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340B Program

Hospitals Lose Challenge to Rate Cuts for Safety-Net Drugs (1)

By MEG McEVOY

A hospital industry group lost its argument to get an appeals court to stop Medicare discount drug payment cuts.

The American Hospital Association and other hospital groups lost a challenge over the HHS's nearly 30 percent reduction in the Medicare reimbursement rates that safety-net hospitals receive for certain drugs they buy on discount. The hospitals get discounts for these drugs under the federal 340B drug pricing program, under which pharmaceutical companies have to lower drug prices for participating hospitals.

A three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit said July 17 it did not have jurisdiction to hear the hospitals' case and that they must challenge the rates by going back to the Medicare agency.

The industry groups, which include AHA, the Association of American Medical Colleges, and America's Essential Hospitals, had argued that the rate adjustment wipes out \$1.6 billion of reimbursements—money the hospitals use to provide other health services to needy populations. The hospitals said the Medicare rate adjustments were so significant that they ran counter to the statutory scheme of the 340B program.

"I've heard from many hospitals that [the rate cuts have] been a hard pill to swallow for them and it has caused budgetary issues," Justin Linder, of counsel with Dughi, Hewit & Domalewski PC in Cranford, N.J., told Bloomberg Law. Linder works on drug pricing and health-care regulatory matters.

Rate Cuts In 2017, the Centers for Medicare & Medicaid Services looked at the Medicare reimbursement rates for hospitals getting discounted drugs from pharma companies under 340B, a program administered by the Health Resources and Services Administration at the Department of Health and Human Services. In July 2017, the CMS proposed changing the reimbursement rate for outpatient drugs reimbursed through the outpatient prospective payment system, which pays hospitals directly for administering outpatient drugs and providing services.

The proposed rule reduced payment rates from "average sales price" of the drugs plus 6 percent, to hospi-

tals' actual acquisition cost of the drugs, which the CMS estimated to be average sales price minus 22.5 percent.

The hospitals objected to the change during the agency's notice and comment period, but the agency adopted the payment reduction in November 2017.

In January, the U.S. District Court for the District of Columbia denied the hospitals' request for an injunction to prevent the rate cuts because they "failed to present any claim to the Secretary [of HHS] for final decision."

Appeals Court Decision At oral argument, the D.C. Circuit panel seemed skeptical that the hospitals had not waited until the new rates went into effect and then challenged their reimbursements under those rates at the agency level.

In its opinion, the court found that the hospitals' claims had not been properly presented to the agency for appeal. Although the AHA had filed comments in an informal rulemaking process, the court did not find that that was an appealable final decision under the Medicare statutes.

According to the court, the hospitals must exhaust their administrative remedies available through the HHS.

"We are deeply disappointed that the courts have once again failed to rule on the merits of our case," the hospital groups said in a statement provided to Bloomberg Law.

"As today's decision stated, 'The question presented is not whether they may obtain judicial review of their challenges . . . but when and how they may do so through the special-review scheme for Medicare claims.'"

The hospital groups said they plan to refile their case in district court now that the new rates have gone into effect and some reimbursement appeals have been denied at the agency level.

Linder said that because the hospitals must re-file, it will be many months before there is an ultimate decision on the rates.

"Now that the presentment issue has been resolved," the real question that a court must determine is "whether it is within the discretion of the [HHS] secretary to make these adjustments without judicial review," Linder said.

The case is *Am. Hosp. Assoc. v. Azar*, D.C. Cir., No. 18-05004, 7/17/18.

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