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Decision on Payment Reductions Looks Fleeting as Ruling Also Provides HHS With Instructions on Cost-Cutting Goals

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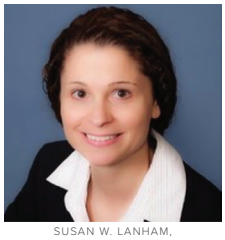

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UNDER THE FEDERAL 340B PROGRAM, hospitals and eligible health care clinics that serve low-income or rural populations can qualify for federally negotiated manufacturer discounts on purchases of prescription drugs.[1]

Approximately 50,000 entities participate in the 340B program, where pharmaceutical manufacturers are instructed to supply outpatient medications to participating providers at discounted rates of 20% to 50%.[2] Participating hospitals depend on profits from the differential between their reimbursement for these drugs and the discounted rates they disburse to finance affordable patient care in underserved communities.

On June 15, 2022, the US Supreme Court ruled that major cuts to 340B payments were unlawful, an important victory for participating hospitals. But this win may be transitory, as the Supreme Court also gave the US Department of Health and Human Services (HHS) clear instructions on achieving its cost-cutting goals.

The Medicare statute lays out 2 options for HHS to calculate reimbursement rates.[3] Under the first option, HHS may survey hospitals to determine drug acquisition costs, with reimbursement rates set at the average acquisition cost. HHS may then vary the average acquisition cost by hospital group, as indicated by survey data. Under the second option, HHS may survey drug manufacturers to determine their average sales price (ASP).[4] Importantly, this second option does not explicitly give HHS the authority to vary the ASP by hospital group, though HHS has been given authority to adjust the ASP up or down as necessary to achieve statutory purposes.

From the statute's passage until 2018, HHS exclusively used the second option,

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setting reimbursement rates at 106% of the ASP for all hospitals.[5] Because 340B hospitals purchase drugs at a discount to the average sales price, these hospitals received a payment that non-340B hospitals could not obtain. They achieved the same reimbursement rate as non-340B hospitals while enjoying significant cost savings. In 2018, HHS determined that because it had the authority to adjust drug reimbursement rates under the second option, it could vary reimbursement rates between 340B hospitals and non-340B hospitals as a cost savings measure. HHS argued that it had this authority even if it did not conduct the hospital survey as provided under the first option.[1]

HHS determined that 340B hospitals would be reimbursed only 77.5% of the ASP, rather than the 106% non-340B hospitals received. This adjustment represented a $1.6 billion annual cut to 340B hospital reimbursements.[1]

When the Supreme Court unanimously ruled that HHS incorrectly calculated the reimbursement rates, it was on the basis that HHS did not follow the correct procedure. Under the statute, if HHS surveys only drug manufacturers, it is free to adjust

the reimbursement rates up or down but it may not set different reimbursement rates for distinct groups of hospitals. HHS can vary reimbursement rates among hospital groups only if it surveys hospitals to determine the average acquisition cost.[1]

The Supreme Court expressly endorsed HHS paying reduced reimbursements to 340B hospitals so long as HHS survey hospitals for drug acquisition cost information.[1] Consequently, 340B hospitals are not guaranteed to receive the drug reimbursement windfalls moving forward. Indeed, before the case was decided, HHS began surveying hospitals for drug acquisition costs.[1] Although the survey was not complete, the calculation of 2020 reimbursement rates, reimbursements for 2021, 2022, and 2023 could be determined from the survey data.[6]

Practical Implications

More legal battles around the 340B Program are likely. Because the statute imposed specific requirements on HHS in conducting the hospital surveys,[7] further litigation may be required to fully establish whether the 2020 survey sufficiently supports the differing reimbursement rates for 340B hospitals. The Department of Health and Human Services, Office of Inspector General, is investigating several pharmaceutical companies for restricting contract pharmacies' access to 340B drugs.[8] The result of the investigations could be fines against these pharmaceutical companies, which will undoubtedly instigate lawsuits from drugmakers. The program's lack of reporting requirements and transparency will continue to create additional concern and scrutiny. Details regarding the amounts being paid and saved and how those savings are used are required to determine if the legislation's 340B program goals are met.[2]

Hospitals participating in the 340B program should be aware of the uncertainty in Medicare reimbursement when considering funding. HHS has prioritized cost savings. However, the Supreme Court noted that the 340B drug reimbursement windfall offsets costs hospitals incur providing care to disadvantaged communities,[9] including rural populations, as well as uninsured and underinsured patients.[2]

One item to observe closely is the 2023 Outpatient Prospective Payment System proposed rule released by the Centers for Medicare & Medicaid Services (CMS).[10] For 2023, CMS proposed a payment rate of ASP minus 22.5% for drugs and biologicals obtained through the 340B program.[11] Therefore, the CMS payment plan in this proposed rule could shed some light on its approach, not only on future payments but also on remedying past underpayments. ■

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