The labyrinth of 340B litigation — what covered health care entities should know

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JULY 11, 2023

The federal 340B Drug Pricing Program ("340B"), which is intended to help safety-net health care providers stretch their financial resources to reach more financially vulnerable patients and deliver comprehensive services, is being shaped by key 2023 legislation and litigation. Simply put, 340B provides discounts on outpatient pharmaceutical drugs for certain health care providers ("covered" or "qualifying" entities).

In 2020, the total sales of 340B-discounted drugs were estimated to be $38 billion, or roughly 7% of the total U.S. drug market. As such, the pending resolution of the various issues concerning 340B will have a monumental financial impact on the health care industry — specifically as it concerns pharmaceutical manufacturers and 340B-covered entities.

An overview of the 340B program

In 1990, the Medicaid Drug Rebate Program ("MDRP") was created by Congress to lower the cost of pharmaceuticals reimbursed by state Medicaid agencies. The MDRP requires pharmaceutical companies to enter into a rebate agreement with the Secretary of the Department of Health and Human Services ("HHS") as a precondition for coverage of their drugs by Medicaid. Further, the program requires pharmaceutical manufacturers to pay rebates to state Medicaid programs for "covered outpatient drugs," defined under the rebate statute — an amount determined in part on the manufacturer's best price for a certain drug.

In 1992, Congress enacted the federal 340B Drug Pricing Program with the intention of extending to safety-net providers the same relief from high drug costs provided in the MDRP. Specifically, 340B requires pharmaceutical manufacturers to enter into a pharmaceutical pricing agreement ("PPA") with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. Essentially, the PPA states that the manufacturer agrees to provide a front-end discount on covered outpatient drugs purchased by "covered entities" that serve the nation's most vulnerable patient populations.

In other words, 340B allows covered entities to purchase physician-administered and outpatient drugs at a discounted rate from pharmaceutical manufacturers participating in the Medicaid program. The drug would then be reimbursed by an insured patient's health plan at a higher price. As such, the covered entity should use the gains from the sale of the drug to provide uncompensated health care to underinsured or uninsured patients.

Covered entities include disproportionate share hospitals and several types of non-hospital entities referred to as federal grantees: federally qualified health centers (FQHC), tribal/urban Indian clinics, Native Hawaiian health centers, children's hospitals and stand-alone cancer hospitals.

Key 340B litigation — what covered entities should know

American Hospital Association et al. v. Becerra et al.

In June 2022, the Supreme Court (SCOTUS) held that HHS had set unlawful Medicare reimbursement rates for hospitals participating in the 340B program in 2018 and 2019 and remanded the case to the lower courts where it was determined that the Centers for Medicare and Medicaid Services (CMS) must remedy the affected covered entities.

In sum, the case arose after CMS reduced Medicare reimbursement to hospitals by nearly 30% for pharmaceutical drugs acquired through the 340B program after research indicated that some participating hospitals were profiting excessively from 340B. Specifically, CMS intended to reduce reimbursement by an amount that equals the price of the discounted drugs that 340B covered entities were receiving — directly conflicting with the intended purpose of the program to create safety-net funding to covered entities providing a disproportionate amount of care to underinsured and uninsured patients.

As a result, the American Hospital Association (AHA) along with various covered entities challenged the reduced payment rates as unlawful. SCOTUS explained that the Medicare statute provides HHS with two options when setting reimbursement rate costs for outpatient prescription drugs. First, if HHS has conducted a survey of a covered entities' acquisition costs for certain outpatient drugs, then HHS may vary the reimbursement rates by hospital group.

However, if HHS does not conduct the survey it is required to set the rates based on the average sales price of the drugs as charged by the manufacturer. SCOTUS held that because the 2018 and 2019 CMS reimbursement cuts were varied by hospital group without the conducting of a survey, the rates were unlawful. In addition,

the Court observed that the unlawful reimbursement rates caused economic consequences to the tune of an estimated $1.6 billion annually.

SCOTUS remanded the issue to the D.C. Circuit Court of Appeals, which in turn remanded the issue to the federal District Court for the District of Columbia which found that CMS had to immediately resume paying 340B hospitals at the lawful rate. Currently, many affected covered entities anxiously await for CMS to reveal a repayment plan for the losses suffered in 2018 and 2019.

Covered entities should be concerned that CMS may try to claw back Medicare payments made to non-340B facilities to compensate the affected covered entities which would likely fuel an influx of legal battles between health care industry representatives and the government over the future and scope of the 340B program.

Genesis Healthcare, Inc., v. Becerra et al.

In 2017, the Health Resources and Services Administration (HRSA) conducted an audit of Genesis Healthcare, a holding company with subsidiaries that provide care services. HRSA discovered that 340B drugs were dispensed to ineligible patients.

Genesis filed suit challenging its removal, asserting HRSA was outside of its authority when attempting to enforce agency guidance beyond the allotted parameters expressed in the 340B Statute. The statute requires that 340B-covered entities may not resell or otherwise transfer 340B drugs to individuals who are not patients of a covered entity. Consequently, the HRSA terminated, and subsequently reinstated, Genesis after a complex series of legal actions.

Specifically, Genesis sued HHS over HRSA's narrow definition of eligible patients and a district court ruled in favor of HRSA's argument that the lawsuit was rendered moot by HRSA's reinstatement of Genesis into the 340B program, which Genesis appealed.

In July 2022, the 4th U.S. Circuit Court of Appeals disagreed with the trial court's mootness ruling citing the persistent problems relating to HRSA's 1996 definition of an eligible 340B patient. As a result, the case was remanded to the district court for further proceedings to address Genesis' allegation that the HRSA definition of "patient" is contradictory to the plain language of the 340B statute.

Although the Court has not addressed the definition of an eligible patient, covered entities should be aware that if the Court finds in favor of Genesis and invalidates the current definition, covered entities would be able to capture significantly more patients under the program. Such an expansion of the program would increase reimbursement for covered entities and the pharmacies that distribute the 340B drugs.

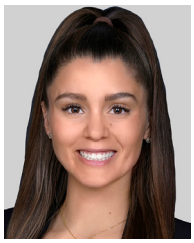
Conclusion

In sum, the 340B program has become defined by piecemeal case law, and without clear congressional guidance addressing the core design failures of the 340B program, frequent litigation and state policy actions will continue to disrupt the program and confuse participants. The pending decisions regarding the resolution of these fundamental issues are likely to be made in 2023 and determine the scope and direction of the 340B program.

Abbye E. Alexander and Christopher J. Tellner are regular, joint contributing columnists on health care litigation for Reuters Legal News and Westlaw Today.

About the authors





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This article was first published on Reuters Legal News and Westlaw Today on July 11, 2023.