Challenges to 340B and States' Laws Will Impact the Future Scope of the Law

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The 340B Drug Discount Program was enacted to combat a rise in drug costs and allow hospitals that serve low-income communities or treat a high-volume of uninsured patients to purchase outpatient prescription drugs at steep discounts. The program was established under section 340B of the Public Health Service Act, 42 USC, 256b, for "safety net" hospitals and clinics treating patients who cannot otherwise afford their drugs. Where the patient is insured, the hospitals can charge insurers the full list price for the drugs, with the intention that the hospitals would invest that savings back in those communities. Recent years have seen a surge of lawsuits brought both by the pharmaceutical manufacturers who participate in Medicaid, as well as 340B eligible providers (known statutorily as "covered entities"). The U.S. Department of Health and Human Services' (HHS) and states' authority to regulate the program hangs in the balance.

Background

Under the 340B statute, drug manufacturers that participate in federally funded health programs, must sell certain outpatient prescription drugs to covered entities at a lower cost "ceiling price." Third-party payors (insurance companies, including Medicare Advantage Organizations or MAOs) must reimburse the covered entities at the list price. The covered entities typically use contract pharmacies, which sell the drugs to the covered entities' patients.

The 340B program has provided critical health care access throughout the U.S. for more than 30 years. More than $100 billion in drug sales each year fall under the 340B program. Legal issues concerning the program have significant economic implications.

This article summarizes the range of 340B litigation that has arisen in the past few years.

Supreme Court Deems Unlawful Payment Reductions Between 2018 and 2020

Beginning in 2018, Medicare cut pharmaceutical payment rates to hospitals receiving the 340B discounts on the theory that these providers had a lower acquisition cost. Following the 340B payment reductions, the American Hospital Association and other organizations challenged the cuts in federal court, leading to the Supreme Court's unanimous decision in *American Hospital Assoc. et. al. v. Becerra, et. al.* deeming the 340B payment reductions from 2018-2022 invalid and ordering CMS to make 340B providers whole. 142 S. Ct. 1896 (2022). The opinion called the case "straightforward" due to CMS's clear statutory violation under 42 U.S. Code Section 1395l. There are two options for changing reimbursement rates but neither option provides a differentiation between 340B hospitals and other hospitals.

Under the final rule, CMS will pay approximately 1,600 eligible 340B hospitals a single lump sum payment of the calculated amount owed. This comes as a welcome relief for hospitals after years of litigation. However, CMS has taken the position that these payments must be "budget neutral." As a result, under the final rule, CMS will reduce outpatient payment rates for other services going forward until it recoups the entire amount of the lump sum payments. CMS will begin the offset in 2026 by adjusting the outpatient prospective payment system conversion factor by minus 0.5% until the full amount of the 340B lump sum payments are offset, estimated to be 16 years.

Notably, the final rule issued on November 2, 2022, addresses the concern reflected in comments to the proposed rule that MAOs could experience a windfall if they are not required to make refunds to hospitals and then benefit from the budget-neutral reductions in future rates. CMS responded to this concern by stating that "these comments are out of the scope of the final rule," pointing out that "CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities." Notwithstanding CMS's response, CMS does in fact have regulatory authority over MAOs.

Many MAO contracts adopt original Medicare outpatient payment rates, and some hospitals are now pursuing contractual claims against MAOs that refuse to make retroactive payments to hospitals in line with CMS's approach for original Medicare under the final rule. For some 340B hospitals, questions about how much reimbursement they should have received will be decided by courts. The decisions will affect their bottom lines, and ultimately have an impact on the care they provide to vulnerable communities.

Third Circuit and D.C. Circuit Find Against HHS's Regulation of Drug Makers' Restrictions

Over four years ago, certain drug manufacturers began limiting 340B providers that use contract pharmacies to distribute to patients by implementing restrictive policies, for example, to only use one contract pharmacy. The reason for the policy, according to the manufacturers, was to prevent duplicate discounting and diversion of 340B drugs. In the manufacturers' view, 340B hospitals, contract pharmacies, and clinics were susceptible to fraud, abuse, and duplicate discounts. In other words, these entities, in the view of the manufacturers, could exploit the statute for their own profit at the manufacturers' expense. In response, HHS sent violation letters to manufacturers that implemented such restrictions. These enforcement letters stated that the restrictions were in violation of the 340B statute and if not lifted, the manufacturers would face civil monetary penalties. The manufacturers, in turn, sued HHS.

The Third Circuit and D.C. Circuit sided with the pharmaceutical companies and

against the position set forth in HHS's advisory opinion that "section 340B requires manufacturers to deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner." *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 458 (D.C. Cir. 2024). The cases were essentially about whether Congress's silence in the 340B statute on the issue of use of contact pharmacies could be filled in by HHS in advisory opinions and guidance. In the Third Circuit case, the drug manufacturers argued that the law did not require them to supply discount drugs to an unlimited number of contract pharmacies. The Court agreed that Section 340B did not mention contract pharmacies, an intentional omission by Congress. Therefore, the Court found HHS's efforts to enforce its own interpretation was unlawful.

According to the Third Circuit:

> "Statutory silences, like awkward silences, tempt speech. But courts must resist the urge to fill in words that Congress left out. … The Department of Health and Human Services claims that drug makers must deliver certain discounted drugs wherever and to whomever a buyer demands. But the relevant law says nothing about such duties. So, HHS's efforts to enforce its interpretation against the drug makers here are unlawful."

Sanofi Aventis U.S. LLC v. United States Dep't of Health & Human Servs., No. 22-1676, 5 (3d Cir. 2023).

The policy at issue in the D.C. Circuit case stated that the manufacturer would honor the 340B price to contract pharmacies only where the pharmacy was within 40 miles of the covered health care facility. The D.C. Circuit "agree[d] entirely" with the Third Circuit on the question of whether drug manufacturers may impose contractual conditions on how their products are distributed to covered entities. The D.C. Circuit found that Novartis Pharmaceuticals and United Therapeutics did not violate 340B by implementing policies to limit the number and kinds of contract pharmacies that will distribute the lower-priced drugs. Echoing the Third Circuit, the D.C. Circuit wrote that it "cannot plausibly interpret statutory silence to subject manufacturers to whatever delivery conditions any covered entity might find most convenient." *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 461 (D.C. Cir. 2024). The Court ruled that the agency guidance was wrong: 340B does not restrict drug manufacturers from setting their own "restrictive conditions" such as "minimum purchase amounts."

The D.C. Circuit showed awareness that the 340B interpretation could swing too far in the other direction, emboldening drug companies to set more distribution conditions in ways that would limit discounted drugs and thwart Congress' intention. This decision should not be understood as a free pass for drug makers to set broader restrictive conditions. The Court was clear that other restrictions could violate 340B. And even HHS in its' guidance issued in 2010 allowed that there could be commercially reasonable distribution conditions. Whether drugmakers will push the legal envelope of their own distribution terms and where the agency and the courts will draw the lines when they see limitations go too far remains to be seen.

In the meantime, in the aftermath of the Supreme Court's decision in *Loper-Bright v. Raimondo*, which eradicated "Chevron deference," a court's mandate to uphold a federal agency's reasonable interpretation of a statute, challenges to the scope of HHS's interpretations of the federally mandated 340B program may continue to mount.

Eighth Circuit Decides that States Can Regulate Contract Pharmacies

By contrast with the D.C. and Third Circuits, in *PhRMA v. McClain*, the Eighth

Circuit examined the constitutionality of Arkansas Act 1103, which prohibits drug companies from declining to distribute 340B discounted drugs to contract pharmacies. The Eighth Circuit found the Act constitutional, reasoning:

> "Act 1103 does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B… Arkansas is simply deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements. There is no obstacle for pharmaceutical manufacturers to comply with both Act 1103 and Section 430B."

Although the Eighth Circuit was confronted with a question of state law, as compared to the agency advisory opinion responding to the manufacturer policies before the Third Circuit and D.C. Circuit, the difference in outcome could tee up review by the Supreme Court and another high court decision on the 340B statute.

After the Eighth Circuit ruled that the 340B statute does not preempt state laws regulating contract pharmacy use, states have enacted similar legislation, which now face legal challenges. In the same vein as the *McClain* case, this summer drug manufacturers sued the state Attorney Generals in Kansas, Maryland, Minnesota, Mississippi, and West Virginia, alleging that the state laws that block the manufacturers from implementing distribution restrictions are unconstitutional and improperly permit contract pharmacies to demand impermissible discounts. These disputes are working their way to judgment with two cases pending before the Fifth Circuit and other potential appeals heading to the Tenth and Fourth Circuits.

The Seventh Circuit Examines Similar Legal Questions Without Decision

A similar issue is currently pending before the Seventh Circuit. In *Eli Lilly & Co. v. United States Dep't of Health & Human. Servs.*, the drugmaker would only ship its 340B drugs when the covered entity did not have its own pharmacy or where the covered entity owned the contract pharmacy. The district court rejected the argument that an unconstitutional private taking occurs when the government requires that a drug company transfer its drugs to contract pharmacies as a condition of obtaining coverage of its drugs under federal health insurance programs. The court there reasoned that the plaintiff's voluntary participation in these programs "foreclosed the possibility that the statute could result in an imposed taking of private property." No. 1:21-CV-00081, (S.D. Ind. Oct. 29, 2021). The lower court explained that drug manufacturers:

> "have voluntarily chosen to participate in the 340B program and are thus free to terminate their participation if and when they may choose to do so …. We concede that in withdrawing from the 340B program Lilly would no longer receive coverage or reimbursement for its products under Medicaid and Medicare Part B, which would result in a significant financial impact for Lilly, but 'economic hardship is not equivalent to legal compulsion for purposes of takings analysis.'"

The Seventh Circuit heard arguments and the parties' filed supplemental briefs almost two years ago but at the time of this writing the Court has not published a decision. So, it remains unclear whether the Seventh Circuit will split from the D.C. and Third Circuits and whether the Supreme Court will see a need to weigh in. What is clear is that the outcome of this litigation will have an impact on the 340B program.

If the program is evaluated again by the Supreme Court, the unanimous *AHA v. Becerra* opinion contains hints that while the Justices see value in the 340B program ("340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support."), they believe that "the 340B story may be more complicated than HHS portrays it. In all events, this Court is not the forum to resolve that policy debate." Ultimately, if state legislation prohibiting manufacturer restrictions on 340B contract pharmacies is struck down, Congress may need to amend the statute.

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