

Resurrection of the 340B Mega Rule - Health Resources and Services Administration (HRSA)

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In November 2014, we provided an update, which noted that the ***Health Resources and Services Administration (HRSA)*** had halted publication of the ***340B Mega Rule***. HRSA, however, has now resurrected the Mega Rule having recently submitted the “340B Program Omnibus Guidelines” to the Office of Management and Budget, which is pending review.

The substantive contents of the rule are not yet available to the public. Commentators, however, are predicting that it will address a number of issues (e.g. definition of patient, contract pharmacy compliance requirements, hospital eligibility criteria and eligibility of off-site outpatient locations).

After the HRSA’s previous rule making was invalidated because it was found to be “substantive”, the HRSA issued an “interpretive” rule, which is the subject of current litigation to further determine the scope of HRSA’s rule making authority. The parties have submitted motions for summary judgement, and several *amici curiae* have filed briefs. The parties are currently waiting to hear from the court. ***PhRMA v. HHS***, Docket # 1:14-cv-01685-RC (D.D.C. Oct 09, 2014).

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