PUBLICATION

HHS to Continue Enforcing Orphan Drug Exclusion from 340B Program [Ober|Kaler]

June 26, 2014

The Department of Health and Human Services (HHS) through its Office of Health Resources and Services Administration (HRSA) announced last week that, although a court recently struck down its regulation addressing application of the 340B discount program for orphan drugs, it will continue to enforce its policy as a statutory interpretation of the applicable law.

Background

Orphan drugs are designed to treat rare diseases and, as such, are not likely to attract efforts to research, invest in and produce those drugs without the incentives to pharmaceutical manufacturers that Congress has passed. Orphan drugs are, however, often also used to treat non-rare diseases or conditions. The Affordable Care Act expanded the 340B discount drug program to additional covered entities but denied most of those entities the ability to obtain the discount pricing for orphan drugs: “For covered entities described…, the term 'covered outpatient drug' shall not include a drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition.” 42 U.S.C. § 256b(e).

Covered entities and their trade organizations asked HRSA to clarify that this provision only applied to exclude orphan drugs from the 340B manufacturer discount if the drugs were being used in accordance with their orphan indication, and that the discount would be available if the drugs were used for other non-rare diseases or conditions. Manufacturers, on the other hand, sought an interpretation that they were not required to provide the 340B discount for any orphan drugs, regardless of their use. In May of 2011, HHS proposed its orphan drug regulation to exclude only those orphan drugs that are used for their orphan indication. HHS finalized that rule in July of 2013, effective October 1, 2013.

Court Challenge

On September 26, 2013, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit against HHS in the United States District Court for the District of Columbia, challenging HHS's rule. *PhRMA v. HHS*, No. 13-1501. In a ruling dating May 23, 2014, the court vacated the agency's rule and granted summary judgment and an injunction for PhRMA, finding that HHS had overstepped its regulatory authority in issuing the rule. The court applied the *Chevron* two-step analysis, which first requires the court to determine whether Congress has directly spoken to the precise question and, if not, to determine whether the agency's interpretation is reasonable. The court only got as far as step one, finding that Congress clearly had not given HHS the general authority to promulgate broad sweeping 340B regulations or the specific authority for the regulation it promulgated.

The decision leaves the door open on whether the agency has the authority to adopt its understanding of the statute as an “interpretive rule” rather than a “legislative rule.” Unlike a legislative rule, an interpretive rule does not need go through notice and comment rulemaking. Although the court invited the agency to submit briefs in support of its authority to prevail under an interpretive rule theory, the agency declined to do so.

HRSA's Current Position

On June 18, HRSA announced that it would continue to enforce its interpretation of the orphan drug provisions of the 340B statute. It asserted that although the court rejected the agency's recent regulation, it did not invalidate the agency's interpretation of the statute. HRSA is therefore continuing to enforce the interpretation that allows entities subject to the orphan drug exclusion to purchase orphan drugs at the 340B prices when orphan drugs are used for indications other than treating rare diseases or conditions. The agency is still within the time limits of filing an appeal of the court's decision but it is unclear whether it will do so.

Ober|Kaler's Comments

HRSA's continued enforcement of the orphan drug exclusion as an interpretive rather than a legislative rule is still subject to challenge. However, we are not aware of any such challenges to date. Thus, HRSA still expects providers and manufacturers to continue to comply with HRSA's interpretation of the rule, allowing covered entities the benefit of the rebate for orphan drugs ordered outside of their orphan use.

In addition, the court's ruling brings into question what will happen with the long anticipated 340B "mega regulation," which was expected to be issued this June. Covered entities and manufacturers were anticipating that this regulation would bring long overdue guidance on a number of 340B issues, including provisions addressing the definition of an eligible patient, requirements for contract pharmacy arrangements, criteria for hospital eligibility and participation by off-site hospital facilities. However, the court's ruling clearly found no grant of broad authority to HHS/HRSA for rulemaking. HRSA has not indicated whether it will proceed to publish the mega regulation this summer as anticipated.