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Legal Sidebar

# Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program

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The 340B Drug Discount Program enables eligible hospitals and other safety net providers to purchase outpatient prescription drugs at discounted prices. The Health Resources and Services Administration (HRSA), an operating division of the U.S. Department of Health and Human Services (HHS), administers the program. In recent years, both legal and policy disagreements have arisen between HHS, drug manufacturers, eligible providers (known as "covered entities"), and other stakeholders about the size of the program, how it should function, and who should benefit from it. For example, disagreements about covered entities' use of retail pharmacies to distribute 340B drugs to patients have led to a number of lawsuits that challenge both the Secretary of HHS's and states' authority to regulate the program.

This Legal Sidebar discusses recent judicial opinions ruling on HHS's and states' ability to regulate the 340B program. The U.S. Court of Appeals for the Third Circuit (Third Circuit) (*Sanofi-Aventis U.S. LLC v. HHS*), the U.S. Court of Appeals for the D.C. Circuit (D.C. Circuit) (*Novartis Pharmaceuticals Corp. v. Johnson*), and the U.S. Court of Appeals for the Eighth Circuit (Eighth Circuit) (*Pharmaceutical Research and Manufacturers of America (PhRMA) v. McClain*) each addressed interpretations of the 340B statute, focusing on the lack of statutory language around contract pharmacy use while addressing different legal questions associated with the same. According to the Third and D.C. Circuits, the statute restricts HHS from taking certain actions to address covered entities' use of contract pharmacies, which has enabled some drug manufacturers to effectively create 340B pricing restrictions for their drugs. The Eighth Circuit, assessing a different legal question, upheld an Arkansas law that prohibited such manufacturer restrictions, finding that the state prohibition was not preempted by the 340B statute.

## Background

The 340B statute requires the Secretary of HHS to enter into purchase price agreements (PPAs) with drug manufacturers who participate in federal health care programs. The PPAs require manufacturers to "offer" to sell certain outpatient prescription drugs at a ceiling price, which is calculated based on a statutory formula. The statute provides a list of covered entities that may purchase drugs from manufacturers at the discounted ceiling price, including Federally Qualified Health Centers (FQHCs), Rural Referral Centers, and some hospitals, such as Disproportionate Share Hospitals and Children's Hospitals. Covered entities can generate revenue from 340B (known as "340B savings") by dispensing these lower-cost drugs to

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patients and receiving list price reimbursement from third-party payers (e.g., insurance companies). Rather than distributing 340B drugs through their own in-house pharmacies, the majority of covered entities contract with retail pharmacies, known as contract pharmacies, who then sell drugs to patients. In accordance with the statute, 340B drugs may be provided only to patients of covered entities, and the statute prohibits covered entities from receiving duplicate discounts from both Medicaid and 340B. For additional information, see CRS In Focus IF12232, *Overview of the 340B Drug Discount Program*, by Hannah-Alise Rogers.

In summer 2020, some drug manufacturers began announcing restrictions on 340B covered entities that distribute 340B drugs using contract pharmacies. These restrictions vary, but they generally aim to limit covered entities to distribution to one contract pharmacy. Manufacturers say that the restrictions are necessary to prevent duplicate discounting and unlawful distribution of 340B drugs to nonpatients (also known as *diversion*), arguing that such practices have grown more prevalent in recent years and that HRSA does not adequately police them. The restrictions have financial consequences for covered entities, who argue they are now paying more for certain 340B drugs and are unable to generate 340B savings from them. Currently, there are at least 20 manufacturers with such restrictions.

HRSA responded to the restrictions in 2021 by issuing violation letters to manufacturers, informing them that their policies violated the 340B statute and threatening civil money penalties if they continued. Several manufacturers then sued the agency, claiming it lacked the authority to issue the violation letters because the statute permitted manufacturers to enact such restrictions. Several district court decisions were appealed to the D.C. and Third Circuits as well as the U.S. Court of Appeals for the Seventh Circuit (Seventh Circuit). The Third and D.C. Circuits have issued rulings, discussed below, finding that HHS lacked authority to issue violation letters. The Seventh Circuit has not yet issued a decision. More information about the district court decisions may be found in CRS Legal Sidebar LSB10842, *Courts Evaluate the Role of Contract Pharmacies in the 340B Drug Discount Program*, by Hannah-Alise Rogers.

At the same time that manufacturers were challenging HHS's authority to regulate contract pharmacy use, several states began considering legislation to make it unlawful for drug manufacturers to restrict contract pharmacy use by covered entities within that state. For example, in May 2021, the Arkansas General Assembly enacted Act 1103, which says that manufacturers may not prohibit pharmacies "from contracting [with] or participating with any [covered] entity." PhRMA challenged the state law, arguing that it was preempted by the 340B statute and the Commerce Clause. In December 2022, the district court held that the 340B statute and the Food, Drug, and Cosmetic Act (FDCA) did not preempt the Arkansas law. The Eighth Circuit affirmed this ruling, and its decision is discussed below.

# Litigation Concerning HHS's Regulation of Contract Pharmacies: The Third and D.C. Circuits' Decisions

After HHS issued violation letters to several drug manufacturers for restricting access to 340B pricing for covered entities that used contract pharmacies, some manufacturers, including Sanofi-Aventis, AstraZeneca, Novo Nordisk, Novartis, and United Therapeutics, sued the agency to challenge its authority to issue the letters. In the *Sanofi-Aventis* case, the District Court for the District of New Jersey upheld HHS's action, in part, finding that the drug manufacturer's 340B pricing restriction policy was unlawful; Sanofi appealed, and the government cross-appealed. The Third Circuit's decision on appeal focused on two issues: whether the 340B statute permits drug manufacturers to limit covered entity drug purchases that are distributed by contract pharmacies and whether the statute gives HHS the authority to stop such practices. Similarly, in the *Novartis* case, the D.C. Circuit reviewed the D.C. District Court's order setting aside HHS's violation letter. The issue on appeal was whether HHS's enforcement letter was

"arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under the Administrative Procedure Act.

In reaching its decision in favor of manufacturers, both the Third and D.C. Circuits began by considering the language of the 340B statute. The Third Circuit reasoned that the manufacturers' policies restricting contract pharmacy use were lawful because "[n]o . . . language in Section 340B requires delivery to an unlimited number of contract pharmacies." The D.C. Circuit's opinion further pointed out that the Secretary of HHS "lacks rulemaking authority over the 340B program." Both courts analyzed the statute's specific words, including that manufacturers are required to "offer" to sell 340B drugs, which are "purchased by" covered entities at or below a "ceiling price." The courts observed that the text of the statute did not speak directly to the delivery of drugs to contract pharmacies. The Third Circuit disagreed with HHS's argument that such terms required manufacturers to "offer" to sell and deliver drugs wherever the covered entity demands, holding this argument to be "one giant leap from the text," and observing that "when Congress's words run out, covered entities may not pick up the pen." The D.C. Circuit reached the same conclusion as the Third Circuit, finding that HRSA's position would "produce absurd consequences." The D.C. Circuit reasoned that under ordinary principles of contract law, offers may include price and nonprice terms. As for the statute's silence on contract pharmacies, the D.C. Circuit found that "[s]tatutory silence implies that manufacturers *may* impose distribution conditions by contract," consistent with the Supreme Court's ruling in *Christensen v. Harris County*, in which the Court held that a federal employment statute's silence on the imposition of contractual conditions did not implicitly prohibit the conduct.

The circuit courts also looked to the legislative history and overall purpose of the 340B statute, with the Third Circuit observing that "neither calls for a different outcome." With respect to the legislative history, the Third Circuit observed that previous attempts by Congress to amend the 340B statute to reference contract pharmacy use "can support opposite inferences," that either Congress did not want contract pharmacies to be part of the program, or that their use was so widespread that they were unnecessary to mention. The D.C. Circuit similarly disagreed with HRSA that the 340B statute's legislative history, specifically Congress rejecting an amendment that would have limited drug discounts to "on-site pharmacy services," supported a different result. The court stated that even if the "on-site pharmacy" amendment was significant, it "hardly suggests that Congress opted for the opposite extreme of categorically requiring manufacturers to deal with an unlimited number of contract pharmacies."

The courts were likewise unpersuaded by the government's argument that allowing drug manufacturers to limit contract pharmacy usage would "thwart Congress's purpose in enacting Section 340B." For example, the Third Circuit acknowledged that many covered entities would be unable to access 340B discounts without contract pharmacies, as most do not have their own pharmacies in-house. It found that "Congress might have expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy" but that this was a "far cry" from HHS's position that the statute allows covered entities to use an unlimited number of contract pharmacies. The D.C. Circuit also discussed HRSA's invocation of Justice Scalia's "predicate-act canon" of statutory interpretation, under which a court should disfavor a statutory construction that would frustrate congressional purpose or otherwise render a statute ineffective. The D.C. Circuit said, however, that "wider distribution" of 340B drugs via contract pharmacies "was not necessarily better," and that the agency's prior prohibition on the use of multiple contract pharmacies, which lasted nearly 20 years, "hardly rendered the scheme [of 340B] self-defeating or ineffectual."

The Third Circuit also pointed to other structural clues in the 340B statute to support its holding, citing the subsection of the statute that allows covered entities to contract with "prime vendors" to purchase and distribute drugs. The Third Circuit reasoned that Congress could have included similar language to permit covered entities to contract with outside pharmacies to distribute drugs or could have imposed delivery-related requirements on manufacturers, but it did not do so. The court also cited other language within the

Veteran's Health Care Act that enables Department of Veterans Affairs hospitals to access drug discounts that are purchased under "contracting systems." The court presumed that, because the 340B statute did not contain similar language, Congress did not intend for covered entities to contract with outside pharmacies to distribute 340B drugs.

Unlike the Third Circuit, the D.C. Circuit dedicated a portion of its opinion to analyzing the manufacturers' specific conditions on offers to sell drugs to 340B covered entities. For example, one manufacturer's condition is that it will deliver 340B drugs only to a covered entity's in-house pharmacy or a single contract pharmacy; the court observed that such a condition neither "precluded [the manufacturer] from making a bona fide 'offer'" to sell a 340B drug nor increased the requisite 340B ceiling price, in violation of the statute. The court did note, however, that a future, more "onerous" condition "might violate the statute," leaving open a window for future challenges.

# Litigation Concerning State Attempts to Regulate Contract Pharmacies: The Eighth Circuit's Decision

PhRMA sued the State of Arkansas after it passed a law that prohibited drug manufacturers from restricting covered entities in the state from accessing 340B pricing when using contract pharmacies to distribute 340B drugs. The district court found that the state law was not preempted by the 340B statute, and PhRMA appealed this ruling to the Eighth Circuit. The issue on appeal concerns whether the 340B statute preempts Arkansas Act 1103, which was intended "to protect contract pharmacy arrangements in Arkansas." In addition to prohibiting manufacturers from disrupting contracts between pharmacies and covered entities, the law also prevents manufacturers from denying 340B pricing to community-based pharmacies in the state that receive 340B drugs for distribution.

The preemption doctrine stems from the Supremacy Clause, which states that federal laws made under the authority of the Constitution are the "supreme Law of the Land." Federal law preempts state law where (1) Congress expressly states its intention to prevent state regulation (express preemption), (2) state law stands as an obstacle to accomplishing the federal law's purpose (obstacle preemption), (3) Congress implicitly occupies the field (field preemption), or (4) where it is impossible to simultaneously comply with state and federal law (impossibility preemption). The Supreme Court has held that "[a] field is occupied when the federal regulatory scheme is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." PhRMA argued that Act 1103 is unconstitutional because the 340B Program occupies the field of federal law, it presents an obstacle to drug manufacturers who are attempting to comply with the 340B statute, and it is impossible to comply with both the state law and other federal laws under the FDCA.

The Eighth Circuit ultimately concluded that the 340B statute did not preempt Act 1103. In support of its decision, the Eighth Circuit first highlighted several facts about both the federal program and the state law. It considered the structure of the 340B statute, which it broke into three essential components: (1) capping manufacturer prices; (2) restricting covered entities from engaging in duplicate discounting or diversion; and (3) creating compliance mechanisms for both manufacturers and covered entities. Citing the Third Circuit's decision in *Sanofi Aventis*, the Eighth Circuit observed that "the 340B Program is silent about delivery and distribution of pharmaceuticals to patients." The court noted, however, that "pharmacies are essential, and legally required" for the functioning of the pharmaceutical supply chain, and that they "have always been important participants in delivering 340B drugs to patients." Although retail pharmacies are vital to the functioning of 340B, the court said they are merely "agent[s] of the covered entity," which both purchases and assumes legal responsibility for the drugs. The court then looked at the specific wording of the Arkansas law, observing that its primary focus is the agreements between covered entities and contract pharmacies.

After reviewing the relevant facts, the Eighth Circuit began its analysis with field preemption, quoting a Supreme Court decision holding that field preemption occurs when Congress leaves "no room for the states to supplement" federal law. Noting that the text of the statute does not mention the delivery of drugs, the court found that "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." The court further reasoned that Congress was aware that the regulation of pharmacies has traditionally been an issue of state law and thus "Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." Although the Arkansas law empowers the state to penalize drug manufacturers who refuse to distribute drugs to covered entities' contract pharmacies, the court said this does not interfere with HHS's jurisdiction over the program, which concerns disputes between manufacturers and covered entities regarding pricing of drugs, rather than the distribution of those drugs.

The court further found that the Arkansas law is not unconstitutional due to obstacle preemption, because rather than creating an obstacle to 340B compliance, the Arkansas law "assists in fulfilling the purpose of 340B" by protecting the relationship between contract pharmacies and covered entities and ensuring that covered entities can distribute their drugs to patients. The court concluded that the state law "is simply deterring … manufacturers from interfering with a covered entity's contract pharmacy arrangements," and thus manufacturers could, and indeed have, complied with both the 340B statute and state law.

Finally, the court dismissed PhRMA's impossibility preemption argument that it was impossible to comply with both the state law and the FDCA's REMS provisions, which restrict distribution of certain drugs to ensure public safety. The court observed that covered entities are responsible for meeting REMS requirements, but that "just because a medication is subject to multiple legal requirements does not make it impossible to comply" with state law.

Now that the Eighth Circuit has ruled on the Supremacy Clause and federal preemption issues, litigation will continue on PhRMA's claims that the state law is invalid under the Commerce Clause, which the district court has not yet addressed. PhRMA argues that because the state law will "inevitably regulate commerce wholly outside" of its borders, it should be invalidated under the dormant Commerce Clause doctrine.

# Considerations for Congress

Taken together, the Third, D.C., and Eighth Circuit rulings seem to suggest that states may use their authority to regulate pharmacies within their state to address the use of contract pharmacies in the 340B Program, even if HHS cannot do so. According to the Third and D.C. Circuits, the federal government lacks the authority to broadly prevent manufacturers from adopting policies that attempt to restrict covered entities' use of contract pharmacies, but the Eighth Circuit ruling suggests that states may address this problem by legislating on retail pharmacies. Without clarification from Congress on the appropriate role of contract pharmacies in the 340B program, uncertainty over their use may continue. Additionally, the matter could be further complicated if the Seventh Circuit splits from the Third and D.C. Circuits' rulings and finds that the 340B statute does enable HHS to enforce the 340B statute in such a way that would prevent manufacturers from restricting contract pharmacy use. If such a contrary ruling were to occur, HHS may be able to address manufacturers' policies in some states but not in others.

Even assuming that no contradictory rulings are issued, the decisions from the circuit courts did not resolve all facets of the contract pharmacy issue, and disagreements between HHS, drug manufacturers, and 340B covered entities are likely to continue. For example, in its ruling, the Third Circuit did not explicitly resolve the question of how many contract pharmacies a 340B covered entity should be permitted to use, finding HHS's "unlimited number" argument unpersuasive while simultaneously acknowledging that contract pharmacies seem vital to the program and that without them, many covered entities would be unable to generate 340B savings. The Third Circuit reasoned, "Congress might have

expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy. But this is a far cry from the government's current position that covered entities may use an unlimited number of contract pharmacies." Several manufacturers have subsequently interpreted the court's opinion to permit covered entities without a pharmacy in-house to use one contract pharmacy, and HHS has not publicly commented on whether it intends to take any action to try to expand this number. Similarly, the D.C. Circuit suggests that while the statute does not "categorically prohibit manufacturers from imposing conditions" on contract pharmacies and the specific conditions at issue did not violate 340B "on their face," this conclusion "do[es] not foreclose the possibility" that the conditions could violate the 340B statute "as applied in particular circumstances" or that "other, more onerous conditions might violate the statute."

Additionally, in light of the Eighth Circuit's ruling that the 340B statute does not preempt state laws regulating contract pharmacy use, other states may enact similar laws. A number of states considered enacting 340B legislation in 2023, and stakeholders expect a similar trend in 2024. For example, on March 27, 2024, West Virginia became the third state to enact protections for 340B covered entities' use of contract pharmacies. More changes to state law could lead to legal challenges and litigation in other federal district and circuit courts, and conflicting rulings are possible, depending on how those courts rule on the preemption question. Litigation will also continue in the Eighth Circuit, because the district court has not yet ruled on whether the Arkansas law is invalid under the dormant Commerce Clause.

Amidst this litigation, several Members of the 118th Congress have expressed interest in making changes to the 340B statute. For example, in June 2023, a group of six Senators released a letter to stakeholders and the public seeking information on how Congress could "further the original intent of the [340B] program" and strengthen its ability "to support entities serving eligible patients." In February 2024, the group released a discussion draft of a bill to reform the program, along with a supplemental request for information highlighting stakeholder concerns about contract pharmacy use, the prevention of duplicate discounts, transparency issues, and ensuring that drugs are dispensed only to eligible patients. In late 2023 and early 2024, one Senator also requested information from 340B stakeholders, including FQHCs and contract pharmacies, as a part of his investigation into how certain entities generate revenue from the 340B program. Additionally, the House is considering legislation to address contract pharmacy use, such as the PROTECT 340B Act. Further congressional action to address these or other issues could impact the outcome of the litigation and the program as a whole.

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