340B Reimbursement Cut Update: 135 Hospitals File Suit to Block Rate Cuts Previously Ruled Unlawful

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On December 16, 2019, a nationwide coalition of hospitals <u>sued HHS</u> to block implementation of the 340B rate cuts contained in the <u>2020 Hospital Outpatient Prospective Payment System ("OPPS")</u> <u>Final Rule</u>. As detailed in our <u>prior blog</u> post, the 2020 OPPS Final Rule reduces by nearly 30% the Medicare Part B reimbursement for certain drugs provided by hospitals to outpatient beneficiaries that are acquired through the 340B Program. The final rule purports to continue the reimbursement cuts for 340B drugs first implemented in 2018, despite the fact that those cuts (and the 2019 OPPS rule continuing those cuts) are the subject of <u>ongoing litigation</u> in which the cuts were determined to be unlawful. For a detailed walk-through of the 2020 OPPS Final Rule and litigation up to this point, please see our prior three blog posts <u>here</u>, <u>here</u>, and <u>here</u>.

While the industry waits for the Court of Appeals for the D.C. Circuit to rule on CMS's appeal of the district court's injunction of the 2018 and 2019 340B reimbursement cuts, a large group of hospitals has moved to enjoin identical reimbursement cuts for 2020 before they take effect in *Advocate Bromenn Regional Medical Center v. Azar*. The new complaint was filed in the U.S. District Court for D.C., which previously held that the 2018 and 2019 cuts are unlawful.

The complaint asserts that the hospitals have exhausted their administrative appeals rights, further administrative is futile, and, therefore, the matter is ripe for judicial review. The hospitals note specifically that: 1) their administrative appeals to the rate cuts have been dismissed or denied; 2) no adjudicator within CMS has the authority to invalidate 340B rate cuts implemented through regulation; and 3) CMS has taken the position that there is no administrative review of the 340B reimbursement disputes.

Interestingly, the instant case was brought by a coalition of hospitals and not the American Hospital Association, as in the prior cases. However, unsurprisingly, the compliant relies heavily on the D.C District Court's ruling that found the <u>2018 reimbursement cuts for 340B drugs unlawful</u>. There, the Court ruled that CMS acted *ultra vires*, or beyond its authority, when it implemented the Medicare Part B OPPS reduction for 340B drugs. The Court held that a reimbursement cut approximating 30% was just too extreme to qualify as an "adjustment" under the law. The new case was assigned to Judge Contreras, the same judge who found the 2018 and 2019 cuts unlawful.

Given that the 2020 reimbursement cuts are identical to those previously enjoined by the same district judge, an injunction of the 2020 OPPS reimbursement cuts seems likely, assuming plaintiffs have standing to sue at this time. Regardless, the final outcome of this challenge will be heavily influenced by the decision anticipated from the Court of Appeals on the 2018 and 2019 reimbursement rates. That ruling itself will likely be subject to requests for rehearing and an eventual request for Supreme Court review.

For now, the 2018 and 2019 reimbursement rates remain subject to a stay, and barring an injunction from the district court, the 2020 reimbursement rates went into effect January 1, 2020. We will provide updates periodically as the litigation develops.

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