

Issue Brief

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Hospitals Prevail On 340B Drug Dispute with CMS at United States District Court for the District of Columbia

On Dec. 27, the U.S. District Court for the District of Columbia denied Defendants (the Department of Health and Human Services) motion to dismiss and granted Plaintiffs motion for a permanent injunction, regarding the Centers for Medicare & Medicaid Services' rulemaking to reduce purchased 340B drugs from Average Sales Price plus 6.0 percent to ASP minus 22.5 percent.

The court notes that “Defendants, HHS and its secretary contend that the rate adjustment was statutorily authorized and necessary to close the gap between the discounted rates at which Plaintiffs obtain the drugs at issue — through Medicare’s “340B program” — and the higher rates at which Plaintiffs were previously reimbursed for those drugs under a different Medicare framework.”

The court concludes that it has jurisdiction to provide relief in this case. The court says, “While Plaintiffs are entitled to some relief, the potentially drastic impact of this court’s decision on Medicare’s complex administration gives the court pause. Accordingly, the court orders supplemental briefings on the question of a proper remedy.”

The court’s decision notes that hospitals participating in the 340B program purchase 340B drugs at steeply discounted rates, and when those hospitals prescribe 340B drugs to Medicare beneficiaries, HHS reimburses them at the Outpatient Prospective Payment System rates. Before 2018, the relevant OPPS (payment) rate for 340B drugs was ASP plus 6.0 percent. Further, the court says that this rate resulted in a significant gap between what hospitals paid for 340B drugs and what they received in Medicare reimbursements for those drugs, because the 340B program allowed participating hospitals to buy the drugs at a far lower rate than ASP plus 6.0 percent.

In regards to Plaintiffs exhausting administrative remedies, the court notes, “Plaintiffs have presented claims for reimbursement to the secretary under the 2018 OPPS Rule, and because Plaintiffs’ exhaustion of their administrative remedies would be futile, the court waives Plaintiffs’ exhaustion requirement and exercises its subject matter jurisdiction under 42 U.S.C. § 405(g).”

The decision document says, “The question for the court, then, is whether the change at issue here —reducing

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continued

the default 340B drug reimbursement rate of ASP plus 6.0 percent to ASP minus 22.5 percent — is so substantial as to be a patient violation of the secretary’s § (t)(14)(A)(iii)(II) adjustment authority.” The court further says, “The changes that the secretary imposed are not modest. Indeed, by changing the formula from the statutory default of ASP plus 6.0 percent to ASP minus 22.5 percent, the secretary is imposing a nearly 30 percent reduction from the formula that Congress expressly set as the standard. When viewed together, the rate reduction’s magnitude and its wide applicability inexorably lead to the conclusion that the secretary fundamentally altered the statutory scheme established by Congress for determining specified covered outpatient drugs reimbursement rate, thereby exceeding the secretary’s authority to ‘adjust’ SCOD rates under § (t)(14)(A)(iii)(II).”

CONCLUSION

“For the foregoing reasons, Plaintiffs’ motion for a preliminary injunction (ECF No. 2) is DENIED AS MOOT, the Secretary’s Motion to Dismiss (ECF No. 14) is DENIED, and Plaintiffs’ Motion for a Permanent Injunction (ECF No. 2) is GRANTED, insofar as Plaintiffs are entitled to equitable relief. Fashioning that relief, however, requires supplemental briefing from the parties addressing the relief’s proper scope and implementation. Consequently, it is HEREBY ORDERED that:

1. The parties shall provide supplemental briefing on the appropriate remedy, limited to no more than 25 pages per brief, within 30 days of this Memorandum Opinion’s issuance; and

2. The parties shall respond to those briefs, limited to no more than 15 pages per response, within 14 days after the supplemental briefs are filed.

An order consistent with this Memorandum Opinion is separately and contemporaneously issued.”

COMMENT

While it appears hospitals have won a significant case against HHS, the issue appears far from resolved. As noted above, the court seeks additional information as to “fixing” the amounts in question.

The court notes that under the budget neutrality requirement, reducing 2018 340B reimbursement rates allowed the secretary to increase reimbursements for other drugs and services covered under Medicare Part B; increasing 340B reimbursement rates likewise would require the secretary to reduce reimbursements elsewhere in the program.

For instance, in finalizing the 2018 OPPS Rule, the secretary stated that the reduced payments for separately payable drugs purchased through the 340B program would increase payment rates for other nondrug items and services paid under the OPPS by an offsetting aggregate amount.

The court says, “Retroactive OPPS payments that Plaintiffs seek here would presumably require similar offsets elsewhere; a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018.”

*Analysis provided for MHA
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