HRSA withdraws proposed 340B "Mega Reg" in favor of future agency guidance

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On November 14, the Health Resources and Services Administration (HRSA) posted on its website that it was withdrawing its extensive proposed rule (dubbed the "Mega Reg" by pundits and agency staffers) regarding the 340B Drug Pricing Program. Instead, HRSA plans to issue agency guidance (with notice and comment periods for the public) in 2015 on a broad range of policy and practical issues regarding the 340B Program. HRSA still plans to issue proposed rules on civil monetary penalties for manufacturers, calculation of the 340B ceiling price, and the establishment of resolution procedures for administrative disputes involving the 340B Program.

The Mega Reg has been expected for some time and appeared to be drawing closer to publication when a draft of the regulation was submitted for review to the Office of Management and Budget in April 2014. However, a May 23, 2014, federal court ruling found that HRSA did not have the statutory authority to issue regulations changing the Orphan Drug provision of the 340B Program. This ruling called into question whether HRSA had the statutory authority to issue the Mega Reg, as the same arguments that prevailed against the Orphan Drug rulemaking would apply in the broader 340B Program context.

Following the ruling, HRSA issued agency guidance with substantially similar content as the overturned regulations regarding Orphan Drugs. HRSA has maintained that such a course is not prohibited by the court's ruling. HRSA's current withdrawal of the proposed Mega Reg and its plans to issue agency guidance on similar topics are consistent with its actions regarding the Orphan Drug rule. The ruling stated that HRSA did have the statutory authority to issue rules on three topics:

1. The standards for the imposition of civil monetary penalties;
2. The methodology for the calculation of ceiling prices; and
3. Procedures for resolving administrative disputes involving drug manufacturers and covered entities.

HRSA signaled last week that it is in these three areas that it intends to issue proposed rules, as opposed to agency guidance.

The withdrawal of the Mega Reg does not affect the current operation of the 340B Program. Covered entities and manufacturers should continue to rely on existing law and HRSA guidance on the 340B Program. In advance of next year's guidance release, covered entities should review their current 340B Program compliance and operation.