HHS lacked authority to issue a regulation with the force and effect of law on this subject. The court raised the possibility that HHS could issue the rule as an interpretive rule rather than a legislative rule. HHS followed that strategy, issuing guidance that was substantively identical to the prior Final Rule as an Interpretive Rule in July 2014.

PhRMA then challenged this Interpretive Rule under the Administrative Procedure Act (APA) as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance of law. HHS argued to the contrary that its interpretation best balanced the interests of orphan drug development and the expansion of the 340B Program to new entities. HHS also argued that the Interpretive Rule could not

be challenged under the APA because it did not constitute final agency action, and that even if the rule could be challenged, it should be afforded judicial deference. PhRMA countered that the Interpretive Rule both constituted final agency action and contravened the plain language of the 340B Program statute.

In October 2015, the D.C. District Court rejected HHS' arguments and struck down the Interpretive Rule as inconsistent with the 340B Program statute. The court first held that HHS' interpretation could be challenged under the APA as a final agency action. The court concluded that the case presented a purely legal question of statutory interpretation, and the Interpretive Rule imposed an immediate and significant practical burden on the regulated entities. The court then turned to the ultimate question of whether the Interpretive Rule constituted an agency abuse of discretion or a permissible interpretation of the 340B Program statute. The court rejected HHS' position and struck down the Interpretive Rule as contrary to the plain language of the 340B Program statute.

Impact of Court's Ruling on Covered Entities and Proposed 340B Program Guidance

The court's decision will have an immediate financial impact on the hospitals to which the orphan drug exclusion applies as they will no longer be authorized to purchase orphan drugs at a 340B discounted price when used for non-orphan uses. This will also require impacted covered entity hospitals to revise their policies and procedures to the extent they had previously authorized such practice based on the Interpretive Rule.

Additionally, the court's decision could be used as a roadmap for future challenges to HRSA's proposed Omnibus Guidance. There is little doubt that, once finalized, the proposed Omnibus Guidance will reflect HRSA's final administrative judgment about the 340B Program statute, just as the orphan drug rule did. Many of the changes proposed in the Omnibus Guidance could be challenged on the legal basis that they fail to properly interpret the 340B Program statute. Depending on how HRSA finalizes the guidance, stakeholders may also be able to make the argument that the Omnibus Guidance imposes an immediate and significant burden, and that a court could allow a direct challenge to the Omnibus Guidance under the APA in the same way that the D.C. District Court permitted PhRMA to challenge the Interpretive Rule. As covered entities are preparing comments for submission to HRSA regarding the proposed Omnibus Guidance (comments are due October 27, 2015), they should consider how this recent court decision may influence the comments that they can make, and should be aware that the two court cases invalidating HRSA's orphan drug rule offer a clear warning to all stakeholders that HRSA's guidance may not be the final word.

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