



## Federal court overturns 340B Drug Discount Program reimbursement cuts – future still uncertain

January 31, 2019

On December 27, 2018, the District Court for the District of Columbia issued a decision in [American Hospital Association, et al. v. Azar, No.18-2084\(RC\) \(D.D.C. December 27, 2018\)](#), holding that the cuts imposed by the Department of Health and Human Services (HHS) on certain drugs purchased through the 340B Drug Discount Program were an improper overstepping of the government's authority.

In its 2018 Outpatient Prospective Payment System (OPPS) rule, HHS reduced the reimbursement rate for the majority of drugs purchased under the 340B program from their historic reimbursement rate of average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. This reimbursement reduction went into effect on January 1, 2018. The plaintiff group, which consists of a number of national and regional hospital associations and several individual hospitals and hospital systems, had previously challenged the government's rate reduction in a suit [dismissed](#) earlier last year and [refiled](#) in September 2018. The cuts imposed by HHS were forecast to reduce reimbursement to 340B program-enrolled hospitals by roughly \$1.6 billion in 2018.

The plaintiffs in the case were seeking both an injunction that would prohibit the rate



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cut from continuing in the future, as well as reimbursement from the government for the difference between what hospitals were paid for 340B-purchased drugs in 2018 and what they would have been paid under the pre-2018 reimbursement calculation. Plaintiffs argued that the rationale and justification for HHS' change in reimbursement was beyond its statutory authority, because it calculated the new ASP minus 22.5 percent using an estimate based on hospitals' average acquisition cost rather than relying on the average sales prices of the drugs.

The district court agreed with plaintiffs that the change in reimbursement calculation made by HHS was beyond its statutory authority. While HHS characterized the changes as merely an "adjustment" in rates, the court agreed with plaintiffs that the change was a more wholesale and basic change to the fundamental structure of the reimbursement and was, therefore, outside the statutory authority on which HHS had relied.

Though the court granted a permanent injunction against continued application of the payment reduction, it neither awarded plaintiffs the retroactive damages they sought nor vacated the portions of the 2018 OPSS rule that imposed the cuts. The court found that such a result, at this stage, would be highly disruptive to overall Medicare reimbursement because of (1) the large volume of Medicare payments already issued for 2018 and (2) the Medicare budget neutrality provisions requiring refunds given to hospitals in this context to be taken away from providers in some other equal fashion. Because of these complications, the court ordered the parties to submit supplemental briefings within 30 days outlining viable solutions based on the court's findings regarding HHS' actions.

Until the court reaches a decision based on the supplemental briefing, reimbursement rates for hospitals for 340B drugs will not change from the 2018 levels.