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SUMMARY

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As federal lawmakers engage in efforts to target high prescription drug prices, states have also taken actions intended to reduce drug prices and make drugs more affordable for consumers. States have enacted a variety of legislative measures, including some that restrict drug manufacturers from pricing their drugs at certain levels, and others that regulate the business practices of pharmacy benefit managers (PBMs), pharmacies, and other participants in the pharmaceutical supply chain. In some instances, pharmaceutical manufacturers and other stakeholders have sued to challenge various state drug pricing laws, and in general, plaintiffs in these cases claim that such laws violate certain constitutional provisions and doctrines that restrict state authority and sovereignty. This report reviews selected state efforts to enact prescription drug pricing legislation and analyzes related legal challenges.

To combat excessive or so-called "unconscionable" prescription drug prices, some states have enacted laws prohibiting drug manufacturers from increasing their prices beyond certain levels. Drug manufacturers and pharmaceutical trade associations have challenged at least three state "price-gouging" laws on the basis that they are unconstitutionally vague and invalid under the Dormant Commerce Clause. In one case, an appeals court held that a Maryland state law was unconstitutional under the extraterritoriality principle of the Dormant Commerce Clause, because the state law regulated wholly out-of-state transactions. *See* Association for Accessible Medicines (AAM) v. Frosh, 887 F.3d 664 (4th Cir. 2018). By comparison, in a different lawsuit, an Illinois district court has denied a motion to preliminarily enjoin an Illinois price-gouging law, finding that the plaintiff was not likely to succeed on the merits of its case because the state law did not violate the extraterritoriality principle of the Dormant Commerce Clause. *See* AAM v. Raoul, 805 F. Supp. 3d 854 (N.D. Ill. 2025).

Prescription Drug Affordability Boards (PDABs) are independent, state-level boards that review prescription drug costs. Some states have authorized their PDABs to take additional actions to lower the prices of certain drugs. A drug manufacturer filed lawsuits to challenge the actions of Colorado's PDAB, and these cases have involved the Board's decisions to set a payment limit on the manufacturer's products. *See, e,g.,* Amgen Inc. v. Mizner, No. 24-CV-00810, 2025 WL 947474 (D. Colo. Mar. 28, 2025). The manufacturer has claimed, in part, that the state PDAB law runs afoul of the Fourteenth Amendment's Due Process Clause, because the law interferes with the company's patents, and the law violates the Dormant Commerce Clause, because it generally controlled commerce occurring outside state boundaries.

Congress created the 340B Drug Discount Program to enable certain health care providers to purchase outpatient prescription drugs at lower costs. As part of the program, manufacturers sign a contract under which they are required to "offer" to sell certain drugs at a "ceiling price" to certain covered entities. Covered entities may make 340B drugs available to patients through the use of "contract pharmacies." Several states have enacted legislation to limit drug manufacturers from restricting contract pharmacy use by covered entities in their state, and these state laws have spurred several lawsuits. Drug manufacturers and trade industry groups have challenged the laws, arguing they are preempted by the 340B statute and violate the Dormant Commerce Clause. At least three federal appeals courts have held that the state 340B laws are not preempted by the 340B statute because they regulate in-state pharmacies and drug distribution inside the state, but one federal circuit court disagreed. *See, e.g.*, PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024) (holding state law was not preempted); PhRMA v. McCuskey, 171 F.4th 675, *reh'g en banc granted*, 176 F.4th 830 (4th Cir. 2026) (holding state law was preempted).

PBMs are entities that play many roles in the drug distribution chain. As states have enacted measures to regulate PBMs, PBMs and other parties have challenged the validity of such measures, commonly on the basis that they are preempted by the Employee Retirement Income Security Act (ERISA), a federal law that regulates private-sector, employment-based health plans. Plaintiffs allege that ERISA preempts the state PBM laws because such laws have a direct regulatory effect on ERISA-governed plans, plan design, and how plans manage drug benefits. In *Rutledge v. Pharmaceutical Care Management Ass'n* (PCMA), 592 U.S. 80 (2020), the Supreme Court addressed the interplay between state PBM laws and ERISA preemption and held that ERISA did not preempt an Arkansas statute that regulated PBM pharmacy reimbursement practices. Following *Rutledge*, lower courts have examined ERISA preemption challenges to a variety of state PBM laws, with mixed results.

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Introduction

At the federal level, the 119th Congress has engaged in efforts to lower prescription drug prices and make drugs more affordable for patients and providers.[1] At the same time, the executive branch has taken various actions to attempt to lower drug prices, including by advocating for Congress to codify most-favored-nation pricing, launching its own platform to facilitate direct-to-consumer sales, and creating new demonstration programs to test new drug payment models for Medicare and Medicaid.[2]

Against this backdrop, states have also engaged in efforts to reduce drug prices via various legislative mechanisms. States have taken a variety of approaches, ranging from directly regulating the price that manufacturers may charge for particular drugs, to regulating the business practices of pharmacy benefit managers (PBMs), pharmacies, and other participants in drug supply and payment chains. As discussed in this report, some of these state efforts have been challenged by pharmaceutical companies and other industry stakeholders, and the outcomes in these cases have been mixed. Some of these legal challenges have presented constitutional questions related to state authority to enact laws that directly affect drug prices, while other lawsuits involve complex questions about the interaction between state and federal law.

This report reviews recent selected examples of state efforts to enact prescription drug pricing legislation and analyzes related legal challenges. The report first introduces the constitutional provisions, including Supreme Court precedent, that are relevant to the challenges against the state laws, in order of prevalence in the discussed cases. The report provides legal background on the doctrines of federal preemption, the Dormant Commerce Clause, the Fifth Amendment Takings Clause, the Fourteenth Amendment Due Process Clause, and the Contracts Clause. The report then reviews lawsuits brought against various state efforts to regulate drug prices, including through price-gouging laws, laws establishing Prescription Drug Affordability Boards (PDABs), laws attempting to protect pharmacies and covered entities in the 340B Drug Discount Program, and laws that attempt to influence the business practices of PBMs. Each section of the report concludes with selected legal considerations for Congress in light of the ongoing legal challenges and outstanding constitutional questions.

[1] *Making Medicines More Affordable: How Competition Can Lower Drug Prices: Hearing Before the S. Comm. On Health, Ed., Lab. & Pensions*, 119th Cong. (2026); *Lowering Health Care Costs for All Americans: An Examination of the Prescription Drug Supply Chain: Hearing Before the H. Subcomm. on Health*, 119th Cong. (2026); *Medicines and IP: Balancing Innovation and Access: Hearing Before the H. Subcomm. on Cts., Intell. Prop., A.I. and the Internet*, 119th Cong. (2026); *see also* Consolidated Appropriations Act, 2026, Pub. L. No. 119-75, §§ 6701–6702, 140 Stat. 173, 703–37 (amending Medicare Part D statute to add additional oversight to certain pharmacy benefit managers (PBM) services).

[2] Exec. Order No. 14297, 90 Fed. Reg. 20749 (May 12, 2025); CRS In Focus IF13281, *TrumpRx: Background and Implementation*, by Laura A. Wreschnig and Michele L. Malloy (2026); *see also Fact Sheet, President Donald J. Trump Launches TrumpRx.gov to Bring Lower Drug Prices to American Patients*, WHITE HOUSE (Feb. 5, 2026), https://www.whitehouse.gov/fact-sheets/2026/02/fact-sheet-president-donald-j-trump-launches-trumprx-gov-to-bring-lower-drug-prices-to-american-patients/ [https://perma.cc/F3RK-ZFQ3] (explaining TrumpRx); *GENEROUS (GENErating Cost Reductions for U.S. Medicaid) Model*, CTR. FOR MEDICARE & MEDICAID SERVS. (June 12, 2026), https://www.cms.gov/priorities/innovation/innovation-models/generous [https://perma.cc/5QJ7-QGX6] (explaining new Medicaid Model to implement most-favored-nation pricing).

Legal Bases for Challenges to State Drug Pricing Laws

In the United States, both the federal government and states regulate entities involved in the U.S. pharmaceutical supply chain. Relying on their traditional powers to regulate for the health, safety, and welfare of residents, states have enacted laws that aim to protect residents from high drug prices.[3] The federal government also shares certain concurrent authority over the pharmaceutical supply chain emanating from its enumerated powers in the Constitution, and these provisions may limit a state's ability to enact legislation to impact drug prices. The range of lawsuits filed in recent years over state attempts to regulate drug prices reflects this overlapping authority. This section provides background on the relevant federal case law interpreting constitutional provisions and federal statutes, which are presented in their order of prevalence in the cases discussed herein.

Federal Preemption of State Law

The preemption doctrine derives from the Supremacy Clause of the Constitution, which establishes that the laws of the United States "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[4] In general terms, federal preemption occurs when a validly enacted federal law supersedes a conflicting state law.[5] As a result, when federal and state laws are in conflict, the state law is generally supplanted, leaving it void and without effect.[6] The preemption doctrine is a key element of the United States' system of federalism, and it has been recognized as the "most common constitutional ground upon which state laws are judicially invalidated."[7] In analyzing the preemptive effect of federal law, the Supreme Court has indicated that "pre-emption claims turn on Congress's intent," and Congress may express such intent through explicit preemption language, as well as through a statute's structure and purpose.[8]

There are two general categories of preemption: express preemption and implied preemption. With respect to the first category, a federal statute may displace existing state law through direct

[3] *See, e.g.*, MD. CODE ANN., HEALTH–GEN. § 2-803(d) (West 2017) (Maryland statute prohibiting price-gouging of certain generic drugs); LA. REV. STAT. ANN. § 40:2884 (2023) (Louisiana law prohibiting drug manufacturers from denying, restricting, or otherwise interfering with "acquisition . . . or delivery of a 340B drug" to a contract pharmacy).

[4] *See* U.S. CONST. art. VI, cl. 2. For a general discussion of the Supremacy Clause and federal preemption, see Libr. of Cong., *Overview of Supremacy Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artVI-C2-1/ALDE_00013395/ (last visited June 25, 2026).

[5] *See generally* Murphy v. Nat'l Collegiate Athletics Ass'n (NCAA), 584 U.S. 453, 479 (2018) ("[P]reemption . . . concerns a clash between a constitutional exercise of Congress's legislative power and conflicting state law.") (citing Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372, n.6 (2000)). For more information on federal preemption, see CRS Report R45825, *Federal Preemption: A Legal Primer*, by Bryan L. Adkins, Alexander H. Pepper, and Jay B. Sykes (2023).

[6] *See* Maryland v. Louisiana, 451 U.S. 725, 746 (1981) (Under the Supremacy Clause, state laws that conflict with federal law are "without effect."); Wickard v. Filburn, 317 U.S. 111, 124 (1942) ("[N]o form of state activity can constitutionally thwart the regulatory power granted by the commerce clause to Congress."); *see also* Mut. Pharm. Co., Inc. v. Bartlett, 570 U.S. 472, 480 (2013) ("Under the Supremacy Clause, from which our pre-emption doctrine is derived, any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." (quoting Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 108 (1992))).

[7] *See* GREGORY E. MAGGS & PETER J. SMITH, CONSTITUTIONAL LAW: A CONTEMPORARY APPROACH 286 (4th ed. 2018).

[8] *See, e.g.*, N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995) (holding that state law imposing surcharges on certain employer sponsored health care plans was preempted by Employee Retirement Income Security Act (ERISA)).

language in a congressional enactment, often called an express preemption clause.[9] In those instances, determining the scope of the preemption clause is generally a matter of statutory interpretation.[10] For the second category, implied preemption, congressional intent to preempt state law may be inferred, including in cases in which there is a conflict between federal and state law. Such implied conflict preemption may occur if it is "impossible for a private party to comply with both state and federal requirements,"[11] or if implementation of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[12] In addition, state action is preempted in instances in which Congress has evidenced its intent to occupy a given field.[13] Field preemption of state law "occurs when a federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'"[14]

Historically, the Supreme Court has "addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law."[15] This canon of construction, referred to as the "presumption against preemption," generally instructs that courts should not read federal law to preempt state law, particularly in cases involving states' historic police powers,[16] "unless that was the clear and manifest purpose of Congress."[17] Judicial decisions in the

[9] *See* Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 203 (1983) ("It is well-established that within Constitutional limits Congress may preempt state authority by so stating in express terms." (citing Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977))); *see also* Nat'l Meat Ass'n. v. Harris, 565 U.S. 452 (2012) (unanimously holding that the Federal Meat Inspection Act expressly preempted the challenged state law).

[10] *See, e.g.,* Chamber of Com. v. Whiting, 563 U.S. 582, 594 (2011) ("When a federal law contains an express preemption clause, we 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent.'" (quoting to CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993))).

[11] English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990); *see also Mut. Pharm. Co.*, 570 U.S. at 480 (holding that federal drug labeling requirements preempted a state law tort claim against a drug manufacturer, as it was impossible for the manufacturer to comply with both a state-law duty to enhance the warnings on a particular drug label and also a federal-law duty not to alter the label).

[12] Hines v. Davidowitz, 312 U.S. 52, 67 (1941); *see also* Geier v. Amer. Honda Motor Co., Inc., 529 U.S. 861, 881–86 (2000) (state tort lawsuit that depended on claim that manufacturers had a duty to install an airbag was preempted by federal regulation on motor vehicle safety standard because suit would stand as an obstacle to the accomplishment of the objectives of that standard, which was to seek a gradually developing mix of alternative passive restraint devices for safety-related reasons).

[13] *See, e.g., Pac. Gas & Elec. Co.*, 461 U.S. at 212–13 (holding that California law regarding the construction of nuclear powerplants was not preempted by federal law).

[14] Murphy v. NCAA, 584 U.S. 453, 479 (2018) (quoting R.J. Reynolds Tobacco Co. v. Durham County, 479 U.S. 130, 140 (1986)); *see also* Pennsylvania v. Nelson, 350 U.S. 497, 502, 504 (1956) (citing one test of preemption of state power as "(t)he scheme of federal regulation (is) so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it" and holding that Congress intended to occupy the field of sedition laws. (alteration in original) (quoting Rice v. Santa Fe Corp., 331 U.S. 218, 230 (1947)).

[15] N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654 (1995) ("Indeed, in cases like this one, where federal law is said to bar state action in fields of traditional state regulation, we have worked on the 'assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" (citations omitted) (quoting *Rice*, 331 U.S. at 230))); *see also* CTS Corp. v. Waldburger, 573 U.S. 1 (2014) ("It follows that 'when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption."'" (quoting Altria Grp., Inc. v. Good, 55 U.S. 70, 77 (2008))).

[16] The term *police power* has been used to refer to the states' general power of governing, such as regulating to promote public health, safety, and welfare. *See, e.g.,* Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 536 (2012) ("Our cases refer to this general power of governing, possessed by the States but not by the Federal Government, as the 'police power.'").

[17] *Rice*, 331 U.S. at 230 (1947); *see also, e.g.*, Wyeth v. Levine, 555 U.S. 555, 565 (2009) ("[I]n all pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act (continued...)

past decade have cast doubt on whether the presumption against preemption applies in all cases. For example, in the context of implied preemption, in a 2026 decision, three Justices of the Supreme Court reaffirmed that the presumption against preemption applies in areas that "[s]tates have traditionally occupied,"[18] while in other cases, the Court has resolved implied preemption questions without referencing the canon.[19] In 2016, the Court suggested in a majority opinion that the presumption may not apply in express preemption cases,[20] and lower courts have reached varying conclusions about the application of this decision.[21]

Dormant Commerce Clause

The Commerce Clause of the Constitution provides that "[t]he Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[22] Although a literal reading of the Commerce Clause grants Congress the authority to regulate interstate, foreign, and Tribal commerce, the Supreme Court has long interpreted the Clause to also have a negative or "dormant" aspect that restrains the states' power to regulate interstate commerce (even in the absence of preempting congressional legislation).[23]

The Supreme Court first articulated the doctrine that would become known as the Dormant Commerce Clause in 1824, when the Court struck down a state-created monopoly on the basis that it was preempted by an existing federal law.[24] In the decision, the Court acknowledged that the Constitution granted Congress the exclusive power to regulate interstate commerce, but explained that such power would have to be balanced with the state's authority to regulate matters that could influence commerce.[25] In early Dormant Commerce Clause cases, the Court also provided an additional justification for the doctrine, namely that states should not be able to enact laws that would constrain the national government and economy as a whole.[26]

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unless that was the clear and manifest purpose of Congress.'" (alterations in original) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996))).

[18] *See* Hencely v. Fluor Corp., 146 S. Ct. 1086, 1102 (2026) (Alito, Roberts, and Kavanaugh, JJ., dissenting) (quoting *Wyeth*, 555 U.S. at 565).

[19] *See, e.g.*, Hughes v. Talen Energy Mktg., LLC, 578 U.S. 150 (2016) (holding state public service commission's order providing subsidies to new electric generators was preempted by the Federal Power Act).

[20] Puerto Rico v. Franklin Cal. Tax-Free Tr., 579 U.S. 115 (2016) ("[B]ecause the statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" (quoting Chamber of Com. of United States v. Whiting, 563 U.S. 582, 594 (2011))).

[21] *Compare, e.g.*, Triumph Foods, LLC v. Campbell, 156 F.4th 29, 50 (1st Cir. 2025) ("When a federal statute has an express preemption clause, 'we do not invoke any presumption against [preemption].'" (alteration in original) (quoting Nw. Selecta, Inc. v. González-Beiró, 145 F.4th 9, 15 (1st Cir. 2025))), *with* Lupian v. Joseph Cory Holdings LLC, 905 F.3d 127, 131 n.5 (3d Cir. 2018) ("[W]e have determined that, because [*Franklin California*] . . . did not address claims involving areas historically regulated by states, we would continue to apply the presumption against preemption to express preemption claims.").

[22] U.S. CONST. art. I, § 8, cl. 3.

[23] Libr. of Cong., *Overview of Dormant Commerce Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-7-1/ALDE_00013307/ (last visited June 25, 2026).

[24] Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824).

[25] *Id.* at 209. For more information about early Dormant Commerce Clause jurisprudence, see Libr. of Cong., *Early Dormant Commerce Clause Jurisprudence*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-7-3/ALDE_00013309/ (last visited June 25, 2026).

[26] *E.g.*, Minnesota Rate Cases, 230 U.S. 352, 400 (1913) (noting that "states are not permitted directly to regulate or restrain that which, from its nature, should be under the control of the one authority, and be free from restriction, save as it is governed in the manner that the national legislature constitutionally ordains.").

The Court has since articulated two overarching principles that govern its Dormant Commerce Clause jurisprudence. First, the Court has held that state laws which discriminate against out-of-state actors are *per se* invalid under the Dormant Commerce Clause, unless the state can show that its law is narrowly tailored and advances a legitimate local purpose.[27] Second, with respect to state laws that do not facially discriminate against out-of-state actors (i.e., laws that are applied "evenhandedly" both in- and out-of-state), the Court will uphold the law "unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."[28]

In addition to these two principles, some courts and legal scholars have pointed to a third tenet of Dormant Commerce Clause jurisprudence known as "the extraterritoriality principle,"[29] although other courts and scholars have argued that the extraterritoriality principle is not or should not be a stand-alone doctrine.[30] The extraterritoriality doctrine—drawn from Supreme Court cases including *Baldwin v. G.A.F. Seelig, Inc.*, *Brown-Foreman Distillers Corp. v. New York State Liquor Authority*, and *Healy v. Beer Institute*[31]—provides that states may not directly regulate wholly out-of-state transactions. These cases generally concern state laws that attempted to regulate extraterritorial, or wholly out-of-state, transactions, and which the Supreme Court declared invalid under the Dormant Commerce Clause.[32]

For example, in *Healy*, the State of Connecticut enacted a "contemporaneous" statute that required out-of-state shippers to affirm that the prices for their beer shipments to Connecticut wholesalers were not higher than the prices charged to states that border Connecticut.[33] The Court's majority concluded that the state law violated the Dormant Commerce Clause, reasoning that the statute undeniably attempted to control "commercial activity occurring wholly outside the boundary of the State," and whose practical effect "is to create just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude."[34]

The *Healy* majority also distilled the Court's previous Dormant Commerce Clause cases into three principles to describe the extraterritoriality doctrine. First, the Court found that the Dormant Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the state."[35] The Court noted specifically that the extraterritoriality doctrine did not allow the state to legislate

[27] South Dakota v. Wayfair, 585 U.S. 162, 173 (2018). The Court has also found that economic protectionism is not a legitimate state purpose and will effectively result in an automatic ruling against the discriminating state. *See* Nat'l Pork Producers Council (*Pork Producers*) v. Ross, 598 U.S. 356, 369 (2023) (collecting cases).

[28] Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (citing Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 443 (1960)).

[29] *See, e.g.*, Ass'n of Accessible Meds. (AAM) v. Frosh, 887 F.3d 664 (4th Cir. 2018) (holding state law prohibiting generic drug price gouging violated extraterritoriality principle of the Dormant Commerce Clause); *but see also* Energy & Env't Legal Inst. v. Epel, 793 F.3d 1169, 1172 (10th Cir. 2015) (describing the extraterritoriality principle as "the least understood of the Court's three strands of dormant commerce clause jurisprudence.").

[30] *See, e.g.*, Dawinder Sidhu, *Interstate Commerce x Due Process*, 106 IOWA L. REV. 1801 (2021) (arguing Dormant Commerce Clause jurisprudence should be understood within a due process framework); *see also* AAM v. Raoul, 805 F. Supp. 3d 854, 860 (N.D. Ill. 2025), *appeal docketed*, No. 25-2960 (7th Cir. Oct. 31, 2025) (finding that the Supreme Court's decision in *Pork Producers* "cast[s] doubt" on the extraterritoriality doctrine elaborated earlier in *Baldwin* and *Healy*).

[31] Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935); Brown-Foreman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573 (1986); Healy v. Beer Inst., 491 U.S. 324 (1989).

[32] *Baldwin*, 294 U.S. at 511; *Brown-Foreman Distillers Corp*., 476 U.S. at 573; *Healy*, 491 U.S. at 324.

[33] *Healy*, 491 U.S. at 326.

[34] *Id.* at 337.

[35] *Id.* at 336 (quoting Edgar v. MITE Corp., 457 U.S. 624, 642–43 (1982) (plurality opinion)).

the "scale of prices" that are used by other states.[36] Second, the *Healy* Court cited the *Brown-Foreman* decision to support the assertion that statutes directly controlling wholly out-of-state transactions are invalid, even if the extraterritorial effects were unintended.[37] Third, the Court said that the "practical effect" of the state law in question must be evaluated on both the consequences of the statute itself as well as the potential implications if other states adopted similar legislation.[38] Taken together, the Court said, the Connecticut statute regulating beer prices based on prices charged out-of-state could not stand.[39]

Over the years following the 1989 *Healy* decision, the Court has applied a more limited version of the extraterritoriality principle. For example, in 2003, the Court held in *Pharmaceutical Research and Manufacturers of America (PhRMA) v. Walsh* that a Maine statute requiring the state to attempt to negotiate additional Medicaid rebates from drug manufacturers did not violate the Dormant Commerce Clause.[40] One of PhRMA's arguments against the Maine law was that it violated the extraterritoriality principle, citing *Baldwin* and *Healy*.[41] The *Walsh* majority distinguished *Baldwin* and *Healy* on the basis that Maine's statute did not require the manufacturers to sell their drugs to a wholesaler at any particular price, and it did not tie the price of a drug sold in Maine to a product sold out-of-state.[42] The Court also held that Maine's prescription drug program would not "impose a disparate burden on any competitors."[43] In the aftermath of *Walsh*, some federal appellate courts interpreted the decision as having "cast[] doubt on the continued viability of the broad extraterritoriality principle."[44]

The Supreme Court most recently discussed the extraterritoriality doctrine in the 2023 case *National Pork Producers Council v. Ross*, wherein a majority of the Court appeared to further limit the scope of the extraterritoriality principle.[45] The plaintiffs in *Pork Producers* challenged a California law requiring humane production conditions for pork sold inside of the state, arguing that there was an "almost *per se* rule" against state laws that "have the 'practical effect of controlling commerce outside the State', even when those laws do not purposely discriminate against out-of-state economic interests."[46] The Court disagreed with the plaintiffs'

[36] *Id.* (quoting *Baldwin*, 294 U.S. at 528).

[37] *Id.* (citing *Brown-Foreman Distillers Corp*., 476 U.S. at 573).

[38] *Id.*

[39] *Id.* at 337.

[40] PhRMA v. Walsh, 538 U.S. 644 (2003) (plurality opinion). Seven justices signed on to Parts I, II, III, and VI of the opinion. *Id.* at 648. With respect to the remainder of the opinion, only a plurality of justices signed Parts IV, V, and VII. *Id.*

[41] *Id.* at 669 (citing *Baldwin*, 294 U.S. at 521; *Healy*, 491 U.S. at 324).

[42] *Id.*

[43] *Id.* at 670.

[44] Ward v. United Airlines, Inc., 986 F.3d 1234, 1240 (9th Cir. 2021). The court explained in *Ward*, "We have read the Court's decision in *Pharmaceutical Research* as holding that the extraterritoriality principle derived from the *Healy* line of cases now applies only when state statutes have the practical effect of dictating the price of goods sold out-of-state or tying the price of in-state products to out-of-state prices." *Id.*; *accord* Energy and Env't Legal Inst. v. Epel, 793 F.3d 1169, 1174–75 (10th Cir. 2015); *see also* Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris, 729 F.3d 937, 951 (9th Cir. 2013) (distinguishing *Baldwin* and *Healy* because state law banning foie gras sales from force fed geese did not mandate a price for any particular product and did not tie the in-state price to an out-of-state price).

[45] Nat'l Pork Producers Council v. Ross, 598 U.S. 356 (2023). The Court further noted that almost all of the pork consumed in the State of California is imported from other states. *Id.* For more information about the Court's ruling in *Pork Producers*, see CRS Legal Sidebar LSB11031, *Supreme Court Narrows Dormant Commerce Clause and Upholds State Animal Welfare Law*, by Kate R. Bowers (2023).

[46] *Pork Producers,* 598 U.S. at 371 (quoting Brief for Petitioners at 19, *Pork Producers*, 598 U.S. 356 (2023) (No. 21-468)). In support of this argument, the petitioners cited the Court's rulings in *Healy*, *Baldwin*, and *Brown-Foreman*. *Id.*
(continued...)

characterization of an "almost *per se* rule," distinguishing its rulings in *Baldwin*, *Brown-Foreman*, and *Healy* on the basis that the state laws at issue in those cases "'plainly discriminated' against out-of-staters," and "amounted to 'simple economic protectionism.'"[47] Here, the plaintiffs conceded that the California law was not discriminatory.[48] The Court did not elaborate further on the parameters of the extraterritoriality principle, and divergent interpretations of the Court's ruling in *Pork Producers* have emerged.[49]

The Fifth Amendment's Takings Clause

The Takings Clause of the Fifth Amendment provides that "private property" shall not "be taken for public use, without just compensation."[50] The Supreme Court has clarified that the Takings Clause "does not prohibit the taking of private property, but instead places a condition on the exercise of that power" by requiring the government to fairly compensate someone whose property rights are taken.[51] To prove a taking has occurred, a party must demonstrate that the claimed property at issue is protected by the Takings Clause, and that it was "taken" by the government.[52] To show that the taking was unconstitutional, the party must prove either that (1) the taking was not for public use, or (2) that the party has not received just compensation.[53]

The Takings Clause applies only to "private property" interests protected under the Fifth Amendment.[54] Relevant to this report, personal property (such as a drug) is protected,[55] but whether patents related to a drug are property protected by the Takings Clause is a much-debated issue.[56] Assuming that the property at issue is constitutionally protected, a court would next

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On the matter of these three prior rulings, the majority remarked, "A close look at those cases, however, reveals nothing like the rule petitioners posit. Instead, each typifies the familiar concern with preventing purposeful discrimination against out-of-state economic interests." *Id.*

The California law at issue in *Pork Producers* specifically barred the sale of pork from animals that are confined not in accordance with California state standards. *Id.* at 363.

[47] *Id.* at 371–72 (first quoting Dean Milk Co. v. Madison, 340 U.S. 349, 354 (1951); and then quoting Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 580 (1986)).

[48] *Id*. at 370–71 ("petitioners *disavow* any discrimination-based claim," writing that "'the dormant Commerce Clause ... bar on protectionist state statutes that discriminate against interstate commerce ... is not in issue here.'") (quoting Brief for Petitioners at 2 n.2, *Pork Producers*, *supra* note 27).

[49] *Compare* AAM v. Ellison, 140 F.4th 957, 960 (8th Cir. 2025) (distinguishing *Pork Producers* and enjoining the state law on the basis that it had a "specific impermissible extraterritorial effect" of controlling prices outside of the state), *with* AAM v. Raoul, 805 F. Supp. 3d 854, 860–61 (N.D. Ill. 2025) (concluding that *Pork Producers* "does not squarely address whether the dormant Commerce Clause itself prohibits a state from regulating out-of-state transactions based on their downstream consequences"), *appeal docketed*, No. 25-2960 (7th Cir. Oct. 31, 2025).

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

[51] Lingle v. Chevron U.S.A. Inc., 544 U.S. 528, 536 (2005) (quoting First Eng. Evangelical Lutheran Church of Glendale v. County of Los Angeles, 482 U.S. 304, 314 (1987)); For more information about the Takings Clause, see Libr. of Cong., *Public Use and Takings Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/amdt5-9-2/ALDE_00013281/ (last visited June 25, 2026).

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

[53] Kelo v. New London, 545 U.S. 469, 483 (2005) ("For more than a century, our public use jurisprudence has wisely eschewed rigid formulas and intrusive scrutiny in favor of affording legislatures broad latitude in determining what public needs justify the use of the takings power."), *superseded by statute*, Property Rights Protection Act, 26 PA. CONS. STAT. §§ 201–208 (2026), *as stated in* Wolfe v. Reading Blue Mountain, 320 A.3d 1164 (Pa. Aug. 20, 2024).

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

[55] *See* Horne v. Dep't of Agric., 576 U.S. 350 (2015).

[56] In *Horne*, the Court reiterated its previous observation that "[[a] patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just (continued...)

analyze whether it has been "taken" under two doctrinal frameworks: per se takings or regulatory takings.

Historically, the Court has recognized certain physical invasions of property under a per se rule: an appropriation of property, even if minor, is a taking that requires compensation.[57] For example, in *Loretto v. Teleprompter Manhattan CATV Corp.*, the Court held that a law requiring landlords to permit cable companies to install equipment on the exterior of their buildings constituted a per se taking, because the law authorized a permanent, if only minimal, physical occupation of the property.[58] Other instances in which the Court has recognized a per se taking are when the government took title to a share of a farm's agricultural crop,[59] or when an owner was deprived of all of his property's economic use or value.[60]

When the per se framework does not apply, the Court has still recognized a "regulatory taking" when a government action significantly affects property rights, holding that if the regulation "goes too far[,] it will be recognized as a taking."[61] The Court has avoided a "set formula" to determine where regulation ends and a taking begins,[62] instead noting that regulatory takings cases require "essentially ad hoc, factual inquiries."[63] In *Penn Central Transportation Co. v. City of New York*, the Court established some general principles for determining whether a government regulation amounts to a taking. The Court considered factors including (1) "the economic impact of the regulation"; (2) whether the regulation interfered with "distinct investment-backed expectations"; and (3) the character of the government's action.[64]

The Court applied the *Penn Central* framework in *Ruckelshaus v. Monsanto*, which concerned public disclosure of trade secrets that were submitted by a pesticide manufacturer to the Environmental Protection Agency (EPA).[65] The Court acknowledged that the manufacturer held a property interest in the data containing trade secrets, but it held that the EPA regulation requiring disclosure did not constitute a taking when a manufacturer did not have a "reasonable investment-

compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser." *Id*. at 359–60 (first alteration in original) (quoting James v. Campbell, 104 U.S. 356, 358 (1882)). Some legal scholars have argued, however, that patents should not be considered "private property" for purposes of the Fifth Amendment. *See, e.g.*, Robin Feldman, *Patents as Property for the Takings*, 12 N.Y.U.J. INTELL. PROP. & ENT. L. 198 (2023) (arguing that patents should not fall within the purview of the Fifth Amendment's Compensation Clause).

[57] *See, e.g.* Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 434–35 (1982) ("In short, when the 'character of the governmental action' is a permanent physical occupation of property, our cases uniformly have found a taking to the extent of the occupation, without regard to whether the action achieves an important public benefit or has only minimal economic impact on the owner." (citation omitted) (quoting Penn Cent. Transp. v. City of New York, 438 U.S. 104, 124 (1978))).

[58] *Id.*

[59] Horne v. Dep't of Agric., 576 U.S. 351, 361 (2015).

[60] *See* Agins v. City of Tiburon, 477 U.S. 255, 260 (1980); Lucas v. S.C. Coastal Council, 505 U.S. 1003 (1992).

[61] Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922). For more information on regulatory takings, see Libr. of Cong., *Early Jurisprudence on Regulatory Takings*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/amdt5-9-5/ALDE_00013284/ (last visited June 25, 2026).

[62] *Penn Cent. Transp. Co.*, 438 U.S. at 124.

[63] *Id.*

[64] *Id.* at 124. For more information about the *Penn Central* analysis and how it is used to evaluate regulatory takings, *see* Libr. of Cong., *Regulatory Takings and Penn Central Framework*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/amdt5-9-6/ALDE_00013285/#ALDF_00022171 (last visited June 25, 2026). Regarding the third factor, the Court explained that "a 'taking' may more readily be found when the interference with property can be characterized as a physical invasion by a government, than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good. *Id.* (citation omitted).

[65] Ruckelshaus v. Monsanto Co., 467 U.S. 986, 990 (1983).

backed expectation" that the data would remain confidential.[66] The Court reasoned that manufacturers voluntarily participated in a regulatory scheme that required their products to be registered with the federal government in order to be sold on the U.S. market.[67] The Court also found that the disclosure requirement was rationally related to the legitimate government interest of ensuring safety in the sales and use of pesticides.[68] For these reasons, the Court held that the manufacturer did not have a "reasonable investment-backed expectation" in some of the data it submitted, and thus that no taking of that data occurred.[69]

The Due Process Clause of the Fourteenth Amendment

The Due Process Clause of the Fourteenth Amendment provides that a state may not "deprive any person of life, liberty, or property, without due process of law."[70] The concept of due process prevents states from making laws that unfairly deprive citizens of their right to life, liberty, or property, and individuals may challenge state laws that curtail such rights.[71] For example, a drug company that claims to be harmed by a state or federal law related to the drug's price might argue that the state has not provided adequate procedures or process such that a deprivation of the company's property could constitutionally occur.[72] In the civil context, the Supreme Court has set forth a three-factor balancing test to evaluate whether specific procedures satisfy the Due Process Clause.[73] The first factor looks at the private interest affected by the government's proposed action; the second weighs the likelihood that a deprivation of life, liberty, or property will occur if the government's procedure is used and the probable value of additional procedural safeguards.[74] The third factor evaluates the government's interest, including any fiscal or administrative burden in providing additional procedural safeguards.[75] Courts have used these factors in a wide range of civil cases to balance the interests of the government against those of individuals.[76]

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[66] *Id.* at 1005.

[67] *Id.* The Court observed, "[A]s long as [the manufacturer] is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a [product] registration can hardly be called a taking." *Id.* at 1007.

[68] *Id.* at 1005.

[69] *Id.* at 1006. The Court also held that when the company had a reasonable expectation that EPA would protect the trade secret data it submitted, the government's unauthorized disclosure of that data constituted a regulatory taking when just compensation was not provided. *Id.* at 1011.

[70] U.S. CONST. amend. IVX.

[71] Fuentes v. Shevin, 407 U.S. 67, 81 (1972). The Supreme Court has interpreted the Due Process Clause as protecting both procedural and substantive rights. Given the subject matter of this report and the challenges that pharmaceutical companies and industry groups have brought against state laws regulating drug prices, only procedural due process is discussed. For more information about the Due Process Clause generally, see Libr. of Cong., *Due Process Generally*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/amdt14-S1-3/ALDE_00013743/ (last visited June 25, 2026).

[72] *See, e.g.*, Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs., 150 F.4th 76 (2d Cir. 2025) (drug manufacturer argued that selection of its drug for price negotiation in the Medicare Drug Price Negotiation Program violated its right to procedural due process, among other claims); Complaint, Amgen Inc. v. Mizner, No. 25-3452 (D. Colo. Oct. 30, 2025), Dkt. No. 1 (drug manufacturer claimed that a state law setting an upper price limit on the sale of its drug violated its right to procedural due process).

[73] Matthews v. Eldridge, 424 U.S. 319, 335 (1976).

[74] *Id.*

[75] *Id.*

[76] *See, e.g.*, Cleveland Bd. of Educ. v. Loudermill, 470 U.S. 532 (1985) (regarding the termination of a government employee); Brock v. Roadway Express, Inc., 481 U.S. 252 (1987) (plurality opinion) (regarding government regulation (continued...)

As part of Due Process Clause jurisprudence, the Supreme Court has recognized that a statute may be so vague that it deprives a person of due process, a concept known as the *void-for-vagueness* doctrine.[77] To avoid being void-for-vagueness, a reasonable person must be able to understand what kind of conduct a statute prohibits. Although the doctrine is most often discussed in the criminal law context, it can arise in civil cases as well.[78] The Supreme Court has held that a civil statute violates the Due Process Clause when it is "so vague and indefinite as really to be no rule or standard at all."[79] On the other hand, "a non-criminal statute is not unconstitutionally vague 'if persons of reasonable intelligence can derive a core meaning from [the] statute.'"[80] The burden for demonstrating vagueness is high, and the Supreme Court has noted that a statute in question must "strip a participant of his rights to come within the principle of the [case law]."[81]

Contract Clause

The Contract Clause, found in Article I of the Constitution, provides that "No state shall . . . pass any . . . Law impairing the Obligation of Contracts."[82] The Supreme Court has interpreted this clause to limit a state's power to enact legislation that (1) breaches or modifies an existing state contract; or (2) impermissibly regulates a private contract.[83] The general purpose of the Contract Clause is to "encourage trade and credit by promoting confidence in the stability of contractual obligations,"[84] which is balanced with the state's power to "safeguard the vital interests of its people."[85] Much of the Court's Contract Clause jurisprudence considers how best to balance the state versus federal interests at issue in the regulation of contracts.[86]

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of private employment); City of Los Angeles v. David, 538 U.S. 715 (2003) (regarding waiting period before a hearing).

[77] For more information on the void-for-vagueness doctrine, see Libr. of Cong., *Void for Vagueness*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/amdt14-S1-7-3/ALDE_00000261/ (last visited June 25, 2026).

[78] *See, e.g.*, Gentile v. State Bar of Nev., 501 U.S. 1030 (1991) (holding that a state supreme court rule prohibiting an attorney from making certain statements to the media was void for vagueness); Keyishian v. Bd. of Regents, 385 U.S. 589, 603–04 (1967) (holding state statute requiring state employees to certify that they were not communists implicated employees' First Amendment rights and was void for vagueness). Although, as one court put it, "The void-for-vagueness doctrine operates in much reduced force outside of its core area of application, criminal law." Griffin v. Bryant, 30 F. Supp. 3d 1139, 1170 (D.N.M. 2014).

[79] Boutilier v. Immigr. & Naturalization Servs., 387 U.S. 118, 123 (1967) (quoting A.B. Small Co. v. Am. Sugar Refin. Co., 267 U.S. 233, 239 (1925)).

[80] Cotton States Mut. Ins. Co. v. Anderson, 749 F.2d 663, 669 n.9 (11th Cir. 1984) (alteration in original) (quoting High Ol' Times, Inc. v. Busbee, 673 F.2d 1225, 1228 (11th Cir. 1982)).

[81] *Boutilier*, 387 U.S. at 123.

[82] U.S. CONST. art. I, § 10, cl. 1. For a more detailed overview of the Contract Clause, see Libr. of Cong., *Overview of Contract Clause*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S10-C1-6-1/ALDE_00013037/ (last visited June 25, 2026).

[83] U.S. Tr. Co. v. New Jersey, 431 U.S. 1, 19–20 (1977). While the federal government must abide by the constitutional requirements of due process, the Supreme Court has made clear that the Contract Clause does not apply to the federal government. Union Pac. R.R. Co. v. United States (Sinking-Fund Cases), 99 U.S. 700, 718–19 (1878).

[84] *U.S. Tr. Co.*, 431 U.S. at 15 (citing Home Bldg. & Loan Ass'n v. Blaisdell, 290 U.S. 398, 427–28 (1934)).

[85] *Blaisdell*, 290 U.S. at 434; *see also* El Paso v. Simmons, 379 U.S. 497, 509 (1965) (holding state statute regarding forfeiture of lands did not violate the Contract Clause).

[86] *See, e.g.*, *Blaisdell*, 290 U.S. at 436 ("The states retain adequate power to protect the public health against the maintenance of nuisances despite insistence upon existing contracts"); *see also* Allied Structural Steel Co. v. Spannaus, 438 U.S. 234, 242–45 (1978) (holding that the Contract Clause imposes limits on a state's ability to alter its contractual obligations even when the state would otherwise be validly exercising its police power).

To evaluate whether a state law is invalid under the Contract Clause, the Court will first determine whether the statute impairs a contractual obligation of the state.[87] If a contractual obligation is impaired, the Court will next decide whether the Contract Clause prohibits the impairment.[88] The Court has recognized that states "must possess broad power to adopt general regulatory measures without being concerned that private contracts will be impaired, or even destroyed, as a result."[89] The Court has simultaneously acknowledged, however, that a state's police power and public interest in legislating "is not always sufficient" to overcome the Contract Clause's limitation.[90]

The Court has considered several factors to determine whether a state statute violates the Contract Clause. For example, in *Allied Structural Steel Co. v. Spannaus*, the Court struck down a Minnesota law requiring employers with more than 100 workers to retroactively make contributions to employees' pension plans under certain circumstances.[91] In finding that the law substantially impaired the contractual relationship between the employer and its employees, the Court observed that in contributing to the fund, the company relied on the fact that its employees could not have a vested interest in the plan unless they met the company's terms.[92] Additionally, the Court characterized the effect of the law on the employer as "severe" because it retroactively modified the amount of money that the company agreed to pay employees over a period of more than ten years.[93] Moreover, the Court found that the state failed to show "that this severe disruption of contractual expectations was necessary to meet an important general social problem."[94] For these reasons, the Court held that the state law violated the Contract Clause.

Varied State Actions Addressing Drug Prices

The U.S. pharmaceutical supply chain involves many players, including drug manufacturers, wholesalers, pharmacies, health plans, and consumers, and the prices consumers pay for drugs are often influenced by the complex relationships among these entities.[95] This section reviews selected mechanisms enacted by state legislatures to control drug prices and explores the legal challenges to those mechanisms filed by various industry stakeholders. The section first addresses state initiatives that have targeted drug prices directly, including price-gouging statutes and PDABs. The outcomes of litigation related to the constitutionality of price-gouging statutes, which were first enacted in 2017, may have consequences for more recent cases addressing whether state PDABs may set price limits on "unaffordable" drugs. Other state initiatives have attempted to regulate the complex arrangements between the entities that make up the drug

[87] *U.S. Tr. Co*., 431 U.S. at 17. The Court has observed that generally, "a statute is itself treated as a contract when the language and circumstances evince a legislative intent to create private rights of a contractual nature enforceable against the State." *Id.* at 17 n.14 (comparing Dodge v. Bd. of Educ., 302 U.S. 74, 78–79 (1937), with Indiana *ex rel*. Anderson v. Brand, 303 U.S. 95, 104–05 (1938)).

[88] *U.S. Tr. Co*., 431 U.S. at 21. The Court has observed, "[t]he severity of the impairment measures the height of the hurdle the state legislation must clear." *Spannaus*, 438 U.S. at 245.

[89] *U.S. Tr. Co*., 431 U.S. at 22.

[90] *Id.* at 21.

[91] *Spannaus*, 438 U.S. at 238.

[92] *Id.* at 245–46.

[93] *Id.* at 246.

[94] *Id.* at 247.

[95] *See* CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*, by Laura A. Wreschnig et al. (2021).

supply chain, including 340B covered entities and PBMs. The outcomes of these cases raise questions about the extent to which states may regulate alongside concurrent federal laws.

State Laws Banning Price Gouging

To combat what they view as excessive prescription drug prices, some states have enacted laws banning drug manufacturers from increasing their prices beyond certain levels, often over a set period of time. According to data from the National Academy of State Health Policy, between 2018 and 2025, at least twenty-one states considered some type of legislative ban on price gouging for prescription drugs.[96] These state proposals varied in scope and regulatory mechanism, and not all succeeded in becoming law; for example, in 2019, New Jersey considered but did not enact legislation that would have banned drug manufacturers from charging excessive prices for drugs developed with public funding.[97] That same year, New York considered a bill that would have made it unlawful for a drug manufacturer or wholesaler to sell any pharmaceutical at an "unconscionably excessive price," which was to be determined by a court.[98]

Some of the state legislation aimed at stopping price gouging was enacted. For example, the Illinois legislature first considered a bill to ban manufacturer price gouging of generic drugs and biosimilars in 2018,[99] and a similar measure was eventually enacted in 2024.[100] After their enactments, at least three state price-gouging laws were challenged by drug manufacturers and pharmaceutical trade associations on the basis that they are unconstitutionally vague and are invalid under the Dormant Commerce Clause.[101]

This section explores three court opinions in three different cases challenging state prescription drug price-gouging statutes, focusing on legal questions surrounding the boundaries of the Dormant Commerce Clause and the application of the extraterritoriality principle. All three lawsuits were brought by the Association for Accessible Medicines (AAM), a trade industry group that represents drug manufacturers that produce generics and biosimilars.

The Fourth Circuit Invalidates Maryland Law

In 2017, the State of Maryland enacted one of the first state drug price-gouging laws, which prohibited drug manufacturers and wholesalers from "price gouging in the sale of an essential off-patent or generic drug."[102] A drug would become subject to the law if it was made available for

[96] This number is based on CRS's analysis of National Academy of State Health Policy data on State Legislation to Lower Prescription Drug Costs in the years 2018 through 2025. *See 2026 State Legislation to Lower Prescription Drug Costs*, NAT'L ACAD. OF STATE HEALTH POL'Y (July 17, 2026), https://nashp.org/state-tracker/2026-state-legislation-to-lower-prescription-drug-costs/ [https://perma.cc/T796-NJBE].

[97] A.B. 5950, 218th Gen. Assemb., 2d Annual Sess. (N.J. 2019); A.B. 1590, 218th Gen. Assemb., 1st Annual Sess. (N.J. 2019); A.B. 3987, 218th Gen. Assemb., 1st Annual Sess. (N.J. 2019).

[98] S.B. 141, 2019–2020 Senate, Reg. Sess. (N.Y. 2019).

[99] H.B. 4900, 100th Gen. Assemb., Reg. Sess. (Ill. 2018).

[100] H.B. 3957, 103d Gen. Assemb., Reg. Sess. (Ill. 2024); 2023 Ill. Laws 367.

[101] *See, e.g.*, AAM v. Frosh, 887 F.3d 664 (4th Cir. 2018) (challenging Maryland price-gouging statute); AAM v. Ellison, 140 F.4th 957, 960 (8th Cir. 2025) (challenging Minnesota price-gouging statute); AAM v. Raoul, 805 F. Supp. 3d 854, 860–61 (N.D. Ill. 2025) (challenging Illinois price-gouging statute), *appeal docketed*, No. 25-2960 (7th Cir. Oct. 31, 2025).

[102] *Frosh*, 887 F.3d at 666 (quoting MD. CODE ANN., HEALTH–GEN. § 2-802(a) (West 2017)). The law was passed over the Maryland Governor's veto. *Id.* The law defined *price gouging* as "an unconscionable increase in the price of a prescription drug," and *unconscionable increase* was further defined as an increase to the price of a drug that is not justified on the basis of production costs and results in a consumer lacking a meaningful choice about whether or not to purchase the drug at such an excessive price. *Id.* (quoting MD. CODE ANN., HEALTH−GEN. § 2-801(c) (West 2017)).

sale in Maryland, and the law could be enforced by the Maryland Attorney General via a civil fine or legal action to enjoin the drug's sale.[103] AAM challenged this law in *AAM v. Frosh*, arguing, in part, that it violated the Dormant Commerce Clause.[104] The thrust of AAM's argument in *Frosh* was that the state law violated the extraterritoriality principle, because the law effectively regulated drug sales outside of Maryland and concerned drugs that never entered the state.[105]

After a Maryland District Court partially granted the state's motion to dismiss, AAM appealed the decision to the U.S. Court of Appeals for the Fourth Circuit (Fourth Circuit).[106] A divided three-judge panel of the Fourth Circuit held that the state law was unconstitutional under the extraterritoriality principle of the Dormant Commerce Clause because it regulated wholly out-of-state transactions.[107] The Fourth Circuit expressed that the Supreme Court's Dormant Commerce Clause jurisprudence was driven by two main concerns: "economic protectionism" and the prevention of state regulations that are "designed to benefit in-state economic interests by burdening out-of-state competitors."[108] Citing the Supreme Court's decisions in *Healy*, *Brown-Foreman*, and the plurality in *Edgar*, the majority explained that the extraterritoriality principle was "derived from the notion that 'a State may not regulate commerce occurring wholly outside of its borders.'"[109]

Although the state argued that the price-gouging law applied only to transactions that occurred in Maryland, the Fourth Circuit majority determined that the plain language of the law allowed Maryland "to enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland," and that the "upstream" sales that the act was intended to regulate would take place outside of Maryland.[110] Moreover, the majority found that the "unconscionable" price that the statute prohibited was not about the price that a consumer would pay but instead was based on the drug's wholesale acquisition cost.[111] Therefore, the majority said, the law "seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland."[112] The majority characterized the law as "effectively a price control statute," rather than an "upstream pricing impact," because it "attempts to dictate the price" that a manufacturer might charge outside the state.[113]

The Fourth Circuit majority distinguished the Supreme Court's decision in *Walsh*, where the Court found that a Maine law that allowed the state to negotiate additional rebates for Medicaid drugs from drug manufacturers or subject their sales to a prior authorization procedure did not

[103] *Id.* (citing MD. CODE ANN., HEALTH−GEN. § 2-803(d) (West 2017)).

[104] *Id.* at 667.

[105] *Id.* at 670.

[106] *Id.* at 667. The district court granted the state's motion to dismiss the Dormant Commerce Clause challenge, but it denied the part of the state's motion directed to AAM's claim that the law was unconstitutionally vague, finding AAM's argument "at least plausible." AAM v. Frosh, No. 17-CV-01860, 2017 WL 4347818 (D. Md. Sep. 29, 2017), *rev'd,* 887 F.3d 664 (4th Cir. 2018).

[107] *Frosh,* 887 F.3d at 674–75.

[108] *Id.* at 667 (quoting Brown v. Hovatter, 561 F.3d 357, 363 (4th Cir. 2009)).

[109] *Id.* (quoting Star Sci., Inc. v. Beales, 278 F.3d 339, 355 (4th Cir. 2002)); *see* Healy v. Beer Inst., 491 U.S. 324, 335–36 (1989); Brown-Foreman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573 (1986); Edgar v. MITE Corp., 457 U.S. 624, 642–43 (1982) (plurality opinion).

[110] *Frosh,* 887 F.3d at 671.

[111] *Id.*

[112] *Id.* at 672.

[113] *Id.*

violate the Dormant Commerce Clause.[114] The Fourth Circuit reasoned that the logic of *Walsh* did not apply because Maryland's law effectively sought to control the price at which a manufacturer sold a drug to a wholesaler, whereas *Walsh* concerned the state's ability to negotiate Medicaid rebates.[115] The Fourth Circuit majority also noted that the Maryland law could frustrate interstate prescription drug sales, because if other states imposed price-gouging statutes, then Maryland's pricing might be different than that of another state, which could preclude a drug manufacturer from simultaneous compliance with both states' laws.[116]

One judge dissented, arguing that the Maryland price-gouging law did not violate the Dormant Commerce Clause and was well within the state's general police powers.[117] The dissent agreed with the state's argument that the law did not have an extraterritorial effect, because it would not reach "any stream of commerce *that does not end in Maryland*."[118] The dissent also argued that "'modern' dormant Commerce Clause jurisprudence 'is driven by concern about economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.'"[119] The dissent contended that the Supreme Court's extraterritoriality jurisprudence, as well as Fourth Circuit case law, "do not support equating a single transaction with commerce," the latter a more expansive concept under the Supreme Court's case law.[120] As a result, the dissent would have concluded that Maryland's price-gouging statute did not regulate "commerce," as the term is used by the Supreme Court, because the law applied "only to upstream sales in streams of transactions that end in Maryland."[121]

The Eighth Circuit Invalidates the Minnesota Law

Five years after the Fourth Circuit decided *Frosh*, the State of Minnesota enacted a prescription drug price-gouging statute in 2023 that aimed to prohibit manufacturers of generic drugs from causing "excessive price increase[s]."[122] That same year, the Supreme Court elaborated on the limitations imposed by the Dormant Commerce Clause in *Pork Producers*.[123] As discussed above,

[114] PhRMA v. Walsh, 538 U.S. 644 (2003). The Court concluded that "unlike [the] price control or price affirmation statutes [at issue in *Baldwin*, *Healy*, and *Brown-Foreman*], 'the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect.'" *Id.* at 669 (quoting PhRMA v. Concannon, 249 F.3d 66, 81–82 (1st Cir. 2001)). The Court noted that the state was "not tying the price of its in-state products to out-of-state prices." *Id.* (quoting *Concannon*, 249 F.3d at 81–82). The Court also found that the Maine law did not run afoul of the Dormant Commerce Clause because it did not "insist that manufacturers sell their drugs to a wholesaler for a certain price." *Id.* (quoting *Concannon*, 249 F.3d at 81–82).

[115] *Id.* at 672.

[116] *Id.* at 673.

[117] *Frosh,* 887 F.3d at 675 (Wynn, J., dissenting).

[118] *Id.* at 677 (Wynn, J., dissenting) (quoting Memorandum in Support of Defendants Motion to Dismiss at 23, AAM v. Frosh, No. 17-CV-01860 (D. Md. Aug. 14, 2017), Dkt. No. 29-1).

[119] *Id.* at 680 (Wynn, J., dissenting) (quoting Dep't of Rev. of Ky. v. Davis, 553 U.S. 328, 3337–38 (2008)).

[120] *Id.* at 681–82 (Wynn, J., dissenting). Judge Wynn quoted Justice Marshall's definition of *commerce* as more than just a "single exchange of goods," but rather a description of "the commercial intercourse between nations, and parts of nations." *Id.* at 682 (Wynn, J., dissenting) (quoting Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 189–90 (1824)).

[121] *Id.* at 683 (Wynn, J., dissenting). Moreover, the dissent distinguished Maryland's price-gouging statute from the state laws at issue in *Baldwin*, *Healy*, and *Brown-Foreman* on the basis that Maryland's law is nondiscriminatory, regulates "upstream transaction[s]", and was not regulating "'wholly' out-of-state 'commerce.'" *Id.* at 684 (Wynn, J., dissenting) (citing Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935); Healy v. Beer Inst., 491 U.S. 324 (1989); Brown-Foreman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573 (1986)).

[122] AAM v. Ellison, 140 F.4th 957, 959 (8th Cir. 2025) (quoting MINN. STAT. § 62J.842, subdiv. 1 (2026)). Under the act, an "excessive price increase" was defined, in part, as one that exceeded a certain percentage of the wholesale acquisition cost (WAC). MINN. STAT. § 62J.842, subdiv. 2.

[123] 598 U.S. 356 (2023).

the case concerned a California law that banned the in-state sale of pork if the animals were "confined in a cruel manner."[124] In upholding the California statute, the Supreme Court rejected the plaintiffs' argument that state laws having the "practical effect of controlling commerce outside the state" were "almost *per se*" invalid, even when they did not discriminate against out-of-state interests.[125]

As was the case with the Maryland price-gouging statute, AAM challenged the Minnesota law as invalid under the Dormant Commerce Clause and requested that the district court issue a preliminary injunction to stop the law from going into effect.[126] The district court granted the motion, finding that the statute likely ran afoul of the Dormant Commerce Clause, and the decision was appealed to the U.S. Court of Appeals for the Eighth Circuit (Eighth Circuit).[127]

In its decision upholding the preliminary injunction, the Eighth Circuit discussed the Supreme Court's then-recent ruling in *Pork Producers*, concluding that it did not save Minnesota's price-gouging statute.[128] The Eighth Circuit characterized the California law at issue in *Pork Producers* as having "a *specific* impermissible 'extraterritorial effect.'"[129] The Eighth Circuit found that Minnesota's price-gouging law was more like the laws at issue in *Baldwin*, *Brown-Foreman*, and *Healy*, because it prevented out-of-state manufacturers from "whatever competitive advantages they may possess," and had the "impermissible extraterritorial effect of controlling prices outside of Minnesota."[130]

The Eighth Circuit also cited its agreement with the Fourth Circuit that Minnesota's law—like the Maryland law at issue in *Frosh*—violated the Dormant Commerce Clause because it attempted to control prices outside the state.[131] Relying on similar reasoning as *Frosh*, the Eighth Circuit concluded that the Minnesota law is best characterized as a price control statute that effectively regulates an out-of-state transaction and therefore has a "specific impermissible extraterritorial effect."[132] The Eighth Circuit also agreed that the Minnesota law was distinguishable from the Maine law at issue in *Walsh*, because Minnesota was "regulat[ing] the price of out-of-state transactions, insist[ing] that out-of-state manufacturers sell their drugs to wholesalers for a certain price, and t[ying] the price of in-state products—prescription drugs—to the price that out-of-state manufacturers charge their wholesalers."[133] The Eighth Circuit denied Minnesota's motion for a rehearing en banc.[134]

[124] *See* discussion *supra* "Dormant Commerce Clause."

[125] *Pork Producers*, 598 U.S. at 371 (quoting Brief for Petitioners, *supra* note 46, at 2 n.2).

[126] *Ellison*, 140 F.4th at 958–59.

[127] AAM v. Ellison, 704 F. Supp. 3d 947 (D. Minn. Dec. 4, 2023), *aff'd*, 140 F.4th 957 (8th Cir. 2025). The case was later dismissed after the parties filed a stipulation agreeing that the state law violated the Dormant Commerce Clause. Stipulation, AAM v. Ellison, No. 23-CV-02024 (D. Minn. Nov. 20, 2025), Dkt. No. 61.

[128] *Ellison*, 140 F.4th at 960 (citing *Pork Producers*, 598 U.S. at 371).

[129] *Id.* (quoting *Pork Producers*, 598 U.S. at 374).

[130] *Id.* (quoting *Pork Producers*, 598 U.S. at 374).

[131] *Id.* Because the Fourth Circuit decided *Frosh* in 2018 before *Pork Producers* was decided, that case did not explore the effect of *Pork Producers* on the analysis of state laws banning drug price gouging. *See* AAM v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018).

[132] *Ellison*, 140 F.4th at 960 (citing *Frosh*, 887 F.3d at 672).

[133] *Id*. at 961 (citing PhRMA v. Walsh, 538 U.S. at 669 (2003)).

[134] Order, AAM v. Ellison, No. 24-1019, 2025 WL 2178535 (8th Cir. Aug. 1, 2025).

A Federal District Court Upholds the Illinois Law

Although the Eighth Circuit agreed with the Fourth Circuit's analysis in *Frosh* and distinguished *Pork Producers*, at least one federal district court has held that *Pork Producers* changes the extraterritoriality analysis of state prescription drug price-gouging laws.[135] In *AAM v. Raoul*, the U.S. District Court for the Northern District of Illinois denied a motion to preliminarily enjoin a 2023 Illinois price-gouging law, finding that the plaintiff was not likely to succeed on the merits of its case because the state law did not violate the extraterritoriality principle of the Dormant Commerce Clause.[136] The district court's decision rested on its interpretation of the Supreme Court's ruling in *Pork Producers*; the court emphasized that *Pork Producers* rejected the "almost *per se* rule" argument that state laws that effectively control out-of-state commerce were invalid.[137] In the district court's view, the Illinois price-gouging law presented an "inverse" of the California law in *Pork Producers*,[138] because the Illinois law regulates "upstream commerce based on downstream effects," whereas the California law regulates "in-state commerce based on upstream conduct."[139] This distinction was significant, the district court said, because it meant that *Pork Producers* did not answer the question of whether the Dormant Commerce Clause "prohibits a state from regulating out-of-state transactions based on their downstream consequences," as Illinois was trying to do.[140] The district court further observed that the Illinois price-gouging law does not discriminate against out-of-state interests, does not benefit or favor in-state businesses, and does not otherwise discourage consumers from participating in interstate commerce.[141]

The district court also reasoned that other U.S. Court of Appeals for the Seventh Circuit (Seventh Circuit) precedent cited by AAM that discussed the extraterritoriality principle was undermined by *Pork Producers*, because the Seventh Circuit had relied on the Supreme Court's decision in *Baldwin* to support the premise that states were forbidden from regulating "wholly out-of-state commerce"—a premise which *Pork Producers* rejected.[142] The district court read *Pork Producers* to call into question the Fourth Circuit's reasoning in *Frosh*, pointing to Judge Wynn's dissent that the Supreme Court's "principle concerns" in articulating its Dormant Commerce Clause jurisprudence were "economic protectionism, discrimination against interstate commerce, and State regulation of a stream of transactions that never crosse[d] through the State's borders."[143] The district court also concluded that AAM's reliance on the plurality in *Edgar* could not alone justify its request for a preliminary injunction because *Pork Producers* "cast doubt on whether the state law in *Edgar* posed a dormant Commerce Clause issue at all, or if it instead implicated horizontal separation of powers more broadly."[144] AAM appealed the district court's ruling in

[135] AAM v. Raoul, 805 F. Supp. 3d 854 (N.D. Ill. 2025), *appeal docketed*, No. 25-2960 (7th Cir. Oct. 31, 2025).

[136] *Id.* Like other state price-gouging laws, the Illinois price-gouging law prohibits generic and biosimilar manufacturers from "engaging in price gouging," and bases the price on a percentage of the WAC. 410 ILL. COMP. STAT. 725/10(a) (2024). The law was enacted in July 2023 and took effect on January 1, 2024. *Id.*

[137] *Raoul*, 805 F. Supp. 3d at 858 (quoting Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 371 (2023)).

[138] *Id*. at 858–59.

[139] *Id.* at 859.

[140] *Id.* (citing Bradley W. Joondeph, *The "Horizontal Separation of Powers" After* National Pork Producers Council v. Ross, 61 SAN DIEGO L. REV. 45, 78–79 (2024)).

[141] *Raoul*, 805 F. Supp. 3d at 860.

[142] *Id.*; *see* Legato Vapors v. Cook, 847 F.3d 825 (7th Cir. 2017); Midwest Title Loans, Inc. v. Mills, 539 F.3d 660 (7th Cir. 2010).

[143] *Raoul*, 805 F. Supp. 3d at 861 (citing AAM v. Frosh, 887 F.3d 664, 684 (4th Cir. 2018) (Wynn, C.J., dissenting)).

[144] *Id.* at 682 (citing Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 376 n.1 (2023)); Edgar v. MITE Corp., 457 U.S. 624 (1982) (plurality opinion)).

Raoul to the Seventh Circuit in October 2025, where it remains pending as of the date of this writing.[145]

Selected Legal Considerations

Unlike the state PDAB laws discussed below, many of which target high-priced, name brand drugs, state price-gouging statutes typically target generic drug prices.[146] Because generic drugs are not patented (which requires a federal process), targeting generic prices via price-gouging statutes allows a state to avoid Supremacy Clause and federal patent preemption challenges.[147] At the same time, much of a state's ability to ban prescription drug price gouging in the future will depend on how courts apply the Dormant Commerce Clause jurisprudence, and particularly, the extraterritoriality principle.[148] As of this writing, courts have found legislation banning price gouging constitutional in at least one state (Illinois), while price-gouging legislation was found unconstitutional for states in the Fourth and Eighth Circuits.[149] Future cases regarding the constitutionality of state price-gouging statutes could lead to more circuit courts deciding the constitutionality of those laws, raising the potential of Supreme Court review. Should the Supreme Court decide to review any price-gouging legislation decisions, it could address the issue of whether the Dormant Commerce Clause permits states to legislate in this way. If so, the Court could potentially clarify its recent decision in *Pork Producers*, or it could otherwise provide further insight into how the extraterritoriality principle may apply. Given the complexity of the domestic pharmaceutical supply chain and its interstate nature, the future of state price-gouging bans could be affected by subsequent rulings that clarify the extraterritoriality principle.

As part of Congress's consideration of prescription drug costs and related issues, it may consider the extent to which state legislatures are able to regulate prescription drug price through price-gouging bans. Whether existing Dormant Commerce Clause doctrine allows states to enact these laws may affect the perceived opportunity for congressional action on drug prices. In other words, if courts universally interpret the Dormant Commerce Clause to prohibit states from enacting price-gouging bans, then only Congress would be able to enact legislation to constrain the practice.

State Laws Creating Prescription Drug Affordability Boards

Prescription Drug Affordability Boards (PDABs) are independent, state-level boards that review prescription drug costs and make recommendations aimed at improving affordability.[150] Some state PDABs may also set price ceilings (UPLs, or upper payment limits) for in-state payers for certain high-cost drugs, although not all PDABs are authorized to set UPLs.[151] As of August

[145] Plaintiff's Notice of Appeal, AAM v. Raoul, No. 25-2960 (7th Cir. Oct. 31, 2025), Dkt. No. 1.

[146] Many states began targeting the prices of generic drugs after a 2007 Federal Circuit ruling that D.C.'s Prescription Drug Excessive Pricing Act, which targeted the prices of brand name drugs, was conflict preempted by federal patent law. Biotech Indus. Org. (BIO) v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007).

[147] *See, e.g.*, *NASHP's Proposal for Protecting Consumers from Prescription Drug Price Gouging*, *How can Patent Preemption Problems be Avoided*, NAT'L ACAD. FOR STATE HEALTH POL'Y (July 6, 2020), https://nashp.org/nashps-proposal-for-protecting-consumers-from-prescription-drug-price gouging/ [https://perma.cc/48J9-3MBW] (an aid to states to avoid patent preemption problems when regulating prescription drug prices).

[148] *See Frosh*, 887 F.3d at 664; AAM v. Ellison, 140 F.4th 957 (8th Cir. 2025); *Raoul*, 895 F. Supp. 3d at 854.

[149] *See Frosh*, 887 F.3d at 664; *Ellison,* 140 F.4th at 962; *Raoul*, 895 F. Supp. 3d at 854.

[150] For more background information on PDABs, see CRS Legal Sidebar LSB11390, *Litigation over State Attempts to Lower Drug Costs: Prescription Drug Affordability Boards (PDABs)*, by Hannah-Alise Rogers (2026).

[151] *Compare* COLO. REV. STAT. § 10-16-1407 (2023) (authorizing PDAB to set a UPL), *with* N.J. STAT. ANN. § 45:14-82.11 (2023) (no authorization for PDAB to set a UPL).

2026, there are at least ten states with active PDABs, with several other state legislatures considering legislation to create a PDAB.[152] Colorado became the first state to establish a price ceiling for a drug when it set a UPL on Enbrel (interacept), a drug manufactured by Amgen and approved by the FDA to treat various autoimmune inflammatory diseases, in 2025.[153] As of the date of this writing, at least one other state PDAB has established a UPL.[154]

While there is variation in state laws with respect to PDABs and UPL authority, this report uses Colorado as an illustrative example of the process. To establish a UPL, Colorado law first requires the board to conduct an affordability review to determine if the drug is "unaffordable for Colorado consumers."[155] Only if a drug is "unaffordable" may the state decide to set a UPL.[156] The state established a UPL for Amgen's drug Enbrel in October 2025, after an affordability review found the drug "unaffordable" for Colorado consumers; the UPL was set at $600 per 50mg unit.[157]

[152] *Prescription Drug Affordability Boards: Potential Risks to Pharmacy Reimbursement*, NAT'L ALLIANCE OF STATE PHARM. ASS'N (Aug. 13, 2026), https://naspa.us/resource/pdab/ [https://perma.cc/2RVG-FKF9].

In January 2026, after a new state governor took office, the Commonwealth of Virginia became the latest state to advance PDAB legislation when the state House passed H.B. 483, but it was vetoed by the new governor in May 2026. H.B. 483, 2026 Gen. Assemb., Reg. Sess. (Va. 2026). Similar legislation that would have created a Virginia PDAB was twice vetoed by the previous state governor. Brandon Jarvis, *Youngkin Vetoes Prescription Drug Affordability Board*, VA. SCOPE (Mar. 24, 2025), https://www.virginiascope.com/youngkin-vetoes-prescription-drug-affordabilty-board/ [https://perma.cc/Y3TT-R548].

[153] Sara Wilson, *Colorado Becomes First State to Cap Price of Prescription Drug*, COLO. NEWSLINE (Oct. 7, 2025), https://coloradonewsline.com/2025/10/07/colorado-first-state-cap-price-prescription-drug/ [https://perma.cc/8295-HWY9].

[154] In April 2026, the Maryland PDAB voted in favor of establishing a UPL for the diabetes drug Jardiance after finding that the drug was unaffordable for Maryland consumers. Further, in May 2026, the PDAB voted in favor of setting a UPL on Ozempic. These prices are scheduled to take effect in 2027. *See* MD. PDAB, OZEMPIC: UPPER PAYMENT LIMIT FRAMEWORK (2026), https://pdab.maryland.gov/Documents/Cost%20Review/2026/Ozempic.Upper%20Payment%20Limit%20Framework.v.2.0.pdf [https://perma.cc/N3XT-ZUCW]; PDAB Staff, Jardiance: Upper Payment Limit Framework, Presentation at Maryland PDAB Meeting (Nov. 17, 2025), https://pdab.maryland.gov/Documents/meetings/2025/2025.11.17.Jardiance.UPL%20Framework%20Presentation.pdf [https://perma.cc/TY2A-M6KA].

[155] COLO. REV. STAT. § 10-16-1406 (2026). During the affordability review, the board is required to consider a variety of information, including a drug's WAC, the availability and cost of any therapeutic alternatives, a comparison of the relative financial effects on health, medical, and social services costs compared to those of the drug's therapeutic alternatives, the effect of the price on access to state consumers, typical patient cost-sharing for the drug, the impact on 340B safety net providers, and orphan drug status. *Id.* § 10-16-1406(4)(a)–(g). The board is also required to consider input from the medical and scientific community, patients, and the state's rare disease advisory council. *Id.*§ 10-16-1406(4)(h).

[156] *Id.* § 10-16-1407(1)(a).

[157] Press Release, Colo. Consumer Health Initiative, Consumer Advocates Praise Prescription Drug Affordability Board's Decision to Set First-in-Nation Upper Payment Limit on the Expensive Drug Enbrel Colo. Consumer Health Initiative (Oct. 3, 2025), https://cohealthinitiative.org/media-releases/consumer-advocates-praise-prescription-drug-affordability-boards-decision-to-set-first-in-nation-upper-payment-limit-on-the-expensive-drug-enbrel/ [https://perma.cc/HMY9-BJF7].

The state UPL mirrors the maximum fair price for Enbrel under the Medicare Drug Price Negotiation Program. *Selected Drugs and Negotiated Prices*, CTR. FOR MEDICARE & MEDICAID SERVS. (May 22, 2026), https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-negotiated-prices [https://perma.cc/4LKV-QTW7]. 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).

Amgen Challenges Colorado PDAB Law

To date, Amgen has brought two cases against the Colorado PDAB. Amgen brought its first lawsuit after Colorado found the drug "unaffordable" for Colorado consumers, but before the state set a UPL.[158] The first case was dismissed in 2025, after a federal district court ruled that the company could not establish third-party standing to challenge the law.[159] Although Amgen appealed the district court's findings to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), the company dismissed the appeal after Colorado set a UPL for Enbrel.[160] Amgen's second lawsuit was filed in October 2025, directly challenging Enbrel's UPL, which the PDAB had set a few weeks earlier.[161] As was the case in its first lawsuit, Amgen asserted three claims: first, that the Colorado PDAB law is preempted by federal patent law; second, that the law violates the Due Process Clause of the Fourteenth Amendment; and third, that the law violates the Dormant Commerce Clause.[162]

In its second lawsuit, Amgen attempted to establish that it has standing to challenge Colorado's PDAB law. The company first argues that the plain meaning of the statute applies the UPL for Enbrel directly to Amgen, "so long as the drug is eventually dispensed or administered in Colorado."[163] In other words, Amgen argues that it has standing because it is directly regulated by the Colorado PDAB law. The company further states that even if the UPL applies only to "downstream transactions" and not to drug manufacturers, Amgen will still "suffer substantial, irreparable harm" as a result of the UPL on Enbrel.[164] Amgen argues that when the UPL takes effect, even if it does not apply directly to drug wholesalers (who typically purchase drugs from manufacturers at wholesale acquisition cost [WAC]), the company will still be harmed because "wholesalers will not agree to purchase a product [from Amgen] for more than what they can lawfully recover from reselling that product."[165] Amgen also asserts that the UPL will cause the

[158] Amgen Inc. v. Mizner, No. 24-CV-00810, 2025 WL 947474 (D. Colo. Mar. 28, 2025), *appeal dismissed*, No. 25-1641, 2026 WL 262636 (Fed. Cir. Feb. 2, 2026).

In a two-part analysis, the court first found that the drug company was not directly regulated by the law, because the UPL set by the state PDAB applied "only to downstream transactions for the actual sales and reimbursements of the prescription drug dispensed to Colorado consumers." *Id.* at *6. The court also observed that the legislative history of the state's PDAB statute indicated that the UPL was meant to "apply specifically to the state and municipalities, contractors and vendors, commercial health plans, providers, and pharmacies." *Id.* For these reasons, the court found, Amgen was required to establish standing as a third party, because the company was not directly regulated by the law. *Id.* at *7.

The district court then held that Amgen could not establish third-party standing, because the company could not show a "predictable chain of events leading from the government action to the asserted injury." *Id.* (quoting FDA v. All. for Hippocratic Med., 602 U.S. 367, 385 (2024)).

[159] *Id*. The district court disagreed with Amgen's argument that "basic economics and common sense" supported its third-party standing, finding that the company merely assumed that any UPL set for Enbrel (in the future) would be lower than the WAC. *Id*. In addition, the court said that the company did not factor into its standing argument the "complexity of the [drug distribution] supply chain," including rebates and other discounts that could also impact pricing. *Id.*

[160] Plaintiffs' Notice of Appeal, Amgen Inc. v. Colo. PDAB, No. 25-1641 (Fed. Cir. Apr. 14, 2025), Dkt. No. 1; *see also* Joint Stipulation to Voluntarily Dismiss Appeal, *Amgen Inc.*, No. 25-1641 (Fed. Cir. Jan. 9, 2026), Dkt. No. 41 (dismissing first case).

[161] Complaint, Amgen Inc. v. Mizner, No. 25-CV-03452 (D. Colo. Oct. 30, 2025).

[162] *Id.* at 36, 40, 42.

[163] *Id.* at 30.

[164] *Id.*

[165] *Id.* at 31.

company to incur further lost revenue in the form of administrative costs for renegotiating contracts with wholesalers and modifying its payment systems.[166]

On the merits, Amgen relies on the Federal Circuit's ruling in *Biotechnology Industries Organization (BIO) v. District of Columbia* to argue that the Colorado's PDAB law is preempted by federal patent law.[167] In *BIO*, the Federal Circuit held that the District of Columbia's Prescription Drug Excessive Price Act, which prohibited drug manufacturers from charging "excessive" prices for certain drugs, was preempted by federal patent law because it interfered with patent exclusivity rights.[168] Amgen argues that patent law is exclusively a matter of federal law and that "Congress has taken special care to safeguard [drug development] incentives for innovation in the pharmaceutical field and has struck a careful and deliberate balance . . . while encouraging generic and biosimilar competition after the end of the relevant patent terms."[169] Amgen further argues that because the PDAB statute does not contain an exception for patented drugs, it interferes with the balance Congress set in federal patent laws, including the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) (which governs the entry of generic drugs).[170]

In addition to arguing that the Colorado PDAB statute is preempted by federal patent law, Amgen also claims that the state law runs afoul of the Fourteenth Amendment's Due Process Clause. Amgen argues that the law interferes with the company's property rights in its patents on Enbrel, which include a right to determine the price at which it will sell its drug.[171] The drugmaker argues that the PDAB statute violates the Due Process Clause because it does not provide adequate standards for the determination of "unaffordab[ility]" or UPLs.[172] Amgen refers to the Supreme Court's decision in *Mathews v. Eldridge*, guaranteeing property owners the right to be heard "at a meaningful time and in a meaningful manner," which the company claims includes "meaningful standards to limit and channel the exercise of governmental power."[173]

Finally, Amgen claims that Colorado's PDAB law runs afoul of the Dormant Commerce Clause, because it "directly controls commerce occurring wholly outside the boundaries of a State."[174] The company points to the Fourth Circuit's 2018 decision in *Frosh* to support its argument that the state law violates the principle of extraterritoriality, because it regulates drug sales that "occur entirely outside the State of Colorado."[175] According to Amgen, because the UPL set by the Colorado PDAB applies to all purchases of Enbrel that are dispensed to in-state patients, this means that the UPL applies "even to wholly out-of-state, upstream transactions, as long as the drug is eventually dispensed . . . in Colorado."[176]

Colorado answered the complaint in January 2026, generally denying Amgen's claims.[177] Amgen filed a motion for a preliminary injunction to pause the Colorado PDAB law while the underlying

[166] *Id.* at 34.

[167] *Id.* at 37; *see* BIO v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007).

[168] *BIO*, 496 F.3d at 1372.

[169] Complaint, *supra* note 161, at 37–38.

[170] *Id.*; *see, e.g.*, Pub. L. No. 98-417, 98 Stat. 1585.

[171] Complaint, *supra* note 161, at 40.

[172] *Id.* at 41. Amgen also points to other cases addressing adequate due process in the context of price control statutes. *Id.* at 41–42; *see, e.g.,* Mich. Bell Tel. Co. v. Engler, 257 F.3d 587, 592–93 (6th Cir. 2001).

[173] Complaint, *supra* note 161, at 40–41 (quoting Mathews v. Eldridge, 424 U.S. 319, 333 (1976)).

[174] *Id.* at 43 (quoting Healy v. Beer Inst., 491 U.S. 324, 336 (1989)).

[175] *Id.* at 5, 43 (citing AAM v. Frosh, 887 F.3d 664, 668 (4th Cir. 2018)).

[176] *Id*. at 43–44.

[177] Answer, Amgen Inc. v. Mizner, No. 25-CV-03452 (D. Colo. Jan. 16, 2026), Dkt. No. 45.

merits of the suit are being resolved.[178] The court granted the preliminary injunction in July 2026, holding that Amgen was likely to suffer substantial irreparable harm from the UPL, that it was likely to succeed on the merits of its claim that the UPL is preempted by federal patent law, and that the balance of the equities and the public interest did not outweigh the fact that UPL was likely unconstitutional.[179] The court reasoned that the Federal Circuit's decision in *BIO* controlled here, because in setting the UPL for Enbrel, Colorado was attempting to rebalance the patent system, which was something only Congress can do.[180]

Selected Legal Considerations

As more states are moving to establish both PDABs and UPLs, additional lawsuits against such actions may be filed. For example, in April 2026, the Maryland PDAB voted to establish a UPL on Jardiance, a brand name drug that is used to treat type 2 diabetes, among other conditions.[181] Because Jardiance is currently protected by patents, the manufacturers (Eli Lilly and Boehringer Ingelheim) could challenge Maryland's PDAB on preemption, due process, or Dormant Commerce Clause grounds, just as Amgen did against Colorado's PDAB law.[182] If such a suit is filed, drug manufacturers might rely on the Fourth Circuit's decision in *Frosh* to argue that Maryland's PDAB statute, like the Maryland drug price-gouging ban at issue in *Frosh*, is invalid under the Dormant Commerce Clause.[183]

A court's analysis of whether the Maryland drug pricing law violates the Dormant Commerce Clause could depend on how the court characterizes the state's PDAB law; for example, if a court were to conclude that the law impacts "upstream" sales (i.e., sales outside of the state), then the court might find, as it did in *Frosh*, that such state law's structure violates the Dormant Commerce Clause.[184] On the other hand, it is possible that a court could distinguish the price-gouging ban in *Frosh* from Maryland's PDAB law. Unlike the price-gouging ban, which the *Frosh* court said tied the "'unconscionable' price" charged by the manufacturer to the WAC (which is based on out-of-state sales), the Maryland PDAB's statutory scheme is focused on affordability and requires more administrative input from the state.[185] For example, before Maryland can establish a UPL, the board is required to study the pharmaceutical payment and distribution systems across the state, identify "affordability challenges" for in-state consumers, and conduct cost reviews.[186] If the cost review concludes that the drug's price will lead to "affordability challenges," only then may the state actually set a UPL for a drug.[187] Thus, in

[178] Plaintiffs' Motion for Preliminary Injunction, *Amgen Inc.*, No. 25-CV-03452 (D. Colo. Nov. 21, 2025), Dkt. No. 18.

[179] Amgen, Inc. v. Mizner, No. 25-CV-03452, 2026 WL 1943512 (D. Colo. July 1, 2026), *appeal docketed*, No. 26-2111 (Fed. Cir. Aug. 4, 2026).

[180] *Id.* at *3. The preliminary injunction order was based only on Amgen's patent preemption claims; the court does not address Amgen's other arguments, including the due process and Dormant Commerce Clause claims. *Id.* at *1.

[181] *See* Karl Hille, *Maryland Caps Diabetes Drug Costs for Government Health Plans*, BALT. SUN (Apr. 14, 2026, at 2:37 EST), https://www.baltimoresun.com/2026/04/13/diabetes-drug-jardiance/.

[182] The Maryland PDAB's investigation of Jardiance found that there are eleven patents listed in the FDA's Orange Book that cover the drug. MD. PDAB, JARDIANCE (EMPAGLOFOZIN) DOSSIER (2025), https://pdab.maryland.gov/Documents/Dossiers/July%2023%2C%202025/JARDIANCE%20DOSSIER.2025.07.23.1100.V2.1.FINAL%20%281%29.pdf [https://perma.cc/RL38-MZGR].

[183] AAM v. Frosh, 887 F.3d 664 (4th Cir. 2018).

[184] *Id.* at 671.

[185] *See id*; *see also* MD. CODE ANN., HEALTH−GEN. § 21-2C-02 (West 2026) (creating the Maryland PDAB as an independent entity and providing that the purpose of the PDAB is to "protect" state actors from "the high costs of prescription drug products").

[186] MD. CODE ANN., HEALTH−GEN. §§ 21-2C-07, 21-2C-08 (West 2026).

[187] *Id*. §§ 21-2C-13, 21-2C-14.

determining the UPL, the state is not relying on out-of-state sales, meaning that a court may not characterize the law as regulating "upstream" transactions.[188]

Only federal courts can dispositively resolve the debates about whether UPLs set by state PDABs violate the Dormant Commerce Clause. Apart from that constitutional issue, Congress could address the patent law preemption issue by clarifying whether and to what extent the Patent Act preempts state attempts to regulate patented pharmaceuticals.[189]

State Laws Addressing the 340B Drug Discount Program

Congress created the 340B Drug Discount Program (340B program, or the program) through the Veterans Health Care Act of 1992 to enable certain health care providers serving low-income and uninsured patients to purchase outpatient prescription drugs at lower costs.[190] The program is administered by the Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services (HHS).[191] In accordance with the statute, HHS and drug manufacturers sign a contract (PPA, or purchase price agreement) in which manufacturers are required to "offer" to sell certain drugs at a "ceiling price," which is calculated based on a statutory formula.[192] Manufacturers must offer covered outpatient drugs to covered entities either at or below this ceiling price, if the drugs are available to any other purchaser at any price.[193]

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, Disproportionate Share Hospitals, and other providers that care for rural or underserved populations.[194] Covered entities may generate significant revenue from the 340B program by reselling discounted drugs to their patients and receiving reimbursement from the patient's insurance (if applicable) as though the covered entity paid full price for the drug. Covered entities may make 340B drugs available to patients either through their own in-house (or on-site) pharmacy or by contracting with third-party retail pharmacies, which have come to be known as "contract pharmacies."[195]

The statute prohibits covered entities from receiving duplicate discounts from both the Medicaid and the 340B programs, and covered entities are also prohibited from selling or otherwise distributing drugs to anyone who is not a patient[196] of the covered entity (a practice known as *diversion*).[197] Since 2020, legal disputes have arisen between HRSA, drug manufacturers, and covered entities regarding how HRSA enforces the statute, including the statutory provisions

[188] *See Frosh*, 887 F.3d at 671.

[189] *Cf.* BIO v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (recognizing that "[t]here is no express provision in the patent statute that prohibits states from regulating the price of patented goods," but that, in regulating drug prices, a state cannot frustrate the "the full purposes and objectives of Congress." (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941))).

[190] Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (codified as amended at 42 U.S.C. § 256b).

[191] *340B Drug Pricing Program*, HRSA (Aug. 2026), https://www.hrsa.gov/opa [https://perma.cc/Y79Q-U56C].

[192] 42 U.S.C. § 256b(a)(1).

[193] *Id.*

[194] *Id.* § 256b(a)(4).

[195] *Contract Pharmacy Services*, HRSA (June 2024), https://www.hrsa.gov/opa/implementation-contract [https://perma.cc/H3MC-YKZZ].

[196] At least one federal court has invalidated HRSA's definition of *patient* as applied to a specific covered entity. *See* Genesis Healthcare, Inc. v. Becerra, 701 F. Supp. 3d 312 (D.S.C. 2023).

[197] 42 U.S.C. § 256b(a)(5)(A)(i) (prohibition on duplicate discounting); *id.* § 256b(a)(5)(B) (prohibition on diversion).

prohibiting duplicate discounting and diversion.[198] Several federal appellate courts have held that drug manufacturers may limit the sale of 340B drugs to covered entities that use contract pharmacies.[199] As a result, covered entities purchasing certain drugs are unable to generate 340B revenue from an unlimited number of contract pharmacies.

As a result of the litigation regarding contract pharmacy use, several states began considering legislation to stop drug manufacturers from restricting contract pharmacy use by covered entities in their state.[200] While these state laws may differ slightly in scope, they generally aim to stop manufacturers from interfering with contracts between covered entities and their dispensing pharmacies. For example, in May 2021, Arkansas became the first state to enact a state-level contract pharmacy law, which provided that manufacturers could not "deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing."[201] Other state laws soon followed.

For example, in 2023, Louisiana enacted a law prohibiting drug manufacturers from denying, restricting, or otherwise interfering with "acquisition . . . or delivery of a 340B drug" to a contract pharmacy, unless otherwise prohibited by HHS.[202] Violations of the prohibition are considered violations of Louisiana's Unfair Trade Practices and Consumer Protection Law.[203] Colorado's law goes one step further than Louisiana's, prohibiting manufacturers and other entities not only from denying or restricting 340B drug acquisition or delivery to a covered entity or its contract pharmacy, but also from requiring covered entities to submit claims data to manufacturers.[204] West Virginia's contract pharmacy law is similar to Colorado's, as it prevents manufacturers from limiting 340B drug distribution to in-state pharmacies contracted with a covered entity, and also prohibits manufacturers from requiring covered entities to submit claims data as a condition of receiving a 340B drug.[205]

Individual drug manufacturers and PhRMA have challenged these and other state contract pharmacy laws in federal district courts around the country.[206] These lawsuits assert a number of different legal theories, including that the state laws are preempted by the 340B statute and that they are invalid under the Dormant Commerce Clause.[207] This section explores the legal

[198] For more information about 340B legal disputes, see CRS Report R48696, *The 340B Drug Discount Program: Litigation Topics and Trends*, by Hannah-Alise Rogers (2025).

[199] 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); Novartis Pharms. Corp. v. Johnson, 102 F.4th 452 (D.C. Cir. 2024). One appeal remains pending at the Seventh Circuit. *See* Notice of Appeal, Eli Lilly & Co. v. HHS, No. 21-3405 (7th Cir. Dec. 30, 2021).

[200] NAT'L ASS'N OF CMTY. HEALTH CTRS., STATE-LEVEL 340B LAWS AND LEGISLATION TRACKER (2026), https://www.nachc.org/wp-content/uploads/2026/04/4_15_26_nachc_state-level-340b-laws-and-legislation_tracker.pdf [https://perma.cc/99H6-AZCY].

[201] ARK. CODE ANN. § 23-92-604(c)(2) (West 2021).

[202] LA. REV. STAT. ANN. § 40:2884 (2023).

[203] *Id.* § 40:2885.

[204] COLO. REV. STAT. § 6-29-105(1)(a) (2026). The law forbids manufacturers from requiring Colorado covered entities to turn over "health information, claims or utilization data, purchasing data, payment data, or other data that does not relate to a claim submitted to a federal health care program," unless a covered entity voluntarily provides the information. *Id.* § 6-29-105(1)(b). The law is enforced by the state Attorney General. *Id.* § 6-29-105(3)(a).

[205] W. VA. CODE § 60A-8-6a (2024).

[206] *See, e.g.*, PhRMA v. Fitch, No. 24-CV-160, 2024 WL 3277365 (S.D. Miss. July 1, 2024), *aff'd*, No. 24-60340, 2026 WL 963501 (5th Cir. Apr. 9, 2026).

[207] *See* PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024) (Arkansas); AbbVie, Inc. v. Fitch, 152 F.4th 635 (5th Cir. 2025) (per curiam) (Mississippi); PhRMA v. McCuskey, 171 F.4th 675, *reh'g en banc granted*, 176 F.4th 830 (4th Cir. 2026) (mem.) (West Virginia).

challenges brought against the state laws, focusing specifically on the federal appellate court rulings.

The Eighth Circuit Upholds the Arkansas and Missouri Laws

Both Arkansas and Missouri enacted state laws prohibiting drug manufacturers from limiting the delivery of 340B drugs to an in-state covered entity's contract pharmacy.[208] The laws were challenged by drug manufacturers and PhRMA on the basis that they were preempted by the 340B statute and violated the Dormant Commerce Clause, and both district court decisions made their way to the Eighth Circuit on appeal.[209] The Eighth Circuit decided the Arkansas case (*PhRMA v. McClain*) first, holding that the state law was not preempted by the 340B statute or the Food, Drug, and Cosmetic (FD&C) Act.[210] A few years later, the court reviewed the Missouri law (*Novartis Pharmaceuticals Corp. v. Hanaway*) on an appeal from a decision on a motion for a preliminary injunction and concluded that there was likely no preemption; the court also held that the state 340B law likely did not violate the Dormant Commerce Clause.[211]

Appeals Court Says 340B Statute Does Not Preempt State 340B Laws

PhRMA and drug manufacturer Novartis challenged the Arkansas and Missouri contract pharmacy laws, respectively, on the basis that they were preempted by the 340B statute.[212] The federal district court in Arkansas held that the 340B statute did not preempt the Arkansas law; similarly, the federal district court in Missouri agreed that the state was likely to succeed on the merits, because the Missouri law was likely not preempted by the 340B statute.[213] In both cases, the Eighth Circuit recognized that the 340B statute was "silent" with respect to the delivery of 340B drugs, but it acknowledged that contract pharmacies were an important part of the 340B pharmaceutical supply chain, because they deliver the drugs to patients.[214]

In *McClain*, the Eighth Circuit first addressed field preemption, quoting the Supreme Court's decision in *Arizona v. U.S.*, which held that field preemption occurs when Congress leaves "no room for the states to supplement" federal law.[215] Noting that the text of the 340B statute does not mention drug delivery, 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."[216] Although the Arkansas contract pharmacy law empowers the state to penalize drug manufacturers who refuse to distribute drugs to covered entities' contract pharmacies, the Eighth Circuit said that such enforcement authority does not interfere with HRSA's jurisdiction over the program, which concerns disputes between manufacturers and covered entities regarding the price of drugs,

[208] ARK. CODE Ann. § 23-92-604 (West 2026); MO. REV. STAT. § 376.414.3 (2024).

[209] PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024); Novartis Pharms. Corp. v. Bailey, No. 24-4131, 2025 WL 595189 (W.D. Mo. 2025), *aff'd sub nom.*, Novartis Pharms. Corp. v. Hanaway, 180 F.4th 1097 (8th Cir. 2026).

[210] *McClain*, 95 F.4th at 1139; *see* FD&C Act, 21 U.S.C. §§ 301–399j.

[211] *Hanaway*, 180 F.4th at 1111.

[212] PhRMA v. McClain, 645 F. Supp. 3d 890 (E.D. Ark. 2022) *aff'd*, 95 F.4th 1136 (8th Cir. 2024); *Bailey*, 2025 WL 595189. Additionally, both plaintiffs argued that the state laws were preempted by the FD&C Act. In *McClain*, the parties agreed to stay litigation on the Dormant Commerce Clause issue pending the resolution of the preemption issue. 645 F. Supp. 3d at 894.

[213] *McClain*, 645 F. Supp. 3d at 890; *Bailey*, 2025 WL 595189, at *1.

[214] *McClain*, 95 F.4th at 1142 (quoting Sanofi Aventis U.S. LLC v. HHS, 58 F.4th 696, 703 (3d Cir. 2023)); *accord Hanaway*, 180 F.4th at 1103. The *McClain* court characterized contract pharmacies as "agent[s] of the covered entity," which both purchase and assume legal responsibility for the drugs. *McClain*, 95 F.4th at 1142.

[215] *McClain*, 95 F.4th at 1143 (quoting Arizona v. United States, 567 U.S. 387, 399 (2012)).

[216] *Id.*

rather than their distribution.[217] In *Hanaway*, the Eighth Circuit reiterated its reasoning in *McClain*, declining to reconsider that decision and rejecting the drug manufacturers' field preemption argument.[218]

The Eighth Circuit also held in *McClain* that Arkansas's contract pharmacy law was not unconstitutional due to obstacle preemption. Rather than creating an obstacle to 340B compliance, the Eighth Circuit found that 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.[219] The court concluded that the law is "simply deterring . . . manufacturers from interfering with a covered entity's contract pharmacy arrangements," so manufacturers can simultaneously comply with both the 340B statute and the state law.[220] In *Hanaway*, Novartis tried to avoid the reasoning in *McClain* by making a slightly different argument about obstacle preemption, contending that the Missouri law hampered manufacturers' ability to impose delivery restrictions on covered entities and conflicted with federal law by requiring manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies.[221] However, the Eighth Circuit again pointed to its reasoning in *McClain*, concluding that the analysis of the two state laws was similar, because they both "regulate an area beyond the purview of federal law" and do not create a compliance obstacle with federal law for drug manufacturers.[222] The Eighth Circuit further pointed to the U.S. Court of Appeals for the Fifth Circuit's decisions in *AbbVie, Inc. v. Fitch* and *AbbVie, Inc. v. Murrill* to "reinforce" its conclusion against obstacle preemption.[223]

Appeals Court Says That State 340B Laws Do Not Violate the Dormant Commerce Clause

The Eighth Circuit also held in *Hanaway* that Novartis failed to show that it was likely to succeed on the merits of its claim that Missouri's contract pharmacy law violated the Dormant Commerce Clause, rejecting Novartis's arguments that the law violated the extraterritoriality principle, that it discriminated against interstate commerce, and that it failed the *Pike* balancing test.[224] The court held that the Missouri law did not violate the extraterritoriality principle, because its effect on transactions outside the state was "merely incidental," making the law distinguishable from the price-gouging statute at issue in *Frosh*.[225] Instead of the law regulating "upstream transactions," the Eighth Circuit found that the Missouri 340B law applied only to Missouri's covered entities

[217] *Id.* at 1144.

[218] *Hanaway*, 180 F.4th at 1112–13.

[219] *McClain*, 95 F.4th at 1144–45.

[220] *Id.* at 1145. The court also found that the state law was not preempted by the FD&C Act, because while it is true that covered entities are responsible for meeting the FD&C Act's risk evaluation and mitigation strategies (REMS) requirements, "just because a medication is subject to multiple legal requirements does not make it impossible to comply" with state law. *Id.* at 1145–46.

[221] *Hanaway*, 180 F.4th at 1112–13.

[222] *Id.* at 1113–14 (citing *McClain*, 95 F.4th at 1145).

[223] *Id.* at 1114 (citing AbbVie, Inc. v. Fitch, 152 4th 635 (5th Cir. 2025); AbbVie, Inc. v. Murrill, 166 F.4th 528 (5th Cir. 2026)). Both *Fitch* and *Murrill* are discussed *infra* "The Fifth Circuit Upholds the Louisiana and Mississippi Laws."

[224] 180 F.4th at 1106–11.

[225] *Id.* at 1107. Because it regulated transactions between drug manufacturers and drug wholesalers, the *Frosh* court found that Maryland's prescription drug law targeted "upstream" transactions, even when those transactions did not result in drugs being sold in Maryland. AAM v. Frosh, 887 F.3d 664, 671 (4th Cir. 2018). The Eighth Circuit also observed that "[u]nlike the Maryland [price-gouging statute] in *Frosh*, [the Missouri law] regulates the distribution of 340B drugs without affecting their price." *Hanaway*, 180 F.4th at 1111.

and contract pharmacies.[226] The Eighth Circuit further characterized Missouri's law as similar to the California statute in *Pork Producers*, because while the law "may incidentally bear on [an] out-of-state transaction[]," it does not have "a specific impermissible extraterritorial effect."[227] Similarly, the court held that the Missouri law did not discriminate against interstate commerce because it does not extend a preference to drug manufacturers within the state.[228]

The Eighth Circuit also rejected Novartis's claim that even if the Missouri law had no extraterritorial effect and did not discriminate against out-of-state actors, it violated the Dormant Commerce Clause for failing the *Pike* balancing test.[229] The court acknowledged that various states' contract pharmacy laws could "affect the volume of 340B drugs Novartis delivers in interstate commerce," but it held that increased expenses as the result of complying with state laws was not an insufficient burden on interstate commerce for purposes of *Pike* balancing.[230] Novartis also argued that the burdens of the Missouri law outweighed its benefits by characterizing it as a "direct cash transfer from out-of-state drug manufacturers to in-state hospitals," but the Eighth Circuit disagreed, noting that the purpose of the 340B program was to generate revenue for covered entities.[231]

The Fifth Circuit Upholds the Louisiana and Mississippi Laws

After Louisiana enacted its contract pharmacy law in 2023, and Mississippi enacted its law in 2024, PhRMA, AbbVie, and several other drug manufacturers challenged both laws on the basis that they were preempted by the 340B statute.[232] Together, the plaintiffs made a variety of claims, including that the laws constituted a taking under the Fifth Amendment, violated the Contract Clause, and were unconstitutionally vague under the Fourteenth Amendment Due Process Clause.[233] The district courts found in favor of the states on all counts, and both rulings were appealed to the Fifth Circuit.[234]

Appeals Court Says Federal 340B Statute Does Not Preempt State 340B Laws

The Fifth Circuit approached the appeals similarly, applying the reasoning of its initial decision in *Fitch*, which addressed the Mississippi law, to its later decision in *Murrill*, which addressed the

[226] *Hanaway*, 180 F.4th at 1107–08.

[227] *Id.* at 1108; *see* Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 374 (2023).

[228] *Hanaway*, 180 F.4th at 1108–09. Novartis also argued that the law discriminated against out-of-state actors because the company did not have a physical presence in Missouri, and because the law favored in-state 340B covered entities and pharmacies over an out-of-state drug manufacturer. *Id.* The court rejected these arguments, finding that drug manufacturers were not "substantially similar" to hospitals and pharmacies, and thus that the two could not be compared for purposes of a Dormant Commerce Clause analysis. *Id.* (quoting Dep't of Revenue of Ky. v. Davis, 553 U.S. 328, 341 (2008)).

[229] *Id.* at 1111. Even when a state law is "even-handed[]," and only incidentally affects interstate commerce, it can violate the Dormant Commerce Clause when the burden on interstate commerce outweighs the local benefits. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

[230] *Hanaway*, 180 F.4th at 1110.

[231] *Id*. (quoting Plaintiff-Appellant Novartis Pharmaceuticals Corporation's Opening Brief at 45, *Hanaway*, 180 F.4th 1097 (No. 25-1619)).

[232] *See* AbbVie, Inc. v. Fitch, 152 F.4th 635 (5th Cir. 2025) (per curiam) (Mississippi); AbbVie, Inc. v. Murrill, 166 F.4th 528 (5th Cir.), *opinion withdrawn and superseded on reh'g*, 180 F.4th 747 (5th Cir. 2026) (Louisiana).

[233] *Fitch*, 152 F.4th at 641; *Murrill,* 180 F.4th at 755–56. In *Murrill*, the various plaintiffs brought different challenges to Louisiana's law; the district court resolved all of the cases via a single opinion, and the Fifth Circuit consolidated the appeals. PhRMA v. Murrill, No. 23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024), *aff'd sub nom*., AbbVie, Inc. v. Murrill, 166 F.4th 528 (5th Cir. 2026).

[234] *Fitch*, 152 F.4th at 639; *Murrill,* 180 F.4th at 753–54.

Louisiana law.[235] In both cases, the court was unpersuaded by the manufacturers' arguments that the state contract pharmacy laws were preempted by the 340B statute.[236] Like the Eighth Circuit in *McClain*, the Fifth Circuit characterized both the Louisiana and Mississippi laws as regulating not the 340B program itself, but the delivery of 340B drugs to patients and a contract pharmacy's role in that distribution.[237] The Fifth Circuit first held that the state laws were not field preempted, because the 340B statute is not "so pervasive that Congress left no room for state supplementation."[238] Furthermore, the Fifth Circuit held that the state laws regulated pharmacies, which "do not purchase 340B drugs, and . . . do not receive the 340B price discounts."[239] Citing the Eighth Circuit's decision in *McClain*, the Fifth Circuit agreed that because Congress has not addressed the issue of contract pharmacies in the 340B statute, it is presumed that the state may regulate them.[240]

The Fifth Circuit similarly found that the state laws were not conflict preempted, because "[w]hile 'it is true that Congress made HHS the sole enforcer of Section 340B,' it is also true that Louisiana's Attorney General enforces [the state law]. The two regimes operate in distinct spheres."[241] Because there is no overlap in enforcement of the state laws and the 340B statute, the Fifth Circuit found that there was no conflict with the 340B statute in either state law.[242] So too, the Fifth Circuit rejected the plaintiffs' obstacle-preemption arguments; namely, that the state law regulates pricing because a violation would occur if a drug manufacturer failed to sell a drug to a covered entity at the 340B price.[243] For example, in *Murrill*, the court described such reasoning as "circular," and characterized the state law as regulating conduct, not prices.[244] The court also disagreed with the plaintiffs' argument that the state law "skew[ed]" the 340B program's objectives, observing that the state law "does not disturb the federally regulated relationship between manufacturers and covered entities."[245]

Appeals Court Says State 340B Laws Do Not Constitute a Fifth Amendment Taking

The Fifth Circuit also rejected the plaintiffs' arguments that the 340B state laws constituted either physical or regulatory takings of property under the Fifth Amendment.[246] While the plaintiffs claimed that the state laws constituted a physical taking because it compelled drug companies to transfer their private property (i.e., drugs) to private parties that will then sell them, the Fifth Circuit found that the state laws do not require manufacturers to sell their products at all, and manufacturers are still compensated for the drugs (albeit at the discounted 340B amount).[247] Similarly, the Fifth Circuit found that no regulatory taking had occurred, because the *Penn Central* factors—the laws' economic impacts, their interference with manufacturers' investment-

[235] *See, e.g.*, *Murrill,* 180 F.4th at 758 (citing *Fitch*, 152 F.4th at 646–47).

[236] *Murrill,* 180 F.4th at 758; *Fitch*, 152 F.4th at 647.

[237] *Fitch*, 152 F.4th at 647.

[238] *Murrill*, 180 F.4th at 759 (quoting *Fitch*, 152 F.4th at 646).

[239] *Id.* at 760 (citing PhRMA v. McClain, 645 F. Supp. 3d 890 (E.D. Ark. 2022)); *accord Fitch*, 152 F.4th at 646.

[240] *Murrill*, 180 F.4th at 760 (quoting *McClain*, 95 F.4th at 1144).

[241] *Id.* (footnote omitted) (quoting *Fitch*, 152 F.4th at 647); *accord Fitch*, 152 F.4th at 647–48.

[242] *Murrill*, 180 F.4th at 760–61; *accord Fitch*, 152 F.4th at 647.

[243] *Murrill*, 180 F.4th at 761; *accord Fitch*, 152 F.4th at 647.

[244] *Murrill*, 180 F.4th at 761.

[245] *Id.* at 761–62.

[246] *Id.*; *Fitch*, 152 F.4th at 641.

[247] *Murrill*, 180 F.4th at 763 (citing *Fitch*, 152 F.4th at 643).

backed expectations, and the character of the government action—all weighed in favor of the states.[248] Further, the court observed in *Murrill* that the Louisiana law "advances a core public purpose: ensuring that low-income and rural patients have access to discounted medications."[249]

Appeals Court Says State 340B Laws Do Not Violate the Contract Clause

In *Murrill,* the Fifth Circuit also addressed the claim that the Louisiana contract pharmacy law violated the Contract Clause, because the law "substantially impair[ed] [AstraZeneca's] contractual relationship with the federal government."[250] Specifically, the drug company contended that the state law unlawfully extended 340B covered entity status to retail pharmacies, which imposed new obligations under its PPA.[251] The Fifth Circuit disagreed, reasoning that the state law concerns the relationships between covered entities and their contract pharmacies, and drug companies are not a party to those contracts; the state law, the court found, does not "alter the terms, rights, or obligations" of AstraZeneca's PPA.[252]

In ruling against the drug manufacturer's claims, the Fifth Circuit distinguished the Supreme Court's ruling in *Allied Structural Steel Company v. Spannaus*, in which the Court held that a state law requiring private employers to pay a "pension funding charge" violated the Contract Clause.[253] In *Spannaus*, the state argued that the law was within the state's police power, even though it "substantially altered" the contractual relationship between a private business and its employees.[254] In overturning the state law, *Spannaus* grappled with the tension between the Contract Clause and a state's authority under its police power.[255] The Fifth Circuit said that the Louisiana contract pharmacy law was unlike the state law at issue in *Spannaus*, which regulated pensions, because the Louisiana contract pharmacy law implicated "traditional general areas of state regulation and police power"—namely, pharmacies, which is typically a state-regulated entity.[256] Moreover, drug manufacturers could have reasonably anticipated that the landscape of their business could be changed by a state, as the prescription drug industry is already heavily regulated.[257]

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[248] *Id.* at 763–64; *accord Fitch*, 152 F.4th at 644.

[249] *Murrill*, 180 F.4th at 763–64.

[250] *Id.* at 764.

[251] *Id.* at 764–65.

[252] *Id.* at 765. In its analysis, the Fifth Circuit also distinguished the state law contract pharmacy cases from other cases challenging HRSA's attempted regulation of contract pharmacies through guidance. *Id.* The Fifth Circuit pointed out that the Third and D.C. Circuit decisions in the *Sanofi Aventis* and *Novartis* cases, respectively, were not dispositive in this case, because the Third and D.C. Circuit decisions addressed a different issue—namely, whether HRSA could require drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. *Id.* (referencing 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)). Those cases, the court said, "did not hold—nor suggest—that States lack authority to regulate delivery through their traditional police powers." *Id*. (citing *Novartis*, 102 F.4th at 460, 464; *Sanofi Aventis*, 58 F.4th at 703)). For more information on the Third and D.C. Circuit decisions in the contract pharmacy litigation, *see* CRS Report R48696, *The 340B Drug Discount Program: Litigation Topics and Trends*, by Hannah-Alise Rogers (2025).

[253] *Murrill*, 180 F.4th at 765 (citing Allied Structural Steel Co. v. Spannaus, 438 U.S. 234 (1978)).

[254] *Spannaus*, 438 U.S. at 240.

[255] *Id.* at 242 ("If the Contract Clause is to retain any meaning at all, however, it must be understood to impose *some* limits upon the power of a State to abridge existing contractual relationships, even in the exercise of its otherwise legitimate police power.").

[256] *Murrill*, 180 F.4th at 765 (quoting AbbVie, Inc. v. Fitch, 152 F.4th 635, 646 (5th Cir. 2025) (per curiam)).

[257] *Id.*

The Fourth Circuit Pauses West Virginia's Law

West Virginia's contract pharmacy law, enacted in 2024, prohibited manufacturers from restricting in-state covered entity contract pharmacy use; another part of the law, known as the "[n]o-[a]udits [p]rovision," prohibited drug manufacturers from requiring covered entities to submit claims data as a condition of receiving the 340B price.[258] PhRMA and several other drug companies challenged the state law on the basis that it was preempted by the 340B statute.[259] In a preliminary ruling, the district court agreed, granting PhRMA's request for a preliminary injunction and prohibiting the law from taking effect until the underlying merits of the suit were resolved.[260]

The court held that the no-audits provision was an obstacle to the 340B statute, because without it, manufacturers would be unable to audit covered entities.[261] The district court also held that the state law was preempted because, in order to enforce it, a state official would have to apply and interpret federal law.[262] West Virginia appealed the district court's preliminary injunction ruling to the Fourth Circuit, arguing that its law was "a classic pharmacy regulation that does not change the 340B discount or its availability."[263] The Fourth Circuit's initial ruling, discussed below, was set aside in June 2026, after the court agreed to rehear the case en banc, meaning that all fifteen of the Fourth Circuit's judges would participate in issuing a new ruling.[264] As of the date of this writing, the court is working to schedule the hearing in fall 2026.

The Fourth Circuit panel majority agreed with the district court and held that West Virginia's contract pharmacy law was likely preempted.[265] The majority first addressed whether the presumption against preemption[266] applied by looking at whether and under what conditions a state may interfere with "federal prerogatives."[267] The framework for the court's analysis looked first at the type of state law, and then, because Congress created the 340B statute using its

[258] W.VA. CODE § 60A-8-6a(b)(2) (2026).

[259] PhRMA v. Morrisey, 760 F. Supp. 3d 439 (S.D. W.Va. 2024), *aff'd sub nom*., PhRMA v. McCuskey, 171 F.4th 675 (4th Cir.), *reh'g en banc granted*, 176 F.4th 830 (4th Cir. 2026); *see* W.VA. CODE § 60A-8-6a (2026).

[260] *Morrisey*, 760 F. Supp. 3d at 446.

[261] *Id.* at 451. The court held that the West Virginia law's no-audits provision frustrated the purpose of the 340B statute because the court said that conducting an audit is a prerequisite for a drug manufacturer to have access to the program's alternative dispute resolution process. *Id.* at 452.

[262] *Id.* at 454. Specifically, the court agreed with drug manufacturers that to determine if a drug was "delivered" in accordance with the West Virginia statute, a state official would first need to determine whether the drug in question was a 340B drug and whether it was sold at the 340B price. *Id.* Moreover, the district court characterized the West Virginia law as actually regulating price, rather than drug distribution. *Id.* at 455.

[263] *McCuskey*, 171 F.4th at 682.

[264] Amended Order, PhRMA v. McCuskey, No. 25-1054 (4th Cir. June 2, 2026), Dkt. No 167.

[265] *McCuskey*, 171 F.4th at 687 (ruling set aside).

[266] *Id.* at 688. The presumption against preemption is a canon of construction created by the Supreme Court which instructs that a federal law should not be read to preempt a state law when the state is exercising its police power. *See* Rice v. Santa Fe Corp., 331 U.S. 218, 230 (1947). The use of the doctrine has been inconsistent over the years. *See, e.g.,* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472 (2013) (holding that federal law preempted state law without mentioning the presumption against preemption). For more information about the presumption against preemption, *see* CRS Report R45825, *Federal Preemption: A Legal Primer*, by Bryan L. Adkins, Alexander H. Pepper, and Jay B. Sykes (2023).

[267] *McCuskey*, 171 F.4th at 688.

authority under the Spending Clause, the specific financial arrangement between the federal government and the states.[268]

The Fourth Circuit relied on the Supreme Court's 2005 decision in *Bates v. Dow Agrosciences LLC*, which held that the presumption against preemption applies only to instances in which the state is legislating in an "'area[] of traditional state regulation,' such as health and safety."[269] The Fourth Circuit majority reasoned that the West Virginia contract pharmacy law was not best characterized as "a traditional health-and-safety regulation," but instead as a law that regulates the pharmaceutical industry by "inject[ing] the State into 'the relationship between a federal agency and the entity it regulates.'"[270] The court said the state law does not apply to all drug manufacturers equally but rather targets those that have executed 340B PPA agreements with the government.[271]

Regarding whether the West Virginia law interfered with the Spending Clause bargain between the government and drug manufacturers, the Fourth Circuit majority observed that the 340B program was a collaboration between the state and federal governments, and thus a state law could only "supplement, rather than interfere with, the federal scheme."[272] The court concluded that the West Virginia contract pharmacy law "seeks to add conditions, uninvited, to a federal [340B] spending-power bargain" with state pharmacies.[273] For these reasons, the court said, the presumption against preemption did not apply.[274]

The Fourth Circuit majority then went on to hold that the West Virginia law was field preempted, reasoning that "the field" of preemption was specifically the 340B program's requirements; in addition, the court observed that the West Virginia law targets only manufacturers with a 340B PPA agreement and imposes restrictions on those manufacturers.[275] In this way, the court said, the law "alters the fundamental bargain" that Congress created.[276] The court also observed that the state law created an unfair element of surprise for 340B manufacturers, because "complying with myriad state 340B delivery regimes [would] introduce additional burdens 'not contemplated by Congress in enacting . . . [the 340B statute].'"[277] In addition to "hampering the spending-power bargain," the court noted that West Virginia's law would likely interfere with other aspects of the 340B program, pointing to the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County*, that HHS is the "sole enforcer" of the statute.[278] Finally, the majority agreed with the

[268] *Id.* at 688. Regarding the majority's preemption analysis as framed in Congress's authority under the Spending Clause, the dissent disagreed, arguing that "there is no binding or persuasive authority requiring a different preemption analysis for laws passed under the Spending Clause." *Id.* at 697 (Benjamin, J., dissenting).

[269] *Id*. at 688. (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005)).

[270] *Id.* at 689 (quoting Buckman Co. v. Plaintiffs' L. Comm., 531 U.S. 341, 347 (2001)).

[271] *Id.*

[272] *Id.* at 689–90.

[273] *Id.* at 690.

[274] *Id*.

[275] *Id.* at 691.

[276] *Id.* at 692. The court further stated, "Congress has ousted States from this field. Section 340B did not merely set a floor to which states may add additional obligations. Instead, Congress struck a careful bargain. Recall that Congress incentivized drug manufacturers to offer their products at discounted prices in exchange for access to the massive Medicaid market. . . . Courts have already made clear that Congress *did not* require manufacturers to distribute drugs to an unlimited number of contract pharmacies as part of the 340B program. Yet, unsatisfied with that bargain, West Virginia now seeks to add its own downsides, without offering any additional upside to compensate." *Id.* at 692 (citation omitted) (citing Sanofi Aventis U.S. LLC v. HHS, 58 F.4th 696, 703–04 (3d Cir. 2023)).

[277] *Id.* at 693 (quoting Buckman Co. v. Plaintiffs' L. Comm., 531 U.S. 341, 350 (2001)).

[278] *Id.* (citing Astra USA, Inc. v. Santa Clara County, 563 U.S. 110, 120 (2011)). The court reasoned that the state law (continued...)

district court that the state law would likely interfere with a drug manufacturer's auditing process under the statute, which ties to its ability to request alternative dispute resolution proceedings.[279] Although the majority reached the opposite conclusion as the Eighth and Fifth Circuits on the issue of preemption, the court did not distinguish any of these other precedents.[280]

Selected Legal Considerations

The potential for diverging federal circuit court opinions on the constitutionality of similar state-level 340B contract pharmacy laws could affect the ability of covered entities in different states to access 340B prices. For example, if a drug manufacturer enacted a policy that it would not honor the 340B price unless the covered entity agreed to use only one contract pharmacy, such a policy would prohibit covered entities in states without a legally effective state-level contract pharmacy regime (e.g., West Virginia) from generating 340B savings at more than one contract pharmacy.[281] However, that same drug manufacturer's policy would likely be blocked in a state that has successfully enacted and defended a legally effective state-level contract pharmacy law (e.g., Arkansas, Mississippi, or Louisiana).[282] Moreover, given the diverging decisions that have arisen among the Eighth, Fifth, and Fourth Circuits, it is also possible that the U.S. Supreme Court could intervene by granting a petition for certiorari.[283]

Litigation concerning whether state laws regulating contract pharmacies and covered entities in the 340B program are preempted by the 340B statute is likely to continue. In addition to the Eighth, Fifth, and Fourth Circuit decisions issued on the state contract pharmacy law issue so far, there are several more state contract-pharmacy-law-related appeals pending at the U.S. Court of Appeals for the Tenth Circuit (Tenth Circuit),[284] that resulted from decisions in several district courts in Colorado[285] and Oklahoma.[286] The drug companies that challenged the Oklahoma and

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was preempted because before a state official could determine whether to impose a penalty, it must decide if an offer was made under the 340B statute, which is a question left to HHS's enforcement discretion. *Id.* at 694.

[279] *Id.* In support of this assertion, the court pointed to HRSA's guidance, which provides that to audit a covered entity, a manufacturer must provide a "clear description of why it has reasonable cause to believe" that a covered entity had violated the statute. *Id.* (quoting Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406, 65410 (Dec. 12, 1996)).

[280] *Id.* at 700 (Benjamin, J., dissenting).

[281] *See id.* at 675.

[282] *See* AbbVie, Inc. v. Fitch, 152 F.4th 635 (5th Cir. 2025) (per curiam) (Mississippi); AbbVie, Inc. v. Murrill, 166 F.4th 528 (5th Cir. 2026), *opinion withdrawn and superseded on reh'g*, 180 F.4th 747 (5th Cir. 2026) (Louisiana); PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024) (Arkansas).

[283] PhRMA filed a petition for certiorari with the Supreme Court, requesting that the Court hear its appeal from the Eighth Circuit's ruling in *PhRMA v. McClain*, but the Court denied PhRMA's petition. PhRMA v. McLain, 145 S. Ct. 768 (2024) (mem.).

[284] Novartis Pharms. v. Drummond, No. 25-6182 (10th Cir. filed Nov. 13, 2025); AstraZeneca Pharms. v. Drummond, No. 25-6183 (10th Cir. filed Nov. 13, 2025); AbbVie, Inc. v. Drummond, No. 25-6184 (10th Cir. filed Nov. 13, 2025).

[285] In Colorado, three different Colorado District Court decisions denied drug manufacturers' motions for preliminary injunctions to stop the states' contract pharmacy law from taking effect. Order Denying Plaintiff's Motion for Preliminary Injunction [hereinafter *AbbVie* Order], AbbVie v. Weiser, No. 25-CV-01847 (D. Colo. Oct. 31, 2025), Dkt. No. 115; Order [hereinafter *AstraZeneca* Order], AstraZeneca Pharms. LP v. Weiser, No. 25-CV-02685 (D. Colo. Oct. 31, 2025), Dkt. No. 72; Order [hereinafter *PhRMA* Order], PhRMA v. Weiser, No. 25-CV-02437 (D. Colo. Mar. 18, 2026), Dkt. No. 65. In all three cases, the district courts were unpersuaded by the plaintiffs' arguments that the Colorado law was likely preempted by the 340B statute and federal patent law, and one district court held the state law was not a taking under the Fifth Amendment. *AstraZeneca* Order, *supra*, at 8; *AbbVie* Order, *supra*, at 13, 16, 25, 29 (rejecting plaintiff's argument that the law "effects a *per se* taking" under the Takings Clause); *PhRMA* Order, *supra*, at 14.

[286] AbbVie Inc. v. Drummond, 808 F. Supp. 3d 1266 (W.D. Okla. 2025). In Oklahoma, before the law became (continued...)

Colorado contract pharmacy laws made similar arguments to those discussed above, including that the 340B state laws are preempted by the 340B statute and that they violate the Fifth Amendment Takings Clause.[287] As of this writing, all of the cases remain pending before the Tenth Circuit.[288]

Until 2026, the United States had not taken a position in any of the lawsuits concerning state contract pharmacy laws. In February 2026, the U.S. Department of Justice filed an *amicus* brief in support of AbbVie in its appeal before the Tenth Circuit.[289] In its brief, the government argued that Colorado's 340B law imposes additional conditions on drug manufacturers' participation in 340B and is thus preempted.[290] The government also argued that if states are permitted to enact such laws, they risk disincentivizing drug manufacturers from participating in the Medicare and Medicaid programs.[291]

Congress always has the option of retaining the existing federal framework, allowing the judiciary to adjudicate ambiguities. If Congress seeks to alter potential outcomes of the pending litigation, it has a variety of legislative options. For example, it could amend the 340B statute to expressly preempt states from enacting laws that affect the 340B program, or it could amend the statute to expressly allow states to create such laws. Alternatively, Congress could sidestep the question of state law preemption altogether and amend the statute to clarify how many contract pharmacies a covered entity could use or what kinds of restrictions, if any, manufacturers may place on their offers to sell 340B drugs to covered entities. Congress could also amend the statute to give HRSA additional rulemaking authority, which the agency could use to clarify the parameters of the 340B program and obviate state-level "protection" laws.

State Laws Regulating Pharmacy Benefit Managers

Pharmacy Benefit Managers and State Regulation

PBMs are organizations that facilitate the purchase of drugs through the U.S. pharmaceutical distribution and payment chains.[292] Serving as intermediaries between health care payers,[293] drug manufacturers, and pharmacies, PBMs may negotiate prescription drug prices with manufacturers, design and manage drug formularies, administer prescription drug benefits, and

effective, the district court issued a ruling granting the drug manufacturers' request for a preliminary injunction, finding that the plaintiffs were likely to succeed on the merits of their claim because the state law was preempted by the 340B statute and constituted a taking for purposes of the Fifth Amendment. *Id.* at 1274–80.

[287] *AbbVie, Inc*, 808 F. Supp. 3d 1266. As is the case with the other state laws, a group of drug manufacturers (AbbVie, AstraZeneca, and Novartis) sued the State of Oklahoma after the legislature enacted, over the governor's veto, a 340B contract pharmacy law, which was scheduled to take effect on November 1, 2025. *Id*.

[288] *Novartis Pharms*., No. 25-6182 (10th Cir. filed Nov. 13, 2025); *AstraZeneca Pharms*., No. 25-6183 (10th Cir. filed Nov. 13, 2025); *AbbVie, Inc*., No. 25-6184 (10th Cir. filed Nov. 13, 2025); AstraZeneca Pharms. v. Weiser, No. 25-1466 (10th Cir. filed Dec. 22, 2025); AbbVie, Inc. v. Weiser, No. 26-1244 (10th Cir. filed June 25, 2026); PhRMA v. Weiser, No. 26-1086 (10th Cir. filed Mar. 20, 2026).

[289] Brief for the United States as Amicus Curiae in Support of Appellants, AbbVie v. Weiser, No. 25-1439 (10th Cir. Feb. 25, 2026), Dkt. No. 32. As of the date of this writing, the government has not filed a similar brief in support of plaintiffs AstraZeneca or PhRMA in their appeals before the Tenth Circuit.

[290] *Id.* at 11.

[291] *Id.* at 16.

[292] *See generally* Meredith Freed et al., *What to Know About Pharmacy Benefit Managers (PBMs) and Federal Efforts at Regulation*, KFF (Feb. 9, 2026), https://www.kff.org/other-health/what-to-know-about-pharmacy-benefit-managers-pbms-and-federal-efforts-at-regulation [https://perma.cc/YJM9-MDTJ] (discussing PBM business practices).

[293] As used here, health care payers include private health insurance plans or government health programs such as Medicare Part D or Medicaid.

contract with pharmacies to dispense drugs to health plan enrollees.[294] Beginning around 2017, federal and state lawmakers have scrutinized PBMs and their practices, examining issues such as the impacts that PBMs—and the means by which they generate revenue—may have on prescription drug coverage, pricing, and pharmacy reimbursement.[295]

Relying on traditional powers to regulate health, safety, and other matters, states have established requirements related to PBMs, and these laws vary in nature and scope.[296] State laws address, for example, required information disclosure or reporting, the structure of PBM revenue, and the elements of agreements between PBMs and pharmacies.[297] As states have enacted such measures in an effort to address certain concerns raised by PBMs' roles and functions in the pharmaceutical marketplace, PBMs, their advocates, and other parties have challenged the validity of several state measures, commonly on the basis that such measures are preempted by the Employee Retirement Income Security Act (ERISA).[298]

ERISA Preemption

ERISA is a key federal law that regulates employee benefit plans, including health and retirement plans, offered by private-sector employers.[299] Under ERISA, health plans must comply with various standards, including plan fiduciary standards, reporting and disclosure requirements, and numerous private health insurance market standards established by the Patient Protection and Affordable Care Act and other federal laws.[300] Department of Labor reports from 2026 estimate that there are roughly 2.8 million ERISA-regulated health plans nationwide that cover 135 million plan participants and their families.[301]

According to the Supreme Court, Congress, through ERISA, federalized the regulation of employee benefit plan administration "to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government."[302] This goal is carried out in part through a critical feature of ERISA: its express preemption clause at Section 514(a) in Title I of ERISA.[303] This express preemption clause

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[294] *See* Carrie LeBlanc Jones, *The Role and Regulation of Pharmacy Benefit Managers: A Legal Perspective from Louisiana*, 73 LA. BAR J. 86 (2025).

[295] *See, e.g.*, *State Action on Pharmacy Benefit Managers (PBMs) to Address Prescription Drug Pricing*, NAT'L ACAD. FOR STATE HEALTH POL'Y (July 24, 2023), https://nashp.org/state-action-on-pharmacy-benefits-managers-pbms-to-address-prescription-drug-pricing/ [https://perma.cc/XQ84-SE25] (providing an overview of states' oversight of PBMs in various contexts).

[296] *See State Pharmacy Benefit Manager Legislation*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Mar. 10, 2026), https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/ [https://perma.cc/C4AD-W93K].

[297] *See id*.

[298] *See, e.g.,* Rutledge v. Pharm. Care Mgmt. Ass'n (PCMA), 592 U.S. 80 (2020); *see generally* Allison Garcia, *ERISA Preemption and State PBM Reform: Navigating the Balance of Power*, 35 ANNALS HEALTH L. ADVANCE DIRECTIVE 168 (2025) (discussing ERISA preemption jurisprudence and state PBM regulation). Additionally, plaintiffs have challenged state PBM laws on a variety of other grounds, including preemption under the Medicare Part D statute. *See, e.g.,* PCMA v. Wehbi, 18 F.4th 956 (8th Cir. 2021); *see also* 42 U.S.C. § 1395w-112(g) (incorporating *id.* § 1395w-26(b)(3)). Discussion of these additional claims is beyond the scope of this report.

[299] *See* ERISA, Pub. L. No. 93-406, 88 Stat. 829 (1974) (codified as amended at 29 U.S.C. §§ 1001–1461).

[300] For more information about ERISA's requirements, see CRS Report R48470, *ERISA: Legal Framework and Recent Supreme Court Litigation*, by Jennifer A. Staman (2025).

[301] DEP'T OF LAB., 2026 REPORT TO CONGRESS: ANNUAL REPORT ON SELF-INSURED GROUP HEALTH PLANS n.7 (2026), https://beta.dol.gov/research-data/report/2026-report-congress-annual-report-self-insured-group-health-plans#f7 [https://perma.cc/B73C-MDHM].

[302] *See* Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990).

[303] *See id.*; *see* § 514(a), 88 Stat. at 897.

broadly preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[304]

In numerous opinions, the Supreme Court has interpreted the "relate to" language as applying to any state law that "has a connection with or reference to such a plan."[305] The Court has observed that a state law has an impermissible "connection with" an ERISA plan if it "governs . . . a central matter of plan administration," or "interferes with nationally uniform plan administration."[306] A state law has a "reference to" an ERISA plan if it acts "immediately and exclusively" on ERISA plans, or if the existence of such a plan is essential to the law's operations.[307] Pursuant to this clause, ERISA may supersede state laws that, for example, aim to regulate plan benefits, or the administration, operation, or structure of employee benefit plans.[308]

The Supreme Court's 2016 decision in *Gobeille v. Liberty Mutual Insurance Co*. illustrates how ERISA's express preemption provision can limit state efforts to enact health care regulatory initiatives.[309] In *Gobeille*, the Court examined a Vermont law that required health insurers—including employer-sponsored health plans governed by ERISA—and other entities that provide and pay for health care services to report health care claims information for inclusion in an all-payer claims database.[310] In a 6-2 decision, the Supreme Court concluded that Vermont's reporting law was preempted to the extent it applied to ERISA plans.[311] Citing ERISA's extensive reporting, disclosure, and recordkeeping requirements, the Court held that Vermont's reporting regime "imposes duties that are inconsistent with the central design of ERISA, which is to provide a single uniform national scheme for the administration of ERISA plans without interference from laws of the several States."[312] Even though the Vermont law's objective was to improve health care costs and outcomes, not to regulate employee benefit plan reporting, the Court's majority reasoned the state law's reporting scheme had the effect of a "direct regulation of a fundamental ERISA function," and that any difference in purpose did not convert this regulation "into an innocuous and peripheral set of additional rules."[313]

Despite ERISA Section 514(a)'s broad scope, the Supreme Court has articulated that "[s]ome state actions may affect employee benefit plans in too tenuous, remote, or peripheral a manner to warrant a finding that the law 'relates to' the plan."[314] For instance, in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co*., insurance companies providing health coverage to ERISA-governed plans challenged a state law that required patients with such coverage to be subject to a hospital surcharge that did not apply to patients covered by Blue Cross

[304] 29 U.S.C. § 1144(a).

[305] *See, e.g*., *Rutledge*, 592 U.S. 80 at 86 (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 147 (2001)).

[306] *Egelhoff*, 532 U.S. at 148.

[307] *See* Cal. Div. of Lab. Standards Enf't v. Dillingham Constr., 519 U.S. 316, 325 (1997).

[308] *See, e.g*., Soehnlen v. Fleet Owners Ins. Fund, 844 F.3d 576, 589 (6th Cir. 2016) (ERISA preempts state laws that, among other things, "mandate employee benefit structures or their administration" or "bind employers or plan administrators to particular choices or preclude uniform administrative practice, thereby functioning as a regulation of an ERISA plan itself." (quoting Penny/Ohlmann/Nieman, Inc. v. Miami Valley Pension Corp., 399 F.3d 692, 698 (6th Cir. 2005))).

[309] *See* Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312 (2016).

[310] *Id.* All-payer claims database data can generally be used by researchers to study the cost, use, and quality of health care within a state. *See id*. at 315.

[311] *Id.* at 326–27.

[312] *Id.* at 326.

[313] *Id.* at 325.

[314] Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 100 n.21 (1982).

& Blue Shield, Medicaid, and certain other coverage arrangements.[315] Although the state law triggered higher costs for ERISA plans, the Court upheld the law, concluding it had an "indirect economic influence" that did not bind administrators to particular choices with respect to a plan.[316] In the wake of *Gobeille*, *Travelers*, and other cases, lower courts have grappled with applying the Court's ERISA precedent and determining whether state legislation survives ERISA preemption, including in the context of state PBM laws.

Supreme Court Upholds Arkansas PBM Law: Rutledge v. Pharmaceutical Care Management Association (PCMA)

PBM advocates and others have filed several legal challenges to state PBM laws, alleging ERISA preempts such laws because they have a direct regulatory effect on ERISA plan design and how plans manage drug benefits. In 2020, the Supreme Court addressed the interplay between one state's PBM law and ERISA preemption in *Rutledge v. PCMA*.[317] At issue in *Rutledge* was an Arkansas statute with mechanisms designed to anchor PBM pharmacy reimbursement rates to pharmacies' drug acquisition costs, to address "concerns that the reimbursement rates set by PBMs were often too low to cover pharmacies' costs."[318] A PBM trade association sued the state, claiming, among other things, that ERISA preempted the Arkansas state law as it applied to PBMs that provide drug benefit services to ERISA plans.[319]

In rejecting the trade association's claims and concluding that ERISA does not preempt Arkansas's PBM law, the Supreme Court employed the Court's traditional test for ERISA preemption: whether the state law has "a connection with or reference to" an ERISA plan.[320] In discussing why the Arkansas law lacked a prohibited "connection with" an ERISA plan, the Court explained that ERISA is "primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways," such as requiring payment for a specific benefit.[321] Relying on *Travelers*, the Court maintained that ERISA does not preempt state requirements that "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage."[322] However, the Court also recognized limits on this flexibility and generally explained that state laws cannot compel ERISA plans to offer a certain type of coverage or administer benefits in a particular manner.[323] The Court further concluded that the Arkansas law did not impermissibly "refer to" ERISA plans because ERISA plans are unrelated to the state law's operation—the law applies to PBMs regardless of whether they manage ERISA plans or not.[324]

Litigation After *Rutledge* Shows Mixed Results

Following *Rutledge*, lower courts have examined ERISA preemption challenges to a variety of state PBM laws, with mixed results. For instance, in *PCMA v. Wehbi*, the Eighth Circuit

[315] N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co, 514 U.S. 645 (1995).

[316] *See id*. at 659–60.

[317] Rutledge v. PCMA, 592 U.S. 80 (2020).

[318] *See id.* at 83–85; 2015 Ark. Acts 900.

[319] *Rutledge*, 592 U.S. at 85.

[320] *Id.* at 86 (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 147 (2001)).

[321] *Id.* at 86–88.

[322] *Id*. at 88 (citing N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co, 514 U.S. 645, 668 (1995)).

[323] *Id.* at 89.

[324] *See id.* at 88–89.

concluded that ERISA did not preempt North Dakota provisions that required PBMs to take certain actions (for instance, provide particular information to health plan sponsors upon request), and to refrain from engaging in certain arrangements (such as those preventing pharmacies from charging a fee for mailing or delivering prescriptions, or those requiring pharmacies to satisfy accreditation standards more stringent than those imposed by North Dakota law).[325] Citing *Rutledge* and other cases, the Eighth Circuit concluded that the state provisions failed the "connection with" test for ERISA preemption, as they generally constituted, "at most, regulation of . . . noncentral 'matter[s] of plan administration' with *de minimis* economic effects and impact on the uniformity of plan administration across states."[326] The Eighth Circuit also indicated that the state laws failed the "reference to" test, as the state provisions applied to PBMs "not only insofar as they administer ERISA plans but also insofar as they administer non-ERISA plans."[327]

In a case with a similar outcome, *Central States Southeast and Southwest Areas Health and Welfare Fund v. McClain*, a multiemployer health plan sued Arkansas's insurance commissioner, alleging that ERISA preempted a state insurance rule that could require PBMs, in connection with ERISA-governed health plans and other entities, to report to the commissioner certain pharmacy compensation information and pay certain dispensing fees to pharmacies as part of drug benefit plan operation (in an effort to foster fair and reasonable pharmacy reimbursement rates).[328] Plaintiffs argued that ERISA preempted the rule because it constituted direct regulation of ERISA health plans, and interfered with key aspects of plan design and administration.[329] Citing *Rutledge*, the Seventh Circuit held that plaintiffs failed to allege a credible ERISA preemption claim, expressing that the dispensing fee requirement "'regulates' only in the manner the Supreme Court blessed in *Rutledge*: cost."[330] While the appeals court acknowledged that the ERISA preemption question related to the compensation reporting requirement presented a "closer call," given the Supreme Court's holding in *Gobeille* (in which the Court held that ERISA preempted a state reporting law), the appeals court explained that the Arkansas reporting requirement served to support the overall purpose of the state statute and facilitated its enforcement.[331] The court expressed, in part, that "*Gobeille's* language is broad, but we must read it in light of the Court's later holding in *Rutledge*. We reject that *Rutledge* blessed 'cost regulations' like the Dispensing Fee Requirement only for *Gobeille* to make it impossible for Arkansas to enforce such a regulation."[332]

By comparison, in *PCMA v. Mulready*, the Tenth Circuit concluded that ERISA largely preempted Oklahoma's PBM requirements that govern financial arrangements between PBMs and pharmacies, as applied to ERISA plans.[333] Among other requirements, the state laws at issue—aimed at addressing "the sway [PBMs] hold over independent pharmacies"—generally restricted PBMs from using certain discounts to encourage insured individuals to use preferred, in-network pharmacies, and compelled PBMs to design networks so that a certain percentage of covered

[325] PCMA v. Wehbi, 18 F.4th 956, 964–70 (8th Cir. 2021).

[326] *Id*. at 968–69.

[327] *Id*. at 969–70.

[328] Complaint for Declaratory Judgment and Other Relief, Cent. States, Se. & Sw. Areas Health & Welfare Fund v. McClain, No. 25-CV-03938 (N.D. Ill. Apr. 11, 2025), Dkt. No. 1.

[329] *Id.* at 13.

[330] Cent. States Se. & Sw. Areas Health & Welfare Fund v. McClain, No. 25-2727, 2026 WL 2510865 at *1–4 (7th Cir. Aug. 26, 2026).

[331] *See id*. at *5–6.

[332] *Id.* at *6.

[333] *See* PCMA v. Mulready, 78 F.4th 1183 (10th Cir. 2023), *cert denied*, 145 S. Ct. 2843 (2025) (mem.),

individuals live within a set distance from a participating brick-and-mortar pharmacy.[334] Additionally, the state law included an "any willing provider" provision, which required PBMs to allow any pharmacy willing to accept a PBM's terms and conditions in its preferred pharmacy network.[335]

In its opinion, the Tenth Circuit reasoned that the Oklahoma laws "effectively abolish[ed] the two-tiered network structure" by preventing PBMs from contracting only with certain pharmacies (e.g., mail-order pharmacies) as a means of controlling costs.[336] The appeals court further explained that the network requirements as applied to ERISA plans were "quintessential state laws that mandate benefit structures," and thus, forbidden by the Act.[337] The appeals court also distinguished the Oklahoma laws from those at issue in *Rutledge*, noting that not only did the Oklahoma laws impose higher costs on PBMs, they also prevented PBMs from offering plans with certain network designs.[338] Subsequently, Oklahoma's Attorney General filed a petition for Supreme Court review, and the Court declined to review the case.[339]

In *McKee Foods Corp. v. BFP Inc.*, the U.S. Court of Appeals for the Sixth Circuit (Sixth Circuit) examined whether ERISA preempts Tennessee requirements generally aimed at barring PBMs from incentivizing patients to use PBM-managed pharmacies (in an effort to protect small, rural pharmacies in the state).[340] The state provisions at issue restricted PBMs and others, as part of their pharmacy benefit contracts, from compelling plan participants to pay certain higher out-of-pocket costs when obtaining prescriptions, or interfering with a patient's choice of pharmacy, including through the use of financial or other incentives.[341] Additionally, similar to the Oklahoma laws at issue in *Mulready*, one of the challenged Tennessee requirements directed PBMs to allow any pharmacy willing to accept a PBM's terms and conditions to participate in its preferred pharmacy networks.[342]

In affirming a district court's decision that ERISA preempted the Tennessee provisions, the Sixth Circuit expressed that the state provisions governing out-of-pocket costs and other financial incentives impermissibly restricted ERISA plans' cost-sharing arrangements for in-network pharmacies—"an important facet of pharmacy network structure."[343] The appeals court also indicated that the any-willing provider requirements compelled ERISA plans to adopt a specific benefit structure by impeding their ability to establish a limited pharmacy network, thus triggering ERISA preemption.[344]

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[334] *Id.* at 1190–91; OKLA. STAT. tit. 36, § 6963(E) (2024); *id.* § 6961(A)–(B); *see also* Flowers v. Caremark PCS Health, LLC, 180 F.4th 1084, 1091 (8th Cir. 2026), in which the Eighth Circuit affirmed a district court's motion to dismiss an ERISA preemption challenge related to certain Arkansas PBM requirements. As part of its opinion, the appeals court expressed that ERISA superseded state "geographic coverage requirements" that direct PBMs to ensure that a specified minimum percentage of plan members live within a certain distance from a retail community pharmacy. *See id*. The appeals court distinguished the Arkansas geographic coverage requirements from the North Dakota laws at issue in *Wehbi,* generally explaining that the Arkansas laws had a more profound impact on ERISA plan administration. *See id.* at 1089–90.

[335] *See* OKLA. STAT. tit. 36, § 6962(B)(4) (2024).

[336] *PCMA*, 78 F.4th at 1199.

[337] *Id*.

[338] *Id*. at 1199–1200.

[339] Mulready v. PCMA, 145 S. Ct. 2843 (2025) (mem.).

[340] McKee Foods Corp. v. BFP Inc., 173 F.4th 242, 252–53 (6th Cir. 2026).

[341] *See id*.

[342] *See id.* at 263–64.

[343] *See id.* at 267.

[344] *See id*.

Several other cases challenging state PBM laws on ERISA preemption grounds are pending before federal district and appellate courts. Cases include the following:

Iowa Ass'n of Business and Industry (ABI) v. Iowa Commissioner of Insurance

In June 2025, the State of Iowa enacted Senate File 383, targeting "PBM practices that harm both patients and independent pharmacies."[345] The state act created several new requirements for PBMs and other parties, including requirements related to pharmacy network participation, and PBM financial arrangements and reimbursement amounts (for instance, a requirement to pass through negotiated rebates from drug manufacturers to health plans). In *ABI*, an Iowa business association, ERISA plans, and plan sponsors sued the state's insurance commissioner, asserting in part that ERISA preempted various provisions of Senate File 383.[346] In July 2025, the U.S. District Court for the Southern District of Iowa determined that "several provisions [of the Act] impermissibly dictate the structure and administration of employee benefit plans by mandating network compositions, cost-sharing arrangements, and contractual terms that ERISA reserves to plan sponsors and fiduciaries," and the court granted a preliminary injunction in the case.[347] Parties to the litigation appealed this judgment, and the appeal is pending in the Eighth Circuit.[348]

ERISA Industry Committee (ERIC) v. Minnesota Department of Commerce

In *ERIC*, a nonprofit trade association representing multistate employers and labor union representatives, as well as other plaintiffs, filed suit to challenge a Minnesota act that generally prohibits PBMs and affiliated plans from using financial incentives to encourage patients to use certain PBM-affiliated pharmacies.[349] The law also restricts PBMs and affiliate plans from imposing certain limits on medication access if there are certain ownership interests between the PBM and the pharmacy.[350] Plaintiffs allege that the state provisions are preempted by ERISA and are unlawful on other grounds.[351] The case is pending before the U.S. District Court for the District of Minnesota.

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[345] Letter from Kim Reynolds, Governor of Iowa, to Paul Pate, Sec'y. of State of Iowa (June 11, 2025), https://www.legis.iowa.gov/docs/publications/LGE/91/Attachments/SF383_GovLetter.pdf [https://perma.cc/B9AV-Q69J].

[346] Complaint for Injunctive and Declaratory Relief, ABI v. Iowa Comm'r of Ins., No. 25-CV-00211 (S.D. Iowa June 23, 2025), Dkt. No. 1.

[347] ABI v. Ommen, 799 F. Supp. 3d 795, 859 (S.D. Iowa 2025). Plaintiff PBMs and other parties have filed at least two other lawsuits challenging Senate File 383 on ERISA preemption and First Amendment grounds. *See* Order on Stipulated Preliminary Injunction, Optumrx, Inc. v. Ommen, No. 25-CV-00452 (S.D. Iowa Jan. 6, 2026), Dkt. No. 14 (stipulated injunction pending disposition of appeal and cross-appeal in *ABI* case); Stipulated Injunction, Wellmark Inc. v. Ommen, No. 25-CV-00377 (S.D. Iowa Oct. 29, 2026), Dkt. No. 9 (same).

[348] ABI v. Ommen, No. 25-2591 (8th Cir. filed Aug. 12, 2025).

[349] *See* Complaint for Injunctive and Declaratory Relief [hereinafter *ERIC* Complaint], ERIC v. Minn. Dep't of Com., No. 24-cv-04639 (D. Minn. Dec. 27, 2024), Dkt. No. 1; MINN. STAT. § 62W.03 (2026).

[350] *See* MINN. STAT. § 62W.07 (2026). *See also* Express Scripts, Inc. v. Richmond, No. 25-CV-00520, 2025 WL 2111057 (E.D. Ark. July 28, 2025) (a legal challenge to Arkansas Act 624, which includes restrictions on PBM ownership of pharmacies). The U.S. District Court for the Eastern District of Arkansas granted a preliminary injunction in *Express Scripts* because the court determined that plaintiffs were likely to prevail on their claims that the Act violated the dormant commerce clause and were preempted by the TRICARE statute. *See id*. at *23. The preliminary injunction has been appealed to the Eighth Circuit. Express Scripts, Inc. v. Richmond, No. 25-2529 (8th Cir. filed Aug. 5, 2025).

[351] *See ERIC* Complaint, *supra* note 349, at 28–29.

PCMA v. Bonta

The *Bonta* case concerns a California provision that imposes fiduciary duty on PBMs with respect to ERISA plans.[352] The state provision specifies that PBMs have "a duty to be fair and truthful toward the client, to act in the client's best interests, to avoid conflicts of interest, and to perform its duties with care, skill, prudence, and diligence."[353] PCMA sued the Attorney General of the State of California, claiming, among other things, that the state law impermissibly singles out ERISA plans for regulation, conflicts with ERISA's scheme for regulating plan fiduciaries, and directs plans to structure benefits in a particular way, by compelling plans to consider PBM's fiduciary responsibilities in designing and administering the plan.[354] In July 2026, the U.S. District Court for the Central District of California granted California's motion to dismiss the complaint, holding that PCMA lacked standing to sue, as the trade organization failed to allege sufficient facts to demonstrate that its members suffered an injury caused by the California law.[355] The district court allowed PCMA to file an amended complaint in the case, and the lawsuit is pending before the district court.[356]

Selected Legal Considerations

In *Rutledge*, the Supreme Court concluded that state PBM laws may avoid ERISA preemption even if the laws indirectly affect costs or alter incentives for providing benefits in ERISA-governed plans.[357] However, the Court recognized limits on this flexibility: the state requirement at issue cannot compel plans to offer a certain type of coverage or administer benefits in a particular manner.[358] The question of which state PBM laws permissibly regulate health care costs for plans, and which ones impermissibly "dictate plan choices" remain the subject of active litigation.[359] As courts continue to examine an array of different state PBM laws, it appears that some of the laws most susceptible to ERISA preemption challenges thus far may be state any-willing-pharmacy laws and other provisions aimed at addressing the structure or composition PBM pharmacy networks.

Additionally, as litigation over state PBM laws proceeds, courts may examine ERISA's so-called "savings clause" in determining whether a state PBM law survives ERISA preemption. There are exceptions to ERISA's express preemption provision, including an exception for state laws that "regulate insurance."[360] This savings clause permits states to regulate health insurance matters offered *through* ERISA-governed plans without running afoul of ERISA's preemptive scheme, but not the plans themselves.[361] Application of the savings clause is cabined by ERISA's "deemer clause," which generally provides that a state law that "purport[s] to regulate insurance" cannot deem an employee benefit plan to be an insurance company for purposes of regulation.[362] In interpreting this provision, the Supreme Court has held that a common type of health plan, a self-

[352] PCMA v. Bonta, No. 26-cv-00012 (C.D. Cal. filed Jan 2, 2026).

[353] CAL. BUS. & PROF. CODE § 4441(c)(2) (West 2026).

[354] *See* Complaint, *Bonta*, No. 26-cv-00012 (C.D. Cal. Jan. 2, 2026), Dkt. No. 1.

[355] PCMA v. Bonta, No. 26-CV-00012, 2026 WL 2138551, at *5 (C.D. Cal. July 24, 2026).

[356] *See* Second Amended Complaint, *PCMA*, No. 26-CV-00012 (C.D. Cal. Aug. 14, 2026), Dkt. No. 39.

[357] *See Rutledge*, 592 U.S. at 88–89.

[358] *Id*. at 89.

[359] *See id*. at 88.

[360] 29 U.S.C. § 1144(b)(2)(A).

[361] *See id*.

[362] *Id.* § 1144(b)(2)(B); *see also* Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724, 733 (1985) (discussing ERISA's savings clause and deemer clause).

insured health plan,[363] cannot be "deemed" an insured plan for the purpose of state regulation.[364] As a result, an employee benefit plan that provides health benefits through an insurance company can, in effect, be regulated by state insurance law as well as ERISA. On the other hand, a plan that is self-insured may only be subject to ERISA's requirements. In the context of ERISA preemption challenges to state PBM laws, some parties have argued that at least some types of state laws may escape ERISA preemption, because the laws constitute the "regulation of insurance" under ERISA's savings clause.[365] However, there may be limits to the application of this argument, particularly with respect to self-insured plans. While ERISA's savings clause has not been analyzed as part of the holding in the cases discussed in this report,[366] this issue may be evaluated in pending or future cases.[367]

It is also possible that recently enacted federal legislation governing PBMs may impact the ongoing litigation. On February 3, 2026, Congress passed the Consolidated Appropriations Act, 2026 (CAA 2026), which includes new provisions governing ERISA plans and their arrangements with PBMs.[368] Effective for plan years beginning in August 2028, these new provisions generally require entities providing PBM services to report specified information to employment-based health plans (and insurers offering such coverage) regarding a range of prescription drug coverage and pricing metrics.[369]Additionally, as part of arrangements with ERISA health plans and insurers offering health plan coverage, entities providing PBM services must remit to the health plan or insurer any rebates and other compensation received from drug manufacturers, distributors, or other applicable entities "related to utilization of drugs or drug spending" under the given plan.[370]

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[363] Under self-funded (or self-insured) plans, instead of using health insurance (i.e., where an employer pays a premium to an insurer to cover the claims of plan participants), an employer acts as the insurer itself and pays the health care claims of the plan participants. While self-insured plans may use an insurance company or other third party to administer the plan, the employer bears the risk associated with offering health benefits. *See Self-insured Plan*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/self-insured-plan/ [https://perma.cc/XA4S-LQQQ] (last visited June 30, 2026).

[364] FMC Corp. v. Holliday, 498 U.S. 52 (1990); *see also* DEP'T OF LAB., *supra* note 301 (annual report containing information on self-insured health plans and financial information of employers that sponsor such plans).

[365] *See, e.g.*, Brief for the United States as Amici Curiae Supporting Neither Party Urging Affirmance in Part and Reversal in Part, PCMA v. Mulready, No. 22-6074 (10th Cir. Apr. 10, 2023) (Solicitor General expressed the position that ERISA preempted Oklahoma's pharmacy network requirements, but the requirements were largely exempted from preemption under ERISA's savings clause for insurance).

[366] In *McKee Foods*, the Sixth Circuit explained that because the state insurance commissioner and the district court did not analyze whether ERISA's savings clause applied to the Tennessee PBM laws at issue, the argument was forfeited. *See* McKee Foods Corp. v. BFP Inc., 173 F.4th 242, 268 (6th Cir. 2026). However, the appeals court briefly spoke to ERISA's savings and deemer clauses, expressing generally that because the Tennessee provisions defined PBMs to include ERISA plans themselves, the savings clause was inapplicable, and because of the deemer clause, ERISA supplanted the state laws. *See id*. at 268–69.

[367] Analysis of ERISA's savings clause may be particularly relevant for state any-willing-pharmacy laws. The Supreme Court examined any-willing-provider laws and ERISA's preemptive scheme in *Kentucky Association of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003). In that case, the Court found that Kentucky's any-willing-provider laws, which prohibited insurers from discriminating against a health care provider willing to meet the insurer's criteria for participation in the health plan, were saved from ERISA preemption under the savings clause. *Id*. at 357–63, 372.

[368] *See* CAA 2026, Pub. L. No. 119-75, §§ 6701–6702, 140 Stat. 173, 703–37. Additionally, months prior to the enactment of CAA 2026, the Department of Labor issued a proposed rule that would require providers of PBM services and their affiliated providers of brokerage and consulting services to disclose specified information about their compensation to fiduciaries of self-insured ERISA health plans. *See* Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure, 91 Fed. Reg. 4348 (Jan. 30, 2026). It remains to be seen whether the Department of Labor will reissue a new proposed rule or take other action based on the more comprehensive disclosure requirements in CAA 2026.

[369] Pub. L. No. 119-75 § 6701, 140 Stat. at 703.

[370] *Id*. § 6702, 140 Stat. at 733.

As discussed above, in cases such as *Gobeille*, the Supreme Court concluded that ERISA preempts state provisions that constitute regulation of a "fundamental . . . function" of the federal Act. Given that the new CAA 2026 provisions expand ERISA's reach over PBMs and their relationship with ERISA plans, this expansion of relevant federal requirements may raise questions as to whether ERISA more broadly preempts state PBM laws, on the basis that such laws interfere with a "core function" of ERISA.[371] Analysis of such questions by courts, however, will likely entail context-specific review of specific state laws relative to applicable federal requirements.

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[371] *See generally*, Cent. States Se. & Sw. Areas Health & Welfare Fund v. McClain, No. 25-2727, 2026 WL 2510865 at *6 (Seventh Circuit mentions new federal PBM-related requirements and indicates that "these new requirements, once in effect, may change our preemption analysis" related to an Arkansas state law impacting PBMs).