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Hospitals' Appeal Hopes to Undo Medicare Drug Pay Cut

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- *Hospital groups challenge agency rule slashing reimbursement rates for drugs in a safety-net discount program*
- *\$1.6 billion in payments are at stake in challenge to agency authority*

Hospital groups are claiming that an appeals court must act fast to help them avoid losing about \$1.6 billion in Medicare reimbursements for drugs they buy in a safety-net program.

The U.S. Court of Appeals for the District of Columbia Circuit last week heard [oral argument](#) in a case on behalf of hospitals that are suing the Department of Health and Human Services, claiming the agency did not have the authority to enact a nearly 30 percent reduction in the Medicare reimbursement rate safety-net hospitals receive for certain discounted drugs. The hospitals get discounts for these drugs under the federal 340B drug pricing program.

The 340B drug pricing program allows certain health-care providers, including many safety-net hospitals, to receive discounted pharmaceuticals. The appeals court's decision will determine whether the hospitals can challenge the rate-setting in court or whether they are stuck with the reduced rates.

The thorny administrative law case affecting 2018 hospital payments is one piece of an ongoing debate about whether hospitals that get discounts under the beleaguered 340B discount program are helping patients or getting a windfall.

Reduced Payments

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 HHS. 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 hospitals' 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.

The hospitals said in court filings that this amounted to an approximately 30 percent reduction in reimbursement rates. The rate adjustment wipes out \$1.6 billion of reimbursements—money the hospitals use to provide other health services to needy populations, according to the hospitals.

In January, the district court denied the hospitals’ request for an injunction because they “failed to present any claim to the Secretary [of HHS] for final decision.” The hospitals petitioned the D.C. Circuit for review and were granted an expedited appeal.

Procedural Focus

On May 4, the three-judge panel spent nearly all of the hour-long oral argument questioning the hospitals’ subject matter jurisdiction—that is, the question of whether the hospitals needed to ask the agency, rather than the court, for relief.

The problem with getting sent back to the agency, according to the hospitals, is that they won’t be able to challenge the rate-setting itself, only reimbursements under those rates. In a related action concerning Medicare appeals, the agency had said it would dismiss any 340B underpayment claims. The hospitals said this means that presenting their challenge to the agency would be futile, which warrants court review of the matter.

Judge Patricia A. Millett said during oral argument that she sees a number of cases every year challenging how the HHS is calculating prospective payments for hospitals. “I’ve never seen one of those that has been challenged through the mechanism you’re proposing here,” she said.

In the last five minutes of argument, Michael R. Smith, a partner with Zuckerman Spaeder in Washington representing the hospitals, addressed the merits of their claim—that the agency exceeded its authority under the Medicare statute by adjusting reimbursement rates so dramatically without sufficient data.

“That was not an ‘adjustment’ to the average sales price,” the hospitals wrote in their brief. “Instead it was an end-run of the statute used by HHS to establish a price that eliminated most of the benefit of the 340B program”

“We thought the oral arguments went as well as they could have,” Melinda Hatton, general counsel for the American Hospital Association, told Bloomberg Law. “We made all the points we wanted to make on procedural issues, and we are pleased that the court was able to spend a little bit of time on the merits.”

“The AHA very competently set forth the argument that the adjustment can’t be so much that it upsets the statutory scheme,” 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.

Hatton said she feels confident that the court will find the hospitals’ claims are not precluded under the Medicare statute.

Hospitals’ Avenues Forward

There are numerous legal avenues for this case to proceed. The court of appeals could address the merits of the hospitals’ argument about lack of statutory authority without remanding, Hatton said. Or, the appeals court may remand to the trial court to decide the merits.

Hatton said the hospitals will appeal if the court finds against them on the preclusion issue.

The hospitals also now have pending administrative appeals of reimbursements since the rule went into effect in January, some of which have already been denied. These could end up in court on expedited judicial review, unless the agency declines to hear the reimbursement appeals.

In the meantime, the hospitals are “going to continue to get reimbursed at a lower rate,” Linder said. “Some 340B hospitals will likely be unable to fund some of the programs they were using the 340B reimbursement differential to fund. The money just might not be there to fund programs for the uninsured and underinsured.”

“As the administration acknowledged in its briefing, the longer this case goes on the harder it is for them to fix what they’ve done,” Hatton said. “A swift resolution is in the public’s interest.”

The question of whether the 340B program is bloating hospital coffers, and what to do about it, is not going away. The program has been under heavy scrutiny by congressional Republicans and the pharmaceutical industry.

The Senate Committee on Health, Education, Labor and Pensions will hold a [hearing](#) May 15 on oversight reports on the 340B program.

The case is *Am. Hosp. Assoc. v. Azar*, D.C. Cir., No. 18-05004, oral argument 5/4/18 .

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