Congressional Research Service
Informing the legislative debate since 1914

The 340B Drug Discount Program: Litigation Topics and Trends

September 10, 2025

Congressional Research Service
https://crsreports.congress.gov
R48696

CRS REPORT
Prepared for Members and
Committees of Congress

Congressional Research Service
Informing the legislative debate since 1914

SUMMARY

R48696

September 10, 2025

Hannah-Alise Rogers
Legislative Attorney

The 340B Drug Discount Program: Litigation Topics and Trends

Congress created the 340B Drug Discount Program in 1992 in the Veterans Health Care Act (Pub. L. No. 102-585) to enable certain health care safety net providers to purchase drugs at lower costs. The program's authorizing statute requires drug manufacturers that participate in Medicaid to offer to sell outpatient prescription drugs to eligible "covered entities" at discount prices. The law allows covered entities to sell these drugs to their patients as though they paid a higher price, thereby generating "340B savings." The 340B program is administered by the Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services. Congress has made changes to the program over time, including expanding the number of entities eligible for drug discounts and giving HRSA additional enforcement authority under the statute.

The 340B statute prohibits covered entities from selling 340B drugs to individuals who are not patients of the covered entity (a practice known as "diversion"). The statute also prohibits covered entities from receiving duplicate drug discounts through both the Medicaid program and the 340B program. In recent years, legal and policy disagreements have arisen between HRSA, covered entities, and drug manufacturers about how HRSA verifies compliance from both covered entities and manufacturers, as well as how the agency enforces the statute, including the statutory provisions that prohibit duplicate discounting and diversion. This report reviews recent litigation involving the program—covering both how federal courts have interpreted the statute and the resulting consequences for HRSA, drug manufacturers, and covered entities.

The report first discusses litigation brought by drug manufacturers against covered entities over covered entities' use of contract pharmacies to distribute 340B drugs to their patients. The cases address HRSA's ability to enforce its interpretation of the statute against drug manufacturers that impose conditions on their offers to sell 340B drugs to covered entities that use contract pharmacies to distribute those drugs. While the use of contract pharmacies has always been a part of the program, the 340B statute does not directly mention the use of contract pharmacies, and HRSA's guidance about their use has shifted over time. The report discusses the courts' interpretation of the 340B statute, including two opinions from federal circuit courts.

In the aftermath of some of the contract pharmacy litigation, several states have enacted laws to protect contract pharmacies and covered entities inside their state and stop manufacturers from limiting 340B drug distribution by contract pharmacies. The report next turns to litigation brought by the pharmaceutical industry and individual manufacturers challenging these state laws on various statutory and constitutional grounds, including that they are preempted by the 340B statute and that they violate the U.S. Constitution's Dormant Commerce Clause, Contracts Clause, and Fourteenth Amendment. The report discusses several of these challenges in federal district courts around the country, as well as one federal circuit court opinion.

The report next turns to recent cases brought by manufacturers and other industry stakeholders against HRSA over the agency's directive that manufacturers are required to receive HRSA's approval if they wish to offer the 340B discount as a rebate. As with the contract pharmacy limitations, drug manufacturers have alleged that offering the 340B discount as a backend rebate, as opposed to an up-front price discount, would better enable them to police the program and avoid paying duplicate discounts. The section then concludes with a discussion of HRSA's August 2025 guidance about drug rebates.

The report also highlights other litigation involving the 340B program, including covered entities' challenges to HRSA's definition of "patient," which is also undefined in statute but appears in agency guidance, for purposes of preventing drug diversion. It also covers several other high-profile cases involving the program, including a Supreme Court case recognizing that there is no private right of action in the 340B statute, thereby limiting enforcement of the statute to HRSA. Astra USA, Inc. v. Santa Clara County, 563 U.S. 110 (2011).

The report concludes by offering several considerations for the 119th Congress in light of the litigation. It offers an analysis of the legal landscape after the various court rulings involving HRSA, drug manufacturers, covered entities, and states. It also describes several legislative changes that Congress could make to the program if it chose to do so.

Contents

Tables

Appendixes

Contacts

Introduction to 340B

Congress created the 340B Drug Discount Program ("340B" or "the program") in 1992 through the Veterans Health Care Act of 1992 to enable certain health care providers that serve low-income and uninsured patients to purchase drugs at lower costs.[1] The program is administered by the Office of Pharmacy Affairs (OPA) at the Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services (HHS).[2] The program derives its name from its authorizing statute, which is found in section 340B of the Public Health Service Act (PHSA).[3] The statute requires drug manufacturers that participate in federal health care programs to offer certain outpatient[4] prescription drugs to "covered entities" at discount prices.

Under the 340B statute, the Secretary of HHS (the Secretary) is required to enter into contracts, which the statute terms "purchase price agreements (PPAs)," with drug manufacturers that participate in the Medicaid program.[5] Under the terms of the PPAs, drug manufacturers are required to "offer" to sell certain covered outpatient drugs[6] at a "ceiling price," which is calculated based on a statutory formula.[7] Manufacturers must offer covered outpatient drugs to covered entities either at or below the ceiling price, if the manufacturer makes the drug available to any other purchaser at any price.[8]

So-called covered entities are those that are eligible to purchase the discounted drugs; a list of 340B covered entities is found in the statute and includes Federally Qualified Health Centers (FQHCs), Native Hawaiian Health Centers, Tribal and Urban Indian Organizations, Children's Hospitals, Disproportionate Share Hospitals (known as "DSH hospitals"), and other providers that care for rural or underserved populations.[9] Covered entities must certify that they meet all applicable statutory requirements for eligibility.[10] Covered entities may generate significant revenue from 340B, known as "340B savings," by reselling discounted drugs to their patients and receiving reimbursement from the patient's insurance (if applicable) as though the covered entity

[1] Pub. L. No. 102-585, sec. 602(a), § 340B, 106 Stat. 4943, 4962–75 (1992).

[2] *340B Drug Pricing Program*, HRSA (July 2025), http://hrsa.gov/opa [https://perma.cc/P844-JNYZ].

[3] PHSA, ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. § 256b).

[4] The 340B discount does not apply to drugs that are administered to patients while they are hospitalized. 42 U.S.C. § 256b(a)(1).

[5] *Id.*

[6] For purposes of the 340B statute, the term "covered outpatient drug" has the same meaning as that term is used in the Medicaid statute. *Id.* § 256b(b)(1) (referencing *id.* § 1927(k)(2)).

[7] The ceiling price is calculated as the average manufacturer price (AMP) for the drug under Title XIX of the Social Security Act (which authorizes the Medicaid Program) minus a "rebate percentage." *Id.* § 256b(a)(1). The rebate percentage is defined as the drug's average Medicaid rebate during the preceding calendar quarter divided by the drug's AMP during the preceding calendar quarter. *Id.* § 256b(a)(2)(i)–(ii). For more information about AMPs and Medicaid drug prices generally, see CRS Report R43778, *Medicaid Prescription Drug Pricing and Policy*, by Cliff Binder (2014).

[8] 42 U.S.C. § 256b(a)(1).

[9] *Id.* § 256b(a)(4). Over time, Congress has expanded the number of eligible covered entities. For example, the Patient Protection and Affordable Care Act (ACA) amended the 340B statute, adding subsections (a)(4)(M)–(O), allowing certain children's hospitals, critical access hospitals, and rural referral centers to qualify as covered entities. ACA, Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821–23 (2010) (codified at 42 U.S.C. § 256b(a)(4)(M)–(O)).

[10] 42 U.S.C. § 256b(a)(7). The certification and recertification process is done online via HRSA/OPA's website using the Office of Pharmacy Affairs Information System (OPAIS) portal. *See What Is the Purpose of 340B OPAIS?*, HRSA (July 2020), https://www.hrsa.gov/about/faqs/what-purpose-340b-opais [https://perma.cc/B293-9AZK].

paid full price for the drug.[11] Covered entities may make 340B drugs available to patients either through their own in-house (or onsite) pharmacy or by contracting with third-party retail pharmacies, which have come to be known as "contract pharmacies."[12] As discussed in further detail below, neither the distribution of drugs to patients nor the use of contract pharmacies is mentioned in the 340B statute.[13]

Of the eligible covered entities, DSH hospitals account for the largest portion of 340B drug purchases.[14] DSH hospitals are hospitals that see a disproportionate share of low-income patients, and these hospitals are eligible for additional payments from both the Medicare and Medicaid programs.[15] To qualify as a 340B covered entity, a DSH hospital must be either owned or operated by a state or local government, must be a public or private nonprofit corporation that is granted governmental powers by a state or local government, or must be a private nonprofit hospital that contracts with a state or local government to provide care to low-income people who are ineligible for Medicare or who receive Medicaid.[16] DSH hospitals must also have a disproportionate share adjustment percentage of 11.75% or greater, as shown on the hospital's most recent Medicare cost report.[17] DSHs also cannot obtain 340B drugs through a group purchasing arrangement.[18]

The statute places additional requirements on both covered entities and drug manufacturers. For example, covered entities are prohibited from receiving duplicate discounts from both the Medicaid and 340B programs.[19] Covered entities are also prohibited from selling or otherwise distributing drugs to anyone who is not a patient of the covered entity, a practice commonly referred to as "diversion."[20] Covered entities must also permit the Secretary and drug

[11] The 340B statute does not require a covered entity to disclose the amount of 340B savings it generates from the program, nor does it require that 340B savings be passed on to patients in the form of lower-cost drugs.

[12] *Contract Pharmacy Services*, HRSA (June 2024), https://www.hrsa.gov/opa/implementation-contract [https://perma.cc/N23Y-NADE].

[13] *See infra* "Litigation Regarding Contract Pharmacy Use."

[14] According to the most recent data available from HRSA, in calendar year 2023, covered entities purchased more than $66 billion in 340B drugs. Of that amount, DSH hospitals made up 78% ($51,886,954,092) of purchases. *2023 340B Covered Entity Purchases*, HRSA (Oct. 2024), https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases [https://perma.cc/RA4K-SCFM].

[15] 42 U.S.C. § 1396a(a)(13)(A)(iv) (Medicaid); *id.* § 1395ww(d)(5)(F) (Medicare). For more information about DSH payments under the Medicaid program, see CRS Report R42865, *Medicaid Disproportionate Share Hospital Payments*, by Alison Mitchell (2023).

[16] 42 U.S.C. § 256b(a)(4)(L)(i).

[17] *Id.* § 256b(a)(4)(L)(ii). Medicare-certified institutional providers, including hospitals, are required to annually submit cost information to the Centers for Medicare and Medicaid Services (CMS), a division of HHS that administers the Medicare and Medicaid programs, and its contractors. Reported information includes utilization data, facility costs, and charges; the information is compiled and published in a Medicare Cost Report. For more information on cost reports, see *Cost Reports*, CMS (Apr. 18, 2025), https://www.cms.gov/data-research/statistics-trends-and-reports/cost-reports [https://perma.cc/XV6U-XCWY].

[18] 42 U.S.C. § 256b(a)(4)(L)(iii). Health care providers—including hospitals, nursing homes, and clinics—often purchase medical supplies, including prescription drugs, through a group purchasing organization (GPO), which allows them to collectively leverage their purchasing power by making larger volume purchases. In lieu of a GPO, however, the 340B statute directs the HHS Secretary to develop a "Prime Vendor Program," for covered entities to aggregate their purchasing power to achieve additional discounts on 340B savings. *Id.* § 256b(a)(9). According to HRSA, the purpose of the Prime Vendor Program is "to develop, maintain, and coordinate a program capable of distribution, facilitation, and other activities in support of the 340B program." HRSA, *What Is the 340B Prime Vendor Program* (June 2024), https://www.hrsa.gov/about/faqs/what-340b-prime-vendor-program-pvp. The program works to provide 340B drugs at prices below the required 340B price and creates distribution networks to facilitate access. *Id.*

[19] *Id.* § 256b(a)(5)(A)(i).

[20] *Id.* § 256b(a)(5)(B); *see also infra* "Patient" Definition Litigation.

manufacturers to audit their records demonstrating their eligibility as a covered entity.[21] Drug manufacturers may also be audited by HRSA to ensure their compliance with the statute.[22]

Covered entities that fail to comply with statutory requirements may be subject to sanctions. For example, if a covered entity engages in diversion or duplicate discounting, it is liable to the manufacturer for the difference between the drug's actual cost to the covered entity and the 340B price.[23] Additionally, covered entities that knowingly and intentionally engage in diversion or duplicate discounting are required to pay interest on the amounts owed to manufacturers.[24] For "systematic and egregious" violations that are knowing and intentional, a covered entity may lose its eligibility status as a covered entity for a period of time that the Secretary determines appropriate.[25] In accordance with the statute, HRSA has also established an administrative dispute resolution (ADR) process, which governs the resolution of disputes between covered entities and drug manufacturers regarding overcharges, audits, or other compliance issues.[26]

Particularly since 2020, both legal and policy disagreements have arisen between HRSA, covered entities, and drug manufacturers about how HRSA ensures compliance from both covered entities and manufacturers, as well as how the agency enforces the statute, including the statutory provisions that prohibit duplicate discounting and diversion. This report reviews selected litigation involving the 340B program, discussing how federal courts have interpreted the statute and the resulting consequences for HRSA, drug manufacturers, and covered entities. It concludes by offering several considerations for the 119th Congress.

Litigation Regarding Contract Pharmacy Use

After purchasing 340B drugs from drug manufacturers and wholesalers at the discounted price, covered entities must then distribute their drugs to the patients they serve. To do so, many covered entities use a "ship to bill to" arrangement, wherein the covered entity purchases the drugs and, via an agreement with the manufacturer or wholesaler, the purchases are shipped to contract pharmacies for distribution.[27] Under such an arrangement, the covered entity both purchases the drugs and maintains title to them, but the drugs are both stored at and distributed by a third-party contract pharmacy.[28]

HRSA has long regulated the use of contract pharmacies in the 340B program, but the agency's position has shifted over time.[29] Because the 340B statute does not give the agency general rulemaking authority to administer the program,[30] the agency has periodically released

[21] 42 U.S.C. § 256b(a)(5)(C).

[22] *Id.* § 256b(d)(1)(B)(v).

[23] *Id.* § 256b(a)(5)(D).

[24] *Id.* § 2546(d)(2)(B)(v)(I).

[25] *Id.* § 256b(d)(2)(B)(v)(II).

[26] *Id.* § 256b(d)(3); *see also* 42 C.F.R. §§ 10.20–10.25 (2025) (Administrative Dispute Resolution).

[27] *FAQs: Contract Pharmacy – What is a "ship to bill to" arrangement?*, HRSA, https://www.hrsa.gov/opa/faqs [https://perma.cc/A3WH-4TJM] (last visited Dec. 31, 2024).

[28] *Id.*

[29] *Compare* Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Contract Pharmacy Services, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996), *with* Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).

[30] *See, e.g.*, PhRMA v. HHS, 43 F.Supp.3d 28 (D.D.C. May 23, 2014) (challenging HRSA's final rule regarding the orphan drug exclusion in the 340B statute). In this case, HRSA relied upon the 340B statute and other provisions in the Federal Food, Drug, and Cosmetic Act and the Social Security Act for its authority to promulgate the rule, but the court (continued...)

nonbinding, subregulatory guidance to address contract pharmacy use and to serve as a guide for HRSA's enforcement priorities.[31] Contract pharmacies were first mentioned in the agency's 1996 guidance, which acknowledged that, at the time, very few of the approximately 11,500 covered entities used their own in-house pharmacies to distribute 340B drugs, generally due to the prohibitive cost.[32] As a result, the agency allowed covered entities to use up to one contract pharmacy.[33] Such was the policy for the next fourteen years, until the agency issued more contract pharmacy guidance in 2010, this time allowing covered entities to use an unlimited number of contract pharmacies to distribute 340B drugs.[34] The policy continued undisturbed for approximately ten more years, during which time the number of contract pharmacies significantly increased.[35]

Beginning in 2020, several drug manufacturers began announcing restrictions on covered entities that distribute 340B drugs using contract pharmacies rather than in-house pharmacies.[36] The restrictions have varied over time, but they generally aim to limit covered entities' ability to distribute 340B drugs to patients using contract pharmacies.[37] Drug manufacturers and trade associations have defended the restrictions, arguing that some covered entities are taking advantage of manufacturers through the use of duplicate discounting and diversion.[38] They argue that HRSA does not adequately police compliance with the program's statutory requirements.[39] The restrictions have financial consequences for covered entities, who argue that they are now paying more for certain 340B drugs and are unable to generate 340B savings from them.[40]

HRSA has maintained that the manufacturers' restrictions violate the 340B statute; the agency initially responded to the restrictions by issuing violation letters to manufacturers, informing them that their policies violated the statute, which HRSA interpreted as requiring manufacturers to

found that "the statutory provisions HHS has strung together to give it rulemaking authority . . . are specific grants of authority that do not authorize the orphan drug rule implemented here." *Id.* at 40.

[31] Federal agencies, including HHS, possess only the authority granted to them by Congress. For an agency to promulgate legally binding regulations (or "legislative rules"), Congress must provide the agency with that authority via statute. United States v. Mead, 533 U.S. 218, 226–27 (2001); United States v. Storer Broad. Co., 351 U.S. 192 (1956). For more information on agency rulemaking, see CRS In Focus IF10003, *An Overview of Federal Regulations and the Rulemaking Process*, by Maeve P. Carey (2021). For more information on agency guidance, see CRS Legal Sidebar LSB10591, *Agency Use of Guidance Documents*, by Kate R. Bowers (2021).

[32] Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Contract Pharmacy Services, 61 Fed. Reg. at 43550.

[33] *Id.* at 43555.

[34] Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services, 75 Fed. Reg. at 10277.

[35] *See* GAO, DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (2018), https://www.gao.gov/assets/700/692697.pdf [https://perma.cc/HBJ2-PRXK]. At the time this GAO report was published in 2018, there were more than 12,000 covered entities participating in 340B, and almost 20,000 contract pharmacies. *Id.* at 2.

[36] *See, e.g.*, HRSA, Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs (2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/limited-distribution-plan-notice-cialis.pdf [https://perma.cc/D9CW-SNW5].

[37] *See, e.g.*, NAT'L ASS'N OF CMTY. HEALTH CTRS., 340B RESTRICTIONS SUMMARY CHART (2023), https://www.nachc.org/wp-content/uploads/2023/09/340B-restrictions-summary-chart.pdf [https://perma.cc/S4TD-ZSC7].

[38] *See, e.g.*, Nicole Longo, *Illegal Abuse of 340B Hurts Us All*, PHARM. RSCH. & MFRS. OF AM. (PHRMA) (Oct. 3, 2024), https://phrma.org/blog/illegal-abuse-of-340b-hurts-us-all [https://perma.cc/AA86-45Q8].

[39] For more information about HRSA's oversight of 340B, see *Program Integrity*, HRSA (Dec. 2024), https://www.hrsa.gov/opa/program-integrity [https://perma.cc/QS6Y-DT9P].

[40] *See, e.g.*, Dave Muoio, *Safety Net Hospitals Say Pharma's 340B Drug Restrictions Already Endangering Future Services*, Fierce Healthcare (Jan. 31, 2022), https://www.fiercehealthcare.com/hospitals/safety-net-hospitals-say-pharmas-340b-drug-restrictions-are-already-endangering-future [https://perma.cc/D8L7-EYJQ].

provide the 340B price without exception, and threatening civil money penalties for any overcharges if they continued.[41] 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.[42] All of the cases turn on different interpretations of the 340B statute, which does not expressly address the direct distribution of 340B drugs to patients or the use of contract pharmacies. HRSA argued that the 340B statute requires manufacturers to sell 340B drugs to covered entities and deliver them to an unlimited number of contract pharmacies.[43] Manufacturers maintained that the 340B statute requires only that they "offer" to sell 340B drugs to covered entities, and that the contract pharmacy restrictions were merely conditions on an otherwise valid offer.[44] Federal district courts reached various conclusions about the validity of the violation letters and HRSA's interpretation of the 340B statute; some of the courts agreed with HRSA, while others agreed with manufacturers.[45]

Several of the district courts' decisions were appealed to the U.S. Courts of Appeals for the Third, Seventh, and D.C. Circuits. The Third and D.C. Circuits' rulings, discussed below, found that HRSA lacked the authority to issue the violation letters. The Seventh Circuit has not issued a decision as of the time of this writing.

The Third Circuit's Decision in *Sanofi-Aventis U.S. LLC v. HHS* That HHS Overstepped in Enforcement

In *Sanofi-Aventis U.S. LLC v. HHS*, a drug manufacturer challenged the violation letters that HHS issued to the manufacturer in response to the company's restrictions on contract pharmacies.[46] The New Jersey Federal District Court upheld HHS's action, in part, finding that the drug manufacturer's 340B contract pharmacy pricing restriction policy was unlawful.[47] Sanofi appealed, and the government cross-appealed, to the Third Circuit. On January 30, 2023, the Third Circuit issued a decision in *Sanofi*, finding that HHS's enforcement letter was arbitrary and

[41] *See, e.g.*, Letter from Diana Espinosa, Acting Adm'r, HRSA, to Gerald Gleeson, Vice President, Sanofi-Aventis (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/hrsa-letter-sanofi-covered-entities.pdf [https://perma.cc/V6XD-9K3T] [hereinafter Sanofi-Aventis Letter]; *see also* Letter from Diana Espinosa, Acting Adm'r, HRSA, to Derek L. Asay, Senior Director, Eli Lilly & Co. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/hrsa-letter-eli-lilly-covered-entities.pdf [https://perma.cc/VAW5-M35Q].

[42] For a full discussion of the district court cases, *see* CRS Legal Sidebar LSB10842, *Courts Evaluate the Role of Contract Pharmacies in the 340B Drug Discount Program*, by Hannah-Alise Rogers (2022).

[43] Sanofi-Aventis Letter, *supra* note 41, at 1. HRSA argued, "Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.*

[44] Novartis Pharms. Corp v. Espinosa, Nos. 21-cv-1479, 2021 WL 5161783, at *6 (D.D.C. Nov. 5, 2021), *aff'd sub nom.*, Novartis Pharms. Corp. v. Johnson, 102 F.4th 452 (D.C. Cir. 2024).

[45] *Compare Novartis Pharms. Corp.*, 2021 WL 5161783, *and* AstraZeneca Pharms. LP v. Becerra, No. CV 21-27-LPS, 2022 WL 484587 (D. Del. Feb. 16, 2022), *judgment entered*, No. CV 21-27-LPS, 2022 WL 18508603 (D. Del. Mar. 11, 2022), *aff'd in part sub nom.*, Sanofi-Aventis U.S. LLC v. HHS, 58 F.4th 696 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023), *and aff'd sub nom., Sanofi-Aventis*, 58 F.4th 696, *and judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023), *with* Eli Lilly & Co. v. HHS, No. 21-cv-00081, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021) *and* Sanofi-Aventis U.S. LLC v. HHS, 570 F. Supp. 3d 129 (D.N.J. 2021), *aff'd in part, rev'd in part*, 58 F.4th 696.

[46] 58 F.4th 696.

[47] *Sanofi-Aventis*, 570 F. Supp. 3d 129.

capricious in violation of the Administrative Procedure Act (APA).[48] The court focused on two issues: first, whether the 340B statute permitted drug manufacturers to limit covered entities' drug purchases that are distributed by contract pharmacies; and second, whether the 340B statute gives HHS the authority to stop such practices.[49]

The Third Circuit began by analyzing the text of the 340B statute, observing that "[n]owhere does Section 340B mention contract pharmacies."[50] Given that the statute did not speak to the issue in question, the court focused on the ordinary meaning of other words in the statute, including "offer" and "purchased by."[51] The statute requires that manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price" and that drugs "purchased by a covered entity" may not exceed the ceiling price.[52] The court found that, in this context, the term "offer" does not "imply that the offeror [i.e., the manufacturer] must deliver goods wherever and to whomever the buyer demands," and that the manufacturers' conditions on the offers did not prevent their acceptance by covered entities.[53] 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."[54]

The Third Circuit also found that the legislative history and overall purpose of the 340B statute supported its conclusion that manufacturers could place some conditions on their offer to sell drugs to covered entities that use contract pharmacies.[55] 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"—either that Congress did not want contract pharmacies to be a part of the program or that their use was so widespread that they were unnecessary to mention.[56] For this reason, the court found that "neither drafting history nor legislative purpose compels a different result."[57] The court rejected the government's argument that allowing a drug manufacturer to limit contract pharmacy use would "thwart Congress's purpose in enacting Section 340B."[58] Acknowledging that many covered entities do not have their own in-house pharmacies and therefore turn to contract pharmacies to distribute drugs, the court said that "Congress might have expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy." The court warned, though, that the use of one contract

[48] *Sanofi-Aventis*, 58 F.4th 696. The Third Circuit's decision covered several other cases as well. The Third Circuit consolidated the appeals from the district court decisions in Novo Nordisk v. HHS, No. 21-00806, 2021 WL 3668168 (D.N.J. June 1, 2021), and AstraZeneca Pharms. LP v. Becerra, 543 F. Supp. 3d 47 (D. Del. June 16, 2021).

[49] *Sanofi-Aventis*, 58 F.4th at 704.

[50] *Id.* at 703. The court noted that the agency lacked rulemaking authority under the statute and therefore that its interpretation was not entitled to deference under *Chevron*, which was still valid precedent at the time the case was decided. *Id.* For more information on *Chevron* deference and the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* to overturn *Chevron*, see CRS Report R48320, *Loper Bright Enterprises v. Raimondo and the Future of Agency Interpretations of Law*, by Benjamin M. Barczewski (2024).

[51] *Sanofi-Aventis*, 58 F.4th at 703–04.

[52] 42 U.S.C. § 256b(a)(1).

[53] *Sanofi-Aventis*, 58 F.4th at 703.

[54] *Id.* at 704.

[55] *Id.*

[56] *Id.* at 705. The court noted Justice Scalia's warning in *District of Columbia v. Heller* that making inferences from a bill's unenacted drafting history is "perilous." *Id.* (citing District of Columbia v. Heller, 554 U.S. 570, 590 (2008)).

[57] *Sanofi-Aventis*, 58 F.4th at 705.

[58] *Id.* at 706.

pharmacy was "a far cry from" HHS's position that "covered entities may use an unlimited number of contract pharmacies."[59]

The Third Circuit ruled that HHS's violation letters were unlawful and enjoined the agency from enforcing its interpretation of 340B as requiring manufacturers to deliver discounted drugs to an unlimited number of covered entities' contract pharmacies.[60]

The D.C. Circuit's Decision in *Novartis Pharmaceuticals Corp. v. Johnson* That HHS Overstepped in Enforcement

Nearly a year and a half after the Third Circuit's decision in *Sanofi*, in May 2024, the D.C. Circuit decided *Novartis Pharmaceuticals Corp. v. Johnson*, which also considered whether HHS could enforce its interpretation of the 340B statute concerning unlimited contract pharmacy use against drug manufacturers.[61] Like the Third Circuit, the D.C. Circuit also found that the statute did not categorically prohibit manufacturers from imposing conditions on covered entities' contract pharmacy use and that the restrictions Novartis imposed on its 340B drug offers did not violate the statute on its face.[62] The court first considered the text of the statute, including the words "offer," "purchase," and "price," agreeing with the Third Circuit in *Sanofi* that the statute "merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified amount" without speaking to either distribution generally or contract pharmacies specifically.[63] The D.C. Circuit further reasoned that, following Supreme Court precedent, when a statute is silent as to the imposition of certain contractual conditions, this silence implies that such conditions are permissible.[64] In other words, the statutory silence with respect to contract

[59] *Id.*

[60] *Id.* The Third Circuit also considered legal challenges related to HHS's promulgation of the ADR rule, which Sanofi also challenged as unlawful under the APA. *Id.* In accordance with the 340B amendments in the Patient Protection and Affordable Care Act of 2010, HHS established an ADR process by publishing a proposed rule in 2016. *Id.* at 701–02. In 2017, HHS withdrew the rule, via a notice in the Unified Agenda, before eventually finalizing it in 2020. *Id.* at 702. Sanofi argued that the procedural process that HHS used—withdrawing the 2016 proposed rule before finalizing it in 2020—was unlawful under the APA, and that the agency should have issued a new proposed rule. *Id.* at 706. The majority of the Third Circuit disagreed, observing that "[t]he APA does not mention withdrawing proposed rules. Nor has the Supreme Court. So we are reluctant to give withdrawal separate legal significance under the APA." *Id.* The court found that the agency "did not violate the APA by purporting to withdraw the proposed ADR Rule before later finalizing it." *Id.* at 707. One judge dissented, arguing that because the agency withdrew the proposed rule, the final ADR rule should be vacated, and the agency should reissue it. *Id.* at 707 (Ambro, J., dissenting in part).

[61] 102 F.4th 452 (D.C. Cir. 2024). As was the case in the Third Circuit in *Sanofi*, the D.C. Circuit consolidated another district court contract pharmacy appeal from manufacturer United Therapeutics Corporation under *Novartis*; the cases were also consolidated at the district court level. *See* Novartis Pharms. Corp. v. Espinosa, Nos. 21-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021).

[62] *Novartis Pharms. Corp.*, 102 F.4th at 464. Similar to the Third Circuit in *Sanofi*, the D.C. Circuit noted that the Secretary of HHS lacked general rulemaking authority over 340B and thus that its interpretation was not entitled to *Chevron* deference. (The case was decided prior to the Supreme Court's decision in Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024), overturning *Chevron*.) The court instead cited Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944), stating that the agency's interpretation should be followed only to the extent that it had the "power to persuade." *Novartis Pharms. Corp.*, 102 F.4th at 459.

[63] *Novartis Pharms. Corp.*, 102 F.4th at 460. The court looked at a variety of dictionary definitions and treatises of contract law to determine the ordinary meaning of these words. *Id.*

[64] *Id.* at 460 (quoting Christensen v. Harris County, 529 U.S. 576 (2000)) (finding that an employer could compel its employees to take uncompensated leave without violating the Fair Labor Standards Act (FLSA), when the FLSA did not speak to the issue of whether employees could be made to use their leave).

pharmacies and delivery "preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions."[65]

The court also found that the government's position—that covered entities are permitted an unlimited number of contract pharmacies—"would produce absurd consequences." The court used as an example the fact that United Therapeutics distributes some of its products only through specialty pharmacies to ensure that its products are safely used.[66] The court reasoned that under HHS's position, United Therapeutics could be required by a covered entity to distribute its drugs "in a potentially dangerous manner."[67] Neither was the court persuaded by the government's arguments about the statute's legislative history.[68] Even though Congress had considered amending the statute to specify that drugs could be dispensed "through the 'on-site pharmacy services' of covered entities," the fact that it chose not to do so "hardly suggests that Congress opted for the opposite extreme" of allowing an unlimited number of contract pharmacies.[69]

The D.C. Circuit also examined the specific contract pharmacy restrictions imposed by Novartis and United Therapeutics, holding that neither manufacturer's conditions violated the statute.[70] The court reasoned that the manufacturers had agreed to work with at least one contract pharmacy, and that such a practice was similar to the agency's past guidance that allowed covered entities to use one outside pharmacy.[71] The court found that the manufacturers' willingness to work with "at least one" contract pharmacy "neither precludes [them] from making a bona fide 'offer' nor increases [the] contract 'price'" of 340B drugs.[72] In conclusion, the court warned that its decision did not "foreclose the possibility that other, more onerous conditions might violate the statute."[73]

The Seventh Circuit's Decision in *Eli Lilly & Co. v. HHS* That Remains Pending

One additional 340B contract pharmacy appeal remains pending before the Seventh Circuit. The case, *Eli Lilly & Co. v. HHS*, was decided by the Southern District of Indiana in October 2021.[74] The court held that "the fairest and most reasonable interpretation" of the 340B statute read in context "would not authorize drug manufacturers to impose unilateral restrictions on the

[65] *Novartis Pharms. Corp.*, 102 F.4th at 460.

[66] *Id.* at 461.

[67] *Id.*

[68] *Id.* at 462.

[69] *Id.* (citing S. REP. NO. 102-259, at 2 (1992)). 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 effective. *Id.* For more information about the "predicate-act" and other canons of statutory interpretation, see CRS Report R45153, *Statutory Interpretation: Theories, Tools, and Trends*, by Valerie C. Brannon (2023). The D.C. Circuit said, however, that "wider distribution" of 340B drugs via an unlimited number of contract pharmacies "was not necessarily better," and the agency's prior prohibition on the use of multiple contract pharmacies, which lasted nearly twenty years, "hardly rendered the scheme [of 340B] self-defeating or ineffectual." *Novartis Pharms. Corp.*, 102 F.4th at 462.

[70] *Novartis Pharms. Corp.*, 102 F.4th at 463.

[71] *Id.* at 463. For an overview of the evolution of the HHS guidance with respect to covered entities' use of contract pharmacies in 340B, see the court's discussion in AstraZeneca Pharms. LP v. Becerra, 543 F. Supp. 3d 47, 51–52 (D. Del. June 16, 2021).

[72] *Novartis Pharms. Corp.*, 102 F.4th at 464.

[73] *Id.*

[74] No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021).

distribution of [340B] drugs."[75] The district court's ruling was appealed to the Seventh Circuit in December 2021.[76] The Seventh Circuit held oral argument in October 2022,[77] but as of the date of this writing, it has not yet issued a decision.

Litigation Regarding State Attempts to Regulate Contract Pharmacy Use

Alongside ongoing litigation related to HRSA's authority to address manufacturer restrictions on contract pharmacy use, several states began considering legislation to make it unlawful for drug manufacturers to restrict contract pharmacy use by covered entities.[78] State laws protecting contract pharmacy use differ between states, but in general, their main purpose is to prohibit manufacturers from restricting 340B covered entities from using contract pharmacies.[79] Pharmaceutical Research and Manufacturers of America (PhRMA), a pharmaceutical trade industry group, as well as a few drug manufacturers, have challenged several of these state laws on various grounds, including that they are preempted by federal law (including the 340B statute, the Federal Food, Drug, and Cosmetic Act (FDCA), and federal patent law), as well as that they violate the Dormant Commerce Clause.[80] Other claims include that the state laws violate the Contracts Clause of the Constitution, that they are unconstitutionally vague, and that they constitute a taking under the Fifth Amendment.[81] As of the time of this writing, PhRMA and/or drug manufacturers have challenged at least twelve state laws related to contract pharmacy use.[82]

This section first introduces background information related to the constitutional challenges against state contract pharmacy laws, including discussion of the Supremacy Clause, the Dormant Commerce Clause, the Contracts Clause, and the Fourteenth Amendment. The section next provides information about the constitutional challenges to state contract pharmacy laws in a sample of cases from Arkansas, Louisiana, and West Virginia.

[75] *Id.* For more information about the district court's ruling, see CRS Legal Sidebar LSB10842, *Courts Evaluate the Role of Contract Pharmacies in the 340B Drug Discount Program*, by Hannah-Alise Rogers (2022).

[76] Notice of Case Opening, Eli Lilly & Co. v. HHS, No. 21-3405 (7th Cir. Dec. 30, 2021), Dkt No. 1.

[77] Oral Argument, *Eli Lilly & Co.*, No. 21-3405 (7th Cir. Oct. 31, 2022), Dkt. No. 71. After the oral argument, the court ordered the parties to file supplemental briefs to address the court's appellate jurisdiction and arguments regarding whether the agency's enforcement letter, which started the litigation, was a final agency action for purposes of the APA. Order, *Eli Lilly & Co.*, No. 21-3405 (7th Cir. Nov. 1, 2022), Dkt. No. 72. The parties filed these additional briefs in November 2022 and January 2023. Appellants' Supplemental Jurisdiction Memorandum, *Eli Lilly & Co.*, No. 21-3405 (7th Cir. Nov. 14, 2022), Dkt. No. 74; Citation of Additional Authority, *Eli Lilly & Co.*, No. 21-3405 (7th Cir. Jan. 30, 2023), Dkt. No. 75.

[78] NAT'L ASSOC. OF CMTY. HEALTH CTRS., STATE-LEVEL 340B LAWS AND LEGISLATION TRACKER (2025), https://www.nachc.org/wp-content/uploads/2025/06/06_20_25_nachc_state-level-340b-laws-and-legislation_tracker.pdf [https://perma.cc/F5V3-SW5T].

[79] *See, e.g.*, S.B. 751, 2024 Gen. Assemb., 2d Reg. Sess. (Mo. 2024); S.B. 69, 2025 State Leg., Gen. Sess. (Utah 2025); H.B. 548, 2023 State Leg., Reg. Sess. (La. 2023).

[80] *See, e.g.*, PhRMA v. McClain, 645 F. Supp. 3d 890 (E.D. Ark. 2022), *aff'd*, 95 F.4th 1136 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024) (mem.).

[81] *See, e.g.*, PhRMA v. Murrill, Nos. 23-997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024).

[82] *See, e.g.*, PhRMA v. Fitch, No. 24-160, 2024 WL 3277365 (S.D. Miss. July 1, 2024) (appeal pending before the Fifth Circuit); *see also* Order, Novartis Pharms. Corp. v. Brown, No. 1:24-cv-1557 (D. Md. Sept. 5, 2024), Dkt. No. 57 (appeal pending before the Fourth Circuit).

Background

Preemption and the Supremacy Clause

The preemption doctrine stems from the Supremacy Clause of the federal Constitution, which states that federal laws made under the authority of the Constitution are the "supreme Law of the Land."[83] Federal law preempts state law where (1) Congress expressly states its intention to preempt 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 of federal law (*field preemption*); or (4) it is impossible to simultaneously comply with both state and federal law (*impossibility preemption*).[84] The 340B statute does not contain an express preemption clause (i.e., a clause stating that the 340B statute supersedes all state laws); the litigation over state contract pharmacy laws has focused on other forms of preemption, most especially field preemption.[85] The Supreme Court has held that a field of law is occupied for purposes of preemption when "the scheme of federal regulation [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."[86]

The Dormant Commerce Clause

Article I, Section 8 of the U.S. Constitution provides that Congress has the power to "regulate Commerce with foreign Nations, and among the several States."[87] The Supreme Court has interpreted the Commerce Clause as not only a "positive grant of power to Congress," but also as a limitation on the states' ability to enact laws that unduly restrict interstate commerce, even if Congress has not legislated in that area—referred to as the Dormant Commerce Clause.[88] Two principles have emerged from the Supreme Court's modern Dormant Commerce Clause decisions.[89] First, states may not legislate in ways that discriminate against out-of-state goods or "nonresident economic actors."[90] Such state laws are considered *per se* invalid (i.e., they are presumed to violate the Dormant Commerce Clause) and are struck down—unless the state can show that the law is narrowly tailored and advances a legitimate local purpose and that the state had no nondiscriminatory alternatives.[91] Second, a state may not make even a facially neutral law

[83] U.S. CONST. art. VI, cl. 2.

[84] For more information about preemption of state law generally, *see* CRS Report R45825, *Federal Preemption: A Legal Primer*, by Bryan L. Adkins, Alexander H. Pepper, and Jay B. Sykes (2023).

[85] *See, e.g.*, *PhRMA*, 645 F. Supp. 3d at 898.

[86] Rice v. Santa Fe Corp., 331 U.S. 218, 230 (1947) (citing Pa. R. Co. v. Pub. Serv. Comm'n, 250 U.S. 566, 569 (1919); Cloverleaf Butter Co. v. Patterson, 315 U.S. 148 (1942)).

[87] U.S. CONST. art. I, § 8.

[88] Comptroller of Treasury of Md. v. Wynne, 575 U.S. 542, 548–49 (2015) (citing Okla. Tax Comm'n v. Jefferson Lines, Inc., 514 U.S. 175, 179 (1995)). For more information about the Dormant Commerce Clause generally, see Cong. Rsch. Serv., *Overview of Dormant Commerce Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-7-1/ALDE_00013307/ (last visited Aug. 1, 2025).

[89] Cong. Rsch. Serv., *Modern Dormant Commerce Clause Jurisprudence Generally*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-7-4/ALDE_00013310/ (last visited Aug. 1, 2025).

[90] Tenn. Wine & Spirits Retailers Ass'n v. Thomas, 588 U.S. 504, 505 (2019) (citing Dep't of Revenue of Ky. v. Davis, 553 U.S. 328, 338 (2008)); National Pork Producers Council v. Ross, 598 U.S. 356 (2023). *See also* CRS Legal Sidebar LSB11031, *Supreme Court Narrows Dormant Commerce Clause and Upholds State Animal Welfare Law*, by Kate R. Bowers (2023).

[91] 588 U.S. at 505.

that unduly burdens interstate commerce.[92] To evaluate the constitutionality of such facially neutral laws, the Court has applied a balancing test and would likely uphold laws that serve a "legitimate" local purpose if the local benefit clearly exceeds the burden on interstate commerce.[93]

The Contracts Clause

The Contracts Clause provides that states may not enact laws that "impair[] the Obligation of Contracts."[94] While the Supreme Court has held that the clause does not generally prevent a state from enacting laws to protect public welfare,[95] it has also said that a state may not breach or modify its own contracts and may not generally regulate private contracts.[96] To determine whether a violation of the Contracts Clause has occurred, the Supreme Court first asks whether the state law substantially impairs a contractual relationship, considering whether the law "undermines the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating his rights."[97] If the law is found to impair a contractual relationship, the Court has then asked whether the state law advances "a significant and legitimate public purpose" in an "appropriate and reasonable" manner.[98]

The Fourteenth Amendment and Vagueness

The Fourteenth Amendment prohibits states from depriving "any person of life, liberty, or property, without due process of law."[99] The Supreme Court has held that a law is unconstitutionally vague in violation of the Fourteenth Amendment when it "(1) fails to apprise persons of ordinary intelligence of the prohibited conduct, or (2) encourages arbitrary and discriminatory enforcement."[100] For example, in striking down a city ordinance making it illegal for more than three people to act in an "annoying" manner while standing on a city sidewalk, the Court found the ordinance unconstitutionally vague because "[c]onduct that annoys some people does not annoy others."[101] The Court reasoned that the ordinance was vague "not in the sense that it requires a person to conform his conduct to an imprecise but comprehensible normative standard, but rather in the sense that no standard of conduct is specified at all."[102]

---

[92] Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970). The balancing test elaborated by the Supreme Court in *Pike* is discussed further in CRS Legal Sidebar LSB11031, *Supreme Court Narrows Dormant Commerce Clause and Upholds State Animal Welfare Law*, by Kate R. Bowers (2023).

[93] *E.g.*, Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986) (citing Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970)).

[94] U.S. CONST. art. I, § 10. For general information about the Contracts Clause, see Cong. Rsch. Serv., *Overview of Contracts Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S10-C1-6-1/ALDE_00013037/ (last visited Aug. 1, 2025).

[95] Home Bldg. & Loan Assn. v. Blaisdell, 290 U.S. 398, 434–35 (1934).

[96] U.S. Tr. Co. v. New Jersey, 431 U.S. 1, 17 (1977).

[97] Sveen v. Melin, 584 U.S. 811, 819 (2018) (quoting Allied Structural Steel Co. v. Spannaus, 438 U.S. 234, 244 (1978)).

[98] *Sveen*, 584 U.S. at 819 (quoting Energy Reserves Grp., Inc. v. Kan. Power & Light Co., 459 U.S. 400, 411–12 (1983)).

[99] U.S. CONST. amend. XIV, § 1.

[100] City of Chicago v. Morales, 527 U.S. 41, 90 (1999) (Scalia, J., dissenting).

[101] Coates v. City of Cincinnati, 402 U.S. 611, 614 (1971).

[102] *Id.*

The Fifth Amendment Takings Clause

The Fifth Amendment provides, "No person shall be . . . deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."[103] When assessing whether a Takings Clause violation has occurred, the Supreme Court has previously addressed questions including (1) whether the plaintiff has a property interest that is protected by the Takings Clause; (2) whether a taking has occurred; (3) whether the taking was for public use; and (4) what constitutes just compensation.[104] The Takings Clause applies only to constitutionally protected property interests,[105] and a taking may result from the seizure of physical property as well as when a regulation amounts to what the Court has termed a "regulatory taking," which is the principle that "if a government regulation goes too far[,] it will be recognized as a taking."[106] Although the Court has avoided a "set formula to determine where regulation ends and taking begins,"[107] and has stated that regulatory takings cases require "essentially ad hoc, factual inquiries,"[108] it has established some general principles for determining when regulatory takings occur.[109]

The Eighth Circuit Decision Upholding Arkansas's Contract Pharmacy Law in *PhRMA v. McClain*

In May 2021, the Arkansas General Assembly enacted Act 1103 (the "Arkansas contract pharmacy law" or "the law"), which in part provided that manufacturers may not prohibit in-state pharmacies "from contracting [with] or participating with any [340B covered] entity."[110] The law also prohibited manufacturers from denying 340B pricing to "Arkansas-based community pharmac[ies]" that receive 340B drugs for distribution.[111] PhRMA challenged the state law, arguing in part that it was preempted by federal statute.[112] In December 2022, the Arkansas Federal District Court held that neither the 340B statute nor the FDCA preempted the Arkansas contract pharmacy law.[113] PhRMA appealed the ruling to the U.S. Court of Appeals for the Eighth Circuit (Eighth Circuit), which affirmed the district court's ruling in September 2023.[114]

---

[103] U.S. CONST. amend. V.

[104] *See, e.g.*, Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1000–01 (1984).

[105] *See Ruckelshaus*, 467 U.S. at 1001.

[106] Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922). *See also* CONG. RESEARCH SERV., Amdt 5.9.5 *Early Jurisprudence on Regulatory Takings*, https://constitution.congress.gov/browse/essay/amdt5-9-5/ALDE_00013284/.

[107] Penn. Cent. Transp. Co. v. City of N.Y., 438 U.S. 104, 124 (1978).

[108] *Id.*

[109] Factors to consider include (1) the economic impact of the regulation; (2) whether the regulation has interfered with a "distinct investment-backed expectation"; and (3) the character of the government's action. *Id.* For more information about the *Penn Central* analysis and how it is used to evaluate regulatory takings, *see* CONG. RESEARCH SERV., Amdt. 5.9.6 *Regulatory Takings and Penn Central Framework*, https://constitution.congress.gov/browse/essay/amdt5-9-6/ALDE_00013285/#ALDF_00022171.

[110] H.B. 1881, sec. 1, § 23-92-604(c)(1), 2021 Gen. Assemb., Reg. Sess. 3 (Ark. 2021).

[111] *Id.* sec. 1, § 23-92-604(c)(2).

[112] PhRMA v. McClain, 645 F. Supp. 3d 890, 894–95 (E.D. Ark. 2022), *aff'd*, 95 F.4th 1136 (8th Cir. 2024). PhRMA also challenged the Arkansas contract pharmacy law on the basis that it violated the Dormant Commerce Clause. *Id.* The parties agreed to pause litigation on the Dormant Commerce Clause claim pending resolution of the preemption issue. *Id.* at 894.

[113] *Id.* at 894–95.

[114] *PhRMA*, 95 F.4th 1136 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024) (mem.). The Eighth Circuit subsequently (continued...)

The Eighth Circuit's analysis upholding the state law focused on the 340B preemption claims, while also addressing the parties' FDCA preemption arguments. In concluding that the Arkansas contract pharmacy law was not preempted by the 340B statute, the court first considered the structure of the state law, which it broke into three essential components: (1) capping manufacturer prices; (2) restricting covered entities from engaging in duplicate discounting and diversion; and (3) creating compliance mechanisms for both manufacturers and covered entities.[115] Citing the Third Circuit's decision in *Sanofi*, discussed above, the Eighth Circuit observed that "the 340B Program 'is silent about delivery' and distribution of pharmaceuticals to patients."[116] The court noted, however, that "[retail] 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."[117] Although retail pharmacies are vital to the functioning of 340B, the court characterized them as merely "agent[s] of the covered entity," which both purchases and assumes legal responsibility for the drugs (generally under a "ship to bill to" method).[118] The court then looked at the specific wording of the Arkansas contract pharmacy law, observing that its primary focus was to target the agreements between covered entities and contract pharmacies made within the state.[119]

The Eighth Circuit first addressed the arguments related to field preemption, quoting the Supreme Court's decision in *Cipollone v. Liggett Group*, which held that field preemption occurs when Congress leaves "no room for the states to supplement" federal law.[120] Noting that the text of the 340B 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."[121] 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."[122] Although the Arkansas contract pharmacy law empowers the state to penalize drug manufacturers who refuse to distribute drugs to covered entities' contract pharmacies, the court said such enforcement authority does not interfere with HHS's jurisdiction over the program, which concerns disputes between manufacturers and covered entities regarding the price of drugs, rather than their distribution.[123]

The court further found that the Arkansas contract pharmacy 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.[124] The court concluded that the law "is simply deterring . . . manufacturers from

---

denied PhRMA's motions for a rehearing by the panel and a rehearing en banc before the full Eighth Circuit. PhRMA v. McClain, No. 22-3675, 2024 WL 1919676 (8th Cir. May 2, 2024). As of the time of this writing, the litigation regarding the Dormant Commerce Clause claims has not recommenced.

[115] *PhRMA*, 95 F.4th at 1141.

[116] *Id.* at 1142.

[117] *Id.*

[118] *PhRMA*, 95 F.4th at 1142.

[119] *Id.* at 1143.

[120] *Id.* (citing Cipollone v. Liggett Grp., 505 U.S. 504 (1992) and quoting Arizona v. United States, 567 U.S. 387, 399 (2012)).

[121] *PhRMA*, 95 F.4th at 1143.

[122] *Id.* at 1144.

[123] *Id.*

[124] *Id.* at 1144–45.

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.[125]

Finally, the Eighth Circuit was not persuaded by PhRMA's FDCA preemption argument. PhRMA argued that it was impossible to comply with the both the state law and the FDCA's risk evaluation and mitigation strategies (REMS) provisions, which restrict the distribution of certain drugs in furtherance of public safety.[126] 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.[127]

PhRMA appealed the Eighth Circuit's ruling to the Supreme Court, but the Supreme Court denied the petition for certiorari on December 9, 2024.[128] As of the time of this writing, the parties have not moved forward with litigating the plaintiffs' other constitutional claims.

The Louisiana Federal District Court Decision Upholding Louisiana's Contract Pharmacy Law in *PhRMA v. Murrill*

In 2023, the State of Louisiana enacted Act 358, which prohibits drug manufacturers from denying, restricting, prohibiting, or interfering with "the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B [covered] entity . . . ."[129] The act further provided, "[a] manufacturer . . . shall not interfere with a pharmacy contracted with a 340B entity," and stated that the law was not to be construed to be in conflict with any other federal law.[130] PhRMA, AstraZeneca, and AbbVie all sued the Louisiana attorney general; the Louisiana Federal District Court consolidated the cases under the heading *PhRMA v. Murrill*, issuing a decision in the case on the parties' respective summary judgment motions in September 2024.[131] Similar to the arguments before the Eighth Circuit in *McClain*, the plaintiffs argued that the 340B statute preempted Louisiana's contract pharmacy law.[132] The plaintiffs also argued that the state law was unconstitutionally vague, that it violated the Contracts Clause, and that it constituted a taking under the Fifth Amendment.[133]

In its decision granting summary judgment for the state, the court first addressed the plaintiffs' preemption arguments, which included field, conflict, and obstacle preemption.[134] With respect to field preemption, the court agreed with the Eighth Circuit's reasoning in *McClain* that the plaintiffs' arguments were not supported by the statute's text.[135] The court noted that the 340B statute "is silent with respect to the role of pharmacies who enter contracts with covered entities to receive and dispense discounted drugs."[136] The court further found that the plaintiffs

[125] *Id.* at 1145.

[126] *Id.*; *see also* 21 U.S.C. § 355-1. The Food & Drug Administration (FDA) administers the REMS program, which ensures the safe distribution and use of drugs for which the Secretary determines that a risk evaluation and mitigation strategy is necessary. *Id.*

[127] *PhRMA*, 95 F.4th at 1145–46.

[128] PhRMA v. McClain, 145 S. Ct. 768 (2024) (mem.).

[129] H.B. 548, sec. 1, §§ 2884(A), 2886(B), 2023 State Leg., Reg. Sess. (La. 2023).

[130] *Id.*, sec. 1, § 2884(B).

[131] No. 23-997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024).

[132] *Id.* at *1.

[133] *Id.* at *3.

[134] *Id.* at *5.

[135] *Id.* (*citing* PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024)).

[136] *Id.*

"mischaracterize[d] the relationship between covered entities and their contract pharmacies" and "overstate[d] the extent to which the federal government 'occupies' the field" with respect to covered entities and contract pharmacies.[137]

The court also disagreed with the plaintiffs that the Third Circuit's ruling in *Sanofi* created "a federal right" for manufacturers to restrict contract pharmacy use under 340B.[138] To the contrary, the court reasoned that the *Sanofi* holding undercut plaintiffs' field preemption argument, because in that case, the Third Circuit's holding was based on the fact that the statute was silent about contract pharmacies.[139] Similarly, the court found that "*Sanofi*'s holding is fatal to [the] conflict preemption claim," because if the 340B statute does not mention contract pharmacies, the state law "cannot, by definition, *conflict* with 340B."[140] The court also held that the state law was not preempted by federal patent law, because the law "does not, on its face, target patent rights or, by its terms, apply only to patented drugs or the price of patented drugs."[141] Finally, the court also rejected the plaintiffs' obstacle preemption claims, finding that the state law "arguably *advances* Congress' objectives with respect to the 340B program," rather than presenting an obstacle to them.[142]

In addition to the preemption arguments, the plaintiffs also argued that the Louisiana law's use of the term "interfere" was unconstitutionally vague in violation of the Due Process Clause of the Fourteenth Amendment.[143] The state law provides that a drug manufacturer "shall not deny, restrict, prohibit, or otherwise interfere with" acquisition or delivery of 340B drugs to contract pharmacies.[144] The plaintiffs argued that the act failed to specify the type of conduct that would rise to the level of "interference" within the meaning of the statute, which does not define the term.[145] The court also agreed with the state's argument that the "associated-words canon" of statutory construction[146] should apply, and that the court should look at the other words in the list of prohibited actions to give meaning to the word "interfere."[147] As a result, the court held that "interfere" should be "construed as proscribing actions that prevent or hinder the acquisition or delivery of Section 340B drugs to contract pharmacies," and was not unconstitutionally vague.[148]

With respect to the plaintiffs' arguments that the Louisiana law compelled "direct, confiscatory sales to private pharmacies," amounting to a taking in violation of the Fifth Amendment, as applicable to the states by the Fourteenth Amendment, the district court disagreed.[149] The court held that no taking had occurred, because the state law only prevented manufacturers from

[137] *Id.* at *6.

[138] *Id.*

[139] *Id.* at *7.

[140] *Id.* at *8.

[141] *Id.* at *9.

[142] *PhRMA*, 2024 WL 4361597, at *9.

[143] *Id.* at *10.

[144] *Id.*

[145] *Id.*

[146] *Id.* For more information on the tools of statutory interpretation, including the associated words (or *noscitur a sociis*), see CRS Report R45153, *Statutory Interpretation: Theories, Tools, and Trends*, by Valerie C. Brannon (2023).

[147] *PhRMA*, 2024 WL 4361597, at *10.

[148] *Id.*

[149] *Id.* at *14.

placing restrictions on in-state covered entities using multiple contract pharmacies and did not compel drug manufacturers to actually sell their products to those pharmacies.[150]

Similarly, the court held that the manufacturers' Contracts Clause arguments also failed, disagreeing with their characterization of the Louisiana law as expanding the number of 340B covered entities (to be inclusive of contract pharmacies).[151] The court found that the state law "does not expand or otherwise enlarge" the statute's beneficiaries, but rather affects only "the *delivery* or *acquisition*" of the drugs, which neither expands nor contradicts the PPAs, "because, like the statute, the PPA is silent as to delivery to or acquisition of Section 340B drugs to contract pharmacies."[152]

The district court's ruling in the case was appealed to the U.S. Court of Appeals for the Fifth Circuit in October 2024, and as of the date of this writing, the Fifth Circuit has not yet issued a ruling.[153] The court heard oral argument in the case in September 2025.[154]

The West Virginia Federal District Court Order Expressing Skepticism of State Contract Pharmacy Law in *PhRMA v. Morrisey*

While much of the litigation brought by industry groups and pharmaceutical companies against state contract pharmacy laws thus far has leaned in favor of states, at least one federal district court was at least initially persuaded by PhRMA's arguments and granted a preliminary injunction to stop a West Virginia contract pharmacy law from taking effect.[155] Like several of its contemporaries, the West Virginia law prohibits drug manufacturers from denying, restricting, or prohibiting "the acquisition . . . or delivery of a 340B drug to[] a location authorized by a 340B entity to receive such drug," unless otherwise prohibited by HHS.[156] Unlike some of the other state laws, though, the West Virginia provision also stops drug manufacturers from requiring covered entities to submit claims data to them as a condition of delivery for 340B drugs, unless covered entities are otherwise required by HHS to submit such information.[157] The law contains an enforcement provision allowing the attorney general of West Virginia and the state pharmacy board to fine or impose criminal liability on noncompliant manufacturers.[158]

PhRMA, as well as drug manufacturers Novartis and AbbVie, challenged the law in West Virginia Federal District Court, each making different arguments, and all requesting a preliminary injunction to halt enforcement of the state law.[159] In December 2024, the district court granted the plaintiffs' motion for preliminary injunction, finding that the 340B statute likely preempts the law, distinguishing the case from similar cases addressing contract pharmacy use in other jurisdictions.[160] In determining whether to grant the plaintiffs' motion for a preliminary

[150] *Id.*

[151] *Id.* at *12.

[152] *Id.*

[153] Notice of Appeal, PhRMA v. Landry, No. 6:23-CV-00997 (W.D. La. Oct. 16, 2024), Dkt. No. 84.

[154] Oral Argument, PhRMA v. Murrill, No. 24-30673 (5th Cir. Sept. 2, 2025), Dkt. No. 153.

[155] PhRMA v. Morrisey, 760 F. Supp. 3d 439 (S.D. W. Va. 2024), *appeal filed sub nom.*, PhRMA v. McCuskey, No. 25-1054 (4th Cir. Jan. 16, 2025).

[156] W.VA. CODE § 60A-8-6a(b)(1) (2024).

[157] *Id.* § 60A-8-6a(b)(2).

[158] *Id.* § 60A-8-6a(c)–(d)(1)(A).

[159] *PhRMA*, 760 F. Supp. 439, 446 (S.D. W. Va. 2024). The cases have not been consolidated and are proceeding separately, but the parties agreed to proceed on the motions for preliminary injunction all together. *Id.* at 448.

[160] *Id.* at 458.

injunction, the district court analyzed four factors from the Supreme Court's decision in *Winter v. Natural Resources Defense Council, Inc.*, including (1) the plaintiffs' likelihood of success on the merits; (2) whether the plaintiffs would likely suffer irreparable harm; (3) whether the equities balanced in the plaintiffs' favor; and (4) whether the public interest supported the injunction.[161]

First, the court found that a preliminary injunction was proper because plaintiffs were likely to succeed on the merits of their claim.[162] The court found that the state law likely created an obstacle to the dual purposes of the 340B program of providing discounted drugs to covered entities and prohibiting them from engaging in duplicate discounting or diversion, because the law restricts manufacturers from collecting claims data from covered entities.[163] While West Virginia argued that the law was not an obstacle to the 340B statute because manufacturers could get necessary claims data from covered entities by simply requesting it, the court posited that a covered entity could decline such a request, leaving the manufacturer with "no alternatives,"[164] which could prevent it from "formulat[ing] the 'reasonable cause' necessary to conduct an audit in the first place."[165]

The court also concluded that the West Virginia law's enforcement provisions were likely contrary to the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County* because the law was indirectly attempting to regulate a 340B drug's price.[166] In *Astra*, the Supreme Court found that a covered entity could not sue a drug manufacturer for noncompliance with the 340B statute because the 340B statute did not create a private right of action.[167] Relying on the same rationale, the district court reasoned that "if West Virginia attempted to enforce 340B through litigation, *Astra* would directly prevent such a suit as an improper method of 340B enforcement. Why, then, does it matter if the chosen improper enforcement is litigation or legislation?"[168] The court further concluded that allowing the state law to stand could also contradict *Astra*'s holding by prompting both state and federal adjudications of 340B matters, which was another reason for the program to have "centralized enforcement" by HRSA.[169]

The *Morrisey* court also distinguished its decision from other 340B state contract pharmacy law decisions finding that such laws were not preempted by the 340B statute. For example, the court pointed to the Eighth Circuit's finding in *McClain* that PhRMA had not presented any evidence of obstacle preemption.[170] The district court said that in *Morrisey*, the plaintiffs demonstrated, and

---

[161] *Id.* at 449 (citing Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7 (2008)).

[162] *PhRMA*, 760 F. Supp. 3d at 451.

[163] *Id.* at 453. The court noted that drug manufacturers would need such claims data in order to initiate an ADR proceeding against a covered entity. *Id.*

[164] *Id.*

[165] *PhRMA*, 760 F. Supp. 3d at 453.

[166] *Id.* at 456 (citing Astra USA v. Santa Clara County, 563 U.S. 110 (2011)). *See also* discussion *infra* "The U.S. Supreme Court's Decision in Astra USA, Inc. v. Santa Clara County Finding No Private Right of Action in the 340B Statute."

[167] *Astra USA*, 563 U.S. at 120.

[168] *PhRMA*, 760 F. Supp. 3d at 457 (citing *Astra USA*, 563 U.S. at 110).

[169] *PhRMA*, 760 F. Supp. 3d at 458 (citing *Astra USA*, 563 U.S. at 120).

[170] *PhRMA*, 760 F. Supp. 3d at 459 (citing PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024)). A few days prior to the court's decision in *Morrisey*, the plaintiffs filed a notice containing additional information in support of their motion for a preliminary injunction. Plaintiff's Notice of Supplemental Authority, PhRMA v. Morrisey, No. 2:24-cv-00271 (S.D. W. Va. Dec. 12, 2024), Dkt. No. 66. The plaintiffs stated that drug manufacturer Sanofi-Aventis had recently obtained, via a Freedom of Information Act request, a copy of a contract between a retail contract pharmacy and a covered entity. *Id.* The contract stated that the contract pharmacy takes title to the 340B drugs upon delivery to the pharmacy. *Id.* The contract further stated that the contract pharmacy is not an agent of the covered entity. *Id.* The plaintiffs argued that (continued...)

West Virginia did not dispute, that enforcement of the state law could result in the West Virginia attorney general having to make determinations of federal questions (e.g., what constitutes diversion under the 340B statute).[171] The court also observed that other courts considering similar questions regarding the legality of state contract pharmacy laws had not discussed the potential implications of the Supreme Court's ruling in *Astra*.[172]

As for the other *Winter* factors related to the court's grant of a preliminary injunction, the district court found that the plaintiffs had demonstrated that they are likely to suffer irreparable harm in the absence of a preliminary injunction.[173] While the drug manufacturer plaintiffs offered several arguments about the potential harm they would suffer as a result of the law, several of their points focused on the state law's steep enforcement penalties, which could lead to "unrecoverable financial losses," which the court found "sufficient to meet irreparable harm."[174] The court also held that the plaintiffs had sufficiently demonstrated that the balance of equities and the public interest both fell in their favor, but it warned that the preliminary injunction "does not grant drug manufacturers a blank check" to not otherwise comply with their 340B obligations.[175]

The district court's ruling was appealed to the U.S. Court of Appeals for the Fourth Circuit (Fourth Circuit) on January 16, 2025.[176] The Fourth Circuit is scheduled to hear oral arguments in the case on September 9, 2025.[177]

Rebate Litigation

As the litigation around contract pharmacy use continues, drug manufacturers are still seeking ways to address duplicate discounting and diversion in the 340B program. Another proposal from manufacturers to reduce diversion and duplicate discounting is to offer the 340B price as a rebate, as opposed to an up-front discount.[178] In other words, manufacturers propose to offer covered entities a rebate for a 340B drug after it has been dispensed to a patient, theoretically giving them more control over which drugs to "offer" at the 340B price. Currently, the only HRSA-approved use of rebating to honor the 340B discount is for human immunodeficiency virus (HIV) drugs

such information undercuts the Eighth Circuit's decision in *McClain*, which was premised in part on the covered entities retaining title to the 340B drugs and on the contract pharmacy essentially acting as the agent of the covered entity. *Id.*

[171] *PhRMA*, 760 F. Supp. 3d at 459.

[172] *Id.* at 458 (citing AbbVie Inc. v. Fitch, No. 1:24-cv-184, 2024 WL 3503965, at *10 (S.D. Miss. July 22, 2024)).

[173] *PhRMA*, 760 F. Supp. 3d at 463.

[174] *Id.* at 462–63 (citing Air Evac. EMS v. Dodrill, 548 F. Supp. 580, 594–95 (S.D. W. Va. 2021).

[175] *PhRMA*, 760 F. Supp. 3d at 464. The government argued that the state law was favorable to the public interest, as it would have increased access to 340B drugs, but the court was not persuaded, reasoning that the state's logic "misses the point of the 340B Program," which was "for the benefit of the *covered entities*." *Id.*

[176] Case Docketed, PhRMA v. McCuskey, No. 25-1054 (4th Cir. Jan. 16, 2025), Dkt. No. 1. The Fourth Circuit consolidated PhRMA's appeal with two other cases, Nos. 25-1055 and 25-1056, both of which were brought by drug manufacturers to challenge the West Virginia contract pharmacy law. Order, *PhRMA*, No. 25-1054 (4th Cir. Jan. 16, 2025), Dkt. No. 4.

[177] Oral Argument Notification, *PhRMA*, No. 25-1054 (4th Cir. July 10, 2025), Dkt. No. 91.

[178] In recent guidance, HRSA defined a 340B rebate as "a reimbursement made from the manufacturer to the covered entity in the amount of the standard acquisition cost (i.e., wholesale acquisition cost) of a covered outpatient drug less the statutory 340B ceiling prices as defined . . . in the [PHSA]." HRSA, 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program," 90 Fed. Reg. 36163 (Aug. 1, 2025). Rebating is often used by drug manufacturers and pharmacy benefit managers in other contexts—for example, the Medicare Drug Rebate Program—to lower the prices of drugs after they are sold. *See, e.g.*, CRS Report R43778, *Medicaid Prescription Drug Pricing and Policy*, by Cliff Binder (2014).

distributed through the AIDS Drug Assistance Program (ADAP), a component of the Ryan White HIV/AIDS Program that assists low-income individuals with HIV with accessing their medications.[179] In 1998, HRSA issued guidance in the *Federal Register* regarding the rebating of 340B drugs for state AIDS Drug Assistance Programs (ADAPs) to ensure that Ryan White Clinics, which are 340B covered entities, could receive the 340B price.[180] HRSA limited the applicability of the 1998 guidance permitting rebates to state ADAPs, allowing states to submit their rebate claims to manufacturers.[181] The notice also cautioned that all of HRSA's previously issued guidance related to the prevention of duplicate discounting and drug diversion applied to the ADAPs.[182]

In August 2024, more than twenty-five years after HRSA's ADAP notice permitting the rebating of certain 340B drugs, Johnson & Johnson became the first drug manufacturer to propose a larger-scale rebate model policy, which it planned to apply only to 340B DSH hospital purchases of its drugs Stelara and Xarelto.[183] The policy stated that beginning October 15, 2024, the company would make these two drugs purchased by DSH hospitals available at the 340B price through a rebate only, instead of an up-front discount.[184] The company further highlighted its commitment to the 340B program, stating that the rebate policy would "significantly improve program integrity while at the same time enabling covered entities to obtain the 340B price on eligible 340B sales."[185] Around the same time, several other drug manufacturers announced similar intentions to implement new rebating policies for certain 340B drugs sold to particular categories of covered entities.[186]

---

[179] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 63 Fed. Reg. 35239 (June 29, 1998); *see also Part B: Grants to States and Territories*, HRSA: RYAN WHITE HIV/AIDS PROGRAM (May 2025), https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-grants-states-territories [https://perma.cc/8G6Y-GHQE]. The Ryan White HIV/AIDS Program (RWHAP) has a component that provides grants to states to cover medical services and medications for low-income patients with HIV. *Id.* The grants are awarded to states in accordance with a statutory formula that bases the state's payment on the number of individuals with HIV in that state. *Id.* According to HRSA, approximately half of the patients with HIV in the United States receive support through RWHAP. *Program Parts and Initiatives*, HRSA: RWHAP (Dec. 2024), https://ryanwhite.hrsa.gov/about/parts-and-initiatives [https://perma.cc/8AYK-TZFV]. For more information about RWHAP, see CRS Report R44282, *The Ryan White HIV/AIDS Program: Overview and Impact of the Affordable Care Act*, by Judith A. Johnson and Elayne J. Heisler (2016).

Additionally, HRSA published guidance in August 2025 announcing a voluntary rebate model pilot program that would allow drug manufacturers whose drugs were selected for price negotiation through the Medicare Drug Price Negotiation Program for price year 2026 to submit a rebate model plan to HRSA no later than September 15, 2025. HRSA, 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 36163 (Aug. 1, 2025). The guidance stipulates specific information that manufacturers must provide to HRSA in order to effectuate the 340B price of these drugs as a rebate. *Id.* HRSA will provide a comment process for covered entities and other stakeholders to provide feedback about the rebating pilot and could make additional changes in the future. *Id.*

[180] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 63 Fed. Reg. at 35239. Under the 340B statute, Ryan White Clinics are eligible 340B covered entities. 42 U.S.C. § 256b(a)(4)(D).

[181] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 63 Fed. Reg. at 35242.

[182] *Id.*; *see also* Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 27293 (May 7, 1993).

[183] Johnson & Johnson Health Care Sys. Inc., Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO (Aug. 23, 2024), https://sponsors.aha.org/rs/710-ZLL-651/images/Johnson%20%20Johnson%20Innovative%20Medicine%20340B%20Rebate%20Model%20Policy%20Update%2008-23-2024_FINAL.pdf [https://perma.cc/JE3R-63VL].

[184] *Id.*

[185] *Id.* at 3.

[186] Eli Lilly & Co., Lilly Statement on New 340B Litigation (Nov. 15, 2025), https://investor.lilly.com/node/51571/pdf [https://perma.cc/UD7J-7ZD6].

On September 27, 2024, HRSA advised Johnson & Johnson that the company could not implement its rebate proposal without the approval of the HHS Secretary, and that to begin using the rebate model without approval would violate the 340B statute.[187] In response, the company notified HRSA that due to the agency's "threats of excessive and unlawful penalties," Johnson & Johnson would forego implementation of its proposed rebate policy.[188] Shortly thereafter, at least five drug manufacturers filed suit in D.C. Federal District Court to challenge HRSA's interpretation of the statute and the agency's decision to deny manufacturers' requests to implement a rebate model.[189]

This section discusses the litigation related to the rebating of 340B drugs and whether such a practice comports with the 340B statute. As of the date of this writing, two district courts have agreed with HRSA that the 340B statute gives the Secretary discretion to approve manufacturers' rebating policies.[190] After the courts issued the rulings, HRSA released guidance announcing a new rebate pilot program that would allow specific manufacturers to enroll for at least one year in a rebate model.[191] Applications are due September 15, 2025.[192]

The D.C. District Court's Decision in *Johnson & Johnson Health Care Systems, Inc. v. Kennedy* Upholding HRSA's Interpretation of the 340B Statute

After HRSA threatened enforcement regarding Johnson & Johnson's 340B rebate model, the company sued HRSA in D.C. Federal District Court, arguing that the agency lacked the statutory authority to require the HHS Secretary's approval for rebate models.[193] The company also argued that HRSA's actions were arbitrary and capricious, because HRSA treated its rebate model differently than the ADAP model.[194] Several covered entities filed a motion to intervene in the suit, which the court granted.[195] The intervenors sided with HRSA, arguing that the 340B statute requires up-front discounts and that HRSA's secretarial approval requirement does not violate the

[187] Letter from Carole Johnson, Adm'r, HRSA, to Joaquin Duato, CEO, Johnson & Johnson (Sept. 27, 2024), https://sponsors.aha.org/rs/710-ZLL-651/images/sept-27-2024-hrsa-letter-johnson-johnson.pdf [https://perma.cc/QD4P-AUKX].

[188] Letter from Scott White, COO, Johnson & Johnson Health Care Systems Inc., to Carole Johnson, Adm'r, HRSA (Sept. 30, 2024), https://sponsors.aha.org/rs/710-ZLL-651/images/sept-27-24-hrsa-letter-johnson-johnson.pdf [https://perma.cc/C6CK-HQYD].

[189] *See* Complaint, Kalderos, Inc. v. United States, No. 1:21-cv-02608 (D.D.C. Oct. 6, 2021), Dkt. No. 1 [hereinafter Kalderos Complaint]; Complaint, Johnson & Johnson Health Care Sys. v. Becerra, No. 1:24-cv-03188 (D.D.C. Nov. 12, 2024), Dkt. No. 1 [hereinafter Johnson & Johnson Complaint]; Complaint, Eli Lilly & Co. v. Becerra, No. 1:24-cv-03220 (D.D.C. Nov. 14, 2024), Dkt. No. 1 [hereinafter Eli Lilly Complaint]; Complaint, Bristol Myers Squibb Co. v. Johnson, No. 1:24-cv-03337 (D.D.C. Nov. 26, 2024), Dkt. No. 1 [hereinafter Bristol Myers Squibb Complaint]; Complaint, Sanofi-Aventis U.S. LLC v. HHS, No. 1:24-cv-03496 (D.D.C. Dec. 16, 2024), Dkt. No. 1 [hereinafter Sanofi-Aventis Complaint].

[190] *See* Memorandum Opinion, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. June 27, 2025), Dkt. No. 59; Memorandum Opinion at 10 n.6, *Sanofi-Aventis U.S. LLC*, No. 1:24-cv-03496 (D.D.C. May 15, 2025), Dkt. No. 58.

[191] HRSA, 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 36163 (Aug. 1, 2025). See also discussion of rebating guidance *supra* note 179.

[192] *Id.*

[193] Johnson & Johnson Complaint, *supra* note 189, at 48.

[194] *Id.* at 45.

[195] Order, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. May 15, 2025), Dkt. No. 49.

APA.[196] In February 2025, Johnson & Johnson filed a motion for summary judgment, and the government filed a cross-motion for summary judgment shortly thereafter.[197]

In June 2025, the D.C. Federal District Court upheld HRSA's interpretation of the statute, denied Johnson & Johnson's motion for summary judgment, and granted the government's cross-motion for summary judgment.[198] The court began its decision by analyzing the text, structure, and purpose of the 340B statute, finding that the text supported HRSA's interpretation, because the statute deferred to the Secretary to "tak[e] into account any rebate or discount" in determining the 340B price.[199] The court found that the most reasonable interpretation of the statute's phrase "taking into account any rebate or discount" was that the statute gave the Secretary the discretion to "consider" rebates and discounts.[200] In support of its position that it could freely implement its 340B rebate model, Johnson & Johnson pointed to the D.C. Circuit's holding in *Novartis* that statutory silences imply that a party may freely act. The court declined to apply *Novartis* because "the statute's grant of authority to the Secretary [to consider rebates and discounts] is explicit, not silent."[201] The court further disagreed with the intervenor covered entities' arguments that rebating was not allowed in the 340B program at all, pointing to the statute's explicit reference to rebates.[202]

The court found that the purpose and history of the 340B statute also supported the government's interpretation that the Secretary has the discretion to approve or reject a manufacturer's proposed rebate model.[203] The court observed HRSA's long-standing practice of determining the "most effective and most efficient" pricing mechanisms to ensure that covered entities received the 340B discount.[204] When HRSA allowed ADAPs to access the 340B discount through rebates, the court said this was an example of the agency exercising its discretion to "tak[e] into account" a rebate.[205] The court concluded that "[b]ased on the plain and unambiguous language of the 340B statute, and supported by its purpose and history, HRSA has the authority to 'provide' for discounts, rebates, or both."[206]

The court was further unpersuaded by Johnson & Johnson's arguments that HRSA's decision to reject its rebate model was arbitrary and capricious, and it also did not agree with the company that the APA required HRSA to first undergo notice and comment rulemaking prior to sending a letter warning Johnson & Johnson of potential penalties associated with implementing an unapproved rebate model.[207] The court characterized HRSA's September 27, 2024, letter to the company as an interpretive rule, which does not require the agency to undergo a notice and

[196] Motion of 340B Health et al. for Leave to File an Oversized Amicus Brief in Support of Defendants at 14, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. Apr. 2, 2025), Dkt. No. 43.

[197] Plaintiff's Motion for Summary Judgment, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. Feb. 3, 2025), Dkt. No. 18; Defendants' Cross Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. Apr. 2, 2025), Dkt. No. 41.

[198] Memorandum Opinion, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. June 27, 2025), Dkt. No. 59.

[199] *Id.* at 11 (quoting 42 U.S.C. § 256b(a)(1)).

[200] Memorandum Opinion, *supra* note 198, at 14. The court further observed that Johnson & Johnson "reads 'as provided by the Secretary' out of the statute entirely." *Id.* at 15.

[201] *Id.* at 15.

[202] *Id.* at 16.

[203] *Id.* at 19.

[204] *Id.*

[205] Memorandum Opinion, *supra* note 198, at 20.

[206] *Id.* at 21.

[207] *Id.*

comment process.[208] The court further reasoned that even if HRSA had not sent Johnson & Johnson a letter warning of potential penalties, the agency would have had an adequate basis to bring an enforcement action against the company.[209]

The crux of Johnson & Johnson's arbitrary and capricious argument was that the agency treated its rebate model differently than the typical up-front discount models, without sufficient explanation.[210] The court agreed with HRSA's conclusion that a shift to a rebate model would be a material change that could result in a hospital or other covered entity "floating revenue" to a drug manufacturer. [211] HRSA also noted that, unlike the voluntary ADAP rebate model that the Secretary had approved, Johnson & Johnson's rebate model was mandatory, and several covered entities had already objected to it.[212] The court reasoned that "giving covered entities the ability to choose between available pricing mechanisms is consistent with [the agency's] past practice."[213] The court further rejected Johnson & Johnson's argument that HRSA failed to consider important aspects of the problems of duplicate discounting and diversion.[214]

Although the court upheld HRSA's interpretation of the statute, it noted that the agency had also represented that it was actively considering Johnson & Johnson's rebate request while simultaneously continuing to address 340B program integrity.[215] The court advised that it hoped the agency would soon "provide meaningful guidance" regarding manufacturer rebate policies.[216]

Johnson & Johnson appealed the district court's decision granting the government's motion for summary judgment to the D.C. Circuit in June 2025. [217] As of the time of this writing, the court has not yet set a date for oral arguments.[218]

The D.C. Federal District Court's Order in *Sanofi-Aventis U.S. LLC v. HHS* Upholding HRSA's Interpretation of the 340B Statute

In 2024, several other drug manufacturers also filed federal suit in D.C. Federal District Court to challenge HRSA's position that manufacturers were required to seek the agency's preapproval before implementing models to rebate 340B drugs.[219] Together, the manufacturers made a variety

[208] *Id.* at 22.

[209] *Id.*

[210] *Id.*

[211] *Id.* at 24.

[212] *Id.* at 25.

[213] *Id.* at 26.

[214] *Id.* at 28. The court found that HRSA's position in its letter to Johnson & Johnson focused on the secretarial approval policy and that the agency had not claimed that Johnson & Johnson could never implement a rebate policy, only that it required the Secretary's approval to do so. *Id.* For this reason, the court found that HRSA's assertions in its letter to Johnson & Johnson were "sufficiently explained." *Id.* (citing Xcel Energy Servs. Inc. v. FERC, 41 F.4th 548, 557 (D.C. Cir. 2022) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983))).

[215] Memorandum Opinion, *supra* note 198, at 28–29.

[216] *Id.* at 29.

[217] Notice of Appeal, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. June 27, 2025), Dkt. No. 61.

[218] *See* Per Curiam Order, Johnson & Johnson Health Care Systems Inc. v. Kennedy, No. 25-5236 (D.C. Cir. Aug. 21, 2025).

[219] The plaintiffs are (in order of filing date) Kalderos, Inc. (a health care technology company with whom Eli Lilly contracted to develop a rebate platform), Johnson & Johnson, Eli Lilly, Bristol Myers Squibb, and Sanofi-Aventis. *See* cases cited *supra* note 189. While the court did not consolidate these cases, the court ordered a joint hearing in the cases and issued one decision. *See* Minute Order, Eli Lilly & Co. v. Kennedy, No. 1:24-cv-03220 (D.D.C. Feb. 25, (continued...)

of claims similar to those brought by Johnson & Johnson, including that HRSA lacked the authority to require preapproval of manufacturer rebating.[220] Sanofi-Aventis, one of the plaintiffs, also argued that HRSA's decision to deny its request to use a rebate platform was arbitrary and capricious.[221] At least two manufacturers claimed that HRSA violated their Fifth Amendment Due Process rights, because the agency's "siloed administration" of both the 340B program and the Medicare Drug Price Negotiation Program would lead to manufacturers paying even more duplicate discounts, which is prohibited under the Social Security Act.[222] Similar to the *Johnson & Johnson* case, the parties filed motions for summary judgment, and in April 2025, the D.C. Federal District Court heard oral arguments in several of the cases together. [223]

In May 2025, the D.C. Federal District Court granted the government's motion for summary judgment with respect to plaintiffs Kalderos, Johnson & Johnson, Eli Lilly, and Bristol Myers Squibb, and granted in part the government's motion for summary judgment with respect to plaintiff Sanofi-Aventis.[224] The court first addressed the plaintiffs' APA challenges, including claims that HRSA lacked the statutory authority for its rebate preapproval requirement and that

2025); *see also* Minute Order, Sanofi-Aventis U.S. LLC v. HHS, No. 1:24-cv-03496 (D.D.C. Feb. 26, 2025) [hereinafter Sanofi-Aventis Minute Order].

While all of the drug manufacturer plaintiffs were making similar claims, their rebate proposals differed. For example, Bristol Myers Squibb's proposal would apply only to 340B covered entity purchases of its drug Eliquis. Memorandum Opinion at 10 n.6, *Sanofi-Aventis U.S. LLC*, No. 1:24-cv-03496 (D.D.C. May 15, 2025), Dkt. No. 58. Novartis's proposal would apply a rebate model to all drug purchases made by DSH hospitals. *Id.* Sanofi's rebate proposal would apply to all drug purchases made by certain categories of covered entities, including DSH hospitals, critical access hospitals, sole community hospitals, some health centers, and rural referral centers. *Id.* Sanofi's proposal is discussed *infra* note 221.

As with the *Johnson & Johnson* case discussed above, several covered entities—including UMass Memorial Medical Center, Genesis Healthcare, and 340B Health (an organization that advocates for 340B hospitals)—intervened in these cases. *See e.g.*, Order, *Sanofi-Aventis U.S. LLC*, No. 1:24-cv-03496 (D.D.C. Mar. 4, 2025), Dkt. No. 32. The court found that HHS could not adequately represent the interests of the intervenors and that the covered entities and 340B Health were permitted to intervene as a matter of right, because they would be directly impacted by the court's ruling. *Id.* at 5–6.

[220] *See*, *e.g.*, Sanofi-Aventis Complaint, *supra* note 189, at 24–26.

[221] As of the date of the D.C. Federal District Court's decision, the agency had not yet denied any other manufacturer's request for a rebate. Sanofi proposed to rebate 340B drugs for certain 340B covered entities "in the form of a credit," which the company would apply to a provider's bill before payment. Memorandum Opinion, *supra* note 219, at 11. In this way, the company argued, the 340B price was still being guaranteed, because the provider would complete a payment only at the 340B price (i.e., the commercial price minus the rebate). *Id.* Additionally, under Sanofi's model, the manufacturer would determine which of its drugs had been dispensed to eligible 340B patients by analyzing claims data. *Id.*

[222] *E.g.*, Bristol Myers Squibb Complaint, *supra* note 189, at 28. Under the Inflation Reduction Act, the law that created the Medicare Drug Price Negotiation Program, manufacturers are not required to provide the maximum fair price (i.e., the negotiated price) to individuals who are patients of 340B covered entities. 42 U.S.C. § 1320f-2(d)(1). Both Bristol Myers Squibb and Novartis manufacture drugs that were selected for price negotiation in the Medicare Drug Price Negotiation Program. *See* CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2026 (2023), https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf [https://perma.cc/FM3C-NEEP].

For more information about the Medicare Drug Price Negotiation Program, see CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*, by Hannah-Alise Rogers (2023).

[223] *E.g.*, Plaintiff's Motion for Summary Judgment, *Sanofi-Aventis*, No. 1:24-cv-03496 (D.D.C. Feb. 20, 2025), Dkt. No. 27; Defendants' Cross Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment, *Sanofi-Aventis*, No. 1:24-cv-03496 (D.D.C. Mar. 27, 2025), Dkt. No. 41. *See* Sanofi-Aventis Minute Order, *supra* note 219 (explaining that the court was not officially consolidating the cases but would hear the parties' motions for summary judgment together).

[224] Memorandum Opinion, *supra* note 219.

HRSA had acted contrary to law.[225] The court first analyzed the text of the 340B statute, emphasizing that its plain meaning provides the Secretary the authority to approve "any rebate[s] or discount[s]."[226] The court also pointed to legislative history in support of HRSA's position[227] and noted that the agency had not ever "disclaimed" its authority to preapprove other 340B price models.[228] For example, even though HRSA approved the ADAP model after it had been implemented, the court reasoned that this did not mean that HRSA lacked authority to preapprove the model.[229]

The manufacturers also argued that HRSA's disapproval of their proposed rebate models was arbitrary and capricious because HRSA treated the plaintiffs' rebate proposal differently than the ADAPs without sufficient reason and because the agency failed to consider that the rebating of 340B drugs would allow manufacturers to prevent duplicate discounting and diversion.[230] The court found that HRSA had provided a "rational explanation" for the difference in treatment between the plaintiffs' rebate proposals and the ADAP rebate proposal—namely, that ADAPs generally cannot access the 340B price via up-front discounts.[231] As in *Johnson & Johnson*, the court noted that the ADAP rebates were optional, but that manufacturers' rebate policies in the present case would be mandatory and were vigorously opposed by covered entities.[232]

The plaintiffs also argued that HRSA failed to consider that their proposals would curb the use of duplicate discounting and diversion among the 340B and Medicaid programs and the Medicare Drug Price Negotiation Program.[233] The court agreed with the plaintiffs that while HRSA planned to coordinate with CMS regarding the drug negotiation, "the absence of a definitive oversight plan [to prevent duplicate discounting] is concerning."[234] With respect to Eli Lilly, Novartis, and Bristol Myers Squibb, the court found that HRSA had not yet made a final decision to deny the companies' requests to use the rebate model and thus that it would be "premature" to assess HRSA's actions prior to the agency's final determination.[235] With respect to Sanofi-Aventis, however, the court found that HRSA's rejection of the company's proposed rebate model could be arbitrary or capricious, because the agency did not "address concerns that Sanofi . . . raised about

[225] *Id.* at 18.

[226] *Id.* at 20 (quoting 42 U.S.C § 256b(a)(1)).

[227] The court pointed to a House Energy and Commerce Committee report noting that 340B prices "would be implemented, *at the discretion of the Secretary*, either by a point-of-purchase discount, a rebate, or other mechanism." *Id.* at 20 (quoting H.R. REP. NO. 102-384(II), at 8, 12, 16 (1992)).

[228] Memorandum Opinion, *supra* note 219, at 21.

[229] *Id.*

[230] *Id.* at 23, 26.

[231] *Id.* at 24 (citing Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45823, 45824 (Aug. 29, 1997) (requesting comment on a proposal to rebate 340B purchases by ADAPs)).

[232] Memorandum Opinion, *supra* note 219, at 24.

[233] Indeed, CMS's guidance implementing the initial year of the Medicare Drug Price Negotiation Program stated that CMS would not "assume responsibility for nonduplication of discounts between the 340B ceiling price" and Medicaid rebates. Memorandum from CMS to Interested Parties 231 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf [https://perma.cc/8WCS-84TZ].

[234] Memorandum Opinion, *supra* note 219, at 27. The manufacturers argued that the claims data generated by their rebate models would better enable them to track and thereby prevent duplicate discounting. *Id.* at 28.

[235] *Id.* at 28–29.

unlawful duplications and diversions."[236] Thus, the court granted in part Sanofi's motion for summary judgment and remanded the case to HRSA for further consideration. [237]

Finally, the court concluded that manufacturers Bristol Myers Squibb and Novartis had not established a Fifth Amendment Due Process challenge, because the manufacturers voluntarily chose to participate in both the 340B program and the Medicare Drug Price Negotiation Program.[238] Additionally, the court found that even if the manufacturers' duplicate discount losses are protected property for purposes of the Fifth Amendment, the audit and ADR processes enumerated in the 340B statute provide adequate process for manufacturers to redress any potential losses.[239] The ruling was not appealed.

"Patient" Definition Litigation

In addition to the litigation regarding manufacturers' ability to place guardrails on the 340B program, either by conditioning contract pharmacy use or by guaranteeing the 340B price through a rebate instead of an up-front discount, there have also been disagreements between HRSA and covered entities about who qualifies as a patient for purposes of the 340B program. The 340B statute forbids covered entities from distributing their 340B drugs to individuals who are not patients of the covered entity, but the statute does not define who a patient is.[240] The scope of the "patient" definition is a significant factor in a covered entities' ability to generate 340B savings. Determining whether an individual is a patient of the covered entity for purposes of 340B can quickly become complicated and can raise several questions. For example, if an individual receives primary care at a covered entity but seeks specialty care elsewhere, can the covered entity generate 340B savings from the specialty doctor who is not employed by the covered entity? Does it matter if the individual was referred to the specialist by a covered entity physician? For how many years does an individual retain his or her patient status? What if the individual has not been seen by the covered entity in several years, but the individual keeps filling the associated (or new) prescriptions? The answers may depend on agency guidance.

As discussed below, HRSA guidance defining patients of covered entities has shifted over the years. This section discusses how HRSA has defined a 340B patient, the litigation challenging that definition, and recent attempts by HRSA to enforce its "patient" definition.

Background

HRSA's 1996 Guidelines Regarding the Definition of "Patient"

In September 1994, HRSA first indicated that the 340B statute does not define "patient."[241] Although the agency stated that the lack of a definition could lead to covered entities' abuse of the program, HRSA declined to define the term until October 1996, when it published final

[236] *Id.* at 30.

[237] *Id.* The court emphasized, however, that its decision did not "vacate the agency's preapproval requirement" and that Sanofi could not "unilaterally implement its rebate proposal at this juncture." *Id.* at 31.

[238] Memorandum Opinion, *supra* note 219, at 32.

[239] *Id.* at 32–33.

[240] 42 U.S.C. § 256b(a)(5)(B).

[241] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 47884, 47886 (Sept. 19, 1994).

guidelines for the definition.[242] Under the 1996 Guidance, an individual is considered a "patient" of a covered entity (1) if the entity has an established relationship with the individual and maintains records of the individual's care; (2) if the entity is responsible for the individual's care, as evidenced by the individual receiving health services from an employee or contractor of the covered entity (which could include referrals); and (3) for federally qualified health center or look-a-like entities, if the entity furnishes health care services to the individual consistent with the range of services for which it received federal grant funds.[243] In other words, according to the agency, to generate 340B savings from the outpatient prescriptions of an individual, a covered entity had to have a bona fide relationship with the patient and the patient had to receive appropriate health services at the facility.

HRSA's 2015 Proposed Guidelines Regarding Updates to the Definition of "Patient"

HRSA used the "patient" definition outlined in the 1996 Guidance until 2015, when the agency proposed a new, more specific definition of "patient" as part of its "Omnibus Guidance."[244] The 2015 Guidance stated that, for purposes of 340B, an individual would be considered a patient "on a prescription-by-prescription or order-by-order basis" if the individual met all six of the following conditions: (1) the individual received care at a covered entity registered for the 340B program; (2) the individual received care from an employee or contractor of the covered entity, such that the entity billed for the services on the provider's behalf; (3) the individual's medications were prescribed by the covered entity's provider "as a result of the service described in (2)"; (4) if the covered entity was a federal grantee (e.g., an FQHC), the care provided "was consistent with the scope of" the federal grant; (5) the drug was prescribed pursuant to an outpatient health service; and (6) the individual's medical records were "accessible to" the entity and demonstrate its responsibility for the individual's care.[245] In the guidelines outlining this new definition, HRSA explained that it had revised the definition after conducting audits and observing how covered entities applied the definition across different health care settings.[246] The agency later withdrew the 2015 Guidance and continued to use the 1996 Guidance to define the patients of covered entities.[247] The agency did not give a reason for rescinding the guidance.

[242] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

[243] *Id.* at 55157. The third requirement does not apply to DSH hospitals. *Id.* The guidance further provides a special definition of "patient" for individuals who are registered in an AIDS drug purchasing assistance program. *Id.*

[244] 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015). The 2015 Guidance addressed a variety of issues facing the program at that time, including attempting to clarify covered entity eligibility post-ACA changes, placing parameters on contract pharmacies, explaining implementation of the statutory group purchasing organization (GPO) prohibition, and defining the term "patient." *Id.* HRSA issued the Omnibus Guidance after stakeholders brought litigation in 2014 challenging the agency's rulemaking authority under the statute. *See* PhRMA v. HHS, 43 F. Supp. 3d 28 (D.D.C. 2014) (finding HRSA lacked statutory authority to issue certain regulations governing the 340B program).

[245] 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. at 52306–07.

[246] *Id.* at 52306.

[247] Off. of Mgmt. & Budget, Off. of Info. & Regul. Affs., *OIRA Conclusion of EO 12866 Regulatory Review*, REGINFO.GOV (Jan. 30, 2017), https://www.reginfo.gov/public/do/eoDetails?rrid=126712 [https://perma.cc/99YU-CKTH].

The District Court and Fourth Circuit Litigation in *Genesis Healthcare, Inc. v. Becerra* Invalidating HRSA's "Patient" Definition

In 2017, HRSA took action to terminate a covered entity from the 340B program after a periodic audit of the entity's records showed that it had engaged in diversion.[248] The entity, Genesis Healthcare, then sued HRSA in South Carolina Federal District Court, requesting that the court stay implementation of the agency's action to remove it from the program and declare HRSA's definition of "patient" unlawful.[249] A few months later, in response to the lawsuit, HRSA reinstated Genesis as a 340B covered entity but maintained its position that the company had engaged in diversion and should therefore reimburse manufacturers for the underpayments.[250] Subsequent communications between the parties revealed that HRSA would continue to enforce the 1996 Guidance definition of "patient" against Genesis.[251] When Genesis amended its complaint to request that the court "declare that the plain wording of [the 340B statute] requires that any prescription from any source is available to a patient of a covered entity," HRSA withdrew its audit findings altogether and requested the court dismiss the action as moot.[252] The district court granted HRSA's motion dismissing the case; Genesis then appealed this decision to the U.S. Court of Appeals for the Fourth Circuit, which reversed.[253]

In its decision to reverse the district court and remand the case for further proceedings, the Fourth Circuit found that the issues in the suit were not mooted by HRSA's withdrawal of its audit findings because Genesis "remains subject to audit and, as the record states, would still have to comply with HRSA's 1996 Guidelines."[254] In other words, the court found that because HRSA was still trying to enforce its definition of "patient" against the covered entity, the issue between the parties was likely to continue, unless Genesis changed its business model.[255] The court characterized "the real issue" of the suit as a question of "whether the 1996 [Guidance] [is] inconsistent with the statute."[256] The Fourth Circuit thus remanded the case to the district court to make this determination.[257]

In November 2023, the district court issued a decision invalidating HRSA's definition of "patient" as it applied to Genesis.[258] In a March 2019 letter from the agency to Genesis and before the district court, HRSA argued that in order for an individual to qualify as a patient, the individual's prescription had to "originate from a health care encounter with Genesis or one of its contract

[248] Genesis Healthcare, Inc. v. Azar, No. 19-cv-1531, 2019 WL 6909572 (D.S.C. Dec. 19, 2019), *rev'd sub nom.,* Genesis Healthcare, Inc. v. Becerra, 39 F.4th 253 (4th Cir. 2022).

[249] *Id.* at *1.

[250] *Id.* at *2.

[251] *Id.* at *4.

[252] *Id.*at *2.

[253] Genesis Healthcare, Inc. v. Becerra, 39 F.4th 253, 259 (4th Cir. 2022).

[254] *Id.* at 260–61.

[255] *Id.* at 261.

[256] *Id.*

[257] *Id.* at 263. The Fourth Circuit further found that Genesis' challenge to HRSA's use of the 1996 Guidance for purposes of its audit was a final agency action that Genesis could challenge. *Id.* at 262.

[258] Genesis Health Care, Inc. v. Becerra, 701 F. Supp. 3d 312 (D.S.C. Nov. 3, 2023). It should be noted that the court's holding voiding HRSA's interpretation of the "patient" definition as applied to Genesis applies only to Genesis and does not invalidate the underlying "patient" definition itself. *See id.* at 332 n.4.

health providers."[259] Genesis claimed that the agency's definition was too narrow and contradicted the plain wording of the statute, and that the only statutory requirement was that the individual be a "patient" of a "covered entity."[260] In other words, Genesis argued that it could generate 340B savings on all of a patient's prescriptions, even if those prescriptions were not related to care the person received at Genesis.

Because HRSA's definition of "patient" appeared in guidance documents, which lacked the force of law, the court applied *Skidmore* deference, which gives weight to an agency's interpretation of a statute insofar as it has the "power to persuade."[261] After applying *Skidmore*, the court held that HRSA's definition of "patient" was "unpersuasive" and "contrary to the plain language of the 340B statute."[262] The court opted for a broader definition of the term, agreeing with Genesis that "[n]othing in the statute conditions an individual's eligibility as a 340B patient on whether the health care service resulting in the prescription was initiated by the 'covered entity.'"[263]

Because Congress did not define "patient" in the 340B statute, the court consulted various dictionary definitions to interpret the term, finding that the "common definition" was "a person who is receiving medical treatment."[264] The court also noted that the 340B statute's legislative history supported a broader reading of "patient," and that "the only logical conclusion" was that Congress intended to convey the ordinary meaning of the term as it is used in the statute.[265] The court held, "The plain language of the 340B statute does not require a link between a 340B prescription sold by a 'covered entity' to a 'patient' and the origination of that prescription."[266] However, the court agreed with HRSA's argument that an overly expansive "patient" definition would allow covered entities to generate 340B savings from patients who had not received care at

[259] *Id.* at 321. Put another way, in the March 2019 letter to Genesis, HRSA stated its intention to "clarify that in order for an individual to qualify as a 340B patient, [Genesis] must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable FQHC encounter." *Id.* at 322. This definition is similar to the withdrawn 2015 proposed definition in which the agency said it would evaluate 340B patient purchases on a "prescription-by-prescription" or "order-by-order" basis. *See* 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52306–07 (Aug. 28, 2015).

[260] *Genesis*, 701 F. Supp. 3d at 321–22.

[261] *Id.* at 323; Skidmore v. Swift & Co., 323 U.S. 134 (1944). The Court held in *Skidmore*, "The weight of a[n] [agency's] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id.* at 140. Although this case was decided prior to the Supreme Court's overruling of the *Chevron* doctrine in *Loper Bright*, 603 U.S. 369 (2024), the court found that HRSA's definition of "patient" was not entitled to *Chevron* deference because the definition of "patient" was an interpretive rule that lacked the force of law, *Genesis*, 701 F. Supp. 3d at 323.

For more information on *Loper Bright*, see CRS Legal Sidebar LSB11189, *Supreme Court Overrules Chevron Framework*, by Benjamin M. Barczewski (2024). For more information about agency guidance, see CRS Legal Sidebar LSB10591, *Agency Use of Guidance Documents*, by Kate R. Bowers (2021).

[262] *Genesis*, 701 F. Supp. 3d at 324.

[263] *Id.*

[264] *Id.* at 324–25.

[265] *Id.* at 325. The court later noted that Congress had considered amending the statute to specify that a covered entity could not dispense a 340B drug to "an individual *who is not receiving the drug or biological as a patient of the covered entity*." *Id.* at 327 (citing S. REP. NO. 102-259, at 4 (1992)). The amendment was not enacted, however, and the court thus reasoned that "Congress 1) was aware of the potential issues created by a broad definition of the term 'patient,' 2) possessed the tools to limit the definition . . . to those individuals whose prescriptions originated from the 'covered entity,' and 3) in spite of those issues, chose not to limit 340B patient eligibility to prescriptions that originated or were initiated from a covered entity or contract provider." *Genesis*, 701 F. Supp. 3d at 327.

[266] *Genesis*, 701 F. Supp. 3d at 327. The court also rejected several amici pharmaceutical companies' arguments that the statute's definition of "covered drug" support HRSA's narrower definition of "patient." *Id.* at 326.

the covered entity for many years; the court thus found that the statute "require[s] an ongoing patient relationship between the individual and the 'covered entity.'"[267]

The court further observed that "[t]he degree of HRSA's care regarding its interpretation of the term 'patient' since the enactment of the 340B statute leaves much to be desired."[268] The court pointed to evidence that early in the program's history, the agency aimed to develop a "flexible" definition in order to accommodate different covered entity types, and unlike the March 2019 letter from HRSA to Genesis, the 1996 Guidance did not require that a prescription originate from a covered entity provider.[269] The 1996 Guidance had remained in place for almost 20 years, until HRSA proposed a revised definition that considered whether individuals were patients on a "prescription-by-prescription or order-by-order" basis.[270] The court described HRSA's actions as lacking consistency, because even though HRSA withdrew the revised guidelines in 2017, the agency was still trying to enforce the narrowed "patient" definition against Genesis.[271] While the court was sympathetic to HRSA's task of administering the program in the midst of many changes to the prescription drug industry, it found that HRSA was not empowered "to enforce a new interpretation of an unambiguous statutory term that restricts a program that Congress intended to have broad application."[272]

The court voided the March 2019 letter and the definition of "patient" used in it, enjoining the agency from enforcing the definition against Genesis; the agency did not appeal the ruling.[273] However, the decision does not prevent HRSA from bringing future enforcement actions against other entities using the same or a similar definition. The 1996 "patient" definition guidelines remain available on the agency's website.[274]

D.C. Federal District Court Litigation in *Genentech v. HHS* and *Sagebrush Health Services, Inc. v. Kennedy* Regarding HRSA's Certification of Covered Entities

HRSA routinely recertifies covered entities in accordance with the 340B statute, and the process requires covered entities to submit documentation to HRSA regarding their eligibility for the program.[275] In addition, the agency may terminate from the program any covered entity that engages in "systematic and egregious[,] as well as knowing and intentional[,]" drug diversion.[276] HRSA's attempt to recertify a covered entity as well as the agency's termination of a covered entity from the program has led to additional lawsuits, brought by both drug manufacturers

[267] *Id.* at 326. The court declined to specify exactly how many years could pass between visits where an individual would still be considered a patient. However, the court observed that "Genesis voluntarily utilizes a two year look back period" and that the American Medical Association's definition of "patient" was an individual who had received care at the entity within the last three years. *Id.*

[268] *Id.* at 328.

[269] *Id.*

[270] *Id.* at 329.

[271] *Id.*

[272] *Id.* at 330.

[273] *Id.* at 331.

[274] *See 340B Patient Definition Compliance Resources*, HRSA (Jan. 2024), https://www.hrsa.gov/opa/educational-resources/patient-definition-resources [https://perma.cc/C8G7-GV2C]. At the bottom of this webpage listing resources for covered entities regarding compliance with the "patient" definition, the agency states, "HRSA notes that the decision in *Genesis Health Care, Inc. v. Becerra* . . . is applicable solely to Genesis Health Care." *Id.*

[275] 42 U.S.C. § 256b(a)(7)(E).

[276] *See id.* § (d)(2)(B)(5).

(*Genentech*) and covered entities (*Sagebrush*) that could potentially frustrate HRSA's enforcement of the statute.

In 2024 and 2025, several drug manufacturers, including Genentech and Amgen, sued HRSA under the APA, arguing that the agency was certifying certain facilities as covered entities that did not actually qualify for 340B.[277] The facilities, owned by Sagebrush Health Services, Inc., had claimed to be eligible covered entities under 42 U.S.C. § 256b(a)(4)(K), which permits clinics receiving federal funds through their state or local government to provide treatment for sexually transmitted diseases (STDs) to be eligible for the 340B discount.[278] The manufacturers claimed the facilities were not, in fact, STD clinics, but rather were engaged in various medical practices unrelated to STD treatment.[279] The manufacturers further argued that even if the facilities were qualifying 340B covered entities, they were engaged in diversion, because they were using the 340B discount to distribute non-STD drugs to their patients.[280]

In December 2024, after conducting an extensive audit of Sagebrush, HRSA found that fifty-five of the covered entity's sites were ineligible for the 340B program, because Sagebrush had failed to prove that the sites were receiving the requisite state or local funding for treatment of STDs.[281] HRSA eventually terminated twenty of Sagebrush's sites from the 340B program in January 2025.[282] Sagebrush then sued HRSA under the APA, arguing that the site termination was arbitrary and capricious and should be set aside.[283] During the course of that litigation, HRSA terminated the remaining Sagebrush clinics from 340B,[284] but on July 1, 2025, the agency reinstated at least eight previously terminated sites.[285]

On April 14, 2025, HRSA filed a partial motion to dismiss all of the drug manufacturers' claims in *Genentech*, arguing that the court lacked subject matter jurisdiction because the drug manufacturers could not sue the agency without first exhausting their administrative remedies.[286] In other words, HRSA argued that the manufacturers had not undertaken an investigative audit of the covered entities, nor had they attempted to resolve their disputes with Sagebrush through the ADR process.[287] The agency also argued that many of the manufacturers' claims were moot,

[277] Complaint at 2, Genentech, Inc. v. Fink, No. 25-290 (D.D.C. Jan. 31, 2025), Dkt. No. 1; *see also* Complaint, Amgen Inc. v. Becerra, No. 24-3571 (D.D.C. Dec. 20, 2024), Dkt. No. 1 (includes Eli Lilly as a plaintiff). *See also* 42 U.S.C. § 256b(a)(4)(K); *id.* § 247c (authorizing grants to states for research and prevention of STDs).

[278] Complaint at 2, *Genentech*, No. 25-290.

[279] *Id.* at 2.

[280] *Id.*

[281] Complaint at 11–12, Sagebrush Health Servs. v. Kennedy, No. 25-915 (D.D.C. Mar. 27, 2025), Dkt. No. 1.

[282] *Id.* at 14.

[283] *Id.* at 2.

[284] *Id.* at 14. While litigation in these cases remains ongoing, on June 25, 2025, the D.C. Federal District Court denied Sagebrush's motion for a preliminary injunction, finding that the company was unlikely to succeed on the merits of its claim that HRSA wrongfully removed it from the 340B program. Sagebrush Health Services v. Kennedy, No. 1:25-cv-00915, 2025 WL 1784436 (D.D.C. June 27, 2025). In the decision, the court concluded that the entity had not provided "any documentation demonstrating that it informed HRSA that the [s]ites were receiving Section 318 funding at the time of their termination." *Id.* at *4. The court further observed that "the [340B] statute does not require HRSA to take 340B participants' self-reported information at face value or bar the agency from initiating its own inquiries to confirm compliance." *Id.*

[285] Notice of Factual Development, Amgen Inc. v. Kennedy, No. 1:24-cv-03571 (D.D.C. July 14, 2025), Dkt. No. 19.

[286] Memorandum of Points and Authorities in Support of Defendants' Partial Motion to Dismiss, *Amgen*, No. 1:24-cv-03571 (D.D.C. Apr. 14, 2025), Dkt. No. 14.

[287] *See* 42 U.S.C. § 256b(a)(5)(C) (compliance with manufacturer audits); *see also id.* § 256b(d)(3) (administrative dispute resolution process).

because it had terminated many of Sagebrush's sites from the program since the lawsuit began.[288] The manufacturers responded to the government's motion to dismiss by arguing that the 340B statute does not require exhaustion of a claim that the agency recertified a covered entity, because the audit and ADR processes described in the statute do not relate to HRSA's eligibility certification of covered entities.[289] The plaintiffs also asserted that the remedies they seek (i.e., recertification) are not available via the statutory ADR process.[290] They also urged that their claims were not moot, because the agency had not given the manufacturers any assurance that that it would stop certifying entities that did not engage in STD treatment and were therefore, in the manufacturers' view, diverting drugs.[291] The parties continue to disagree, the manufacturers insisted, on whether the Sagebrush sites were ineligible for 340B for "more fundamental reasons," including that they did not provide STD services, they diverted 340B drugs to nonpatients, and they did not receive state or local STD funding in accordance with the statute's eligibility requirements.[292]

On August 4, 2025, the D.C. Federal District Court denied HRSA's partial motion to dismiss, disagreeing with HRSA that the arguments were moot and that plaintiffs could not bring their counts without first exhausting administrative remedies.[293] With respect to HRSA's argument about the need to exhaust administrative remedies, the court found that neither jurisdictional nor prudential exhaustion requirements applied to the case, and thus exhaustion of administrative remedies was not required.[294] The court further pointed to several reasons why the plaintiffs' claims were not moot, including because the clinics that lost their 340B certification could reapply in the future, and because the plaintiffs were challenging HRSA's general certification criteria for 340B.[295] As of the time of this writing, the litigation is proceeding in D.C. District Court, with HRSA due to file an answer to the plaintiffs' complaint later in September 2025.[296]

Other 340B Enforcement Litigation

This section highlights other significant cases that have shaped the 340B program and HRSA's ability to enforce the statute in recent years. Taken together, the cases discussed in this section have all but eliminated covered entities' ability to enforce the 340B statute against drug manufacturers, as courts have continuously held that this enforcement element is an exclusive agency undertaking.[297]

---

[288] Memorandum of Points and Authorities in Support of Defendants' Partial Motion to Dismiss at 12, *Amgen*, No. 1:24-cv-03571. The agency requested that the court dismiss all of the manufacturers' claims except those connected to two particular sites. *Id.*

[289] Plaintiffs' Opposition to Defendants' Partial Motion to Dismiss at 12, *Amgen*, No. 1:24-cv-03571 (D.D.C. May 13, 2025), Dkt. No. 16.

[290] *Id.* at 16.

[291] *Id.* at 18.

[292] *Id.* at 19.

[293] Memorandum Opinion, Amgen, Inc. v. Kennedy, No. 24-3571 (D.D.C. Aug. 4, 2025), ECF No. 21, at 1.

[294] *Id.* at 5 (citing Avocados Plus Inc. v. Veneman, 370 F.3d 1243, 1247 (D.C. Cir. 2004)). The court explains, "Jurisdictional exhaustion must be met when a statute requires parties to exhaust administrative remedies before a court may hear their claim." *Id.* The court described prudential exhaustion as a "judicially created doctrine," in which "courts sometimes decline to hear unexhausted challenges" as a way of "giving agencies the first crack" at advancing particular policies. *Id.* at 7 (citing Marine Mammal Conservancy, Inc. v. Dep't of Agric., 134 F.3d 409, 414 (D.C. Cir. 1998)).

[295] *Id.* at 8.

[296] Order, Amgen, Inc. v. Kennedy, No. 24-3571 (D.D.C. Aug. 18, 2025).

[297] *See generally*, Astra USA, Inc. v. Santa Clara County, 563 U.S. 110 (2011); *see also* AIDS Healthcare Found. v. (continued...)

Private Enforcement of the 340B Statute

Congress can control the enforcement mechanisms of the laws which it creates, including by allowing private individuals the ability to sue to enforce their legal rights under federal statutes. Only if a federal law is enforceable via a private right of action may an individual, rather than the federal government, sue to enforce the law.[298] The Supreme Court has recognized that "[a]ny private right of action for violating a federal statute must ultimately rest on congressional intent to provide a private remedy, and the breadth of the right once recognized should not . . . grow beyond the scope congressionally intended."[299] A private right of action can be expressly stated in the law,[300] and courts have also recognized an implied private right of action from statutory text.[301]

In 2011, the Supreme Court decided *Astra USA, Inc. v. Santa Clara County*, finding that the 340B statute did not create a private right of action for covered entities to sue drug manufacturers to enforce the 340B price.[302] As a result, HRSA is the only entity that may enforce the 340B statute.

The U.S. Supreme Court's Decision in *Astra USA, Inc. v. Santa Clara County* Finding No Private Right of Action in the 340B Statute

Astra came to the Supreme Court on appeal from the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) after Santa Clara County, California, which operated several 340B covered entities, sued nine drug manufacturers, alleging that the manufacturers violated their PPAs with HRSA by overcharging for certain 340B drugs.[303] The question before the Court was whether the third-party covered entities, who directly benefited from the PPAs between HRSA and the drug manufacturers, could sue to enforce those contracts.[304] The covered entities argued that while there was no private right of action under the 340B statute, they should be able to sue to enforce the PPAs, because the contracts "specifically nam[e] covered entities as the recipients of discounted drugs."[305] The Court disagreed, instead characterizing the PPAs as "form agreements" that "simply incorporat[ed] statutory obligations and record[ed] the manufacturers' agreement to abide by them."[306]

The Court reasoned that because the PPAs were essentially just a formalized statement by the manufacturer that it would comply with the statutory requirements, a suit brought by an outside party to enforce the PPA "is in essence a suit to enforce the statute itself."[307] The Court said that

---

Apexus, LLC, No. 23-55425 (9th Cir. Aug. 21, 2024); *see also* United States *ex rel.* Adventist Health Sys. of W. v. AbbVie, 723 F. Supp. 3d 882 (C.D. Cal. Mar. 18, 2024).

[298] *See generally Astra*, 563 U.S. at 110.

[299] Va. Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1102 (1991); Medina v. Planned Parenthood, 145 S.Ct. 1422 (2025).

[300] For example, 42 U.S.C. § 1983 contains an express private right of action for individuals who are subjected to "the deprivation of any rights, privileges, or immunities secured by the Constitution and laws."

[301] The Supreme Court has recognized "an implied private right of action" under Title VI of the Civil Rights Act of 1964, giving individuals the right to bring suits alleging intentional discrimination. Cannon v. Univ. of Chicago, 441 U.S. 677, 709 n.42 (1979).

[302] 563 U.S. at 110.

[303] *Id.* at 116.

[304] *Id.* at 117–18.

[305] *Id.*

[306] *Id.* at 118.

[307] *Id.*

Congress's choice not to include a private right of action in the statute "would be rendered meaningless," if 340B covered entities could simply sue to enforce the pricing obligations in the PPA, as they had done in *Astra*.[308] The Court disagreed with the Ninth Circuit's analysis that allowing the covered entities to sue manufacturers for violating the PPA would be "wholly compatible" with the statutory objectives of providing discounts to safety net providers.[309] Instead, the Court found that, "[f]ar from assisting HHS, suits by 340B entities would *undermine* the agency's efforts to administer both Medicaid and §340B harmoniously and on a uniform, nationwide basis."[310] Private enforcement of the 340B statute could "spawn a multitude of dispersed and uncoordinated lawsuits," from which "conflicting adjudications" could result, creating further problems for HRSA.[311]

The Court also referenced the legislative history of the 340B statute, which, at the time the case was argued, had recently been amended by the Patient Protection and Affordable Care Act of 2010 (ACA).[312] Prior to the ACA's enactment, the HHS Office of the Inspector General reported that HRSA needed additional enforcement authority to ensure that 340B covered entities were receiving the correct 340B discount.[313] Congress responded to this report, the Court said, by creating a formal administrative dispute resolution (ADR) process to facilitate disputes between drug manufacturers and covered entities over incorrect 340B prices.[314] The Court thus concluded that Congress chose to "strengthen and formalize HRSA's enforcement authority" through the ACA's legislative changes, which was further evidence that Congress did not intent to "invit[e] 340B entities to launch lawsuits in district courts across the country."[315]

The Ninth Circuit's Decision in *AIDS Healthcare Foundation v. Apexus, LLC* Regarding Suits Brought Against the 340B Prime Vendor

In the nearly fifteen years since *Astra* was decided, its holding still stands to preclude certain 340B lawsuits. For example, in 2024, the Ninth Circuit applied the Supreme Court's reasoning in *Astra* to a similar case brought by AIDS Healthcare Foundation, a 340B covered entity, against Apexus, the 340B prime vendor.[316] The plaintiff alleged that Apexus failed to sufficiently negotiate 340B discounts, pursuant to its prime vendor contractual agreement with HRSA.[317] In the same way that the Supreme Court found that a covered entity could not sue to enforce a PPA, the Ninth Circuit found that even though the plaintiff benefited from the existence of the prime vendor contract, the covered entity was more appropriately classified as an "incidental beneficiary" to it and thus did not have "enforceable rights" under the agreement.[318]

---

[308] *Id.*

[309] *Id.* at 119 (quoting County of Santa Clara v. Astra USA, Inc., 588 F.3d 1237, 1251 (9th Cir. 2009)).

[310] *Id.* at 120 (emphasis added). The Court also observed that the interests of State Medicaid programs and the 340B program may conflict. *Id.* at 120 n.6. For example, a drug's 340B price and the Medicaid price are often related; the higher the Medicaid price, the higher the state's manufacturer reimbursement. However, a high Medicaid price means a higher 340B price and thus a lower amount of 340B savings. *Id.*

[311] *Id.* at 120.

[312] *Id.* at 121.

[313] *Id.*

[314] *Id.*

[315] *Id.*

[316] AIDS Healthcare Found. v. Apexus, LLC, No. 23-55425, 2024 WL 3886974 (9th Cir. Aug. 21, 2024).

[317] *Id.* at *1.

[318] *Id.* (quoting Smith v. Cent. Ariz. Water Conservation Dist., 418 F.3d 1028, 1037 (9th Cir. 2005)).

Quoting the Supreme Court's decision in *Astra*, the Ninth Circuit observed that the 340B statute "[n]ot only . . . lack[s] a private right of action, but it does not permit covered entities like AIDS Healthcare 'to sue for overcharges under the statute itself.'"[319] Moreover, Congress gave HHS the authority to enforce the provisions of the statute, and in so doing, it "assigned no auxiliary enforcement role to covered entities."[320] In conclusion, though, the court advised that "nothing . . . impedes HRSA from properly enforcing the Agreement's obligation."[321] In other words, HRSA retained the authority to challenge Apexus's performance of its prime vendor contract, but the contract could not be challenged by a covered entity.

The California Federal District Court's Decision in *United States ex rel. Adventist Health System/West v. AbbVie, Inc.* Regarding Alleged False Claims Act Violations

At least one federal district court has also interpreted the Supreme Court's ruling in *Astra* to prevent covered entities from bringing a False Claims Act suit against drug manufacturers for overcharging for 340B drugs. The California Federal District Court held in *United States ex. rel. Adventist Health System* that *Astra*'s holding precluded a suit brought by a covered entity under the False Claims Act (FCA)[322] against a drug manufacturer.[323] The covered entity argued that a drug manufacturer submitted false claims for reimbursement when it did not sell its drugs to certain entities at the 340B price.[324] The manufacturer moved to dismiss the suit, arguing that the *Astra* decision prohibited a covered entity from enforcing the 340B price through the FCA.[325] The court agreed with the drug manufacturer, finding that although there were "obvious difference[s]" between the FCA claims brought by the covered entity and third-party beneficiary contract claims at issue in *Astra*, the logic of *Astra* still applied.[326]

The court interpreted *Astra* to preclude third-party claims that are brought to essentially enforce the 340B price, reasoning that to allow a covered entity to enforce the 340B price via the FCA would render the statute's lack of a private right of action "meaningless."[327] The court also highlighted *Astra*'s reasoning that Congress did not contemplate "spreading the enforcement burden" in the 340B program to covered entities, because to do so would "undermine [HHS's] efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis."[328] The court observed, however, that its analysis "would be more complicated if the FCA claim were brought directly by a federal or state government, or if the claims involved fraud beyond noncompliance with statutory language, e.g., submission of falsely certified data," leaving

[319] *Id.* at *2 (quoting *Astra*, 536 U.S. at 113).

[320] *Id.* (quoting *Astra*, 536 U.S. at 117).

[321] *Id.*

[322] The FCA imposes civil liability on persons or entities who submit false claims for payment to the federal government. 31 U.S.C. §§ 3729–3733. The FCA is often used in the health care context to impose liability on health care providers for various types of billing misconduct when those providers submit claims for reimbursement to the federal government. Civil actions may be brought in federal court by a relator (i.e., a whistleblower), on behalf of both the relator and the U.S. government. For more information about how the False Claims Act is used in the prevention of health care fraud, see CRS Report RS22743, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, by Jennifer A. Staman (2016).

[323] United States *ex rel*. Adventist Health Sys. of W. v. AbbVie, 723 F. Supp. 3d 882 (C.D. Cal. Mar. 18, 2024).

[324] *Id.* at 884.

[325] *Id.* at 885.

[326] *Id.* at 886.

[327] *Id.* (quoting Astra USA, Inc. v. Santa Clara County, 563 U.S. 110, 118 (2011)).

[328] *Id.* at 887 (quoting *Astra*, 563 U.S. at 120).

open the possibility for the federal government to still use the FCA as a potential 340B fraud enforcement mechanism.[329] In other words, although the FCA does not provide a legal mechanism for private plaintiffs (e.g., covered entities) to enforce the 340B statute, it could potentially still be used by the government to enforce the 340B price or to hold a manufacturer liable for falsifying data used by the program.[330]

The covered entity appealed the district court's decision to the Ninth Circuit in April 2024.[331] In April 2025, the Ninth Circuit notified the parties that an oral argument would not be scheduled and that the court had taken the parties' arguments under advisement.[332] The court has not yet issued a decision on the appeal.

Considerations for Congress

This section offers insights for Congress in several parts. First, it explores connections between the web of 340B litigation discussed above, analyzing potential impacts to the program assuming that Congress takes no action to amend the 340B statute. The section highlights how the various court decisions fit together and how they could in some ways appear incongruous. Second, the report explores potential legislative changes that Congress could make to the 340B program if it sought to do so. Finally, the report concludes with other potential considerations for Congress, including developing legal issues.

Effect of Selected Court Rulings on 340B Program

Moving forward, litigation concerning the 340B program is likely to continue, particularly with respect to whether state laws regulating contract pharmacies and covered entities are preempted by the 340B statute. It is possible that more litigation could arise if HRSA continues to attempt to enforce its interpretation of the 340B statute both against drug manufacturers, as in the contract pharmacy litigation (e.g., *Novartis* and *Sanofi* cases),[333] and against covered entities with respect to its "patient" definition (e.g., *Genesis Healthcare* case).[334]

Taken together, the Supreme Court's holding in *Astra* and the rulings in *AIDS Healthcare Foundation* and *Adventist Health System* leave HRSA (or the federal government, more generally) as the sole entity that can enforce the 340B statute; the statute cannot be enforced by private parties, including covered entities.[335] HRSA's enforcement of the 340B statute, however, could be complicated by the Third Circuit's decision in *Sanofi* and the D.C. Circuit's decision in *Novartis*, both of which found that the agency could not enforce its interpretation of the statute

[329] *Id.* ("In sum, the Court finds that *Astra* bars FCA claims by a *qui tam* plaintiff where the allegation of falsity is that the defendants failed to comply with the statutory requirements of the 340B program.").

[330] *Id.*

[331] Notice of Appeal, United States *ex rel.* Adventist Health Sys. of W. v. AbbVie Inc., 723 F. Supp. 3d 882 (C.D. Cal. Mar. 18, 2024) (No. 2:21-cv-04249), Dkt. No. 153.

[332] Order, United States *ex rel.* Adventist Health Sys. of W. v. AbbVie, Inc., No. 24-2180 (9th Cir. Apr. 11, 2025), Dkt. No. 77.1.

[333] Sanofi-Aventis U.S. LLC v. HHS, 58 F.4th 696 (3d Cir. 2023). Novartis Pharms. Corp. v. Johnson, 102 F.4th 452 (D.C. Cir. 2024).

[334] Genesis Healthcare, Inc. v. Azar, No. 19-cv-1531, 2019 WL 6909572 (D.S.C. Dec. 19, 2019), *rev'd sub nom.*, Genesis Healthcare, Inc. v. Becerra, 39 F.4th 253 (4th Cir. 2022).

[335] *See generally* Astra USA, Inc. v. Santa Clara County, 563 U.S. 110 (2011); AIDS Healthcare Found. v. Apexus, LLC, No. 23-55425, 2024 WL 3886974 (9th Cir. Aug. 21, 2024).

against manufacturers to halt their contract pharmacy policies.[336] It is possible that drug manufacturers could construe these rulings as a justification for placing ever more creative restraints on covered entities' access to 340B prices. As long as the manufacturers are still "offering" to sell 340B drugs, there appears to be no conflict with the holdings in *Sanofi* and *Novartis*.[337] Manufacturers also need not be concerned with being sued directly by covered entities for not providing a 340B price, as *Astra* held that such suits are precluded because the 340B statute does not provide a private right of action.[338]

Courts have sided, however, with HRSA's interpretation of the statute in at least some instances; for example, the district court's recent ruling in *Johnson & Johnson*, upholding HRSA's authority to require manufacturers to receive approval for their rebate models, demonstrates that manufacturers do not have free reign to implement whatever rebate models they please and that their policies must still follow the clear requirements of the statute.[339] In the same way, the D.C. Circuit warned in *Novartis* that "more onerous" restrictions on contract pharmacy use from manufacturers could run afoul of the statute's directives.[340]

The various federal circuit court rulings related to HRSA's attempted enforcement of the 340B statute and the preemption of state 340B contract pharmacy laws in some ways leads to discordant results. The Third and D.C. Circuits have both held that the 340B statute does not preclude drug manufacturers from placing reasonable restrictions on their offers to sell drugs to covered entities.[341] Those court rulings were based both on the plain meaning of the 340B statute, (and specifically, the meaning of the word "offer"), as well as the 340B statute's silence as to the distribution of drugs and contract pharmacies.[342] Perhaps ironically, the Eighth Circuit concluded—for much the same reasons—that states could effectively stop manufacturers from imposing such restrictions on covered entities' contract pharmacy use through enactment of a state law.[343] In support of its conclusion that such state laws are not preempted by the 340B statute, the Eighth Circuit reasoned that the 340B statute is silent with respect to contract pharmacy use, and therefore Congress could not have intended for the 340B statute to "occupy the field" and preempt state law.[344] Effectively, however, the ruling from the Eighth Circuit could be read to give states some authority over the 340B program that HRSA itself does not have, at least according to the Third and D.C. Circuits.

Potentially further complicating matters is the fact that almost all of the federal courts (except for the West Virginia Federal District Court) have so far sided with states when they have tried to stop manufacturers from implementing policies that prevent covered entities in their state from doing business with contract pharmacies.[345] From the states' perspective, these laws protecting contract pharmacy use are essential to protecting covered entities' ability to generate 340B savings, and they allow in-state facilities to circumvent manufacturer-imposed restrictions on

---

[336] *See generally* Sanofi-Aventis U.S. LLC v. HHS, 58 F.4th 696 (3d Cir. 2023); Novartis Pharms. Corp. v. Johnson, 102 F.4th 452 (D.C. Cir. 2024).

[337] *Id.*

[338] Astra USA, Inc. v. Santa Clara County, 563 U.S. 110 (2011).

[339] *See* Memorandum Opinion, *Johnson & Johnson*, No. 1:24-cv-03188 (D.D.C. June 27, 2025), Dkt. No. 59.

[340] Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 464 (D.C. Cir. 2024).

[341] *See* Sanofi-Aventis U.S. LLC v. HHS, 58 F.4th 696 (3d Cir. 2023); *see also* Novartis Pharms. Corp. v. Johnson, 102 F.4th 452 (D.C. Cir. 2024).

[342] 58 F.4th at 703; 102 F.4th at 461.

[343] PhRMA v. McClain, 95 F.4th 1136, 1139 (8th Cir. 2024).

[344] *Id.* at 1143.

[345] *See, e.g.*, PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024).

contract pharmacy use. From the manufacturers' perspective, a manufacturer might be able to restrict covered entities' contract pharmacy use in one state but may not be able to impose the same restriction in another state.

The continued legal challenges to state contract pharmacy laws also have the potential to create conflicting court rulings; this is especially true in light of the West Virginia Federal District Court's preliminary findings in *PhRMA v. Morrisey* that the state law is preempted by the 340B statute.[346] While the *Morrisey* court was especially concerned with the state law's provision prohibiting manufacturers from requiring covered entities to submit claims data, which many other state laws do not contain, the court also based much of its preliminary analysis on the Supreme Court's ruling in *Astra*.[347] The court observed, "[I]f West Virginia attempted to enforce 340B through litigation, *Astra* would directly prevent such a suit as an improper method of 340B enforcement. Why, then, does it matter if the chosen improper enforcement is litigation or legislation?"[348] For the Supreme Court's decision in *Astra* to apply, though, a state's contract pharmacy law would have to be fairly characterized as an attempt to regulate the 340B price.[349] The West Virginia Federal District Court characterized the West Virginia contract pharmacy law as regulating the price of a drug, emphasizing that under the contract pharmacy replenishment model, "the question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug" *after* distributing the 340B drug.[350] The West Virginia law did not address drug distribution, the court said, because "the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy."[351] Thus, the court found, the West Virginia law actually regulated the price of the drug, which was precluded by *Astra*. The Eighth Circuit in *McClain* did not address the Supreme Court's decision in *Astra*, instead observing that the Arkansas contract pharmacy law "does not set or enforce [340B] pricing."[352]

Going forward, it is possible that other courts could similarly disagree over whether a state law is found to regulate the distribution or the price of drugs, especially if it generally concerns the contracts formed between covered entities and retail pharmacies. If other courts were to find *Morrisey*'s analysis persuasive and characterize state contract pharmacy laws as pricing regulations prohibited by *Astra*, this could lead to an eventual circuit split over issues of preemption, which could create additional confusion. It is therefore likely that how states fashion their contract pharmacy laws in the future will play a role in whether courts find that they are preempted by 340B.

Potential Legislative Changes

If Congress seeks to alter the requirements of the 340B program by amending the statute, doing so could potentially address some of the programmatic enforcement issues at the center of the recent litigation. For example, Congress could amend the 340B statute to clarify the role that contract pharmacies should play in the program and whether manufacturers may restrict contract pharmacy use, and it could specify how many contract pharmacies a covered entity may use, if

[346] *See generally* PhRMA v. Morrisey, 760 F.Supp.3d 439 (S.D. W. Va. Dec. 17, 2024).

[347] *Id.*

[348] *Id.* at 457 (citing *Astra USA*, 563 U.S. at 110).

[349] *See, e.g.*, *id.* at 456.

[350] 760 F. Supp. 3d at 455.

[351] *Id.*

[352] PhRMA v. McClain, 95 F.4th 1136, 1145 (8th Cir. 2024). The Eighth Circuit did not address the effect, if any, of the replenishment model on the Arkansas contract pharmacy law's characterization as regulating the distribution, rather than the price, of 340B drugs.

any. Another option is for Congress to give the HHS Secretary clear rulemaking authority to make decisions about contract pharmacy use, although such a move could still prompt litigation from drug manufacturers, who could sue to challenge any rule promulgated by the Secretary under any applicable provisions of the APA.

Alternatively, or in addition to these changes, Congress could also give HRSA more direct authority to enforce the 340B program's prohibitions on duplicate discounting and diversion, including by statutorily specifying a definition of a "patient" or by giving HRSA rulemaking authority in statute to define the term "patient" via a legally binding regulation. Additionally, if Congress wished to remove discretion from the Secretary regarding approval of rebates for 340B drugs, Congress could further specify the conditions under which the Secretary must approve a rebate, or it could remove the Secretary's discretion to approve rebates altogether and amend the statute to specifically permit rebating as a way of achieving the 340B price.

Congress could also appropriate additional funding for HRSA to administer the 340B program, which would enable the agency to expend money toward, for example, audits of both manufacturer and covered entity compliance with the program. Congress could also order HRSA to collaborate with CMS to curb the practice of duplicate discounting and drug diversion, and it could appropriate funding for both HHS and the Department of Justice to carry out increased enforcement in these areas.

In terms of the potential collaboration between HRSA and CMS, it remains unclear what effect, if any, the proposed reorganization of HHS will have on the administrative side of the 340B program. In March 2025, the HHS Secretary announced an effort to reorganize the Department, including by consolidating HRSA into the Administration for a Healthy America (AHA) and by transferring the Office of Pharmacy Affairs, which administers the 340B program, to CMS.[353] The HHS Fiscal Year 2026 (FY 2026) Budget in Brief states that transferring the 340B program to CMS will "streamline[] processes and the ability to utilize in-house drug-pricing resources and expertise."[354] The FY 2026 Budget in Brief otherwise recommends that the 340B program receive flat funding, and it does not provide additional information about CMS's newfound oversight of 340B.[355] HHS did not provide any information about the Office of Pharmacy Affairs or the administration of the 340B program in its FY 2026 Congressional Justification.[356]

Although HHS did not include further information about the 340B program or the Office of Pharmacy Affairs in its FY 2026 Congressional Justification, in the Fiscal Year 2025 Congressional Justification, HRSA requested authority to require covered entities to report annually their 340B savings, including a statement of how those savings were used to benefit the covered entity's community.[357] HRSA also requested "explicit regulatory authority to define necessary terms" in the statute and proposed to "strengthen compliance and transparency" related

[353] Press Release, HHS, HHS Announces Transformation to Make America Healthy Again (Mar. 27, 2025), https://www.hhs.gov/press-room/hhs-restructuring-doge.html [https://perma.cc/AY9Y-MPYH]; HHS, FISCAL YEAR 2026: BUDGET IN BRIEF 27 (2025) [hereinafter FY26 HHS BUDGET], https://www.hhs.gov/sites/default/files/fy-2026-budget-in-brief.pdf [https://perma.cc/56NR-GLNF].

[354] FY26 HHS BUDGET, *supra* note 353, at 27.

[355] *Id.*

[356] *See generally*, HHS, FY 2026 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES: ADMINISTRATION FOR A HEALTHY AMERICA (2025), https://www.hhs.gov/sites/default/files/fy-2026-aha-cj.pdf [https://perma.cc/MV83-UVH4].

[357] HHS, FISCAL YEAR 2025 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES: HEALTH RESOURCES AND SERVICES ADMINISTRATION 363 (2024), https://www.hrsa.gov/about/budget [https://perma.cc/3CMM-9CZR].

to contract pharmacy use.[358] Congress could effectuate these changes to the program by amending the statute.

Other 340B Activities to Watch

Against the backdrop of 340B litigation, there are other areas of the 340B program to watch, as they could lead to additional legal challenges. For example, in an Executive Order signed April 15, 2025, President Trump ordered the Secretary of HHS to "take action to ensure that future grants available under section 330(e) of the [PHSA (i.e., the Health Center Program)] . . . are conditioned upon health centers establishing practices to make insulin and injectable epinephrine available" to patients at or below the 340B ceiling price.[359] In June 2025, HRSA announced, consistent with this order, a new policy for FQHCs to pass on the 340B price of insulin and epinephrine to their patients.[360] This policy effectively halts the ability of FQHCs to generate 340B savings on those drugs.[361] Because the statute does not require 340B covered entities to use their 340B savings in any particular manner, it is possible that covered entities that have lost revenue as a result of the policy may seek to challenge the agency's authority to place such a requirement on section 330 funds. Moreover, the announcement does not explain why HHS is making this requirement only for FQHCs, rather than for all 340B covered entities, or how FQHCs should identify patients who are eligible for the discounted drugs.[362]

As general debates about drug prices continue in the 119th Congress, some lawmakers and stakeholders have questioned why the 340B program does not directly benefit low-income patients in the form of reduced drug prices.[363] On the other hand, other stakeholders argue that many 340B covered entities offer lower drug prices to their patients.[364] If Congress seeks to direct the 340B program to benefit patients directly in the form of lowered drug prices, it could amend the statute to make a direct patient benefit a requirement for either some or all covered entities. Congress could also enhance reporting requirements on covered entities by requiring them to demonstrate to the HHS Secretary how they use their 340B savings to benefit the patients they serve. Alternatively, Congress could also refrain from further action.

---

[358] *Id.*

[359] Exec. Order 14,273, 90 Fed. Reg. 16441 (Apr. 15, 2025).

[360] Press Release, HHS, HRSA Announces Action to Lower Out-of-Pocket Costs for Life-Saving Medications at Health Centers Nationwide (June 24, 2025) [hereinafter June 2025 HRSA Press Release], https://www.hrsa.gov/about/news/affordable-medications [https://perma.cc/3HKU-WQLP].

[361] The previous Trump administration issued a rule on December 23, 2020, that became effective January 22, 2021, to condition receipt of new health center awards on a health center agreeing to offer insulin and injectable epinephrine at or below the 340B price. Implementation of Executive Order on Access to Affordable Life-Saving Medications, 85 Fed. Reg. 83822 (Dec. 23, 2020) (codified at 42 C.F.R. § 51). The Biden Administration proposed to rescind the Trump Administration rule in June 2021, citing "undue administrative costs and burdens that implementation would impose on health centers." Proposed Rescission of Executive Order 13937, 86 Fed. Reg. 32008 (June 16, 2021). The Biden Administration also advised it was rescinding the rule due to the additional burden on health centers to identify which of their patients were eligible to receive the discounted insulin and epinephrine, which would be particularly burdensome in light of the COVID-19 pandemic. *Id.*

[362] *See* June 2025 HRSA Press Release, *supra* note 360.

[363] *See, e.g.*, MAJ. STAFF OF S. COMM. ON HEALTH, EDUC., LAB. & PENSIONS, 119TH CONG., CONGRESS MUST ACT TO BRING NEEDED REFORMS TO THE 340B DRUG PRICING PROGRAM 12 (2025), https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf1.pdf [https://perma.cc/9AW6-U25P] (investigative report finding that certain covered entities did not pass 340B discounts directly to their patients).

[364] *See, e.g.*, *340B Benefits Patients and Communities: Examples from the Frontlines*, AM. HOSP. ASS'N, https://www.aha.org/case-studies/2025-03-11-340b-benefits-patients-and-communities-examples-frontlines [https://perma.cc/2S6A-3FVH] (last visited July 29, 2025).

Appendix.

Table A-1. Acronyms

Acronym	Description
ACA	Patient Protection and Affordable Care Act
ADAP	AIDS Drug Assistance Program
ADR	Administrative dispute resolution
AHA	Administration for a Healthy America
AIDS	Acquired immunodeficiency syndrome
APA	Administrative Procedure Act
CMS	Centers for Medicare and Medicaid Services
DSH	Disproportionate Share Hospital
FCA	False Claims Act
FDCA	Federal Food, Drug, and Cosmetic Act
FLSA	Fair Labor Standards Act
FQHC	Federally Qualified Health Center
GPO	Group purchasing organization
HHS	U.S. Department of Health and Human Services
HIV	Human immunodeficiency virus
HRSA	Health Resources and Services Administration
OPA	Office of Pharmacy Affairs
OPAIS	Office of Pharmacy Affairs Information System
PhRMA	Pharmaceutical Research and Manufacturers of America
PHSA	Public Health Service Act
PPA	Purchase price agreement
REMS	Risk evaluation and mitigation strategies
SSA	Social Security Act
STD	Sexually transmitted disease

Author Information

Hannah-Alise Rogers
Legislative Attorney

Disclaimer