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Appeals Court Sides with Drug Manufacturers in 340B Contract **Pharmacy Case**

On Jan. 30, the U.S. Court of Appeals for the 3rd Circuit <u>ruled</u> that drugmakers participating in the 340B prescription drug discount program do not have to provide 340B discounts at an unlimited number of contract pharmacies utilized by hospitals and other covered entities. The appeal considered a split decision from two lower courts, one of which had previously sided with drugmakers and the other which had previously sided with the federal Health Resources and Services Administration (HRSA). In reaching its conclusion, the court ruled the federal statute is silent on the



use of contract pharmacies and the federal government did not have adequate rulemaking authority to warrant agency deference.

At issue are actions initiated in 2020 where drugmakers began to cease offering discounts for 340B drugs dispensed at community pharmacies that contract with hospitals or other 340B-covered entities. As of Feb. 1, 2023, 21 drug manufacturers have announced similar pricing restrictions. According to a 2022 report by the American Hospital Association (AHA), these actions have resulted in drug cost increases of \$500,000 for the average critical access hospital and nearly \$3 million for the average disproportionate share hospital—with some seeing drug costs increase by more than \$10 million annually due to the loss of these discounts.

While HRSA <u>announced in 2021</u> that it would seek civil monetary penalties for drugmakers that continued to illegally deny these discounts, drugmakers countered this action by bringing lawsuits in four separate federal district courts. While two of these courts have issued decisions siding with HRSA, two have also sided with drugmakers. Three of these four decisions have been appealed, with the 3rd Circuit Court's decision being the first appeal decided. It is unclear when the remaining two appeals cases currently before the District of Columbia and 7th Circuit will be decided.

In other 340B news, the AHA is requesting a meeting with the U.S. Department of Health and Human Services (HHS) to discuss how the department should go about finding a remedy for unlawfully underpaying PPS 340B hospitals for five years. This follows a Jan. <u>10 U.S. District Court decision</u> asking the Department to propose a remedial solution. In its <u>letter</u>, the AHA is requesting HHS promptly repay hospitals fully and with interest, while refraining from recouping funds from other hospitals (who bear no responsibility for HHS's actions) in the process. The AHA has argued that while HHS has the authority to use budget neutrality to set future payments in its outpatient prospective payment rule, it lacks any legal authority to use the budget neutrality principle to retrospectively recoup funds.

WHA will continue to closely follow these issues and advocate on behalf of 340B hospitals. Contact WHA Vice President of Federal and State Relations Jon Hoelter with questions.

Other Articles in this Issue

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