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States Lead The Way On Drug Pricing Reform

By **Deborah Gardner and Scott Falin** (February 12, 2020)

Deborah Gardner

Scott Falin

While prescription drug costs remain a major concern of American voters,[1] the public debate has focused largely on federal initiatives. The Trump administration has made drug pricing a centerpiece of its health care agenda, and key congressional leaders from both parties have introduced competing legislation.[2] However, thus far, few consequential policies have been implemented at the federal level.[3]

A different picture emerges at the state level where, over the past few years, state governors and legislatures have been quietly leading the charge on drug pricing initiatives. In 2019 alone, state legislators introduced roughly 300 drug pricing bills, and 37 states enacted at least one such bill.[4] State drug pricing laws take a variety of forms, ranging from importation to rate setting to price transparency.

While states have pressed forward with creative and targeted initiatives aimed at reducing drug costs, constitutional and federal authority often impedes their ability to implement fully the reforms they seek. This article will examine various state efforts to control drug prices and the constitutional and federal limits on those reforms.

State Efforts to Regulate Drug Prices and Industry Challenges

States seeking to lower drug prices within the state most directly have sought to regulate what drug manufacturers may lawfully charge within state borders. States' authority to directly regulate prescription drug prices, however, is limited by constitutional theories of federal preemption and the dormant commerce clause.

Brand Drug Price Controls Confront Federal Preemption Challenges

One impediment to state drug pricing initiatives has been the Constitution's supremacy clause and the concept of federal preemption. A legal challenge to a District of Columbia law is illustrative. In 2005, the district enacted a law that prohibited manufacturers from charging an excessive price for patented prescription drugs.[5]

The Pharmaceutical Research and Manufacturers of America and the Biotechnology Innovation Organization sued the district, arguing that the district's law created a conflict with federal patent law and, therefore, was preempted under the supremacy clause of the Constitution.[6] The supremacy clause establishes that federal constitutional and statutory laws take precedence over state laws.[7]

The plaintiffs asserted that under federal patent law, holders of patents are entitled not only to the "exclusive right to use and sell a patented product," but also to "the right to sell the product at the market price that exclusivity permits."[8]

They claimed that by limiting the price drug makers could set for patented products, the district's excessive price legislation "stands as an obstacle to the accomplishment and execution of Congress's objectives in the patent system."[9] When state laws conflict with, or thwart the purpose of, federal laws, the Constitution's supremacy clause requires that the state law yield to the federal law.

The Federal Circuit agreed with the plaintiffs and invalidated the statute.[10] The court noted that through federal patent law, Congress seeks to incentivize innovation by providing the patent holder with the right to higher profits during a certain period of exclusivity.[11]

By limiting the right of patent holders to charge the prices they desire during the period of exclusivity, the district's statute would diminish the value of a patent, as determined by Congress. Since the district effectively sought "to change federal patent policy within its borders," the Federal Circuit concluded that the district's law would frustrate the purposes of federal patent law.[12]

Generic Drug Price Controls Meet Dormant Commerce Clause Challenges

State reforms also have encountered constitutional challenges under the commerce clause.[13] In 2017, the Maryland legislature enacted a statute that prohibited "unconscionable increase[s]" in the prices for essential off-patent or generic drugs.[14] Maryland excluded patented drugs from the law's scope to avoid the federal preemption issues that had doomed the district's price regulation statute. This time, however, the generic drug industry association sued, challenging the law under the dormant commerce clause.[15]

The commerce clause expressly grants Congress the authority to regulate interstate commerce and, under U.S. Supreme Court precedent, implicitly prohibits states from enacting laws that improperly interfere with interstate commerce.[16] State laws run afoul of this dormant restraint when they discriminate against out-of-state commerce, unduly burden interstate commerce, or regulate wholly out-of-state (i.e., extraterritorial) activity.[17]

In April 2018, the U.S. Court of Appeals for the Fourth Circuit struck down Maryland's law as unconstitutional.[18] Under Maryland's statute, the lawfulness of a generic drug price increase would have been determined by, among other things, the drug's list price (i.e., its wholesale acquisition cost), rather than the retail price that the Maryland consumer ultimately pays.[19]

List prices primarily affect upstream sales (e.g., between a manufacturer and a wholesaler). Since these upstream sales occur almost exclusively outside of Maryland, the Fourth Circuit held that the law operated as an upstream price control that impermissibly regulated out-of-state conduct.[20]

According to the court, the law also violated the dormant commerce clause by interfering with interstate commerce. The circuit court reasoned that the law could substantially burden interstate commerce by forcing drug manufacturers to enter into separate contracts with wholesalers and distributors at different upstream prices depending on the state to which the drugs ultimately would be distributed.[21]

Upper Payment Limits on Drug Prices May Face Constitutional Challenges

In light of the federal courts' hostility towards the district and Maryland's laws regulating the

prices manufacturers charge, states recently have explored a novel approach that instead would regulate what purchasers can pay for drugs within the state. Inspired by model legislation drafted by the National Academy for State Health Policy,[22] nine states in 2019 introduced bills that would vest a drug affordability review board with the power to set an upper payment limit on what purchasers can pay for certain high-priced drugs within the state.[23]

For example, under NASHP's model bill, the upper payment limit would apply to drug purchases by all state programs, local governments, state-licensed commercial health plans, and state-licensed pharmacies, among others.[24] The proposal borrows from state public utility commission approaches as well as Maryland's long-standing, all-payor rate-setting model for hospital services, whereby a commission sets reimbursement rates for inpatient and outpatient hospital services applicable to all public and private payors.[25]

Supporters of upper payment limit legislation believe that this approach would be more likely to survive a constitutional challenge than would state price-control laws. The drug affordability review board technically would not have the power to regulate what manufacturers charge for their products.

Instead, drug manufacturers would "remain free to set whatever price they wish for drugs," and the board would regulate only what buyers could pay for those drugs.[26] In addition, the upper payment limit would apply only to purchases of drugs within a state. Unlike Maryland's 2017 excessive price bill, it would not implicate upstream sales to wholesalers and distributors that occur out-of-state.[27] It thus arguably avoids substantially burdening interstate commerce and thereby implicating the dormant commerce clause.[28]

If enacted, this proposal almost certainly will be challenged in court by the pharmaceutical industry. Despite the subtle distinction between regulating what purchasers pay as opposed to what manufacturers charge, Pharmaceutical Research and Manufacturers of America, or PhRMA, has argued that an upper payment limit is still effectively an unconstitutional price control, which would infringe on the rights held by patent holders and substantially burden interstate commerce.[29]

In an advisory opinion regarding a bill that resembled NASHP's model legislation, the Maryland Attorney General's Office conceded there was some risk that the proposal would be preempted by federal patent law for the same reasons that the Federal Circuit invalidated the district's price-control law for branded drugs.[30] The attorney general also noted that upper payment limits likely would be preempted by the federal Employee Retirement Income Security Act to the extent that they regulate prices paid by self-insured plans, which are generally regulated by federal law.[31]

The constitutionality of state upper payment limits for drugs remains untested in federal court. Thus far, no state has granted a drug affordability review board with rate-setting authority. In 2019, Maine and Maryland ultimately passed their bills, which, as originally drafted, would have established such boards; however, both bills were watered down significantly before enactment and neither grant rate-setting powers (at least for the near future).[32]

For example, Maine's bill, as enacted, creates a board that is limited to establishing nonbinding annual prescription drug-spending targets for public payors and preparing a report for the legislature on potential strategies for addressing drug-spending.[33]

Maryland's enacted bill creates a process for its drug affordability review board to exercise

rate-setting authority starting in 2022, but only if the board receives approval from either the General Assembly's Legislative Policy Committee or both the governor and attorney general, and only with respect to drugs purchased or paid for by state or local governments.[34] Since the price regulating provisions do not take effect until 2022, if ever, the law has not yet been challenged in court.

State Drug Pricing Reforms Within Medicaid Programs

Over the past few years, states also have acted to control prescription drug costs within their Medicaid programs. While states need not provide Medicaid prescription drug coverage under their state plan,[35] if they do (as all states currently do), they must comply with the requirements of the federal Medicaid Drug Rebate Program.[36]

The MDRP requires manufacturers to pay rebates to state Medicaid programs that effectively guarantee states the best price available for each drug.[37] In turn, the MDRP mandates that state Medicaid programs cover virtually all of the participating manufacturers' drugs, subject to only a few limited exclusions.[38]

With federal permission, states may seek to negotiate with manufacturers for supplemental rebates, which are in addition to the rebates required under the federal MDRP statute; however, manufacturers are under no obligation to enter into supplemental rebate agreements, or SRAs.[39]

CMS Limits on Establishing a Closed Medicaid Formulary

The obligation to cover virtually all of the drugs marketed by drug companies who agree to enter into the MDRP limits a state's flexibility to extract further price concessions from those manufacturers. For instance, in 2017, Massachusetts sought a waiver of the MDRP's coverage mandate from the Centers for Medicare and Medicaid Services to implement a closed Medicaid formulary.[40]

A closed formulary limits access to medications typically by not providing coverage for nonformulary drugs (i.e., those not listed on the formulary) other than in instances where the nonformulary drugs are determined to be medically necessary. By contrast, in an open formulary, coverage is not restricted, though some drugs might require prior authorization or higher copayments.

In requesting authority to implement a closed formulary so as to exclude certain drugs from its Medicaid coverage altogether, Massachusetts sought a means to exert more leverage in negotiating supplemental rebates with manufacturers seeking to have their drugs covered by Medicaid. Closed formularies are a common technique for controlling costs in the commercial market as well as in Medicare Part D for most classes of drugs, but are prohibited under the MDRP's broad coverage mandate.[41]

CMS denied Massachusetts' waiver request in June 2018, concluding that the state could not continue to collect rebates under the MDRP, while also waiving the MDRP's coverage mandate.[42] CMS noted, however, that it would consider approving a demonstration project if Massachusetts opted out of the MDRP entirely and, instead, covered prescription drugs through a Section 1115 waiver as opposed to covering drugs through the optional plan benefit under Title 42 of U.S. Code Section 1396a(a)(54).[43]

Such an approach would require a state to sacrifice rebates through the MDRP for all drugs and, instead, negotiate on its own for rebates with each manufacturer. No state has taken

CMS up on its offer, and most commentators are skeptical that any state would be willing to forgo federally required rebates on all drugs in order to pursue greater flexibility in establishing a formulary.[44]

Recently, on Jan. 30, CMS released its long-awaited guidance regarding demonstration projects that would give states the option to receive a capped amount of money per year (commonly known as a block grant) to provide benefits to optional Medicaid populations.[45] In exchange for agreeing to a cap on federal funds, states would have greater flexibility in structuring their Medicaid programs, including the ability to implement a closed formulary without having to sacrifice rebates through the MDRP.[46]

While this approach would appear to provide states with a powerful tool to negotiate drug prices with manufacturers, it is highly likely that state efforts to pursue such a block grant will be met with legal challenges, including that CMS's guidance violates the Medicaid statute.[47]

Federal Constraints on State Supplemental Rebate Initiatives

While states have been unable to used closed formularies as a tool to obtain price concessions from manufacturers, states have sought other means of extracting greater supplemental rebates. Almost all states have policies to manage drug expenditures and utilization, such as maintaining a preferred drug list and requiring prior authorization for nonpreferred and/or high-cost drugs.[48] Manufacturers commonly offer supplemental rebates in exchange for the state including a drug on its PDL or removing prior authorization requirements.[49]

Recently, a few states have enacted legislation to create a more formal process for negotiating supplemental rebates that combines long-standing tools like PDLs and prior authorization with new approaches, such as publicly identifying manufacturers that refuse to enter into SRAs.

In 2017, for example, New York enacted a law that authorized the state Department of Health to disclose publicly high-cost drugs for which the manufacturer refuses to enter into an SRA and to refer those drugs to the state's Drug Utilization Review Board for further review.[50]

If no SRA is reached after the DURB announces a target supplemental rebate, the DURB may require the manufacturer to report various pricing information to the board, while DOH may impose prior authorization and other utilization controls for the manufacturer's products.[51]

Similarly, Massachusetts passed a law in July 2019 that allows the state's Medicaid program to refer expensive drugs without SRAs to the Massachusetts Health Policy Commission.[52] The HPC may require manufacturers to report various pricing information, determine the drug's proposed value, and announce its conclusion as to whether the drug's price is unreasonable or excessive in light of its proposed value.[53]

The HPC is currently drafting regulations, which industry has criticized with respect to the types and volume of information that manufacturers must report as well as the HPC's proposed methodology for determining a drug's value.[54]

While some companies may agree to SRAs they otherwise would not have, laws such as those in New York and Massachusetts face significant constraints on their ability to force

manufacturers to enter into SRAs.

For instance, the laws' penalties of price shaming or utilization controls are likely of limited concern to manufacturers of expensive drugs who already are subject to prior authorization or nonpreferred status, and/or who already have received negative press attention for their high prices. Moreover, even if a manufacturer refuses to enter an SRA, the state must still cover the drug for Medicaid beneficiaries when medically necessary.

For example, in 2018, New York referred the drug of a major manufacturer to the DURB, but was still unable to enter into an SRA with the manufacturer because the drug maker refused to agree to any price concessions. The state was reluctant to impose any of the statute's utilization controls on the drug because it was the only medication of its kind for treating a certain condition.[55]

In addition to pursuing greater supplemental rebates, Massachusetts also has explored other approaches for increasing its receipt of Medicaid rebates. Under the federal 340B program, manufacturers are required to provide discounts on covered outpatient drugs to covered entities, which include certain federal grantees and safety-net hospitals.[56]

However, the statute's duplicate discount prohibition protects manufacturers from having both to offer a 340B discount to the covered entity and to pay MDRP rebates to the state on the sale of a single drug.[57] As a result, covered entities must either carve in Medicaid patients, in which case the entity pays 340B-discounted prices and the state cannot claim rebates for those drugs, or carve out Medicaid patients, in which case the entity does not take advantage of 340B discounts, but the state can collect rebates.

In December 2019, the Massachusetts Medicaid program proposed new regulations that would give the state the authority to require covered entities to carve out designated high cost drugs.[58] This would allow the state to collect MDRP rebates when such designated drugs are dispensed to Medicaid beneficiaries, but would deprive covered entities of access to 340B discounts for those drugs.

New Contracting Initiatives — Value-Based Payment Models

Another recent effort to restrain drug prices has been through Medicaid value-based payment models. CMS has signaled a willingness to support states exploring these models. For example, CMS has approved proposals from Oklahoma, Michigan, Colorado and Massachusetts that would allow the states to tie the amount paid for certain drugs to how well they work.[59] Additionally, CMS has approved Louisiana and Washington's subscription-based models for purchasing expensive hepatitis C drugs.[60]

Commonly referred to as the Netflix model, this arrangement involves the state paying a flat fee to the manufacturer with the winning bid in exchange for unlimited access to its hepatitis C drug over a defined period.[61] The states have structured both outcomes-based and subscription contracts as SRAs, which protect the prices offered to the states from being included in Medicaid's best-price calculations.[62] If the lowered value-based price qualified as the drug's best price, then that price would need to be offered to all other states through the MDRP.

While value-based payment models offer an innovative approach to addressing drug prices, the long-term impact of such models is unclear. Oklahoma, for example, has entered into only four outcomes-based contracts since being the first state to receive CMS approval in June 2018.[63] Additionally, the architects of the subscription-based model caution that it

only will work for a subset of drugs that meet particular market conditions that likely do not apply to most drugs.[64]

State Wholesale Importation Programs

Unable to regulate prices directly and limited in their ability to curb Medicaid drug-spending, some states have looked to alternative sources for purchasing prescription drugs at a lower price. In the past two years, four states — Colorado, Florida, Maine, and Vermont — have enacted legislation to pursue wholesale importation of drugs from Canada.[65] Federal law, international resistance and supply limitations may impede these states' efforts.

The 2003 Medicare Modernization Act authorizes the U.S. Department of Health and Human Services to issue regulations permitting wholesale importation if the HHS secretary certifies that importation will be safe and will result in significant cost savings.[66] Across administrations, HHS has long held that it could not assure the safety of the drug supply chain if it allowed importation.[67] HHS has not finalized any regulations and, as a result, no state has received approval to allow importation.

In December 2019, however, President Donald Trump and his administration reversed the federal government's long-standing opposition to importation in a proposed rule that, when finalized, would authorize demonstration projects developed by states to import certain drugs from Canada.[68]

To receive HHS approval, proposals would need to meet various conditions to ensure consumer safety and sufficient cost savings.[69] Multiple states have expressed interest in pursuing such programs: Florida and Vermont already have submitted proposals to HHS; Colorado and Maine currently are drafting proposals; and others, including New York, have signaled that they will consider the issue in 2020.[70]

While the administration still must finalize a rule before states can proceed, importation appears to be one area where the federal government will work with states to reduce the roadblocks to state drug pricing reforms imposed by federal statutes.

Even if states move forward with importation programs, the impact of such initiatives could be limited. Canada is a relatively small prescription drug market, which limits the degree to which states can rely on imported drugs.[71]

Moreover, the Canadian government likely will do what it can to prevent the diversion of drugs to the U.S. market, while reputable wholesalers may be reluctant to participate out of fear of upsetting manufacturers.[72] As a result, a gray or black market for distribution could develop, which could jeopardize consumer safety and, thus, the viability of such programs.[73]

State Price Transparency Initiatives and Constitutional Challenges

States also have legislated price transparency laws to pressure drug manufacturers into reducing their prices.[74] Such laws generally include at least one of the following components: (1) requiring manufacturers to file reports with detailed financial information for certain drugs, such as those with high list prices or large increases in WAC; (2) requiring manufacturers to notify the state of the launch of new drugs with list prices above some threshold; and (3) requiring manufacturers to give advance notice to the state (and in some cases, private purchasers as well) of upcoming WAC increases above some percentage.

Transparency statutes seek to achieve pricing reform through public disclosure, which supporters hope will shame companies into lowering prices out of fear of negative publicity. Although generally popular with voters,[75] many commentators are skeptical that transparency measures alone will have an appreciable effect on pricing.[76] Moreover, such laws may be vulnerable to constitutional challenges by industry. Thus far, drug makers challenging transparency laws have raised primarily three types of constitutional claims.

Dormant Commerce Clause Challenges to Price Increase Notifications

One manner in which drug manufacturers have challenged state transparency laws is through the dormant commerce clause. Drug makers have asserted state transparency statutes violate the dormant commerce clause when they threaten to limit a manufacturer's ability to set prices in other states or substantially burden interstate commerce.

PhRMA, for example, has raised such arguments in its pending lawsuit challenging California's transparency law, S.B. 17.[77] The bill requires manufacturers to notify state health plans and programs, commercial plans and pharmacy benefit managers of any proposed increase in WAC greater than 16% at least 60 days prior to the increase's effective date.[78]

PhRMA argues that the statute violates the dormant commerce clause by effectively regulating the manufacturer's ability to set prices outside of California. PhRMA contends that since the WAC is the drug's national list price, the law prevents manufacturers from raising list prices in other states until California's 60-day waiting period expires.[79]

As a result, the law allegedly regulates out-of-state transactions and substantially burdens interstate commerce by imposing California price controls on national pricing decisions.[80] In December 2019, PhRMA filed a similar lawsuit challenging Oregon's drug pricing transparency statutes, which also impose a 60-day advance notice provision.[81]

Trade Secret Challenges to Public Disclosures

State price transparency laws also have been challenged as preempted by the federal Defend Trade Secrets Act of 2016. Under the DTSA, a trade secret refers to, among other things, financial, business, scientific or economic information that a company has taken reasonable measures to keep secret and that is of competitive value to the company by virtue of its confidentiality.[82]

For example, a company's confidential information regarding advertising expenses, production costs or pricing calculations are arguably trade secrets,[83] whereas drugs' WACs are not because they are published in pricing compendia available to competitors and the public.

Industry has successfully challenged laws that would allow a state agency to divulge proprietary pricing information reported by the manufacturer. For example, PhRMA and BIO challenged Nevada's transparency statute, which, unlike most state transparency statutes, lacked any safeguards for trade secrets, on multiple constitutional grounds.[84]

The trade groups argued that the law: (1) was preempted under the supremacy clause because it conflicted with the DTSA; (2) violated the takings clause by depriving manufacturers of their property interest in confidential business information without just compensation; and (3) violated the dormant commerce clause by effectively negating all other states' trade secret laws, since once proprietary information is made public in Nevada,

it is no longer a secret in any state.[85] The plaintiffs dropped their case after Nevada agreed to adopt regulations to protect trade secrets.[86]

First Amendment Challenges to Compelled Speech

The First Amendment, which protects freedom of speech, provides another basis for industry to challenge state transparency and disclosure laws. While the First Amendment has not played a significant role in state drug pricing litigation thus far, industry has relied on such arguments in challenging the Trump administration's direct-to-consumer advertisement rule.

In May 2019, HHS released a final rule requiring manufacturers of drugs covered by Medicare or Medicaid to include the drugs' list prices in television ads.[87] Three manufacturers and the Association of National Advertisers sued on the grounds that the rule exceeded HHS' authority to administer the Medicare and Medicaid programs, and violated the First Amendment.[88]

While the trial court vacated the rule on the former grounds, the federal courts may have to return to the merits of the First Amendment arguments later in the appeal process.[89] If so, the outcome of the lawsuit could provide an instructive roadmap for litigating First Amendment claims with respect to state laws that arguably involve compelled speech.

Conclusion

As voters' interest in containing drug prices continues to grow, states have demonstrated a willingness to take drug pricing reform into their own hands. Over the past few years, states have proffered a wide range of drug pricing reforms, testing the constitutional and federal statutory limits on their authority. When possible, industry has invoked these constitutional and federal statutory restraints to block state action in federal court. This standoff between states and industry shows no signs of subsiding in the near future.

Deborah Kantar Gardner is a partner and Scott Falin is an associate at Ropes & Gray LLP.

[1] According to a January 2020 poll, nearly 60 percent of voters identified prescription drug costs as a significant health care issue for them and their families, which came in second place behind only the similar, but less specific issue of "out of pocket costs." See Bipartisan Policy Center, Morning Consult/BPC Poll: Improving America's Current Health Care System Receives Most Support of Leading Reform Plans (Jan. 8, 2020), https://bipartisanpolicy.org/press-release/morning-consult-bpc-poll-improving-americas-current-health-care-system-receives-most-support-of-leading-reform-plans/.

[2] See American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, U.S. Department of Health and Human Services (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf; Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019) (Speaker Nancy Pelosi's sweeping bill to allow for government negotiation of prices, which passed the House on a largely party-line vote in December 2019); Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019) (Senator Chuck

Grassley's bipartisan drug pricing package that was reported out of the Senate Finance Committee in July 2019); Lower Costs, More Cures Act, H.R. 19, 116th Cong. (2019) (Representative Greg Walden's package of primarily bipartisan drug pricing bills).

[3] For a thorough review of the Trump administration and Congress' drug pricing proposals and actions in 2019, see Tom Bulleit and Scott Falin, Drug Pricing: What Happened in 2019, What to Watch in 2020, Law360 (Jan. 14, 2020), https://www.law360.com/articles/1232594/drug-pricing-what-happened-in-2019-what-to-watch-in-2020.

[4] National Academy for State Health Policy, State Legislative Action to Lower Pharmaceutical Costs (as of Dec. 5, 2019), https://nashp.org/wp-content/uploads/2019/09/Rx-end-of-year-Tracker-2019-12.5.2019.pdf.

[5] D.C. Code §28–4553.

[6] Complaint, Pharmaceutical Research Mfrs. of America v. Dist. of Columbia (No. 1:05-cv-02015-RJL) (D.D.C. Oct. 12, 2005).

[7] U.S. Const. art. VI, §1, cl. 2 ("This Constitution, and the Laws of the United States…shall be the supreme Law of the Land….").

[8] Complaint, supra note **Error! Bookmark not defined.** at 9.

[9] Id. at 12.

[10] Biotechnology Indus. Org. v. Dist. of Columbia, 496 F.3d 1362 (Fed. Cir. 2007), affirming Pharmaceutical Research and Mfrs. of America v. Dist. of Columbia, 406 F. Supp. 2d 56 (D.D.C. 2005).

[11] Biotechnology Indus. Org., 496 F.3d at 1371-74.

[12] Id. at 1374.

[13] See U.S. Const. art. I, §8, cl. 3.

[14] Md. Code Ann., Health–Gen. §2-802 (emphasis added).

[15] Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018).

[16] See U.S. Const. art. I, §8, cl. 3; United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 338 (2007). This implied restraint on state authority to regulate interstate commerce is called the dormant Commerce Clause.

[17] See, e.g., United Haulers Ass'n, 550 U.S. at 338-39, 346; Healy v. Beer Inst., Inc., 491 U.S. 324, 336 (1989).

[18] Ass'n for Accessible Meds., 887 F.3d at 671-74. The Supreme Court declined to hear Maryland's appeal in February 2019. Frosh v. Ass'n for Accessible Meds., 139 S.Ct. 1168, 1169 (Feb. 19, 2019).

[19] Md. Code Ann., Health–Gen §2-803.

[20] Ass'n for Accessible Meds., 887 F.3d at 671-73.

[21] Id. at 673-74.

[22] See National Academy for State Health Policy, Model Legislation – Affordability Review (last visited Jan. 26, 2020), https://nashp.org/policy/prescription-drug-pricing/model-legislation/.

[23] See NASHP state legislation tracker, supra note **Error! Bookmark not defined.**.

[24] NASHP, Model Legislation, supra note **Error! Bookmark not defined.**.

[25] See, e.g., National Academy for State Health Policy, Drug Rate Setting Model Act Overview (last visited Jan. 26, 2020), https://nashp.org/wp-content/uploads/2018/08/Rate-Setting-Model-Act-Explanation-final.pdf; Katie Gudiksen, Rate Setting for Health Services: A "Radical" Proposal or a Proven Way to Control Healthcare Costs, The Source Blog (Apr. 27, 2018), https://sourceonhealthcare.org/rate-setting-for-health-services-a-radical-proposal-or-a-proven-way-to-control-healthcare-costs/; Carmela Coyle, Maryland's Triple Aim Roadmap, Health Affairs (Jan. 28, 2014), https://www.healthaffairs.org/do/10.1377/hblog20140128.036634/full/.

[26] National Academy for State Health Policy, Prescription Drug Affordability Review Board Q&A, Center for State Rx Drug Pricing (last visited Oct. 3, 2019), https://nashp.org/wp-content/uploads/2019/04/Final-Prescription-Drug-Affordability-Review-Board-QA-4_1_2019.pdf.

[27] Id.

[28] Id.

[29] See Jared S. Hopkins, Maryland Takes Step Toward Capping Drug Prices, The Wall Street Journal (Apr. 30, 2019), https://www.wsj.com/articles/maryland-takes-step-toward-capping-drug-prices-11556616600; Rachel Baye, Lawmakers Express Support for Prescription Drug Board, WYPR (Mar. 7, 2019), https://www.wypr.org/post/lawmakers-express-support-prescription-drug-board.

[30] Letter from Assistant Attorney General Kathryn M. Rowe to Delegate Joseline A. Pena-Melnyk, The Attorney General of Maryland Office of Counsel to the General Assembly, 1, 11 (Jan. 4, 2019), available at https://www.scribd.com/document/401301021/Maryland-Attorney-General-Letter-on-Prescription-Legislation.

[31] Id.

[32] See H.B. 768, 2019 Reg. Sess. (Md. 2019) (enacted May 25, 2019), http://mgaleg.maryland.gov/webmga/frmMain.aspx?id=hb0768&stab=01&pid=billpage&tab=subject3&ys=2019RS; L.D. 1499, 129th Leg., 2019 First Reg. Sess. (Me. 2019) (enacted June 24, 2019), http://legislature.maine.gov/LawMakerWeb/summary.asp?ID=280073010.

[33] Maine, L.D. 1499, supra note **Error! Bookmark not defined.**.

[34] Maryland H.B. 768, supra note **Error! Bookmark not defined.**.

[35] See 42 U.S.C. §1396a(a)(54).

[36] See 42 U.S.C. §1396r-8; see also Kaiser Family Foundation, Medicaid Rx Drug Benefit: Key Facts, (May 1, 2019), https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/.

[37] See, e.g., Trish Riley, Lower Drug Costs: The Next Frontier for State Flexibility, Health Affairs (Feb. 16, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180214.827973/full/.

[38] See 42 U.S.C. 1396r-8(d). For example, a state may exclude or restrict coverage if a drug is not prescribed for a medically accepted indication or if the drug is included on the MDRP statute's list of excludable drugs, which includes agents used for anorexia, weight loss/gain, fertility, and cosmetic purposes. Id.

[39] 42 U.S.C. §1396r-8(a)(1). Forty-six states and the District of Columbia have entered into at least one single-state or multi-state SRA. Medicaid Pharmacy Supplemental Rebate Agreements (SRA), Medicaid.gov (September 2019), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.

[40] Massachusetts Executive Office of Health and Human Services, MassHealth Section 1115 Demonstration Amendment Request (September 8, 2017), https://www.mass.gov/files/documents/2017/10/27/masshealth-section-1115-demonstration-amendment-request-09-08-17.pdf.

[41] Id. at 8-9. Medicare prescription drug plans must cover virtually all prescription drugs within six protected classes. See 42 USC §1395w-104(b)(3)(G).

[42] Letter from CMS Acting Director Tim Hill to MassHealth Assistant Secretary Daniel Tsai, 2 (June 27, 2018), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf.

[43] Id. Massachusetts would have to ensure that such a demonstration project is cost-neutral for the federal government. Id. Consistent with CMS's response to Massachusetts, the Trump administration's Fiscal Year 2020 budget also included a demonstration project to allow up to five states to opt out of the MDRP and negotiate prices directly with manufacturers. U.S. Department of Health and Human Services, Putting America's Health First: FY 2020 President's Budget for HHS, FY 2020 Budget in Brief, 15, https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf.

[44] See, e.g., Virgil Dickson, CMS Denies Massachusetts' Request to Choose Which Drugs Medicaid Covers, Modern Healthcare (June 27, 2018), https://www.modernhealthcare.com/article/20180627/NEWS/180629925/cms-denies-massachusetts-request-to-choose-which-drugs-medicaid-covers (quoting Matt Salo, executive director of the National Association of Medicaid Directors: "Nobody wants that demo. Massachusetts is saying that the current system works well enough for most patients and most products, so there's no need to throw the baby out with the bathwater").

[45] See Letter from Director Calder Lynch to State Medicaid Directors, SMD #20-001 (Jan. 30, 2020), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf.

[46] Id; Ariel Cohen and James Romoser, States May Use Closed Formularies in Return for Accepting Block Grants, InsideHealthPolicy (Jan. 30, 2020), https://insidehealthpolicy.com/inside-drug-pricing-daily-news/states-may-use-closed-formularies-return-accepting-block-grants.

[47] Dan Diamond and Rachel Roubein, "'Block Grants' No More: Trump's Medicaid Overhaul has New Name, Same Goals," Politico (Jan. 29, 2020), https://www.politico.com/news/2020/01/29/trump-medicaid-overhaul-block-grants-108882.

[48] See, e.g., Congressional Research Service, Medicaid Prescription Drug Pricing and Policy, 32-33 (Nov. 7, 2014), https://crsreports.congress.gov/product/pdf/R/R43778; Health Management Associates and Kaiser Family Foundation, States Focus on Quality and Outcomes Amid Waiver Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2018 and 2019, 73 (Oct. 2018), http://files.kff.org/attachment/Report-States-Focus-on-Quality-and-Outcomes-Amid-Waiver-Changes-Results-from-a-50-State-Medicaid-Budget-Survey-for-State-Fiscal-Years-2018-and-2019.

[49] Congressional Research Service, supra note **Error! Bookmark not defined.** at 2. A state's ability to restrict access, however, is limited because it cannot exclude coverage entirely and must cover non-preferred drugs when medically necessary. States, therefore, risk violating the federal Medicaid statute if they implement overly cumbersome utilization controls. For example, a few years ago, both CMS and federal courts criticized state efforts to limit access to expensive Hepatitis C drugs to only Medicaid beneficiaries with advanced liver damage. See, e.g., Center for Medicaid and CHIP Services, Medicaid Drug Rebate Program Note For State Technical Contacts, Release No. 172 (Nov. 5, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf; B.E. et al. v. Teeter, 2016 WL 3033500 (W.D. Wash. May 27, 2016).

[50] N.Y. Pub. Health Law § 280(3)(a).

[51] See N.Y. Pub. Health Law §§280(5)(c), (6)(a), (7)(a). Specifically, DOH may waive two statutory provisions to restrict access to the drug. N.Y. Pub. Health Law §280(5)(c). First, the Commissioner may waive the "prescriber prevails" provision, which allows a prescriber for a Medicaid fee-for-service beneficiary to override the state's prior authorization limitations for drugs not on the state's PDL if the prescriber determines, in his or her reasonable professional judgment, that the use of the non-preferred drug is warranted. N.Y. Pub. Health Law §273(3)(b). Second, the Commissioner may waive the statutory requirements that Medicaid managed care plans cover all medically necessary prescription drugs in nine specified classes. N.Y. Soc. Serv. Law §§ 364-j(25), (25-a). In addition, DOH may implement the following: (1) subjecting any drug of a manufacturer who has a drug that was referred to the DURB to prior authorization requirements; (2) directing managed care plans to remove from their formularies drugs referred to the DURB; (3) "promot[ing] the use of cost effective and clinically appropriate drugs other than those of a manufacturer who has a drug [before the DURB]"; (4) "allow[ing] manufacturers to accelerate rebate payments under existing rebate contracts"; and (5) any other actions authorized by law. N.Y. Pub. Health Law §280(7)(a).

[52] H.B. 4000, §46, Massachusetts 191st General Court (enacted July 31, 2019), https://malegislature.gov/Bills/191/H4000/BillHistory (to be codified as Section 12A of Chapter 118E of the General Laws).

[53] H.B. 4000, §6, Massachusetts 191st General Court (enacted July 31, 2019) (to be codified as Section 8A of Chapter 6D of the General Laws). The statute does not spell out any consequences for a manufacturer if the HPC concludes the drug's price is "unreasonable or excessive."

[54] See, e.g., Priyanka Dayal McCluskey, Pharmaceutical Industry Mounts Opposition to State's Effort to Curb Drug Costs, The Boston Globe (Dec. 23, 2019), https://www.bostonglobe.com/business/2019/12/23/pharmaceutical-industry-mounts-opposition-state-effort-curb-drug-costs/OlQAjYYeiJ7v5Zv7vkGbiN/story.html. The proposed regulation (958 CMR 12.00), public comments, and other resources regarding the law can be accessed at Drug Pricing Review, Health Policy Commission (last visited Jan. 26, 2019), https://www.mass.gov/service-details/drug-pricing-review.

[55] See Katie Thomas, A Drug Costs $272,000 a Year. Not so Fast, Says New York State, The New York Times (June 24, 2018), https://www.nytimes.com/2018/06/24/health/drug-prices-orkambi-new-york.html. Even if New York wanted to impose such restrictions, the state arguably could not do so because the statute prohibits DOH from exercising its authority to waive certain provisions or implement additional restrictions when such actions would "prevent access by a Medicaid recipient to a drug which is the only treatment for a particular disease or condition." N.Y. Pub. Health Law §§280(5)(c), (7)(b).

[56] 42 U.S.C. §256b.

[57] 42 U.S.C. §256b(a)(5)(A)(i).

[58] See proposed regulation with respect to 130 CMR §§405.000, 406.000, and 410.000, available at https://www.mass.gov/service-details/masshealth-public-hearings (last visited Jan. 23, 2019). Any such designation must comply with the notice and reporting requirements in H.B. 4000, §47, Massachusetts 191st General Court (enacted July 31, 2019) (to be codified as Section 13K of Chapter 118E of the General Laws). H.B. 4000 requires the state to provide notice to affected hospitals and a report to the legislature at least 270 days prior to the effective date of any restriction or limitation on an eligible hospital's access to 340B discounts for a particular drug. Id.

[59] Medicaid State Plan Amendment, Medicaid.gov (July 31, 2019), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MA/MA-19-0001.pdf (Massachusetts); Medicaid State Plan Amendment, Medicaid.gov (Feb. 25, 2019), https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CO/CO-18-0044.pdf (Colorado); Medicaid State Plan Amendment, Medicaid.gov (Nov. 14, 2018), https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MI/MI-18-0009.pdf (Michigan); Centers for Medicare & Medicaid Services, CMS Approves State Proposal to Advance Specific Value-Based Arrangements with Drug Makers (June 27, 2018), https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers (Oklahoma).

[60] Centers for Medicare & Medicaid Services, CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid (June 26, 2019), https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified; Centers for Medicare & Medicaid Services, CMS Approves Washington State Plan Amendment Proposal to Allow Supplemental Rebates Involving a "Subscription" Model for Prescription Drug Payment in Medicaid (June 12, 2019), https://www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving.

[61] See Ted Alcon, Louisiana's Deal for Hepatitis C Drugs May Serve as Model, The Wall Street Journal (Sept. 13, 2019), https://www.wsj.com/articles/louisianas-deal-for-hepatitis-c-drugs-may-serve-as-model-11568347621. Under the MDRP, the state cannot exclude coverage of the Hepatitis C drugs of the manufacturers that did not win the bid; however, it may use PDLs and utilization controls to steer beneficiaries and providers towards the winning manufacturer's product. See, e.g., Louisiana Department of Health, Pharmaceutical Manufacturers' Written Questions & Answers, 5-6 (Feb. 12, 2019), available at http://ldh.la.gov/index.cfm/newsroom/detail/5018.

[62] See 42 C.F.R. §447.505(c)(7).

[63] See Nicholas Fiore et al., Novel State Payment Models for Prescription Drugs: Early Implementation Successes and Challenges, Duke Margolis Center for Health Policy, 4 (Sept. 2019), https://healthpolicy.duke.edu/sites/default/files/u31/novel_state_payment_models_final_revised_091219.pdf (reviewing the early successes and challenges of states pursuing Medicaid value-based models for prescription drugs).

[64] See Mark Trusheim and Peter B. Bach, Next Steps for Netflix: Can 'All You Can Treat' Contracts Work Beyond Hepatitis C?, Health Affairs (Sept. 25, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190924.559225/full.

[65] See National Academy for State Health Policy, 2020 State Legislative Action to Lower Pharmaceutical Costs, https://nashp.org/rx-legislative-tracker/ (tracks state drug pricing legislation since 2015).

[66] See 21 U.S.C. §§384(b), (l)(1).

[67] See Mike Leavitt, Why Drug Importation is Flawed Policy, Morning Consult (Mar. 20, 2017), https://morningconsult.com/opinions/drug-importation-flawed-policy/ ("In fact, my predecessors and successors [as HHS Secretary] from both political parties, along with multiple FDA Commissioners, have consistently found that drug importation carries potential dangers that can't be ignored.").

[68] 84 Fed. Reg. 70796 (Dec. 23, 2019). HHS also announced a second pathway for importation that would allow manufacturers to import their own drugs that were intended for foreign markets and offer them for sale at a lower price in the United States through the use of new National Drug Codes ("NDCs"). Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry, HHS.gov (Dec. 2019), https://www.hhs.gov/sites/default/files/importation-of-certain-fda-approved-human-presciption-drugs-including-biological-products.pdf. It is unclear why manufacturers would take advantage of this pathway. HHS suggested it is developing this pathway in response to past comments by manufacturers that they would like to offer lower-cost versions of their drugs, but could not do so because they were locked into contracts with various supply chain entities. U.S. Department of Health and Human Services, Safe Importation Action Plan, 3 (July 31, 2019), https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html. Some have speculated that HHS created this second pathway to undermine such claims by manufacturers opposed to importation. See, e.g., Sarah Owermohle, Prescription Pulse: A Few Questions on Importation, Politico (Aug. 2, 2019), https://www.politico.com/newsletters/prescription-pulse/2019/08/02/a-few-questions-on-importation-464476.

[69] 84 Fed. Reg. at 70805-807.

[70] Ariel Cohen, New York Gov. Cuomo to Describe Canadian Drug Importation Plan, InsideHealthPolicy (Dec. 27, 2019), https://insidehealthpolicy.com/daily-news/new-york-gov-cuomo-describe-canadian-drug-importation-plan.

[71] Natalie Obiko Pearson and Simran Jagdev, Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, Bloomberg (Aug. 13, 2019), https://www.bloomberg.com/news/articles/2019-08-13/trump-s-canada-drug-import-plan-can-t-happen-without-big-pharma.

[72] Id.

[73] Ropes & Gray, Podcast: IP(DC): Drug Prices, Political Pressures & Patents (Aug. 20, 2019), https://www.ropesgray.com/en/newsroom/podcasts/2019/August/Podcast-IP-DC-Drug-Prices-Political-Pressures-Patents.

[74] For example, California, Colorado, Connecticut, Maine, Nevada, Oregon, Texas, Vermont, and Washington have enacted such laws in recent years. See, e.g., NASHP state legislation tracker, supra note **Error! Bookmark not defined.**.

[75] For example, a Kaiser Family Foundation poll showed 77% of Americans support the Trump administration's proposal to require direct-to-consumer television ads to display the drug's list price. Kaiser Family Foundation, Bipartisan Majorities Support Trump Administration's Push to Get Drug Prices in Advertisements, Even After Hearing Counter-Arguments (Nov. 28, 2018), https://www.kff.org/health-reform/press-release/bipartisan-majorities-support-trump-administrations-push-to-get-drug-prices-in-advertisements-even-after-hearing-counter-arguments/.

[76] See, e.g., Thomas Sullivan, Transparency Push in Pharma: Will it Result in Lower Prices to

Patients?, Policy & Medicine (Aug. 18, 2019), https://www.policymed.com/2019/08/transparency-push-in-pharma-will-it-result-in-lower-prices-to-patients.html; Kelly Davio, State-Level Drug Price Transparency Laws Miss the Mark, Say Researchers, The Center for Biosimilars (Oct. 1, 2019), https://www.centerforbiosimilars.com/news/statelevel-drug-price-transparency-laws-miss-the-mark-say-researchers.

[77] See Amended Complaint, Pharmaceutical Research Mfrs. of America v. David, (No. 2:17-cv-02573-MCE-KJN) (E.D. Cal. Sept. 28, 2018), available at https://nashp.org/wp-content/uploads/2018/10/PhRMA-Revised-Complaint-9_28_2018.pdf.

[78] S.B. 17, 2017 Reg. Sess. (Cal. 2017) (enacted Oct. 9, 2017), http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB17 (codified at Cal. Health & Safety Code §§127675 et seq.). A price increase triggers the advance notice requirement if the proposed increase plus the cumulative increases that occurred within the previous two calendar years prior to the current year is greater than 16 percent. Cal. Health & Safety Code § 127677(a).

[79] Amended Complaint, supra note **Error! Bookmark not defined.** at 2-3, 22.

[80] Id. at 2-3 ("Not only does SB 17 effectively ban out-of-state pricing, it overtly prescribes policy on drug pricing for the entire United States.").

[81] Complaint, Pharmaceutical Research Mfrs. of America v. Savage, (No. 6:19-cv-01996) (D. Ore. Dec. 9, 2019), available at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/December2019_OR_Complaint.PDF.

[82] See 18 U.S.C. §1839(3).

[83] See, e.g., Complaint at 31, Pharmaceutical Research Mfrs. of America v. Sandoval, (No. 2:17-cv-02315) (D. Nev. Sept. 1, 2017), available at https://nashp.org/wp-content/uploads/2018/10/Oringial-Nevada-Complaint-10_4_2018.pdf.

[84] Id. at 2-4. The law was codified at Nev. Rev. Stat. §§439B.600 et seq.

[85] Complaint, supra note **Error! Bookmark not defined.** at 2-4.

[86] Brenna Goth, Pharma Industry Drops Lawsuit Over Nevada Price Law, Bloomberg Law (July 2, 2018), https://news.bloomberglaw.com/health-law-and-business/pharma-industry-drops-lawsuit-over-nevada-price-law.

[87] See 84 Fed. Reg. 20732 (May 10, 2019).

[88] Complaint at 7-8, Merck & Co. v. U.S. Dep't of Health and Human Servs., (No. 1:19-cv-01738) (D.D.C. June 14, 2019), available at https://www.law360.com/articles/1170993/judge-nixes-rule-forcing-drug-prices-in-tv-ads.

[89] Merck & Co. v. U.S. Dep't of Health and Human Servs., 385 F. Supp. 3d 81, 98 (D.D.C. 2019); Rachel Cohrs, HHS to Appeal Court Decision Striking Down DTC Ad Rule, InsideHealthPolicy (Aug. 21, 2019), https://insidehealthpolicy.com/daily-news/hhs-appeal-court-decision-striking-down-dtc-ad-rule.