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INTRODUCTION

Prescription drug costs significantly burden many Americans. A March 2018 poll by the Kaiser Family Foundation found that lowering prescription drug prices topped Americans' list of priorities for the federal government, ranking higher than comprehensive immigration reform or ending the opioid epidemic.[1] Spending on prescription drugs accounted for approximately 10% of the national health expenditures in 2017.[2] While the growth in prescription drug spending has leveled off in recent years, spending on drugs shifted from traditional to specialty drugs, which now account for almost half of all spending, but only about 2% of the prescriptions filled.[3] With rapidly increasing drug prices and insurance coverage that exposes patients to high out-of-pocket costs for specialty drugs,[4] the public has increasingly called for action by government officials to address skyrocketing prices. In response to this outcry, in March 2018, the Trump Administration issued a blueprint that directed the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) to improve competition in the drug market and reform the Medicare Part D program.[5] While HHS announced proposed rules in February 2019 eliminating the Anti-Kickback safe harbor for drug rebates from manufacturers to pharmacy benefit managers serving Medicare and Medicaid programs, those proposed rules were withdrawn in July 2019.[6] In addition, Congressional members from both political parties introduced bills to address rising drug costs, including allowing Medicare to negotiate with drug manufacturers,[7] importing

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[1] Ashley Kirzinger, Bryan Wu, Mollyann Brodie, Kaiser Family Found., *Kaiser Health Tracking Poll – March 2018: Views on Prescription Drug . Pricing and Medicare-for-all Proposals*, (Mar. 23, 2018), https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-march-2018-prescription-drug-pricing-medicare-for-all-proposals/.

[2] Anne B. Martin et al., *National Health Care Spending In 2017: Growth Slows To Post–Great Recession Rates; Share Of GDP Stabilizes*, 38 HEALTH AFFAIRS 96, 100 (2019).

[3] IQVIA, *Medicine Use and Spending in the U.S.* (April 19, 2018), https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022 (last visited Feb 14, 2019).

[4] Adam J. Fein, *Employer Pharmacy Benefits in 2018: More Tiers, Greater Coinsurance, and Lots of High-Deductible Plans,* DRUG CHANNELS (2018), https://www.drugchannels.net/2018/11/employer-pharmacy-benefits-in-2018-more.html (last visited Feb 14, 2019).

[5] The White House, *President Donald J. Trump's Blueprint To Lower Drug Prices*, (May 11, 2018), https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/ (last visited Feb 14, 2019).

[6] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (February 6, 2019) (to be codified at 42 C.F.R. pt. 100).

[7] Medicare Prescription Drug Price Negotiation Act of 2019, H.R. 275, 116th Cong. (2019).

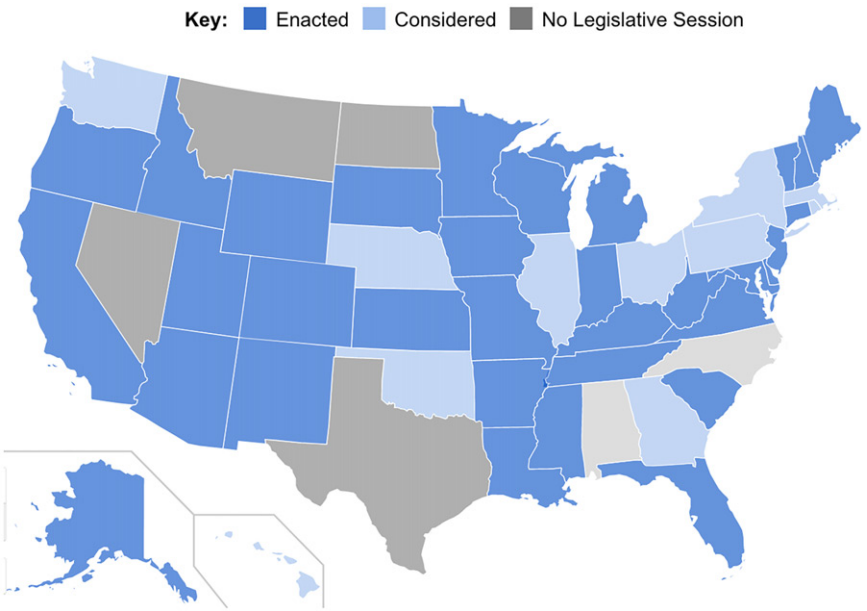

Figure 1. States Considering and Passing Legislation to Address Drug Prices in 2018.

drugs from Canada,[8] and rescinding any government-granted exclusivity for "excessively priced" drugs.[9] To date, however, many of these proposals have not been implemented and only 39% of Americans say they are confident that President Trump and his administration will be able to deliver on the promise to lower drug costs.[10]

As a result, states are increasingly committed to exercising their power to regulate the pharmaceutical market and reduce drug costs. Of the states with active legislative sessions in 2018, only North Carolina and Alabama did *not* consider legislation with the aim of reducing prescription drug costs. Of the forty-four states that introduced bills, thirty-two states passed legislation to address rising drug costs (see Figure 1).

In this article, we analyze the variety of laws recently passed by state legislatures to address rising prescription drug costs, as well as the litigation challenges brought by pharmaceutical manufacturers to many of these laws, and the ever-expanding legal thicket that states must traverse to control drug prices. The extreme difficulty in passing meaningful legislation and finding effective ways to control drug costs must not become a reason for states to cede all regulation of the pharmaceutical

[8] Affordable and Safe Prescription Drug Importation Act of 2019, H.R. 447, 116th Cong. (2019).
[9] Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. (2019).
[10] Kirzinger et al., *supra* note 1, at 3.

industry to the federal government. Instead, it must be a rallying cry for states to try innovative new legislative and regulatory methods to control drug prices and combat legal challenges by the pharmaceutical industry. Defending these new laws will require significant resources, therefore states must balance the effectiveness of a law at controlling drug costs with the likelihood of prevailing in court. In that same vein, due to the high likelihood that new drug price control policies will face significant legal challenges and retaliation from the pharmaceutical industry, policymakers should ensure that they pass only the most effective policies to avoid expending political and financial resources on policies that will do little to improve drug costs. Furthermore, as prescription drugs account for about 10% of the money spent on healthcare,[11] states should consider whether their efforts would be better spent on more general measures to controlling costs for health expenditures (e.g. considering rate-setting for all healthcare services rather than targeting only drugs).

In light of the challenges in passing effective legislation to control drug costs, many states have designed new ways to control drug spending using their role as a purchaser. Some of these programs have saved states millions of dollars in prescription drug costs. While private insurers cannot share in the financial savings from these public programs, they may use them as models for their own cost-control programs. In this article, we describe how states have used their state-employee benefits programs alone or within larger cost-saving initiatives to control drug costs and discuss how they could be expanded to private insurers. Finally, we will offer a series of recommendations to state policymakers regarding options for controlling prescription drug prices.

LEGISLATION CONSIDERED BY STATES TO CONTROL DRUG COSTS

Most states attempt to regulate pharmaceutical pricing through legislation. In 2018, state legislatures considered 227 bills and passed 55 laws to reduce drug costs or improve competition in the pharmaceutical market. These bills aimed to address pharmaceutical costs in eight ways: 1) requiring biosimilar substitution; 2) eliminating gag-clauses for pharmacists; 3) restricting when insurers and pharmacy benefit managers (PBMs) can change formularies or require step therapy; 4) overseeing PBMs; 5) increasing transparency in drug pricing and its impact on insurance premiums; 6) importing drugs from other countries; 7) prohibiting price gouging for drugs; and 8) regulating drug prices. In

[11] Martin et al., *supra* note 2, at 100.

the following section, we briefly describe each kind of legislation.[12] We then describe the legal challenges states face in passing these laws and the potential for industry retaliation. Many of these laws effectively address specific problems in the pharmaceutical market, but very few of them will meaningfully decrease overall expenditures on prescription drugs. Furthermore, the most effective laws for reducing drug costs are those with the highest potential for significant legal challenges or retaliation from industry (see Table 1). As a result, states may face a choice between passing laws with little effect on overall drug costs or assembling the resources needed to fight for more meaningful changes. For the discussion in this section, we grouped recent state legislation into three categories: laws designed to 1) target specific market imperfections, 2) promote competition and improve overall market function, and 3) address prices directly.

1. Laws that Target Specific Market Imperfections

States passed three kinds of laws that are unlikely to face significant legal challenges or industry retaliation. While they are important consumer protection statutes, they only target specific inefficiencies in the pharmaceutical market, and, therefore, are unlikely to significantly decrease overall expenditures for drugs. As a result, the pharmaceutical industry may have chosen to focus their legal challenges on other laws that may have a larger financial impact.

a. Biosimilar Substitution Laws

In 2018, nine states strengthened their generic substitution laws by including substitution requirements for interchangeable biosimilar drugs.[13] The provisions of these laws typically mirror state generic substitution laws, but generally permit or require pharmacists to substitute a lower cost generic or interchangeable biosimilar for a brand name medication, unless the physician indicates otherwise. Currently, only four states – Oklahoma, Arkansas, Mississippi, and Alabama – remain without any biologic substitution law. Existing laws regulating biosimilar

[12] Also discussed in this volume by Trish Riley and Sarah Lanford, *States on the Front Line: Addressing America's Drug Pricing Problem*, 39 J. LEG. MED. __, ___ (2019).

[13] The states are: Alaska, Connecticut, Michigan, New Hampshire, South Dakota, Vermont, West Virginia, Wisconsin, and Wyoming. In contrast to small molecule drugs that are typically synthesized in a reactor, a biologic drug is generally comprised of a large, complex molecule (often a large protein or antibody) and is typically produced in a living system such as a microorganism or other cell. A biosimilar is a biological product that has "no clinically meaningful difference" from an existing FDA-approved biologic drug (the reference product). U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD & DRUG ADMIN. *Biological Product Definitions*, https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf.

TABLE 1. Comparison of legislation considered by states to reduce drug costs.

Category	Legislation	Political Feasibility	Effectiveness in target population/area	Effectiveness at reducing overall drug expenditures	Likelihood of Legal Challenge	Likelihood of Industry Retaliation
I	Biosimilar Substitution	+++	+ (needs FDA to designate drug as interchangeable)	+	–	–
	Gag-clause/ clawback prohibition	+++	++ (reducing out of pocket costs)	+	–	–
	Formulary Restriction	++	+	– (likely to increase costs, but increase patient access to expensive drugs)	–	–
II	PBM regulation	+++	+	- (may increase drug costs if admin costs go up)	+++ (ERISA)	+ (Cost-shifting or hiding fees when possible)
	Price Transparency	+++	+	+(+)	++ (DCC, Trade Secrets)	+
	Drug Importation	+	++	++	++ (Patent law)	+++
III	Price Gouging	- (only law passed ruled unconstitutional)	++ (generic drugs with large price increase)	++	++ (DCC)	Depends on ability of company to cost-shift to other drugs
	Rate Setting	–	+++	+++	+++ (Patent law, DCC)	+++

substitution, however, require the FDA to certify that the biosimilar product is "interchangeable" with the brand name biologic, something it has not yet done. As a result, these laws have little immediate impact. Nonetheless, in 2017 the FDA issued a draft guidance describing the data and studies it requires to determine that a drug is interchangeable,[14] so the FDA biosimilar approval as "interchangeable" may occur in the relatively near future. As a result, these laws may become an increasingly important way for states to control drug costs with little risk of legal challenge from the pharmaceutical industry.

b. Gag-clause prohibitions

In the past few years, many states have also passed legislation to protect patients from paying more for prescriptions when using their insurance than they would if they had no insurance. In their contracts with pharmacies, PBMs and insurers often include provisions, commonly referred to as gag-clauses, that prevent pharmacists from informing customers when their insurance copay or cost-sharing exceeds the price of the drug without insurance. In addition, when a patient pays more in cost-sharing than the PBM or insurer pays to the pharmacy to dispense the drug, many PBMs or insurers "clawback," or keep, the difference. In the last two years, forty states considered and twenty-six states enacted laws prohibiting gag-clauses for pharmacists, making it the most popular pharmaceutical legislation topic of 2018.[15] The growing consensus among state legislatures that pharmaceutical gag-clauses should be banned led Congress to pass two laws: the Patient Right to Know Drug Prices Act (S. 2554), which bans gag-clauses in employer-sponsored and individual drug plans, and the Know the Lowest Price Act (S. 2553), which bans them in Medicare Part D and Medicare Advantage plans.

While the prohibition of gag-clauses and clawbacks in pharmacy contracts represent a meaningful step toward protecting patients from unreasonable out-of-pocket costs, they do not address the underlying costs of the drugs. A study by researchers at the USC Schaeffer Center for Health Policy and Economics found that in 2013, nearly a quarter (23%) of prescriptions involved a patient copayment that exceeded the reimbursement paid by the insurer by more than $2, and total

[14] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD & DRUG ADMIN., *Considerations in Demonstrating Interchangeability With a Reference Product Draft Guidance for Industry* (Jan. 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf.

[15] AK, AZ, AR, CA, CO, DE, FL, IN, KA, KY, LA, MD, MS, MO, NH, SC, SD, UT, VT, VA, and WV passed laws in 2018. CT, GA, ME, NC, and ND passed laws in 2017. Texas passed laws with similar protections in 2012.

overpayments exceeded $135 million.[16] While $135 million is a substantial amount of money, it represents less than 0.05% of drug expenditures in 2013.[17] As a result, these new state laws are unlikely to reduce overall expenditures on drugs, but they show how a critical mass of state legislatures can exert political pressure on Congress to pass legislation based on state laws.

c. Formulary Regulations

The third type of consumer protection legislation governs insurers' and PBMs' use of formularies. In 2018, thirteen states considered and three states passed legislation to protect their citizens by limiting how PBMs and insurers change formularies or require step therapy.[18] For example, Minnesota required insurers to use "evidence-based and peer-reviewed clinical practice guidelines when establishing a step therapy protocol," and to give enrollees and providers "access to a clear, readily accessible, and convenient process to request a step therapy override."[19] While these laws provide better access to drugs for patients, these laws may actually result in higher drug costs because they prevent PBMs and insurers from requiring patients to use more cost-effective treatments. Nonetheless, these consumer protection statutes allow patients to get an expensive medication when their provider determines it is the best treatment for their condition.

2. Laws Designed to Promote Competition and Improve Market Function

In addition to consumer protection statutes, states passed other laws that targeted prescription drug costs. Three of those kinds of laws – regulating PBMs, demanding transparency in drug pricing, and reimporting drugs – do not directly control prices paid for drugs. These laws, however, seek to improve the functioning of the pharmaceutical market by increasing competition or by giving policymakers more information about drug costs.

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[16] KAREN VAN NUYS, ET AL., OVERPAYING FOR PRESCRIPTION DRUGS: THE COPAY CLAWBACK PHENOMENON (Mar. 2018), https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03_Overpaying20for20Prescription20Drugs_White20Paper_v.1-2.pdf.

[17] Micah Hartman et al., *National Health Spending In 2013: Growth Slows, Remains In Step With The Overall Economy*, 34 HEALTH AFFAIRS 150, 152 (2015) (showing prescription drug spending was $271.1 billion in 2013).

[18] When using step therapy, an insurer may require a patient to try a less expensive alternative before "stepping up" to cover a more expensive medication.

[19] H.F. 3196, 90th Leg., 162d Sess. (Minn. 2018).

a. Regulation of Pharmacy Benefit Managers

One of the more popular types of legislation of 2018 was the regulation of PBMs; that year, 32 states considered, and 15 states passed bills requiring PBMs to be licensed in the state or disclose additional information about drug prices. PBMs administer prescription drug benefits for plan sponsors (e.g. self-insured employers, insurance companies, Medicare Part D beneficiaries) by creating drug formularies and negotiating reimbursement rates with drug manufacturers and pharmacies. States have begun to regulate PBM practices because PBM prescription reimbursement can lead to misaligned financial incentives between the PBM and the patient or plan sponsor (i.e. payment practices that encourage drugs with high list prices and commensurately high rebates). Furthermore, many of these reimbursement payments are shrouded in secrecy from the insurers, employers, and patients who pay for the drugs. At least 48 states have laws regulating PBMs, including 29 states that require PBMs to be licensed to operate in the state.[20] Other states require PBMs to publish lists of the maximum allowable costs (MAC), which are used to negotiate rates with pharmacies, and to follow certain procedures when auditing pharmacies.[21] To date, California's AB-315 is one of the most comprehensive laws regulating PBMs. Passed in 2018, the law requires PBMs to register with the state's Department of Managed Health Care (DMHC) and disclose aggregate rebates to purchasers.

Laws to regulate and license PBMs may give states additional oversight of PBMs, but legislators must carefully craft those laws to avoid preemption by federal laws. The Employee Retirement Income Security Act of 1974 (ERISA)[22] has been the most problematic federal law for states to navigate when trying to regulate PBMs. Congress passed ERISA to provide uniform, federal standards for pensions and employee benefit plans, including health plans. Section 514 of ERISA expressly preempts state laws that "relate to any employee benefit plan."[23] Recognizing that the exact scope of ERISA preemption as written in the statute is broad and imprecise, the Supreme Court developed a two-part test to determine if a state law is preempted. Specifically, the Court held a state law

[20] The seventeen states with PBM license requirements prior to 2018 are Connecticut, Georgia, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Mississippi, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Washington, and Wyoming. Alaska, Arkansas, California, Florida, New Jersey, Tennessee, Ohio, Pennsylvania, Rhode Island, Vermont and West Virginia passed new laws in 2018 requiring PBMs to be licensed. Utah passed a law in 2019.

[21] JANET KAMINSKI LEDUC, CONNECTICUT GENERAL ASSEMBLY OFFICE OF LEGISLATIVE RESEARCH, STATE LAWS CONCERNING PHARMACY BENEFIT MANAGERS 6 (Mar. 1, 2018), *available as report 2018-R-0083 at* https://www.cga.ct.gov/2018/rpt/pdf/2018-R-0083.pdf).

[22] 29 U.S.C. § 1144(a) (2012).

[23] ERISA § 514(a) (2012); 29 U.S.C. § 1144(a) (2012).

"relates to" an ERISA plan if it has "[1] a connection with or [2] a reference to such a plan."[24] A state law makes an "impermissible connection" with ERISA plans when it "governs a central matter of plan administration" or "interferes with nationally uniform plan administration."[25] A state law also makes "an impermissible 'reference to' ERISA plans where it 'acts immediately and exclusively on ERISA plans … or where the existence of ERISA plans is essential to the law's operation.'"[26] The judicial interpretation of these standards has, unfortunately, varied significantly from jurisdiction to jurisdiction, significantly muddying the waters for state legislators and industry stakeholders.

In addition, Congress exempted state insurance regulations, including health insurance regulations, from ERISA preemption, but it did not deem self-insured employer benefits to constitute insurance. As a result, states cannot regulate self-insured employer health benefit plans, which provide coverage for approximately 60% of Americans with employer-sponsored insurance plans.[27] Congress passed ERISA to promote interstate commerce and to protect large employers from having to comply with a patchwork of state regulations, but the Supreme Court broadened the preemptive reach of ERISA in *Gobeille v. Liberty Mutual Insurance Co.*[28] The Supreme Court held ERISA preempted a Vermont statute that required all insurers, including self-insured employers, to report their health care claims data, because such reporting had an "impermissible connection with ERISA plans" because it interfered with the uniformity of plan administration.[29] As a result, states have been forced to exempt self-funded employer-based plans and the PBMs that serve them from adhering to state reporting requirements, thereby crippling accurate and comprehensive transparency efforts at the state level.

Consequently, despite state attempts to avoid ERISA preemption, the Pharmaceutical Care Management Association (PCMA), the trade organization representing PBMs, routinely challenges state laws that

[24] Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 324 (1997); N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 656 (1995); Carpenters Local Union No. 26 v. U.S. Fid. & Guar. Co., 215 F.3d 136, 140 (1st Cir. 2000).

[25] Pharm. Care Mgmt. Ass'n v. Gerhart 852 F.3d 722, 728 (8th Cir. 2017) (quoting Gobeille v. Liberty Mut. Ins. Co., 136 S.Ct. 936, 943 (2016)).

[26] Gerhart, 852 F.3d at 728.

[27] Erin Fuse Brown & Ameet Sarpatwari, *Removing ERISA's impediment to state health reform*, 378 N ENGL J MED. 5, 6 (2018); HENRY J. KAISER FAMILY FOUNDATION, HEALTH RESEARCH AND EDUCATIONAL TRUST, EMPLOYER HEALTH BENEFITS: 2017 ANNUAL SURVEY (September 29, 2017), https://www.kff.org/report-section/ehbs-2017-section-10-plan-funding/.

[28] Gobeille v. Liberty Mut. Ins. Co., 136 S.Ct. 936, 943 (2016).

[29] *Id.*

require disclosures from PBMs. In *Pharm. Care Mgmt. Ass'n v. Gerhart*,[30] the PCMA successfully brought an ERISA preemption claim against an Iowa law[31] requiring PBMs to disclose pricing methodology to the state insurance commissioner and their in-network pharmacies. State legislators specifically excluded PBMs serving any "self-funded health coverage plan that is exempt from state regulation pursuant to the federal Employee Retirement Income Security Act of 1974 (ERISA)" from the law. The 8th Circuit Court of Appeals held that this exemption made an "impermissible reference to ERISA" and preempted the entire law.[32] In June 2018, the same court also found that ERISA and Medicare Part D statutes preempted Arkansas's Act 900, which regulates how PBMs set reimbursement rates for pharmacies filling generic drug prescriptions and requires that PBMs pay all pharmacies the same reimbursement rates as affiliated pharmacies.[33] The 8th Circuit found that the Arkansas law both "relates to and has a connection with employee benefit plans."[34] The U.S. District Court for the district of North Dakota, however, deviated from the 8th Circuit's[35] reasoning when it upheld two North Dakota laws containing multiple provisions that place restrictions on PBMs.[36] In a more nuanced and probing opinion, that court found that neither law "govern[ed] a matter central to ERISA plan administration" and the effect on health plans was "too tenuous to constitute interference with nationally uniform plan administration."[37] These seemingly conflicting court decisions leave states in a quagmire with few clear boundaries on ERISA's ever-growing preemptive reach. Until the Supreme Court gives states guidance about the limits of what constitutes an improper reference or connection to an ERISA plan, any state seeking to regulate PBMs will likely face legal challenges with uncertain outcomes.[38] The complexity and opacity of ERISA preemption mean that states will need help from the federal government to enact meaningful regulation of PBMs.

Furthermore, recent consolidation in the PBM market further increases the importance of transparency and oversight. Three PBMs (CVS Caremark, OptumRx, and Express Scripts) control approximately

[30] Gerhart, 852 F.3d 722.
[31] IOWA CODE § 510B.8 (2019).
[32] Gerhart, 852 F.3d at 727-732.
[33] Pharm. Care Mgmt. Ass'n v. Rutledge, 891 F.3d 1109, 1114 (8th Cir. 2018).
[34] *Id.* at 1112.
[35] Pharm. Care Mgmt. Ass'n v. Tufte, 326 F. Supp. 3d 873, 884 (D.N.D. 2018).
[36] S.B. 2258, 2017 Leg., 65th Sess. (N.D. 2017); S.B. 2301, 2017 Leg., 65th Sess. (N.D. 2017) (enacted as N.D. CENT. CODE § 19-02.1-16.1).
[37] Tufte, 326 F. Supp. 3d at 887.
[38] As of this writing, the Supreme Court is considering a petition for a writ of certiorari from the state of Arkansas to hear an appeal in Pharm. Care Mgmt. Ass'n v. Rutledge (18-540).

75% of the PBM market,[39] and all three of them are or will likely become vertically integrated with an insurer, essentially eliminating standalone PBMs.[40] Both the vertical and horizontal consolidation leaves many experts and lawmakers questioning whether the remaining PBMs have the necessary incentive to negotiate strongly for their beneficiaries and pass those savings on to plan sponsors. Moreover, vertical integration between insurers and PBMs obfuscates negotiated payments for prescriptions drugs, leaving payers, lawmakers, and researchers with little data to determine whether PBMs save payers money. As a result, laws to ensure that PBMs act in the interest of their beneficiaries remain critical, but ERISA hinders the ability of states to demand transparency from PBMs.

b. Pricing Transparency/Reports on Drug Prices

In addition to demanding transparency regarding PBM rebates and practices, some state legislatures sought to increase the transparency of drug prices overall and how those prices affect insurance premiums. These laws give policymakers data to understand how prescription drugs affect insurance premiums in their state. In addition, they shine a light on supra-competitive drug pricing practices, potentially shaming manufacturers into lowering them. In 2017, two states – California and Nevada – passed pricing transparency laws to increase transparency in drug prices. Following on that momentum, in 2018, twenty-four states considered and six states passed legislation to improve drug price transparency.[41]

These laws do not directly control drug costs; nevertheless, the information gathered by state agencies can guide future legislative or regulatory actions. In California, for example, the Office of Statewide Health Planning and Development's Prescription Drug Cost Transparency Report found that specialty drugs accounted for over half of the money insurers spent on prescription drugs, even though specialty drugs only

[39] Adam J. Fein, *Cigna-Express Scripts: Vertical Integration and PBMs' Medical-Pharmacy Future (rerun),* DRUG CHANNELS (2018), https://www.drugchannels.net/2018/05/cigna-express-scripts-vertical.html (last visited Feb 15, 2019).

[40] CVS Caremark is a PBM/Pharmacy group and will soon merge with the insurer Aetna (*see* Al-Muslim, Aisha, *CVS Lays Out Vision for Future as Aetna Merger Looms.*, THE WALL STREET J, Nov. 6, 2018, https://www.wsj.com/articles/cvs-reports-higher-revenue-profit-1541507882.). ExpressScripts and the insurer Cigna have approval from the Justice Department to merge (*see* Abelson, Reed, *Merger of Cigna and Express Scripts Gets Approval From Justice Dep't.*, N.Y. TIMES, Sept 17, 2018, https://www.nytimes.com/2018/09/17/health/cigna-express-scripts-merger.html, and Federal Trade Commission, *20180982: Express Scripts Holding Company; Cigna Corporation. Premerger Notification Granted* (September 17, 2018), https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices/20180982. OptumRx is already owned by the insurer UnitedHealth Group.

[41] CT, LA, ME, NH, OR, VT passed laws; CO, HI, IN, MD, MA, MI, MN, MS, NE, NH, NJ, NY, PA, RI, SC, TN, WA, and WI also considered bills.

accounted for only 1.6 percent of all prescriptions.[42] Similarly, in Nevada, the state determined that "five manufacturers account for 59% of [the essential diabetes drugs] … with a significant price increase … in the last one or two-year periods".[43] These reports derived from price transparency initiatives suggest that interventions targeted at controlling the costs of individual specialty drugs could reduce drug expenditures. Transparency laws alone, however, are unlikely to significantly affect drug prices, especially if manufacturers do not respond to public reports of price increases. These laws have the greatest value when synergistically integrated into statewide policymaking to identify specific market inefficiencies and the most effective interventions. For example, a state considering rate review legislation could use information gleaned from reports mandated through transparency laws to know where to target their interventions.

Not surprisingly, the pharmaceutical industry vigorously challenged both of the 2017 state drug price transparency laws, claiming federal preemption by the dormant commerce clause and trade secret laws. The Constitution gives Congress the power to regulate interstate commerce, and the dormant commerce clause (DCC) is a long-standing judicial interpretation that prohibits states from passing laws that discriminate against out of state competitors or unduly burden interstate commerce. According to the balancing test established by the Supreme Court in *Pike v. Bruce Church Inc.*, a law that "regulates even-handedly to effectuate a legitimate local public interest … will be upheld unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits [provided by the law]."[44] States seeking disclosures of *public* pharmaceutical pricing information, like the wholesale acquisition cost (WAC), a federally defined list price,[45] have a strong claim in favor of a legitimate public interest in obtaining the information. Nonetheless, the Pharmaceutical Research and Manufacturers of America (PhRMA) alleges that the dormant commerce clause preempts California's SB-17 because, under the law, a manufacturer cannot increase the WAC of a drug without waiting 60 days or facing financial

[42] CALIFORNIA DEPARTMENT OF MANAGED HEALTH CARE, PRESCRIPTION DRUG COST TRANSPARENCY REPORT (SB 17) MEASUREMENT YEAR 2017 (January 2019), https://www.dmhc.ca.gov/Portals/0/Docs/DO/sb17.pdf.

[43] NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES, ANALYSIS OF ESSENTIAL DIABETES DRUGS THAT HAD A PRICE INCREASE (Sept. 30, 2018), http://dhhs.nv.gov/uploadedFiles/dhhsnvgov/content/HCPWD/Analysis%20of%20Essential%20Diabetes%20Drugs%20that%20had%20a%20Price%20Increase_09.30.2018.pdf

[44] Pike v. Bruce Church, Inc., 397 U.S. 137, 142, 90 S. Ct. 844, 25 L. Ed. 2d 174 (1970).

[45] 42 U.S.C. § 1395w-3a(c)(6)(B) (2011).

penalties assessed by the state of California.[46] Since many wholesalers and pharmacies base their contracts on the WAC price, PhRMA asserts that California's law becomes a nationwide ban on price increases until the state's 60-day waiting period elapses.[47] The court dismissed the lawsuit for lack of standing,[48] but PhRMA filed a new complaint and the case is still pending.[49]

When a state seeks disclosure of private or confidential information, it must also consider the potential for trade secret preemption. Nevada's drug transparency law specifically amended the state definition of a trade secret to exclude any disclosures required by the law, so that the state could publish any drug pricing information it collected.[50] PhRMA and the Biotechnology Industry Organization (BIO) filed a civil suit alleging that federal trade secret law and the Fifth Amendment takings clause preempted the Nevada law because disclosure of confidential or proprietary information would destroy the value of trade secret property without recompense. PhRMA and BIO, however, withdrew the lawsuit after the state agreed to a process by which manufacturers could request state regulators keep any disclosures confidential.[51]

The experiences of California and Nevada demonstrate that any state lawmakers considering similar legislation should anticipate a vigorous legal challenge from industry. Lawmakers must carefully craft the legislation to thread the needle of federal preemption while facilitating disclosure of data that can be used to guide other state policies. While laws requiring disclosure of public information should survive legal challenges, the information gained will be of limited value. Transparency laws that collect negotiated prices and pricing methodology will prove more effective at addressing rising drug costs, but disclosure of such information may be limited by legal challenges.

c. Importation of Drugs from Canada and Other Countries

In May 2018, Vermont Governor Phil Scott signed S-175 into law, making Vermont the first state to begin development of a wholesale importation program for prescription drugs. Vermont's Agency of Human

[46] Complaint for Declaratory and Injunctive Relief, *Pharm. Research & Manufacturers of Am. v. Brown*, Case 2:17-at-01323 (E.D. Cal. December 8, 2017).

[47] *Id.*

[48] Pharm. Research & Manufacturers of Am. v. Brown, No. 217CV02573MCEKJN, 2018 WL 4144417, *5-*6 (E.D. Cal. Aug. 30, 2018).

[49] Pharmaceutical Research and Manufacturers of America v. David, Case 17-CV-02573 (E.D. Cal. December 8, 2017).

[50] SB-539, 2017 Leg., 79th Sess. (Nev. 2017); NEV. REV. STAT. § 600A.030(5)(b) (2017).

[51] Nevada Department of Health and Human Services, *Approved regulation of the Department of Health and Human Services, LCB File No. R042-18, effective May 31, 2018* (2018), http://dhhs.nv.gov/uploadedFiles/dhhsnvgov/content/HCPWD/Sec%20of%20State%20Official(1).pdf.

Services issued a report to the Vermont Legislature concluding that a drug importation program for 17 of the most costly medications would save up to $5 million annually.[52] To begin importing drugs, however, the Vermont legislature required the state's importation program to comply with any HHS regulations.[53] Congress already permits the reimportation and sale of prescription drugs manufactured in the United States and exported to certain foreign markets, as long as the HHS Secretary can ensure an adequate level of safety and significant cost savings for U.S. consumers.[54] To date, however, no HHS Secretary has ever certified this required level of safety. As a result, while Vermont's law may survive potential legal challenges, the requirement to obtain approval from the federal government currently stymies the impact of this law.

Nonetheless, the concept of allowing the importation of some drugs from other countries to control prices has gained traction. In 2018, eight other states considered legislation to set up their own drug importation program, and thus far in 2019 Colorado, Maine, and Florida passed drug reimportation bills.[55] Even if no state establishes an operational drug importation program, perhaps the growing state demand for federal action will prove more important. In July 2018, HHS Secretary Azar directed the FDA to set up a working group to explore a targeted drug importation program for generic drugs that experience an excessive price increase[56] and, in 2019, Congress introduced multiple bills to import drugs from Canada.[57] What becomes of this explorative effort remains to be seen.

Unlike the other laws discussed in previous sections, the pharmaceutical industry may choose not to challenge these importation programs through legal action, but rather retaliate by rewriting distribution contracts in other countries to disincentivize them from reimporting drugs into the United States. As a result, states passing importation laws may not face lawsuits challenging the constitutionality of these laws as long

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[52] VERMONT AGENCY OF HUMAN SERVICES, REPORT TO THE VERMONT LEGISLATURE: WHOLESALE IMPORTATION PROGRAM FOR PRESCRIPTION DRUGS LEGISLATIVE REPORT (Dec 31, 2018), https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf.

[53] Federal Food, Drug, and Cosmetic Act (FDCA) §804, 21 U.S.C. §384 (c)(3) (2012).

[54] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, 2464-2469 (2003-2004).

[55] 2019 FL S.B. 1452 (NS) and 2019 CO S.B. 5 (NS).

[56] Press Release, U.S. Department of Health and Human Services, *HHS Secretary Azar Directs FDA to Establish Working Group on Drug Importation to Address Price Spikes* (July 19, 2018) (https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html).

[57] Safe and Affordable Drugs from Canada Act of 2019, H.R. 478 and S. 61, 116th Cong. (2019-2020); Affordable and Safe Prescription Drug Importation Act, H.R. 447 and S. 97, 116th Cong. (2019-2020).

as they require approval by the program by HHS. Nonetheless, states should recognize that importation programs may not significantly reduce drug prices as industry will likely make it difficult for foreign entities to resell drugs and for patients to obtain them at lower prices from foreign pharmacies.

3. Direct Rate Regulations or Controls

The third set of laws, direct rate regulation or controls, has the greatest potential to control drug costs, but no state has yet successfully implemented rate setting or price gouging statutes. By directly regulating drug prices or preventing excessive increases in drug prices, these laws give state Attorneys General or agencies more control over the price paid for drugs, not just patient cost-sharing. States considering these measures should recognize that they are likely to face significant legal challenge and retaliation by industry. Nonetheless, states considering price gouging or rate setting provisions are focusing their efforts on policies that are most likely to reduce drug expenditures.

a. Price Gouging Prohibitions

In 2018, fifteen states considered prohibitions against price-gouging for pharmaceuticals by preventing manufacturers from raising drug prices by an "unconscionable" amount. In a now classic example of excessive pharmaceutical price increases, Martin Shkreli, former CEO of Turing Pharmaceuticals, raised the price of Daraprim, a drug that treats rare toxoplasmosis and cystoisosporiasis infections, from $13.50 to $750 per pill overnight.[58] Price hikes like these are increasingly common. The Government Accountability Office (GAO) studied generic drugs covered by the Medicare Part D program and reported that "[m]ore than 300 of the established generic drugs analyzed had at least one extraordinary price increase of 100% or more between first quarter 2010 and first quarter 2015."[59]

In 2017, Maryland passed the first law prohibiting price gouging for essential off-patent or generic drugs (HB 631).[60] The law allowed the Attorney General to bring a civil lawsuit when a price increase for an essential off-patent or generic medication was "unjustified" and "unconscionable." The law did not set a threshold price or price increase

[58] Andrew Pollack, *Drug Goes From $13.50 a Tablet to $750, Overnight*. N.Y. TIMES, September 20, 2015, https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0.

[59] U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-706, GENERIC DRUGS UNDER MEDICARE: PART D GENERIC DRUG PRICES DECLINED OVERALL, BUT SOME HAD EXTRAORDINARY PRICE INCREASES (August 2016).

[60] MD. CODE ANN., Health-Gen. §§ 2-801-803.

that constituted price gouging; instead, it left those questions to the discretion of the Attorney General and the courts. Upon challenge, the law grants the manufacturer the opportunity to justify the price increase.[61] While the law would likely not prevent manufacturers from raising drug prices over time, it should prevent generic manufacturers from exploiting market inefficiencies to raise prices without justification.

The Maryland law, however, was not allowed to take effect. In April 2018, the 4th Circuit Court of Appeals held Maryland's law unconstitutional because it violated the dormant commerce clause.[62] The court held that the law violated the externality doctrine of the dormant commerce clause. Specifically, "a State may not regulate commerce occurring wholly outside of its borders" and the externality "principle applies if it either expressly applies to out-of-state commerce, or has that 'practical effect,' regardless of the legislature's intent."[63] The 4th Circuit Court of Appeals held that Maryland's law applied to drugs made available for sale in Maryland, but not necessarily sold in the state so it regulated transactions that did not result in drugs actually sold in Maryland. Furthermore, "the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug,"* so the court held that Maryland's law regulated sales that occurred outside of the state.[64] Some legal scholars have questioned the validity of this opinion,[65] but in February 2019, the Supreme Court denied certiorari for Maryland's appeal. The decisions in this case and Maryland's considerable legal battle effectively halted other states' efforts to enact prescription price gouging laws – none of the sixteen bills considered in 2018 passed state legislatures, and in 2019, only five states considered similar bills.[66]

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[61] The law also provides that if the increased price was due to increased costs of production or expanded access to the drug, the increase in price is not price gouging.

[62] Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664, 673-74 (4th Cir. 2018).

[63] Ass'n for Accessible Medicines v. Frosh, 887 F.3d at 668 (citing Star Scientific, Inc. v. Beales, 278 F.3d 339, 355 (4th Cir. 2002)).

[64] *Id.* at 671.

[65] See Isaac D. Buck's paper, *States as Activists*, ___ J. LEGAL MED. ___ (2019) for a more detailed explanation of the legal doctrines in the case.

[66] The sixteen states considering legislation in 2018 were: Colorado (SB 152), Illinois (HB 4900), Louisiana (HB 243 and HB 710), Massachusetts (S 652), Michigan (SB 900 / HB 5690), Minnesota (SF 2841/HF 3131), Mississippi (HB 137), New Hampshire (HB 1780), New Jersey (S 1590/A 3987), New York (A 5249/S 7028, A 5733/S 2544, A 7087/S 5262), Rhode Island (H 7022), Vermont (H 713), Virginia (SB 223), Washington (SB 5995/HB 255), and Wisconsin (SB 874/AB 1046). As of this writing, Indiana (SB 415), New Jersey (A 4216/S 2630 and A 3987/S 1590), New York (A 237/S 803, A1452/ S 2893,A 2621/S 1642, A 3829/S 1798 and A 6606/ S 141), Tennessee (HB 887/SB 963), and Virginia (SB 1308) have considered price gouging bans for pharmaceuticals in the 2019 session.

States seeking to protect their residents from excessive price increases should expect a similar legal fight. While states should consider crafting legislation that considers only prices paid by consumers in the state when determining if price gouging occurred, states pursuing these laws should expect strong legal challenges from industry. In addition, states should recognize that even if they are able to enact price gouging laws, they may not have a meaningful impact of drug prices overall. While these laws prevent excessive price increases for generic drugs to treat rare diseases, drug manufacturers may simply increase the price of their drug on release and continue to increase the price below any threshold set in legislation or regulation.

b. Rate Setting

Perhaps the most effective way for a state to control prescription drug costs is to directly set drug prices or establish an all-payer cap, which would set a maximum price for both public and private payers within the state. In 2018, eight states – California, Florida, Maryland, Minnesota, New Jersey, New Mexico, Ohio, and Rhode Island – considered such legislation. Three of those states, Maryland, Minnesota, and New Jersey, introduced bills based on the National Academy for State Health Policy's (NASHP) Rate-Setting Model Legislation. This model legislation establishes a Drug Cost Review Commission, similar to a public utility commission, that establishes a payment cap for certain drugs that payers cannot exceed. Rhode Island's effort, in contrast, sets maximum prices only for drugs for which the State Board of Pharmacy determines are "so high that [they] jeopardize[] the state's ability to meet the needs of the state's population for that drug."[67] Once the board makes that determination, the "board may set the maximum allowable price that the manufacturer can charge for that prescription drug" when sold for use in the state. Other states chose to tie their rates to standard benchmarks. For example, Ohio's bill would prohibit insurers, both private and public (including Ohio's Medicaid program), from paying more than the amount the United States Department of Veterans Affairs (VA) reimburses for the same drug.[68] In an attempt to avoid preemption by ERISA and the Federal Employee Health Benefits Act, the state legislature exempted self-insured employers and the Federal Employees Health Benefits Program from this price cap.[69] While rate setting may be one of the best

[67] S. 2550 and H. 7042, 115th Gen. Assemb., Reg. Sess. (R.I. 2018).
[68] S.B. 253, 133d Gen. Assem., (Ohio 2018).
[69] Ohio Legislative Service Commission, *Bill Analysis SB 253 132nd General Assembly (As Introduced)* (Feb 5, 2018), https://www.legislature.ohio.gov/download?key=9358&format=pdf.

methods for states to control drug costs, no state has yet mustered the political will required to pass such a measure.

Furthermore, any state passing rate setting legislation should expect significant legal challenges from industry. In 2007, PhRMA and the Biotechnology Industry Org (BIO) successfully challenged a District of Columbia law that capped wholesale drug prices at "30% higher than the comparable price in any high income country in which the product is protected by patents or other exclusive marketing rights."[70] The U.S. Court of Appeals for the Federal Circuit held the law preempted by federal patent laws. While legal scholars have asserted that patent law should not preempt the NASHP model legislation and rate regulation of pharmaceuticals should not amount to unconstitutional "regulatory takings" under the Fifth Amendment,[71] any state passing rate setting legislation should expect rigorous legal challenges from industry with uncertain outcomes.

Overall, efforts by states to pass legislation to address rising drug costs have been aggressively challenged by industry. As a result, much of the legislation considered in recent legislative sessions targeted specific anticompetitive practices (e.g. gag-clause prohibitions, price-gouging prohibitions) or are likely to have minimal impact due to efforts to avoid preemption by federal law (e.g. regulation of PBMs and transparency measures). Nonetheless, these new laws form part of a multifaceted state and federal effort to ensure prescription drug affordability and value for patients. In addition to passing legislation, many states also used their power as a purchaser of prescription drugs to adopt new cost control measures without risk of legal challenge.

USE OF STATE PUBLIC EMPLOYEE PLANS PROGRAMS TO CONTROL DRUG COSTS

Some states leveraged their power as health care payers in the state employee or retirement plans to lower prescription drug spending. Often these efforts did not require action by the state legislature. For example, many state employee programs implemented financial incentives to encourage their members to shop for high-value care. For pharmaceuticals, these incentives encourage patients and providers to choose cheaper drugs in a therapeutic class and to promote the use of generic equivalents when possible.

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[70] *Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1365 (Fed. Cir. 2007).

[71] Robin Feldman, et al., National Academy for State Health Policy White Paper, *Federalism, Patents, and the Constitutionality of State Pharmaceutical Regulation (*March 2018), https://nashp.org/wp-content/uploads/2018/03/White-Paper-2018.pdf.

For instance, in 2018, California's Public Employees Retirement System (CalPERS), a state agency that manages retirement benefits for public employees, announced it would expand its reference pricing program to pharmaceuticals.[72] Reference prices are prices set by a payer that establish the highest amount a payer will pay for a particular good or service. Since 2011, CalPERS has used reference pricing to encourage its beneficiaries to shop for higher value care for non-emergency care including joint replacement surgery, outpatient colonoscopies, and cataract surgeries. Beginning in 2019, CalPERS will use reference pricing for pharmaceuticals in three therapeutic classes - nasal corticosteroids, thyroid medications, and estrogens for members using basic health plans serviced by PBM OptumRx.[73] The CalPERS reference pricing system allows patients to obtain a more expensive drug as long as the patient pays the difference between the cost of that care and the reference price. The CalPERS program, therefore, gives patients and providers flexibility in choosing which drug in a class to use by setting the maximum CalPERS would pay for three classes of drugs, but it incentivizes the patient to choose lower cost drugs.

Other states have implemented right-to-shop or savings reward programs for their public employees that, like reference pricing, encourage patients to shop for higher value care. Like reference pricing programs, insurers create savings reward programs to give patients a financial incentive for choosing providers with lower than average costs. Typically, the insurer agrees to share any savings generated when the patient chooses a lower cost provider. As a result, right-to-shop policies give patients a financial incentive to seek lower cost, high-quality care even if they have a flat co-payment or have met their deductible for the year. As with the reference pricing program used by CalPERS, these savings only apply to shoppable services where the patient has the ability to compare costs and quality of multiple providers. With right-to-shop programs, unlike with reference pricing, this financial incentive to seek low-cost, high-quality care is independent of any threshold or reference price.

New Hampshire was the first state to implement a right to shop program in 2015, when they commissioned Anthem to develop a right-to-shop program for state employees. In the first three years of the program, the state

[72] CalPERS, *Pension and Health Benefits Committee Agenda Item 6: Strategy for Reference Pricing Pharmaceuticals by Therapeutic Class (Pilot)* (April 17, 2018), https://www.calpers.ca.gov/docs/board-agendas/201804/pension/item-6-a.pdf.

[73] CalPERS, *Pension and Health Benefits Committee Agenda Item 7(b): Strategy for Reference Pricing Pharmaceuticals by Therapeutic Class* (Nov. 14, 2018), https://www.calpers.ca.gov/docs/board-agendas/201811/pension/item-7b_a.pdf.

saved $11 million.[74] In 2018, Utah passed the state's Health Insurance Right to Shop law in which it required the Public Employees' Benefit and Insurance Program to implement a savings reward program and encouraged other health insurers to develop and implement similar programs by amending the Insurance Code.[75] The success of existing right-to-shop programs has increased their popularity rapidly. In 2018, Florida, Oklahoma, Arizona, and South Carolina also considered legislation to establish similar right-to-shop programs, and Nebraska passed legislation to allow shared savings provisions in insurance benefits, and, in just the first two months of 2019, Illinois, Minnesota, Oklahoma, and Tennessee introduced similar legislation. Nonetheless, states can implement these programs for their public employees without legislative action. For example, Kansas, Kentucky, and Massachusetts recently established programs for their public employees without legislative action. Right-to-shop programs do not directly target drug costs, but states could easily adopt shared savings programs to include financial rewards for choosing cheaper therapeutic alternatives or for using mail-order pharmacies.

To leverage the volume of its state-wide pharmaceutical drug purchasing, California's Governor, Gavin Newsom, ordered the Department of Health Care Services to consider combining the state purchasing for the Medicaid program, CalPERS, and other groups for whom the state provides prescription coverage.[76] In his first executive order, in January 2019, he directed the state to identify the 25 highest cost drugs and set up a bulk purchasing program or negotiate directly with manufacturers to reduce the cost for these drugs. The executive order further required the Department of General Services to develop a framework for providing any discounts received by state bulk purchasing efforts to all purchasers in the state including private insurers. In 2018, Vermont also considered purchasing pharmaceuticals directly from a wholesaler. Vermont's Governor, Phil Scott, signed a law[77] creating a working group to "investigate and analyze prescription drug pricing throughout the prescription drug supply chain in order to identify opportunities for savings for Vermont consumers and other payers and for increasing prescription drug price transparency at all levels of the supply chain." In November 2018, the group recommended that the Department of Vermont Health Access, the state's Medicaid program, explore a contract with a single drug wholesaler to supply drugs to

[74] Josh Archambault, *Right To Shop: The Next Big Thing In Health Care*, FORBES, Aug. 5 2016, https://www.forbes.com/sites/theapothecary/2016/08/05/right-to-shop-the-next-big-thing-in-health-care/#31bda24b4f60.

[75] UTAH CODE ANN. § 31A-22-647 (amended 2018).

[76] Cal. Exec. Order No. N-01-19 (January 7, 2019), https://www.gov.ca.gov/wp-content/uploads/2019/01/EO-N-01-19-Attested-01.07.19.pdf.

[77] VT. ACT. NO. 193, § 11a (2018).

Medicaid-enrolled pharmacies for the Vermont Medicaid program because the working group "believe[d] that both savings and transparency can be achieved through channel simplification."[78] The group, however, did not receive any responses to a request for information from wholesalers. As a result, whether Vermont can realistically implement a direct purchasing arrangement remains unknown. Vermont's experience shows that even when a state has the political will and resources to implement new strategies to control costs, it is still subject to retaliation by the industry. California's bulk purchasing program may be more difficult for industry to ignore because it covers many more people than Vermont's Medicaid program. MediCal, California's Medicaid program, is the largest Medicaid program in the country, covering more than 13 million residents,[79] and CalPERS covers 1.5 million people, making it the second largest employer purchaser of health benefits after the Federal Employees' Health Benefits Program.[80] California's negotiating power may prove more persuasive than that of smaller states, but whether and how California will be able to overcome the political and logistical hurdles to creating a bulk prescription drug purchasing program for diverse state programs and private insurers remains to be seen. Other states should monitor California's progress to determine the value of multi-state purchasing agreements for pharmaceutical drugs.

While constrained in many legislative efforts, states retain a variety of tools at their disposal to control pharmaceutical spending. States should recognize the flexibility they have to tailor their state employee benefits to ensure better value for health care spending. Furthermore, even though these programs may not cover large portions of the population, especially in smaller states, states should recognize that these programs can both save millions of dollars for state budgets and serve as examples of effective cost-savings for private insurers.

SUGGESTIONS FOR STATES

When implementing measures to address rising drug prices, states face significant challenges to enacting meaningful policies. These

[78] VERMONT AGENCY OF HUMAN SERVICES, REPORT TO THE HOUSE COMMITTEE ON HEALTH CARE AND THE SENATE COMMITTEE ON HEALTH AND WELFARE BY THE AGENCY OF HUMAN SERVICES: VERMONT MEDICAID DRUG WHOLESALER SAVINGS INITIATIVE (Nov. 15, 2018), https://legislature.vermont.gov/assets/Legislative-Reports/Sec.11a-Act-193-Prescription-Drug-Cost-Savings-and-Price-Transparency.pdf.

[79] California Department of Health Care Services, *Medi-Cal at a Glance,* (August 2018), https://www.dhcs.ca.gov/dataandstats/statistics/Documents/Medi-Cal_at_a_Glance_Aug2018_ADA.pdf.

[80] CalPERS, *CalPERS Story* (updated April 16, 2019), https://www.calpers.ca.gov/page/about/organization/calpers-story.

difficulties, however, must be seen as a call to action, rather than as an excuse for inertia. States must learn from each other both in testing new legislative actions and developing new programs in their state employee programs. We offer four suggestions for states looking to advance their efforts at controlling drug costs.

First, numerous factors contribute to drug expenditures, and states should ensure that any new policies directly target the reasons for the increase. To use a targeted strategy, however, policymakers need to know the drivers of high drug costs in their state. Since the net price paid by insurers (i.e. the price after rebates and discounts) for drugs is often confidential, policymakers can only guess at which policies will address the critical underlying reasons for increasing drug expenditures. Researchers at the University of Pittsburgh found that *list prices* for drugs (i.e. the WAC) increased at nearly six times the rate of inflation between 2013 and 2015,[81] but a report by IQVIA, an independent institute, found that *net prices* for drugs grew only 1.5% in 2017.[82] Reconciling the reasons for the variation between these two numbers could lead to different policy decisions. For example, if the IQVIA report correctly reports that the net price for drugs is barely increasing, lawmakers should consider policies that target PBMs and insurers who may profit from the bubble between the net and list prices. Although the inability of researchers at the University of Pittsburgh to access net prices severely limited their study, the results suggest that price increases for existing brand-name drugs and the release of new, expensive specialty drugs drove price increases. Policymakers seeking to address these concerns should consider rate-setting or price gouging legislation. The obfuscation of the net cost of drugs hinders the ability of lawmakers to target the most effective policies. Transparency laws, specifically those that seek to obtain net prices by requiring disclosures by PBMs and insurers, remain critical to help build an understanding of what prescription drug prices are and how they affect insurance premiums. Nonetheless, transparency measures alone are unlikely to significantly decrease drug costs. States, therefore, should not pass these laws with the expectation that transparency alone will reduce costs by allowing patients to choose cheaper medications, but rather with the expectation that these laws will allow the state to gather information and support for additional, targeted legislative efforts.

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[81] Inmaculada Hernandez et al., *The Contribution of New Product Entry Versus Existing Inflation in the Rising Cost of Drugs,* 38 HEALTH AFFAIRS 76, 76 (2019).

[82] *Medicine Use and Spending in the U.S.*, IQVIA, (April 19, 2018), https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022 (last visited Feb 14, 2019).

Secondly, states seeking to address drug costs should band together and consolidate purchasing power to mitigate retaliation from industry. For example, wholesalers who declined to participate in a pilot program in Vermont might find it much more difficult to refuse to work with a multi-state purchasing program. In addition, states could *require* participation in bulk purchasing programs from the wholesalers serving the Medicaid program and/or their employee benefit plans, and offer that program to private insurers, as California's governor did in his executive order. Montana's experience with its employee benefit plan demonstrates success in setting prices for health services and demanding transparent pricing for all drugs. Other states can learn from and join Montana in demanding transparency in how the state spends money on health services and setting reasonable rates for all services. Furthermore, if states allow private insurers in these programs, they can significantly increase their bargaining power with drug manufacturers and wholesalers. In 2018, Vermont considered legislation to direct the state's Agency of Human Services to "explore opportunities to work with other states to create a public multistate pharmacy benefit management program."[83] While Vermont did not pass this bill, it demonstrates a willingness to work with other states and a recognition that effective policies to address drug costs likely transcend state borders.

Third, there are no silver bullets. States must recognize that a single policy is unlikely to contain drug expenditures and consider multifaceted approaches. In implementing an interwoven network of policies, states can both address the different underlying reasons for rising drug costs and mitigate retaliation by the pharmaceutical industry. For example, in 2018, Vermont passed legislation banning pharmacist gag-clauses, expanding biosimilar substitution, regulating and mandating disclosures from PBMs, creating a drug importation program, and directly supplying Medicaid recipients with prescription drugs. Although the state faced challenges in implementing some of these laws, it demonstrated its willingness to address the problem of drug costs from multiple angles. In Maryland, the courts overturned the law prohibiting price gouging for prescriptions, so the state should consider other ways to limit price increases, including transparency laws that might shame drug companies into limiting price increases or rate setting policies. The states that address rising drug costs on multiple levels, including laws that target specific market inefficiencies, promote competition, and target the net price of drugs, are most likely to control drug expenditures.

[83] S. 163, Xth Leg., 2017-2018 Sess. (Vt. 2018).

Finally, states should consider whether policies to address drug prices are the most effective use of their resources. Most states have already passed laws that will not likely face industry challenge (i.e. biosimilar substitution and banning of gag-clauses), so states should expect that the pharmaceutical industry will vigorously oppose any action to control drug spending. Furthermore, prescription drugs only account for 10-14% of healthcare expenditures,[84] so states should consider whether to spend their efforts and resources on policies that target drug prices or those that address health costs as a whole, like a public option or single-payer system. A study by Zack Cooper and collaborators found that from 2007 to 2014, prices for hospital inpatient care grew 42 percent while prices for inpatient physician services grew only 18 percent.[85] While that study did not consider prescription drugs, data from the U.S. Centers for Medicare and Medicaid Services shows that the total expenditures on prescription drugs in the U.S. increased by approximately 25 percent from 2007 to 2014, and much of that increase could be due to increased use.[86] These data show that many factors contribute to the increased spending on health care, and states should consider whether policies that address only prescription spending provide the most value for state time and resources.

The legal and political hurdles faced by states trying to implement new strategies to control drug costs are large. Nonetheless, the difficulty American's have in affording prescription medications should encourage states to redouble their efforts to protect their citizens and to call on the federal government to intervene where necessary (e.g. amending ERISA law and clarifying the Medicaid best-price calculations) to allow them to tailor policies to control drug costs to their state. Without government intervention, drug prices will continue to escalate in a way that will hinder the economy and obstruct patients from accessing necessary medication.

CONCLUSION

Prescription drug costs continue to be a top concern for Americans. Economists compared healthcare expenditures in the U.S. to those of

[84] ORG. FOR ECON. COOPERATION AND DEV., HEALTH AT A GLANCE 2017: OECD INDICATORS (2017), https://doi.org/10.1787/health_glance-2017-en.

[85] Zack Cooper et al., *Hospital Prices Grew Substantially Faster Than Physician Prices For Hospital-Based Care In 2007–14*, 38 HEALTH AFFAIRS 184, 186 (2019).

[86] U.S. Centers for Medicare and Medicaid Services, National Health Expenditure Accounts (NHEA), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html.

other countries in the Organization for Economic Cooperation and Development (OECD) and found that "US prices for a market basket of brand-name prescription drugs and medical devices are often two to three times higher than prices in other OECD countries, but there is considerable variation in prices for specific drugs and devices across countries."[87] With inaction by the federal government, nearly every state considered legislation in 2018 to address rising drug costs, and many also made changes to prescription drug coverage by their Medicaid or state employee benefit program. Nonetheless, it remains unclear if these actions will mitigate rising drug costs, especially as experts predict prescription drug costs will continue to contribute to health spending growth.[88] Furthermore, nearly all state efforts to control costs were met with legal challenges or retaliation by the pharmaceutical industry. As a result, states must judiciously expend their resources and political capital to ensure that the policies they implement best address the reasons for the increased spending on pharmaceuticals, and healthcare costs as a whole.

[87] Gerard F. Anderson, Peter Hussey & Varduhi Petrosyan, *It's Still The Prices, Stupid: Why The US Spends So Much On Health Care, And A Tribute To Uwe Reinhardt*, 38 HEALTH AFFAIRS 87, 92 (2019).

[88] Gigi A. Cuckler et al., *National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth*, 37 HEALTH AFFAIRS 482, 484 (2018).