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Legal Sidebar

Courts Evaluate the Role of Contract Pharmacies in the 340B Drug Discount Program

October 13, 2022

Congress created the 340B Drug Discount Program (340B) in 1992 through the Veteran's Health Care Act (P.L. 102-585) to enable safety net providers (those that provide health care services to "uninsured, Medicaid and other vulnerable patients") to purchase drugs at lower costs. The U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) oversees the Program. The authorizing statute—Section 340B of the Public Health Service Act—requires drug manufacturers that participate in Medicaid to offer drugs to "covered entities" at discounted prices. Covered entities include Federally Qualified Health Centers, children's hospitals, and other providers that care for rural and underserved populations. Since its creation, Congress has expanded the Program several times. HRSA estimates that 340B sales constitute about 7.2% of the U.S. drug market, and reports that in 2020, total Program sales exceeded $38 billion.

The majority of covered entities participating in the 340B Program do not have their own "in house" pharmacies but use contract pharmacies to ensure their patients have access to affordable outpatient medications. (A contract pharmacy is an outside pharmacy that is not owned or operated by the covered entity.) Since 2020, a growing number of drug manufacturers claim that covered entities' use of contract pharmacies has increased fraud and abuse and has resulted in duplicate discounts, which are prohibited by the 340B statute. As a result, several manufacturers have imposed price restrictions on covered entities that use contract pharmacies to purchase drugs. The restrictions have financial consequences on these providers, many of whom are now paying thousands of dollars more for 340B drugs. Some in Congress have encouraged HRSA to act on manufacturers' refusal to provide 340B discounts to covered entities that use contract pharmacies. For example, in July 2022, 181 Members of the House of Representatives signed a letter urging the agency to "take quick action to protect the integrity of the program," and impose penalties on manufacturers who imposed conditions on contract pharmacies in violation of the 340B statute.

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LSB10842

Background

The 340B statute requires the Secretary of HHS to enter into purchase price agreements with drug manufacturers that participate in the Medicaid Program. These agreements require manufacturers to sell certain covered drugs at a "ceiling price," which is calculated based on a statutory formula. The statute imposes requirements on both drug manufacturers and covered entities. For example, it prohibits covered entities from receiving duplicate discounts, and manufacturers are subject to civil monetary penalties if they overcharge for covered drugs. The statute also requires HRSA to ensure that both covered entities and manufacturers remain in compliance with the 340B Program.

In summer 2020, drug manufacturers began announcing plans to impose restrictions on covered entities that purchase 340B medications through contract pharmacies. According to an advocacy organization representing 340B covered entities, there are currently eighteen manufacturers imposing such restrictions on contract pharmacies. On May 17, 2021, HRSA sent violation letters to several manufacturers notifying them that the restrictions imposed on covered entities that use contract pharmacies violated the 340B statute. The agency threatened enforcement action, including civil money penalties, if the manufacturers failed to return to compliance. Manufacturers have since challenged the violation letters in four federal district courts across the country.

Litigation over the Violation Letters

A central issue in all of the district court cases is whether HHS acted within the scope of its statutory authority in issuing violation letters to drug manufacturers that impose 340B pricing restrictions on contract pharmacies. This question turns on whether HRSA's interpretation of the 340B statute accords with the statutory text, the Administrative Procedure Act (APA), and other laws. (Although several manufacturers argued that the violation letters constituted a taking under the Constitution's Fifth Amendment, the courts uniformly dismissed these claims, which are not discussed further in this Sidebar.)

When reviewing an agency's actions under the APA, courts set aside those that are "arbitrary, capricious, [or] an abuse of discretion," actions that are "contrary to a constitutional right, power, privilege, or immunity," actions that are taken "in excess of statutory jurisdiction," or actions conducted "without observance of procedure required by law," among other factors. This section explores the parties' legal arguments and the courts' different interpretations of the text, legislative history, and agency's guidance documents.

Legal Arguments Surrounding the 340B Statute

Before the district courts, HRSA argued that the statute's text and legislative history support its reading that manufacturers are required to offer 340B pricing to covered entities that use contract pharmacies. HRSA pointed to the statute's requirements that manufacturers both "offer" and "sell" drugs, which HRSA contended should include their delivery to contract pharmacies. HRSA argued that because the statute's "shall offer" provision lacks language expressly allowing manufacturers to restrict drug sales, manufacturers could not condition discounts on the covered entities' distribution method. HRSA also stated that the legislative history, when read in the context of the statutory text, supported the agency's issuance of the violation letters, because Congress's intent in creating 340B was to enable safety net providers to purchase drugs at lower costs. Finally, HRSA urged that although its position on its power to enforce the 340B statute had evolved over time, the agency's guidance on whether contract pharmacies are permitted in the Program had remained consistent. HRSA reasoned that such consistency supported its authority to issue the violation letters.

Drug manufacturers generally argued that the statutory text, legislative history, and HRSA's guidance on contract pharmacies all supported their view that manufacturers may impose conditions on contract pharmacies and that HRSA acted outside of its statutory authority by issuing the violation letters. The manufacturers contended that the statute's plain language did not require them to deliver drugs to an unlimited number of contract pharmacies because the "shall offer" provision, and specifically the term "offer," does not include drug *delivery* to contract pharmacies. They also pointed to the statute's failure to mention contract pharmacies specifically, arguing their actions in restricting sales to covered entities that use contract pharmacies was permissible, because the statute did not expressly ban it. The manufacturers also pointed to legislative history to argue that Congress intended for 340B pricing to be limited to covered entities alone. The manufacturers also provided evidence that the increasing number of contract pharmacies in recent years had led to fraud and abuse, and they urged that some covered entities were receiving duplicate discounts in violation of the 340B statute. Finally, the manufacturers alleged that HRSA issued inconsistent guidance on whether contract pharmacies were permitted by the Program, which they claimed made the letters "arbitrary and capricious" in violation of the APA.

Courts Setting Aside Violation Letters

Two federal district courts disagreed with HRSA's position that the 340B statute requires drug manufacturers to offer 340B discounts to contract pharmacies, holding that HRSA lacked the authority to issue the violation letters. The courts began with the statute's text, and particularly its directive that manufacturers "shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." In *Novartis Pharmaceuticals Corp. v. Espinosa*, the U.S. District Court for the District of Columbia agreed with the U.S. District Court for the District of Delaware in *AstraZeneca Pharmaceuticals LP v. Becerra* that "the statute's silence on [contract pharmacies] suggests that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." The D.C. district court further found that HRSA failed to explain how the statute's plain language allowed manufacturers to impose some conditions on covered entities, but not others, reasoning that the statute had no language expressly forbidding manufacturers from imposing conditions on covered entities.

Given the lack of statutory clarity on contract pharmacies, the courts also looked to the legislative history in concluding that HRSA violated the APA in its interpretation of the 340B statute. In *AstraZeneca*, the Delaware district court noted that in 1992, Congress considered adding contract pharmacy-specific language to the original 340B statute to clarify that 340B discounts apply to drugs "purchased and dispensed by, or under a contract entered into for on-site pharmaceutical services with" covered entities. Congress later removed this language, which is not part of the 340B statute. In finding that HHS violated the APA, the *AstraZeneca* court stated that the exclusion of this specific language "indicates that Congress did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies."

The courts also pointed to HRSA's guidance under the 340B statute as evidence that the agency violated the APA by sending out violation letters. HRSA argued that the guidance documents issued in 1994, 1996, and 2010 all consistently reflect its "longstanding interpretation of the statute" that covered entities may use contract pharmacies. But in *Novartis*, the D.C. district court concluded that the agency's guidance on contract pharmacies had shifted over time, and this was evidence that HRSA was trying to "fill a gap in the statute," which it did not have the authority to do. Similarly, the Delaware court noted in *AstraZeneca* that HRSA's position on contract pharmacies had evolved and that AstraZeneca's current policy to restrict the sale of drugs to contract pharmacies would actually comply with the 1996 guidance. The courts agreed that HRSA's interpretation of the 340B statute had changed over time, which they reasoned was evidence that HRSA violated the APA and lacked the authority to issue the violation letters.

Courts Upholding Violation Letters

Two other district courts arrived at the opposite conclusion. With respect to the "shall offer" provision, the U.S. District Court for the Southern District of Indiana concluded in *Eli Lilly & Co. v. U.S. HHS* that Congress's use of general language did not mean that drug manufacturers could condition the sale of 340B drugs to contract pharmacies. The court reasoned that the statute must be interpreted in its context, and that "the fairest and most reasonable interpretation . . . would not authorize drug manufacturers to impose unilateral restrictions on the distribution of [340B] drugs." In *Sanofi-Aventis U.S., LLC v. U.S. HHS*, the U.S. District Court for the District of New Jersey agreed, finding that the manufacturers took the "shall offer" provision "afield of its context" and that at least one contract pharmacy is "permissible as a drug dispensing mechanism" under the statute.

The Indiana and New Jersey federal district courts also found the legislative history to support HRSA's interpretation of the 340B statute with respect to contract pharmacies. Like *Novartis* and *AstraZeneca*, the *Eli Lilly* court noted that Congress considered adding language specific to contract pharmacies in 1992. But in *Eli Lilly*, the Indiana district court concluded, "the fact that Congress once considered but rejected restricting covered entities' choice of dispensing mechanism" supported HRSA's interpretation that manufacturers may not restrict sales to covered entities that use contract pharmacies. Moreover, in *Sanofi-Aventis*, the New Jersey district court agreed that the legislative history supported HRSA's position, "most significantly" because Congress had previously considered adding contract pharmacy-specific language but did not. The court's opinion notes that the statute, as currently written, does not limit covered entities' dispensing mechanisms and "[b]ecause Congress *eliminated* a clear limitation on contract pharmacy arrangements in the drafting process, it likely did not intend to *prohibit* them altogether."

Finally, the *Sanofi-Aventis* court analyzed guidance that HRSA issued on contract pharmacies in 1996 and 2010, finding it supported HRSA's authority to issue the violation letters. The court reasoned that the 2010 guidance "clarified" 340B hospitals could use contract pharmacies, stating that "from the beginning, HHS has always affirmatively answered the implicit premise of the letters: contract pharmacies are a permissible drug delivery system under the 340B statute." The court dismissed the manufacturers' arguments that HRSA's guidance was "legally flawed" and violated the APA because it changed over the course of thirty years, finding that HRSA's rationale on contract pharmacies "has remained the same." In *Eli Lilly*, however, the Indiana district court did not go so far. It remanded the violation letters to the agency, holding that while HRSA had sufficient authority to issue the violation letters, doing so was arbitrary and capricious because HRSA did not acknowledge it had changed its position on its enforcement authority under the statute.

Considerations for Congress

Three of the district court cases were appealed to the Courts of Appeals for the Third, Seventh, and D.C. Circuits. Differing outcomes in these cases could lead to more uncertainty surrounding the 340B Program, and potentially lead more drug manufacturers to consider whether to restrict covered entities that use contract pharmacies from 340B drug pricing.

The federal district court *Sanofi-Aventis* observed: "[M]any of the issues in this case would be best addressed were Congress to step in and expressly state its intentions for the direction of the 340B statute, as well as HHS' role in administering it." If Congress considers it appropriate, it could respond in several ways. Given the statutory ambiguity and its silence on the role of contract pharmacies in the 340B Program, Congress could amend the 340B statute to clarify the role that contract pharmacies can play in the Program and whether to impose any additional restrictions on covered entities' use of contract pharmacies. Congress could also clarify HRSA's authority to enforce the statute and any permissible actions the agency could take in the future for alleged violations.

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