



Could relief from the Medicare cuts in reimbursement for 340B drugs be coming soon for hospitals?

July 11, 2019

Update: Following the court's decision in May 2019, both the plaintiff hospitals and HHS filed further motions in the case – the plaintiffs moved for a firm date by which HHS must propose a remedy to the court. HHS moved for reconsideration of the order and requested entry of final judgment, contending that the court's retention of jurisdiction was “clear error” and that an entry of final judgment was necessary for expeditious review on the merits in the appeals court. On July 10, 2019, the district court granted HHS's motion for final judgment and dismissed as moot plaintiffs' motion for a firm date. On July 11, 2019, HHS filed its notice of appeal of the order entering final judgment and related opinion and all prior rulings that merged with the final judgment to the United States Court of Appeals for the District of Columbia circuit. Our July 11, 2019 e-Alert about the court's decision is below. We will continue to monitor this case and provide updates as warranted.

Relief for hospitals that have endured drastic cuts in Medicare reimbursement for the majority of drugs they purchase under the 340B drug discount program may be coming soon. A federal judge recently affirmed his prior decision in the case *American Hospital Association, et al. v. Azar*, No.18-2084 (RC) (D.D.C. May 6, 2019), finding that the drastic cuts to Medicare reimbursement for drugs purchased through the 340B drug discount program exceeded the authority of the Secretary of the Department of Health and Human Services (HHS) and were unlawful. This second [decision](#) comes five months after the first decision, which we [reported](#) on in January 2019. Both decisions held that the cuts in Medicare reimbursement were unlawful.

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 cuts imposed by HHS were forecast to reduce reimbursement to 340B program-enrolled hospitals by roughly \$1.6 billion in 2018. The 2019 OPPS rule continued the reduced reimbursement rates for 2019.

In the court's late 2018 [decision](#), the judge ordered the parties to submit supplemental briefing on the appropriate remedy in light of the judge's finding that the reimbursement cuts were unlawful. The new decision addresses that remedy, as well as the supplemental complaint filed by the same group of plaintiffs alleging that the 340B reimbursement rate for 2019 again exceeded HHS's statutory authority and was unlawful. In the most recent decision, the judge declined HHS's invitation to "reconsider its conclusion" and "enjoin[ed] the 2019 OPPS Rule for the same reason that it enjoined the 2018 OPPS Rule." Noting that injunctive relief (which the plaintiffs requested) is typically appropriate when "there is "only one rational course" for the [a]gency to follow upon remand," the court found that injunction was not appropriate in this case since "HHS has multiple courses [of possible remedy] on remand." The judge remanded the case to HHS, without vacating the 2018 and 2019 OPPS Rules, to give HHS the opportunity to consider and adopt an appropriate remedy. But the court retained jurisdiction of the case and ordered the parties to submit a status report on HHS's progress in remedying "the issues raised in this litigation concerning the 2018 and 2019 OPPS Rules" by August 5, 2019, and commented that it "expects that the agency will act expeditiously to resolve these issues."

Authors
