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Guidance, Not Regulations, Expected for 340B Drug Pricing Program [Ober|Kaler]

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The long-awaited 340B "mega rule," promised by the Health Resources and Services Administration (HRSA) to be published last summer, has now been officially nixed. HRSA recently announced that it will not release the "mega-rule," which was predicted to provide guidance on essential matters relating to the 340B Program. Instead, HRSA will release proposed guidance for notice and comment in 2015, which many hope will address those essential matters.

The 340B Drug Pricing Program grants certain eligible health care providers access to medications at a discounted cost to enable them to provide care to vulnerable patient populations. HRSA oversees the 340B Program. For years, important interpretive issues have plagued the 340B Program, relating to hospital eligibility requirements and the definition of "patient," among others. Industry stakeholders hoped that HRSA's long awaited "mega-rule," scheduled for release in July 2014, would provide guidance for some of those questions.

However, the "mega-rule" was put on hold when a federal judge vacated another 340B regulation related to orphan drugs in May 2014. That regulation required certain Covered Entities to extend 340B discount pricing on orphan drugs when those drugs were provided for non-orphan indications. The ruling followed a challenge by a trade group representing pharmaceutical manufacturers and researchers. The court held that HHS lacks the authority to take part in such rulemaking, and effectively put the legitimacy of the "mega-rule" into question. In the wake of that decision, HRSA published an "interpretive" rule regarding the orphan drug exclusion on July 21, 2014. In addition, HRSA released orphan drug FAQs which indicate that related obligations are statutory and do not arise from its interpretive rule.

Ober|Kaler's Comments

It appears that HRSA plans to proceed with interpretive guidance in lieu of substantive rulemaking. While the lack of binding regulations relating to discounts for orphan drugs for non-orphan indications may not affect all stakeholders, the industry as a whole has been left in a state of uncertainty with respect to the basic workings of the 340B Program and how the agency intends to enforce compliance. Clearly, the fundamental questions regarding eligibility requirements and patient definition remain unanswered. Equally problematic is the question of whether HRSA may package its guidance as interpretive rules and call for stakeholders to conform.