

## **HEALTH LAW NEWS**

AUGUST 27, 2015

## BREAKING: HRSA RELEASES PRELIMINARY VERSION OF PROPOSED 340B OMNIBUS GUIDANCE

On August 27, 2015, the Health Resources and Services Administration ("HRSA") released a notice of proposed 340B Drug Pricing Program Omnibus Guidance. This notice (a copy of which can be found here) proposes to establish long-awaited and significant guidance for covered entities enrolled in, and drug manufacturers participating in, the 340B Program. Once finalized after public comments are submitted and reviewed, this guidance will form the basis of 340B Program compliance for participating covered entities and manufacturers alike. This guidance is scheduled to be published in the Federal Register on August 28, 2015 and will have an open comment period for 60 days after its publication. Interested 340B Program stakeholders must submit comments on or before October 27, 2015. Hall Render is currently analyzing the implications of this guidance and will provide a more substantive discussion of the key provisions in coming days. If you would like additional information about this issue, please contact:

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- Your regular Hall Render attorney.

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