



## **Navigating Legal Challenges to State Efforts to Control Drug Prices: Pharmacy Benefit Manager Regulation, Anti-Price-Gouging Laws, and Price Transparency**

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In the last several years, states have increasingly attempted to use legislative efforts to control drug prices. Trade groups representing the interests of the pharmaceutical industry, however, have challenged the constitutionality of many of these efforts. This issue brief analyzes the legal challenges brought against state laws to address rising drug prices and the legal theories on which these laws are often challenged. Part I reviews how a trade association has used the Employee Retirement Income Security Act of 1974 (ERISA) to threaten state regulation of pharmacy benefit managers (PBMs) in four states and Washington, DC (DC). Part II analyzes *Association for Accessible Medicines v. Frosh* to explain how the Dormant Commerce Clause invalidated Maryland’s prohibition on price gouging or “unconscionable price increases” for drugs. Part III examines how legal challenges arising from federal patent and trade secret laws could hamper state efforts to further drug price transparency. Finally, in each part, using our analysis of key cases, we offer suggestions to states considering similar legislative actions to minimize the risk that courts will overturn them.

### **I. State Regulation of PBMs**

#### **Key Points:**

- **The Employee Retirement Income Security Act of 1974 (ERISA) preempts any state laws that “relate to” employee benefit plans. ERISA challenges have proven the most effective at striking down laws regulating PBMs.**
- **Courts have issued inconsistent rulings about whether laws governing PBMs “relate to” and are therefore preempted by ERISA.**
- **The First Circuit Court found ERISA did not preempt Maine’s 2003 PBM law, but the DC Circuit Court found that ERISA did preempt the same provisions in a DC law (mandating fiduciary duty for PBMs and disclosures over drug costs and PBM benefits). Further, the Eighth Circuit Court held that ERISA preempted certain MAC pricing regulations.**
- **NASHP Model Law B, which contains some of these provisions, may be saved from ERISA preemption, because the law regulates insurers and implicitly excludes self-insured employee benefit plans.**
- **Due to a limited number of court decisions and courts’ inconsistent application of ERISA, states should not hesitate to pass PBM laws as another court may differ significantly in its legal analysis.**

State policymakers face legal obstacles when seeking to regulate pharmacy benefits managers (PBMs), the biggest of which is the doctrine of ERISA preemption. Perhaps most troublesome, is

that ERISA preemption is not settled law, and courts have been inconsistent in its application to PBM regulations. Nonetheless, detailed consideration of the five court rulings on ERISA preemption of PBM regulation provides guidance to states seeking to write laws that better withstand legal challenges. Furthermore, since most federal courts of appeals have not yet reached a conclusion on the matter, how courts in these circuits may rule is a matter of educated guesswork. As a result, states seeking to regulate PBMs may use these rulings as guidelines for crafting new legislation and may find courts in their circuit apply a more measured approach to ERISA preemption. As a result, courts may determine that ERISA does not preempt similar state laws.

### **A. Review of State Statutes Regulating PBMs<sup>1</sup>**

PBMs are middlemen in the drug supply chain. On one end, PBMs negotiate with drug manufacturers to get rebates and discounts. On the other end, PBMs contract with health plans and pharmacies, determining how much health plans pay for drugs and how much PBMs reimburse pharmacies for dispensing drugs. As a result of their position in the market, PBMs have the opportunity to retain rebates or discounts rather than passing savings on to consumers. Consequently, the financial incentives and business practices of PBMs may inflate drug prices and stifle competition. In response, a significant number of states have increasingly considered and passed legislation to target PBM business practices and to reduce high drug prices. These state laws frequently impose five types of regulations: fair pharmacy auditing practices, prohibition of gag clauses, PBM licensure or registration requirements, anti-clawback regulations, and Maximum Allowable Cost (MAC) list regulations. More recently, states have introduced laws prohibiting spread pricing and requiring the pass through of rebates. As states seek to expand regulatory authority over PBMs, they should be aware that some PBM laws more directly targeting PBM business practices may be vulnerable to legal challenges, particularly ERISA preemption.

### **B. Primary Legal Challenge: ERISA**

Nearly every state regulates PBMs in some way and the vast number of state PBM laws have not been challenged. Many of these laws, however, govern how PBMs interact with pharmacies (e.g. regulating fair pharmacy edits and timely updates of MAC lists) and do little to control the cost of drugs or ensure that PBMs act in the best interest of patients and plan sponsors. Nonetheless, laws that govern how PBMs set prices and act on behalf of insurers remain vulnerable to legal challenges and lobbying efforts, often brought by the Pharmaceutical Care Management Association (PCMA), the trade group for PBMs. To date, PCMA challenged five state laws regulating PBMs, and won three of those challenges.<sup>2</sup> While courts in Maine and North Dakota have declined to strike down PBM laws, courts in the District of Columbia, Iowa, and Arkansas have struck down PBM regulations, ranging from disclosure requirements to MAC pricing regulations. In all of these suits, PCMA's most common and successful challenge to state laws regulating PBMs has been ERISA preemption.

#### **1. The Doctrine of ERISA Preemption**

ERISA expressly preempts any and all state laws that "relate to" any employee benefit plan.<sup>3</sup> Congress intended for ERISA to promote nationwide uniformity in employee benefit plan administration. To ensure the "broad scope Congress intended while avoiding the clause's susceptibility to limitless application," the US Supreme Court created a test to determine whether

ERISA preempts state law.<sup>4</sup> Nonetheless, despite more than 20 Supreme Court cases applying the test, the vagueness of the “relate to” provision has not been resolved, sparking a copious amount of litigation resulting in “countless questions about the scope of” ERISA preemption and “seemingly arbitrary and inconsistent answers.”<sup>5</sup>

The “relate to” question, however, does not apply to insurance laws because ERISA specifically saves from preemption any state laws regulating insurance. For a state law to regulate insurance, “the state law must be specifically directed toward entities engaged in insurance . . . [and] the state law must substantially affect the risk pooling arrangement between the insurer and the insured.”<sup>6</sup> The Supreme Court considered “laws regulating the terms of insurance contracts,” as laws regulating insurance.<sup>7</sup> As a result, ERISA will not preempt the application of state insurance laws to fully-insured employee benefit plans.<sup>8</sup> However, ERISA does not deem self-insured employer plans to be insurance, therefore ERISA will preempt the application of state insurance laws to self-insured employee benefit plans.<sup>9</sup> States seeking to regulate PBMs, therefore, must navigate the inconsistency and broadness of ERISA preemption, but may find lessons in prior court decisions that apply ERISA’s preemption test to PBM laws.

## 2. Application of ERISA Preemption to State Laws Regulating PBMs

While ERISA preemption has been the strongest challenge to state PBM laws, PCMA also alleged that state PBM laws violated the Dormant Commerce Clause, the Takings Clause, and others (Table 1). Federal district courts, however, have rejected nearly all types of claims except for ERISA preemption (Table 1). On appeal, the federal appellate courts struck down three of four state PBM laws solely or mainly on ERISA preemption (Table 2), making ERISA preemption the most common and most successful legal challenge against state PBM regulations.

**Table 1: US District Courts’ Response to State PBM Law Challenges**

	Maine	DC	Iowa	Arkansas	North Dakota
<b>ERISA Preemption</b>	X	X	✓	X	✓
<b>Contract Clause (Art. I, Sec. 10)</b>				✓	
<b>Dormant Commerce Clause</b>	✓		✓	✓	
<b>Medicare Part D Preemption</b>				✓	✓*
<b>Takings (5th Amendment)</b>	X		✓		
<b>Void for Vagueness</b>			✓	✓	

✓ = State Law Withstood the Challenge

✓\* = State Law Withstood the Challenge Except in One Instance

X = State Law Preempted or Struck Down

**Table 2: US Court of Appeals’ Acceptance of Challenges to State PBM Law**

	Maine	DC	Iowa	Arkansas
<b>ERISA Preemption</b>	✓	X*	X	X
<b>Dormant Commerce Clause</b>	✓		NR	
<b>Due Process</b>	✓			
<b>FEHBA Preemption</b>	✓			
<b>First Amendment</b>	✓			
<b>Medicare Part D Preemption</b>	✓			X
<b>Takings (5th Amendment)</b>	✓			

✓ = State Law Withstood the Challenge

X = State Law Preempted or Struck Down

X\* = State Law Preempted or Struck Down, in part

NR = Not Reached by the Court

In all five cases, PCMA challenged the statutes prior to or soon after implementation. In the first two cases, *Pharmaceutical Care Management Association v. Rowe*<sup>10</sup> and *Pharmaceutical Care Management Association v. District of Columbia*,<sup>11</sup> PCMA challenged nearly identical statutes<sup>12</sup> in Maine and DC with different outcomes (Table 3). Here, both the Maine and DC laws required that PBMs: 1) owe a fiduciary duty to the covered entity; 2) pass all payment or benefit received from manufacturers or based on volume of sales to the covered entity; and 3) disclose conflicts of interest, financial terms and arrangements between a PBM and drug manufacturer, and the costs of both the substituted and prescribed drug, if the substitute drug costs more. Yet, despite the laws’ similarities, the courts differed in its preemption analysis (Table 3).

**Table 3: On Substantially Similar Laws, Courts Differ in its ERISA Preemption Analysis**

	Maine	DC
<b>Fiduciary Duty to Covered Entity</b>	✓	X
<b>Disclose Conflict of Interest</b>	✓	X
<b>Disclose Costs of Both Drugs and Direct and Indirect Benefits Accrued by PBM</b>	✓	X
<b>Transfer Benefits or Payment Received to Covered Entity Related to Drug Substitution</b>	✓	X
<b>Disclose to Covered Entity All Financial and Utilization Information Requested by Covered Entity</b>	✓	✓
<b>Transfer Benefits or Payment Received to Covered Entity Based on Volume of Sales</b>	✓	✓
<b>Disclose All Financial Terms/Arrangements Between Manufacturer/Labeler</b>	✓	✓

✓ = Provision Upheld

X = Provision Struck Down

NC = Not Challenged by PCMA

In *Rowe*, the First Circuit held that ERISA did not preempt Maine's PBM regulations, because PBMs did not exercise discretionary authority or control in the management and administration of the plan. The court found that PBMs performed purely ministerial duties and therefore were not ERISA fiduciaries and not among the "principal players in the ERISA scenario."<sup>13</sup> Additionally, the court further reasoned that Maine's PBM regulations did not restrict employee benefit plans from administering their plans. Because the court interpreted ERISA to only preempt "state laws relating to acts performed by ERISA fiduciaries," the court did not find Maine's law preempted by ERISA.<sup>14</sup> In *DC*, the DC Circuit held the exact opposite by concluding that laws regulating third party administrators of an ERISA plan "function[ed] as a regulation of an ERISA plan itself."<sup>15</sup> There, the court held that the DC law regulated "a PBM's administration of benefits on behalf of an employee benefit plan."<sup>16</sup> In addition, the court found the administration of employee benefits an area of core ERISA concerns. These two findings were enough for the court to decide that ERISA preempted the DC law. To seal the preemption case, the court observed that the PBM law would force employers to decide whether they would administer pharmaceutical benefits on their own or contract with a PBM to administer those benefits. The court further noted that because ERISA preempts any law that bound a plan administrator to a particular choice, much of the DC law was also preempted. However, the court found that ERISA did not preempt voluntary provisions, because these provisions either (a) allowed the PBM and the covered entity to waive that provision by contract, or (b) permitted disclosure only upon request of the covered entity.<sup>17</sup> The court held that opting out of a state law or negotiating a waiver did not affect plan administration and imposed no meaningful burden, allowing those voluntary provisions to stand.<sup>18</sup>

Many years later, PCMA challenged MAC pricing regulation in Iowa (in *Pharmaceutical Care Management Association v. Gerhart*)<sup>19</sup> and Arkansas (in *Pharmaceutical Care Management Association v. Rutledge*).<sup>20</sup> Specifically, Iowa's §510B.8 required PBMs to: 1) submit to the insurance commissioner their pricing methodology for their MAC lists; 2) limit MAC lists to certain drugs; 3) disclose to pharmacies the source of the pricing data for MAC pricing; and 4) have an appeals process for pharmacists that will include retroactive payments if a MAC pricing has been applied incorrectly. Similarly, but distinctly, Arkansas's Act 900, as challenged in *Rutledge*, mandated that PBMs: 1) reimburse pharmacies for generic drugs at a price equal to or higher than the pharmacies' cost for the drug; 2) update their MAC lists at least seven days after a certain increase in acquisition costs; 3) allow pharmacies to reverse and re-bill each claim when a pharmacist cannot procure a drug at a cost that is equal to or less than the MAC price; and 4) allow pharmacies to decline to dispense if they will lose money on a transaction. Unlike *Rowe* and *DC*, where similar laws were decided differently by different courts, in *Gerhart* and *Rutledge* similar laws were decided by the same court in the same way.

In *Gerhart*, the Eighth Circuit perplexingly found that the law's explicit exclusion of self-insured employee benefit plans, which was written to avoid ERISA preemption, nonetheless created an impermissible "reference to" ERISA. As a result, the court held that ERISA preempted the law in question.<sup>21</sup> Additionally, the court found that Iowa's law had an implicit "reference to" ERISA by regulating PBMs who administered benefits for a "covered entity," which included health benefit plans, employers, and labor unions.<sup>22</sup> Because the court believed such entities were subject to ERISA, the court inexplicably concluded that the Iowa law "applies to only PBMs who administer prescription drug benefits for plans subject to ERISA regulation."<sup>23,24</sup>

Furthermore, the court in *Gerhart* found the regulation of PBMs affected ERISA benefits and thus ERISA plan administration. Specifically, the court found Iowa's law interfered with nationally uniform plan administration. For example, the court viewed the provision that allowed pharmacies to appeal MAC reimbursement rates as restricting an administrator's ability to control an ERISA plan's drug benefits.<sup>25</sup> As a result, the Eighth Circuit held ERISA preempted the Iowa law.

In *Rutledge*, the Eighth Circuit, relying heavily on its decision on *Gerhart*, held that Arkansas's and Iowa's laws were "similar in purpose and effect," and thus, ERISA preempted Arkansas's law by the same reasoning in *Gerhart*.<sup>26</sup> As seen above, while both Arkansas and Iowa's law regulated MAC pricing and MAC appeals processes for pharmacies, Arkansas's law proved more extensive than Iowa's law. Arkansas has since appealed the Eighth Circuit's preemption decision to the Supreme Court. Thirty-two states and the District of Columbia have submitted a brief to the Supreme Court arguing that states should be able to regulate PBM conduct without the threat of ERISA preemption. As of Aug. 4, 2019, the Supreme Court has not decided on whether to take up that appeal.

Seemingly emboldened with its successes in the Eighth Circuit, PCMA then sued North Dakota, also in the Eighth Circuit, over two bills regulating PBMs in *Pharmaceutical Care Management Association v. Tufte*.<sup>27</sup> Unlike *Gerhart* and *Rutledge*, the North Dakota bills would have regulated PBM conduct like PBM fee collection in relation to pharmacy performance, clawbacks, gag clauses, disclosures by pharmacies to plan sponsors, conflict of interest prohibitions, and disclosure of spread pricing to the payer. In *Tufte*, the U.S. District Court for the District of North Dakota rejected all but one of PCMA's claims. The court observed that neither bill contained any provisions regarding ERISA matters such as "claimant eligibility determinations, the monitoring of funds for benefit payments, or the keeping of appropriate records for reporting requirements."<sup>28</sup> Furthermore, similarly to *Rowe*, the court did not see how the bills would impose any requirements on ERISA plans or change the administration of ERISA plans. However, the district court found that Medicare Part D preempted the provision requiring disclosure of spread pricing practices, since federal standards already covered this area.<sup>29</sup> Nonetheless, the ruling did not preempt the entire law; it just prohibited its application to PBMs serving Medicare Part D plans, while still requiring other plans to disclose these spread pricing practices. While the district court rejected the ERISA preemption argument, PCMA appealed the district court ruling. Because of the Eighth Circuit's prior decisions in *Gerhart* and *Rutledge*, it is probable that the Eighth Circuit will find that ERISA preempts the North Dakota bills.

### **C. Recommendations for State Laws Regulating PBMs**

While PCMA has brought forth several challenges to PBM legislation, states should be most concerned with ERISA preemption. Only the First Circuit, DC Circuit, and the Eighth Circuit have ruled on challenges to PBM regulation and those decisions have been inconsistent. Pending the *Rutledge* appeal by the US Supreme Court, ERISA preemption remains an unpredictable and uncertain area of law. Due to the limited number of cases and inconsistent application of ERISA preemption by the courts, states should not be intimidated by the Eighth Circuit decisions as another circuit court may differ in its view of ERISA preemption of PBM laws. If other states do not pass legislation, the rulings in the Eighth Circuit may remain the only, overly broad, interpretation of ERISA preemption of laws governing PBM practices.

Furthermore, careful crafting of PBM legislation should mitigate preemption. Specifically, states should not explicitly exclude ERISA plans, but instead include a provision stating that nothing in the law is intended to or should be construed to be in conflict with existing relevant law. Avoiding use of the word “ERISA” in the law should also avoid any misinterpretation of the “relate to” standard for ERISA preemption. Additionally, states may consider whether to allow employers or plan sponsors to opt out of provisions via contract. In *District of Columbia*, the court did not preempt certain sections of DC’s PBM regulation, because such provisions were “in essence voluntary” by allowing the covered entity to contract differently with a PBM over the usage back provision or have the PBM disclose only upon the request of the covered entity.<sup>30</sup> The court did not believe that negotiating a waiver would be considered an administration of benefits and therefore was not preempted by ERISA.<sup>31</sup> Therefore, if a state chose to require that a PBM act or disclose information to a plan sponsor and allowed a plan sponsor to waive that disclosure, the law should survive preemption.

On the other hand, states should feel more comfortable passing provisions to ban clawbacks, mandate licensure, and establish fair pharmacy audit procedures. Despite challenging North Dakota’s gag clauses and anti-clawbacks provisions in *Tufte*, PCMA praised and supported similar provisions in a 2019 New Jersey bill,<sup>32</sup> containing a ban on gag clauses and clawback provisions.<sup>33</sup> PCMA’s explicit support for such a bill suggests PCMA is unlikely to litigate these issues in other states. PCMA has never challenged PBM licensure/registration and fair pharmacy audit procedures, so states choosing to regulate these practices are unlikely to face legal challenges.

Finally, to minimize the risk of litigation, states may require insurers to contract with PBMs in specific ways rather than directly regulating the business practices of PBMs. Using this novel approach, the Maine legislature crafted L.D. 1504 to impose regulatory requirements on insurers (“carriers” in L.D. 1504) rather than on PBMs. Specifically, L.D. 1504 requires carriers to monitor and oversee PBMs to ensure the requirements of the act are met. Among many provisions, the carrier must include fiduciary duty, anti-clawback, and adequate network provisions in its contract with PBMs. Additionally, the carrier or the PBM under contract with a carrier must use a single MAC list, and only certain drugs can be on a MAC list as specified.

As discussed above, ERISA saves insurance law from preemption, so Maine’s law is also likely saved from ERISA preemption. The law regulates the business of insurance by imposing requirements on state-regulated insurance carriers, which includes fully insured employee benefit plans but, importantly, excludes self-insured employee benefit plans governed completely by ERISA. Because ERISA’s saving clause allows state insurance laws to regulate fully insured employee benefit plans governed by ERISA and because the regulation of carriers and the contracts of carriers would be considered a state insurance law, Maine’s law provides a novel path for states seeking to pass PBM regulations that likely avoid ERISA preemption.

To further assist states seeking to regulate PBMs, the National Academy for State Health Policy (NASHP) and the National Community Pharmacists Association (NCPA) with the National Conference of Insurance Legislators (NCIL) drafted versions of model PBM legislation. Table 1 in the Appendix provides a comparison of the three model laws. The NCPA/NCIL model law was intentionally written to sidestep any possible ERISA preemption challenges but, as a result, may have only minimal effects on drug prices. The NASHP model laws, in contrast, contain more comprehensive provisions and may be more likely to be challenged. Nonetheless, NASHP

Model Law B has a low chance of preemption, because it is based on Maine's L.D. 1504. Whether ERISA preempts a law is a matter for a court to decide, but NASHP Model Law B minimizes the risk of ERISA preemption by regulating the insurer and its contract with a PBM. States, seeking to further minimize the risk of ERISA preemption, could also pass a modified NASHP Model Law B that includes Maine's definition of insurer, as described above, which implicitly excludes self-insured employee benefit plans fully governed by ERISA.

In conclusion, because courts have been inconsistent in their applications of ERISA, states should not be chilled from passing laws to more directly regulate the business conduct of PBMs. Nonetheless, states should be cognizant of potential legal challenges, in particular, ERISA preemption. States may craft legislation that avoids explicitly exempting ERISA plans and requires insurers to oversee conduct of any PBM with which they contract. Ultimately, states passing meaningful PBM regulations can use these suggestions but should also be prepared to defend these laws in court.<sup>34</sup>

## II. State Pharmaceutical Anti-Price-Gouging Laws

### **Key Points:**

- **In 2017, Maryland passed the only anti-price-gouging law in the country, but the Association for Accessible Medicines successfully argued that the law violated the Dormant Commerce Clause.**
- **The Dormant Commerce Clause prohibits states from passing laws that discriminate against out-of-state commerce, unduly burden interstate commerce, or regulate commerce occurring outside the state.**
- **In *Association for Accessible Medicines v. Frosh*, the Fourth Circuit held that Maryland's price gouging law violated the Dormant Commerce Clause, because the Maryland law regulated the initial price of a drug between a manufacturer and a wholesaler, which typically occurs outside the state of Maryland and the law applied to any drug offered for sale in Maryland, not just those actually sold in the state.**
- **Future price gouging laws should be written to apply only to drugs actually sold in a state or to in-state groups, but even these laws may still face challenges based on the Dormant Commerce Clause. Nonetheless, many legal scholars argue that the Fourth Circuit misunderstood the pharmaceutical industry when making their ruling, so courts in other circuits may find price gouging laws do not violate the Dormant Commerce Clause.**
- **Alternatively, states could enact a Prescription Drug Affordability Review Board, which could identify drugs that pose an affordability challenge for a state and potentially impose an upper limit on payor reimbursements of a drug.**

State policy makers seeking to prevent excessive price hikes or price gouging for pharmaceuticals also face significant legal challenge. The second part of this brief examines Maryland's anti-price-gouging law and how the Association for Accessible Medicine successfully argued that the law violated the Dormant Commerce Clause. While Dormant Commerce Clause jurisprudence is still evolving, *Association for Accessible Medicines v.*



*Frosh*<sup>35</sup> provides insight on how states could formulate constitutionally sound anti-price-gouging laws.

### **A. Review of State Efforts to Enact Anti-Price-Gouging Laws**

In 2017, Maryland passed the first law prohibiting price gouging for essential off-patent or generic drugs,<sup>36</sup> allowing Maryland’s attorney general to bring a civil lawsuit against a manufacturer or wholesaler for “unjustified” and “unconscionable” price increases. The law did not set a threshold price or price increase that constituted price gouging. Instead, it defined an unconscionable increase as “excessive and not justified by the cost of producing the drug or appropriate expansion of access to the drug... and results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price”<sup>37</sup> and left discretion to Maryland’s attorney general and the courts.

Following Maryland’s example, 16 other states considered price gouging prohibitions in 2018,<sup>38</sup> and seven states considered similar bills in 2019.<sup>39</sup> Nearly all of the bills have similar definitions of “unconscionable price increases,” but New York’s and Minnesota’s bills would have applied to all pharmaceuticals sold in the state (not just generics). To date, however, no other state legislature has passed an anti-price-gouging bill and the Maryland law, the only anti-price-gouging law to pass a state legislature, was never allowed to take effect.

### **B. Primary Legal Challenge: The Dormant Commerce Clause**

The Fourth Circuit Court of Appeals invalidated Maryland’s anti-price-gouging law in *Association for Accessible Medicines v. Frosh* on the basis that the law violated the Dormant Commerce Clause.<sup>40</sup> The Commerce Clause is a provision of the US Constitution that grants Congress the power to regulate commerce among the states. The Dormant Commerce Clause is a longstanding judicial interpretation of the Commerce Clause that prohibits states from passing laws that discriminate against out-of-state commerce, unduly burden interstate commerce, or regulate commerce occurring outside the state.<sup>41</sup> Specifically, “a State may not regulate commerce occurring wholly outside of its borders” either expressly or in “practical effect.”<sup>42</sup>

In *Frosh*, the Fourth Circuit sided with the Association for Accessible Medicines (AAM), the trade group representing the interests of manufacturers and wholesalers of generic pharmaceuticals, holding that the Maryland anti-price-gouging law violated the Dormant Commerce Clause by targeting conduct that occurs outside of Maryland. Specifically, the court gave four reasons for its holding. First, because the law applied to prescription drugs *offered for sale* in Maryland, Maryland’s law could apply to drugs never actually shipped to Maryland. Second, “the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*,”<sup>43</sup> a transaction that typically takes place outside the state of Maryland. Third, the court held that the law prohibits prescription drug manufacturers “from charging an ‘unconscionable’ price in the initial sale of a drug [between the manufacturers and wholesalers], which occurs outside Maryland’s borders” and, therefore, went beyond merely having an upstream pricing impact on out-of-state commerce to become a price control statute on out-of-state commerce. Fourth, because the law targets wholesale rather than retail pricing, the court argued that the law could place an undue burden on interstate commerce and manufacturers, who would face conflicting state anti-price-gouging laws.

Maryland appealed the decision, but in February 2019, the Supreme Court denied the petition for certiorari, allowing the Fourth Circuit decision to stand. Yet, the Supreme Court often denies certiorari on issues that have not been raised in multiple appellate courts. If, in the future, another circuit should differ in the Fourth Circuit’s interpretation, the Supreme Court may be more likely to take on the matter to ensure federal uniformity. What is clear is that the Supreme Court’s refusal to hear the claim is not a direct condemnation of all anti-price-gouging laws and should not chill states from regulating price gouging.

### **C. Recommendations for States Laws Prohibiting Price Gouging**

States seeking to pass laws prohibiting price gouging should understand that the “undue burden” standard and externality principle of the Dormant Commerce Clause are evolving judicial interpretations. Furthermore, legal scholars argue that the Fourth Circuit misunderstands the nature of the pharmaceutical industry.<sup>44</sup> Maryland’s law, they argue, may have a small impact on transactions that take place wholly out of state, but a law should not be thrown out for violating the principle of extraterritoriality if the law, both in intent and practical effect, governs in-state commerce. In fact, the Supreme Court upheld a Maine law requiring mandatory rebates from manufacturers to avoid prior authorization requirements in the state Medicaid program. The Court’s decision observed that “Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. Similarly, Maine is not tying the price of its in-state product to out-of-state prices.”<sup>45</sup> In a *Health Affairs Blog* post, Darien Shanske and Jane Hovarth argue that similar reasoning should save price gouging laws targeting the wholesale acquisition cost (WAC), which is the manufacturer’s list price of a drug without rebates or other discounts.

Furthermore, Shanske and Hovarth also argue Maryland’s law does not place an undue burden on interstate commerce. Specifically, drug manufacturers already negotiate and track discounts with specific hospitals and health systems, and these negotiations affect financial transactions, such as between a manufacturer and a wholesaler, in other geographic areas. Because drug manufacturers already manage multiple pricing standards for drugs sold to different entities, ensuring that any increase in the WAC for drugs sold in Maryland is not unconscionable should not amount to an undue burden. Thus, Shanske and Hovarth argue “given the structure of the pharmaceuticals market, and particularly the market for the regulated products, the Maryland law would hardly impose a burden, much less an undue one.”<sup>46</sup>

State legislatures considering similar bills, therefore, could consider tweaking Maryland’s anti-price-gouging law to minimize allegations of unconstitutionality. Specifically, legislators can draft bills to ensure the law applies only to drugs actually sold in a state. For example, a draft of the Minnesota omnibus health and human services finance bill (H.B. 2414) prohibited price gouging for essential prescription drugs sold to: “. . . (i) consumers in Minnesota, (ii) the commissioner of human services for use in a Minnesota public health care, or (iii) a health plan company providing medical care to Minnesota consumers.”<sup>47</sup> Such language should resolve the Fourth Circuit’s first concern regarding the law’s applicability to drugs sold out of state. States may also consider tying price gouging to prices actually paid in the state rather than the federal WAC.<sup>48</sup>

States, however, may find it more difficult to address the other concerns raised by the Fourth Circuit, especially if they want to target manufacturers or base affordability on the WAC. Nonetheless, states may pass very similar legislation and, if challenged by AAM, may be

successful in arguing that state anti-price-gouging laws are constitutionally valid using the arguments similar to those described above. Furthermore, many states have sued manufacturers for price gouging and other anticompetitive practices, which may be an alternate to additional legislation.<sup>49</sup>

States looking for an alternative approach to prevent price gouging may choose to follow Maryland's lead by limiting price increases using a cost-review board. In May 2019, the Maryland legislature passed H.B. 768, based on model legislation from NASHP, to create a Prescription Drug Affordability Review Board (PDARB), which can review the cost of a prescription drug and impose an upper limit on purchases and payor reimbursements for that drug. The upper limit only applies to the state government, the state Medicaid program, and state and local government health benefit plans. The review may be triggered by an increase in the WAC of \$3,000 or more in a 12-month period for a brand-name drug or biologic or an increase of 200 percent or more in a 12-month period for a generic drug.<sup>50</sup> After the review process is triggered, the PDARB considers information from many sources including the manufacturer to "determine if the drug will produce or has produced challenges to the affordability of the drug for the state health care system."<sup>51</sup> After additional review and approval by either the Legislative Policy Committee or the governor and the attorney general, the upper limit may additionally apply to anyone purchasing drugs in the state. While creating a PDARB resolves Dormant Commerce Clause concerns, states may need to argue that PDARBs do not violate patent law. For a more thorough discussion of these issues, policymakers may read NASHP's legal brief, titled *States' Rights: A Patent Law Analysis of NASHP Rate-Setting Model Act*.

In summary, states have a range of options when drafting price gouging laws. Limiting the scope of anti-price-gouging laws to drugs sold to in-state groups like state plans or state consumers will best mitigate Dormant Commerce Clause concerns. Furthermore, states may choose to tie price gouging to some state standard rather than the federal WAC. Nonetheless, states passing price gouging laws should be prepared to defend them in court.

### III. State Mandated Disclosure of Drug Prices and Pricing Methods

#### **Key Points:**

- **Eight states require the manufacturer, PBM, or the insurer to report some pricing information to the state.**
- **State laws that require public disclosure of the WAC or allow manufacturers to claim confidentiality of pricing information submitted to state agencies have not been challenged by industry.**
- **The pharmaceutical industry challenged California and Nevada's laws, arguing these laws violate federal trade secret laws, federal patent laws, and the Dormant Commerce Clause. Of these three, the federal trade secret law may pose the greatest threat.**
- **States can minimize the threat of federal trade secret law by articulating how the public interest in price disclosure outweighs the need for trade secret protection.**
- **To avoid the possibility of litigation, states can either declare that the information is not subject to public disclosure or allow manufacturers to limit disclosures to information already in the public domain.**

In addition to laws regulating PBM practices and price gouging, states have also demonstrated significant interest in laws designed to increase the transparency of manufacturer pricing information. State drug transparency laws have faced legal challenges ranging from the Dormant Commerce Clause to federal trade secret law.

#### **A. Review of State Efforts to Increase Transparency of Drug Prices**

In the past three years, eight states passed laws requiring manufacturers to disclose how they price drugs (Table 4), and NASHP developed comprehensive model legislation to improve pharmaceutical price transparency.<sup>52</sup> Some states, including Vermont and Connecticut, only require disclosures for 10 to 15 drugs that either present affordability concerns for the state or are newly released specialty drugs. Other states require disclosures upon an increase in the WAC. These laws often require manufacturers to disclose their reasons for the price increases. In addition to the laws requiring information on how manufacturers price drugs, Louisiana requires quarterly disclosure of the current WAC for all drugs marketed in the state, and Colorado requires manufacturers to disclose the WAC and the names of at least three generic medications in the same therapeutic class when marketing a drug to prescribers. In general, most states, including Washington, and the NASHP model legislation require disclosures only to a state agency and allow the manufacturer to designate some of the information as confidential.

**Table 4: State Drug Price Transparency Laws**

State	Year Passed	Who Reports			To Whom
		Manufacturer	PBM	Insurer	
California	2017	Yes		Yes	Purchasers get advance notice; Office of Statewide Health Planning and Development (OSHPD)
Connecticut	2018	Yes	Yes	Yes	Manufacturers to Office of Health Strategy; PBMs and Insurers to Insurance Commissioner
Maine	2019	Yes	Yes	Already do	Maine Health Data Organization (MHDO)
Nevada	2017 and 2019	Yes	Yes		Nevada Department of Health and Human Services
Oregon	2018 and 2019	Yes		Yes	Oregon Department of Consumer and Business Services
Texas	2019	Yes	Yes	Yes	Executive Commissioner - WAC and price increase reports get publicly reported
Washington State	2019	Yes	Yes	Yes	Washington Health Care Authority
Vermont	2016	Yes		Yes	Vermont Office of Attorney General AND Green Mountain Care Board (GMCB); but can submit redacted info to GMCB

## B. Legal Hurdles: A Smorgasbord of Legal Challenges

Of the eight state laws with drug transparency provisions, the pharmaceutical industry only challenged the more sweeping provisions in the California and Nevada laws. State laws that require public disclosure of the WAC or allow manufacturers to claim confidentiality of pricing information submitted to state agencies have not been challenged by industry.<sup>53</sup> California’s law requires advance notice of price increases to purchasers, and Nevada’s law redefines trade secrets to allow public disclosure of pricing methodology and detailed accounting information for essential diabetes drugs with price increases above a threshold. In 2019, Nevada expanded the scope of their law to include essential asthma drugs.<sup>54</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO) filed lawsuits alleging the California and Nevada laws were invalid using a litany of legal theories.<sup>55</sup> The validity of any of these claims remains undetermined, since the case in California is ongoing

and the Nevada case is settled. As a result, this section only discusses the most relevant legal claims: violation of federal trade secret laws, federal patent laws, and the Dormant Commerce Clause.

## 1. Federal Trade Secret Challenges

First, PhRMA and BIO alleged that the Nevada law conflicts with, and is therefore preempted by, the federal Defend Trade Secrets Act of 2016 (DTSA). As part of the transparency bill, the Nevada legislature revised state trade secret law to specifically exclude any information that the drug transparency law required to be disclosed. PhRMA and BIO claim that the DTSA provides a floor for trade secret protection, and because, under the new law, the state would publicly disclose information companies considered trade secrets, federal trade secret law preempted changes to the state trade secret law. The validity of this claim was not tested however, as PhRMA and BIO withdrew the lawsuit after the state agreed to a process by which manufacturers could request state regulators to keep disclosures confidential.<sup>56</sup> Consequently, whether other state laws requiring public disclosure of detailed pricing information would survive legal challenges remains uncertain.

Congress passed the DTSA to craft a cohesive federal intellectual property policy and explicitly stated that the DTSA does not preempt state trade secret law.<sup>57</sup> To date, no court has held that the DTSA preempts a state trade secret law. Furthermore, trade secret protection is not absolute. First, many state and federal freedom of information acts allow disclosure of trade secrets when such disclosure is in the public interest. For example, in *O'Grady v. Superior Court*, the California Sixth District Court of Appeal upheld a newspaper's right to publish trade secrets, reasoning that while "trade secrets law reflects a judgment that providing legal protections for commercial secrets may provide a net public benefit. But the Legislature's general recognition of a property-like right in such information cannot blind courts to the more fundamental judgment, embodied in the state and federal guarantees of expressional freedom, that free and open disclosure of ideas and information serves the public good. When two public interests collide, it is no answer to simply point to one and ignore the other. . . . [W]hatever is given to trade secrets law is taken away from the freedom of speech. In the abstract, at least, it seems plain that where both cannot be accommodated, it is the statutory quasi-property right that must give way, not the deeply rooted constitutional right to share and acquire information"<sup>58</sup> Further, prices disclosed to customers, even if not publicly made available, should not receive trade secret protection. In *Applied Industrial Materials Corporation v. Brantjes*, a federal district court held that the price a company paid a supplier and the price that a company charged a customer were not protected under Illinois' trade secret law even though "no publications, newsletters, services or other sources . . . publish[ed] or made known the price of" the product.<sup>59</sup> The court observed that "price information which is disclosed by a business to any of its customers, unlike a unique formula used to calculate the price information which is not disclosed to business's customers, does not constitute trade secret information."<sup>60</sup> With that understanding, drug manufacturers may be hard pressed to claim trade secret protection for prices if drug manufacturers and wholesalers must provide the price to a customer.

Nonetheless, to remove the possibility of litigation, many states either declare that the information is not subject to public disclosure (e.g., Washington) or allow manufacturers to limit disclosures to information already in the public domain (e.g., Vermont). Providing such

guarantees of confidentiality, however, may perpetuate the unfounded notion that prices are trade secrets. In addition, while pricing methodology may constitute a trade secret, laws that require public disclosure of the WAC (e.g., Texas and Louisiana) are unlikely to face trade secret challenges.

## 2. Federal Patent Law Challenges

Second, PhRMA alleged that Nevada’s transparency law conflicted with federal patent law, because it “burden[s] a patent holder’s right to price its product in a manner reflecting the economic incentives the federal patent laws are intended to ensure.”<sup>61</sup> PhRMA derives this claim from *Biotechnology Industry Organization v. District of Columbia*. There, the Federal Circuit struck down a DC law based on a similar claim. The court held that the DC law prohibited the sale of patented drugs at an “excessive price,” because the “penalizing [of] high prices . . . limit[s] the full exercise of the exclusionary power that derives from a patent . . . [thereby] chang[ing] federal patent policy.”<sup>62</sup> While the decision in *Biotechnology Industry Organization* may hinder states’ attempts to set drug prices,<sup>63</sup> the extension of that decision to transparency laws is questionable. Unlike the DC law, the Nevada transparency law does not prevent manufacturers from selling drugs at any price. The law only requires manufacturers to disclose detailed financial information about an essential diabetes drug when a percent increase in the WAC exceeds a percent increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year.<sup>64</sup> The allegation that these reporting requirements unduly burden a patent holder’s rights in a manner that diminishes a patent holder’s exclusionary power granted by federal patent law is dubious. Before the court could adjudicate the matter, however, PhRMA and BIO dropped the allegation and settled the lawsuit.

## 3. Dormant Commerce Clause Challenges

Finally, PhRMA alleged that both the Nevada and California price transparency laws violate the Dormant Commerce Clause, described in Part II. PhRMA and BIO alleged that Nevada’s requirement that a manufacturer submit detailed financial information if it increased the WAC above a threshold amounted to a penalty for price increases. They further alleged that tying the penalty to the WAC, a nationwide price, violated the Dormant Commerce Clause, because it affected the manufacturers’ ability to increase drug prices for drugs bought and sold entirely outside of Nevada.<sup>65</sup> Nevada’s law, however, places no restrictions on the prices charged for drugs, so it remains questionable if a court would find disclosures of information an “undue burden” on interstate commerce and, therefore, hold that such a law violates the Dormant Commerce Clause. PhRMA dropped this claim when settling the Nevada case and has not challenged any other transparency law, except for California’s S.B. 17.

In contrast to the other transparency laws, California’s law requires manufacturers to notify state purchasers 60 days before an increase in the WAC above a threshold.<sup>66</sup> PhRMA alleges that the law is essentially a price-certification statute. PhRMA’s argument relies on *Brown-Forman Distillers Corporation v. New York State Liquor Authority*, where the Supreme Court struck down New York law requiring liquor in New York be sold at the lowest price in the country, thereby regulating other states’ prices.<sup>67</sup> Analogizing *Brown-Forman*, PhRMA alleges that the law would prohibit manufacturers from raising the WAC, a national price, anywhere in the country until California had received 60-day notice. The US District Court for the Eastern District of California has not yet ruled on this issue, so whether the court accepts PhRMA’s

reasoning remains undetermined. States, seeking to avoid this legal challenge, could simply ask for current pricing information rather than advance notification of price increases.

### **C. Recommendations for State Drug Price Transparency Laws**

Most states that passed legislation to mandate transparency from manufacturers have not been challenged by industry. PhRMA and BIO challenged two of the more comprehensive laws using a smorgasbord of legal theories, but no court has ruled on the validity of these claims. Examination of the legal challenges to state drug price transparency laws demonstrates that preemption by federal trade secret laws poses the largest threat to these state laws. Since no court has held that a drug transparency or state trade secret law is preempted by the DTSA, the magnitude of this challenge remains unknown. Specifically, while PhRMA or BIO appear likely to file a lawsuit alleging preemption by trade secret law, states seeking to promote the public interest can pose strong counter arguments to these allegations in court. States can minimize the threat of preemption by collecting only the data needed to fulfill policy goals and by articulating how the public interest in price disclosure outweighs the need for trade secret protection of this information.<sup>68</sup>

States and the public have numerous interests in the disclosure of pharmaceutical price information. For instance, states should be able to make strong arguments in favor of laws enabling them to disclose price information that allows prescribers and patients to choose the highest-value drug at the lowest price. While valuable to providers and the public, transparency laws implemented solely for the sake of transparency or to encourage shopping for cheaper drugs are unlikely to substantially reduce expenditures on drugs. On the other hand, state laws increasing drug price transparency can give policymakers important information to craft new policies to more effectively spend money on pharmaceuticals. To fulfill the goals of collecting data to assess potential policy interventions, states may find it sufficient to require disclosure of additional information to a state agency, which then releases aggregated or anonymized reports. Allowing state agencies access to confidential data may allow state policymakers to analyze the state prescription drug market without the risk of violating federal trade secret law. The state should tailor the disclosure provisions of drug price transparency laws to reflect the public interest served by the legislation.

To assist states in crafting such legislation, NASHP created model legislation mandating disclosures from manufacturers, PBMs, and wholesalers.<sup>69</sup> This legislation requires manufacturers to disclose detailed financial information and to justify price increases to a state agency when releasing a new specialty drug or increasing the WAC of an existing drug by more than 20 percent in 12 months. PBMs and wholesalers must also disclose the volume of drugs sold and any rebates or discounts to a state agency. To ameliorate any allegations of trade secret misappropriation or preemption by the DTSA, the NASHP model legislation requires the state agency to keep any disclosures confidential. While the state agency must issue a report on emerging trends in prescription drug prices, that report may not reveal information specific to any individual reporting entity. Since the law does not disclose any trade secret information, courts are unlikely to find that the DTSA preempts disclosure to a state agency. Agreeing to keep all information collected confidential, however, runs the risk of increasing the ability of manufacturers to argue trade secret protection for this information further hindering other transparency efforts. States may alternatively choose to exempt any information collected as part of these laws from public records requests, but also include a provision that allows a state agency



to disclose that information when the agency makes a determination that the public interest outweighs the interest in protecting that information as a trade secret.<sup>70</sup> In considering this argument, courts may find persuasive the California Court of Appeal's decision in *O'Grady v. Superior Court*, which held that the value of public disclosure of some information outweighed the value of trade secret protection.<sup>71</sup>

States passing transparency legislation may face legal challenges: most likely claiming violation of federal or state trade secret laws. Nonetheless, states have a strong chance of prevailing against these challenges by demonstrating that the disclosures are the minimum amount needed to promote an important public interest, including informing pharmaceutical treatment and purchasing decisions, understanding the state's pharmaceutical market, and informing the design of policy interventions to mitigate affordability problems for state residents.

## **IV. Conclusion**

In this report, we have examined legal challenges to state laws governing pharmacy benefit managers, drug price transparency, and drug price-gouging. Trade groups, like PCMA, PhRMA, and BIO, have sought to stifle state efforts through court challenges. These groups brought forth a variety of legal claims ranging from ERISA preemption to violations of trade secret law and the Dormant Commerce Clause. While no one can predict how courts decide on these claims, states could reduce the risk of legal challenges by using previous court rulings to carefully draft around potential legal challenges. Courts are slowly evolving in their understanding of the pharmaceutical industry, and such evolution may shift to a jurisprudence more accepting of state health reform efforts. Until then, states should continue seeking innovative ways to rein in high drug prices.

## Appendix A

**Table A: Model Laws Differ in Pharmacy Benefit Manager (PBM) Regulations**

	NASHP-A	NASHP-B <sup>72</sup> (L.D. 1504)	NCPA/NCIL
<b>PBM Licensure</b>	X	X	X
<b>Anti-spread Pricing</b>	X	X**	
<b>Prohibit or Disclose Any Conflicts of Interest</b>	X	X <sup>^</sup> *	
<b>Prohibit Gag Clause</b>		X**	X
<b>Insurance Commissioner Allowed to Make PBM Regulation</b>			X
<b>Fiduciary Duty</b>	X	X**	
<b>Anti-clawback</b>	X	X**	
<b>Anti-steering to PBM-owned Pharmacies</b>	X		
<b>Transparency Report Required</b>	X		
<b>Network Adequacy</b>		X**	
<b>MAC Pricing Regulation</b>		X <sup>+</sup>	
<b>Use Compensation from Manufacturer or Labeler to PBM to Lower Premiums/Out of Pocket Costs</b>		X <sup>^</sup>	
<b>Health Insurer Must Retain All Pricing Data and Contracts</b>		X**	

\* *Applicable only for pharmacy and therapeutics committee.*

\*\* *The carrier is required to have this in its contract with a PBM and ensure this requirement is met by the PBM.*

<sup>^</sup> *This requirement must be met by either the carrier or the PBM under contract with a carrier.*

<sup>+</sup> *In Model Law B, MAC pricing regulation includes (1) the use of a single MAC list; (2) identifying which drugs can be on the MAC list; (3) disclosing the sources of the MAC list; (4) providing a process for pharmacies to obtain the maximum allowable payment under the MAC list; (5) updating the MAC list at least every seven days; (6) providing an appeal process that allows pharmacists to rebill; (7) the use of average wholesale price for a brand-name drug without a generic; and (8) reimbursement between a pharmacy and a PBM.*

## Notes

<sup>1</sup> This survey relied on the following sources: Colleen Becker, *States Regulating Pharmaceutical Benefit Managers*, NATIONAL CONFERENCE OF STATE LEGISLATURES (May 2019); *Comparison of State Pharmacy Benefit Managers Laws*, NATIONAL ACADEMY FOR STATE HEALTH POLICY, <https://nashp.org/comparison-state-pharmacy-benefit-managers-laws/> (last visited July 11, 2019); JANET KAMINSKI LEDUC, STATE LAWS CONCERNING PHARMACY BENEFIT MANAGERS (Mar. 2018); NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, PBM REGULATION BY STATE (Feb. 2018), <http://www.ncpa.co/pdf/pbm-regulation-by-state.pdf>; PHARMACISTS UNITED FOR TRUTH AND TRANSPARENCY, STATE REGULATIONS IN PHARMACY BENEFIT MANAGEMENT (2013); RICHARD CAUCHI, COLLEEN BECKER & JOHN ARMSTRONG, 2018 ENACTED STATE LAWS AFFECTING PHARMACY BENEFIT MANAGERS (PBMS) (Jan. 2019); and previous research last conducted in 2017.

<sup>2</sup> See *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005); *Pharm. Care Mgmt. Ass'n v. D.C.*, 613 F.3d 179 (D.C. Cir. 2010); *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017); *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018); *Pharm. Care Mgmt. Ass'n v. Tufte*, 326 F. Supp. 3d 873 (D.N.D. 2018).

<sup>3</sup> 29 U.S.C. § 1144(a).

<sup>4</sup> *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016).

<sup>5</sup> ERWIN CHERMERINSKY, *CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES* 421 (5th ed. 2015).

<sup>6</sup> *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 341–42 (2003) (finding all willing provider laws are not preempted under ERISA, noting that "[n]either of Kentucky's AWP statutes, by its terms, imposes any prohibitions or requirements on health-care providers"). However, the Court cautioned "a state law must be 'specifically directed toward' the insurance industry in order to fall under ERISA's saving clause; laws of general application that have some bearing on insurers do not qualify. . . § 1144(b)(2)(A) . . . saves laws that regulate insurance, not insurers. . . insurers must be regulated 'with respect to their insurance practices.'" *Id.* at 334.

<sup>7</sup> See *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 744 (1985). See also *id.* at 741 (stating that "[t]he insurers nonetheless argue that § 47B is in reality a health law that merely operates on insurance contracts to accomplish its end, and that it is not the kind of traditional insurance law intended to be saved by § 514(b)(2)(A). We find this argument unpersuasive") (emphasis added). The Court here also disagreed that "laws that regulate the substantive terms of insurance contracts are recent innovations more properly seen as health laws rather than as insurance laws." *Id.*

<sup>8</sup> 29 U.S.C. § 1144 (2)(A). See also BARRY R. FURROW ET. AL., *HEALTH LAW: CASES, MATERIALS, AND PROBLEMS* at 425 (8th ed. 2018) (explaining that expression preemption is "subject to the 'savings' clause, which saves from preemption state insurance laws, including laws regulating health insurance. Because of the savings clause, state insurance laws apply to traditional, fully insured employee health plans").

<sup>9</sup> 29 U.S.C. § 1144 (2)(B). See also FURROW ET. AL., *supra* note 8, at 425-26 (explaining "ERISA's savings clause is subject to its own exception, the 'deemer' clause" and that the Supreme Court "interpreted the deemer clause broadly to exempt self-funded ERISA plans entirely from state insurance regulation because such plans are not in business of insurance").

<sup>10</sup> 429 F.3d 294 (1st Cir. 2005).

<sup>11</sup> 613 F.3d 179 (D.C. Cir. 2010).

<sup>12</sup> See *District of Columbia*, 613 F.3d at 186 (calling the Maine law "substantially identical" to the D.C. law).

<sup>13</sup> *Rowe*, 429 F.3d at 305.

<sup>14</sup> *Id.* at 301.

<sup>15</sup> *District of Columbia*, 613 F.3d at 188.

<sup>16</sup> *Id.* at 185.

<sup>17</sup> See *id.* at 186-87.

<sup>18</sup> *Id.* at 187.

<sup>19</sup> 852 F.3d 722 (8th Cir. 2017).

<sup>20</sup> 891 F.3d 1109 (8th Cir. 2018).

<sup>21</sup> The court understood a law to have a reference to ERISA if "the effect of a State law is to exclude some employee benefits plans from its coverage." *Gerhart*, 852 F.3d at 729.

<sup>22</sup> *Id.*

<sup>23</sup> *Gerhart*, 852 F.3d at 730.

<sup>24</sup> Iowa's definition of "covered entity" does not regulate only ERISA regulated plans. In fact, *not all of the organizations defined under covered entity are regulated by ERISA*, which the *Gerhart* court failed to recognize. For

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example, in Iowa’s law, covered entity was defined as “a nonprofit hospital or medical services corporation, health insurer, health benefit plan, or health maintenance organization; a health program administered by a department or the state in the capacity of provider of health coverage; or an employer, labor union, or other group of persons organized in the state that provides health coverage.” The law excluded “a self-funded health coverage plan that is exempt from state regulation pursuant to the federal Employee Retirement Income Security Act of 1974 (ERISA), as codified at 29 U.S.C. § 1001, et seq.; a plan issued for health coverage for federal employees; or a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medical supplemental, disability income, or long-term care, or other limited benefit health insurance policy or contract.”

<sup>25</sup> *Gerhart*, 852 F.3d at 731.

<sup>26</sup> *Rutledge*, 891 F.3d at 1112.

<sup>27</sup> 326 F.Supp.3d 873, 887 (2018).

<sup>28</sup> *Id.*

<sup>29</sup> *See id.* at 896.

<sup>30</sup> *District of Columbia*, 613 F.3d at 186-87.

<sup>31</sup> *Id.* at 187.

<sup>32</sup> The bill in question is S2690. Originally, the three New Jersey bills were S2690, A3993, and A2214. A2214 and A3993 were substituted by S2690 on June 20, 2019. On June 20, 2019, this bill passed both houses unanimously. As of August 4, 2019, the bill is awaiting the Governor’s signature.

<sup>33</sup> While the federal government has passed gag clauses for Medicare and private, commercial plans, states should continue to pursue gag clauses as the federal law does not cover state Medicaid programs. In doing so, states could close any loopholes the federal law left.

<sup>34</sup> In legal challenges, state attorneys general may be able to argue that PBMs are not an ERISA fiduciary or that the state law does not intrude upon ERISA administration. When convinced, courts, like in *Rowe*, can uphold all sorts of PBM regulations, but when unconvinced, courts, like in *Gerhart*, may strike down the law completely.

<sup>35</sup> *Ass’n for Accessible Medicines v. Frosh*, 887 F.3d 664, 668 (4th Cir. 2018).

<sup>36</sup> MD. CODE ANN., Health-Gen. §§ 2-801-803.

<sup>37</sup> *Id.* § 2-801(F).

<sup>38</sup> The sixteen states are: 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).

<sup>39</sup> The seven states are: Indiana (SB 415), Illinois (HB 2882), Massachusetts (S 712), Minnesota (HB 2414 and SF 12 [1st Special Session] [law passed without price gouging provisions]), New Jersey (A 3987/S 1590 and S 4216/S 2630), New York (A 1452/S 2893, A 2621/ S 1642, A 3829/S 1798, and A 6606/S 141), and Virginia (SB 1308). Rhode Island (H 5095) and Tennessee (HB 885) considered pharmaceutical price gouging bans, but they would only apply if the governor declared a state of emergency. In that case, the unconscionable increase is defined as a gross disparity in average price before and after the emergency declaration.

<sup>40</sup> *Frosh*, 887 F.3d at 673-74.

<sup>41</sup> *See ANNA ZARET & DARIEN SHANSKE, THE DORMANT COMMERCE CLAUSE: WHAT IMPACT DOES IT HAVE ON THE REGULATION OF PHARMACEUTICAL COSTS?* (Nov. 2017).

<sup>42</sup> *Frosh*, 887 F.3d at 668 (citing *Star Scientific, Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002)).

<sup>43</sup> *Id.* at 671.

<sup>44</sup> Darien Shanske & Jane Horvath, *Maryland’s Generic Drug Pricing Law Is Constitutional: A Recent Decision Misunderstands The Structure Of The Industry*, HEALTH AFFAIRS BLOG (Jun. 22, 2018), available at <https://www.healthaffairs.org/doi/10.1377/hblog20180621.752771/full/>.

<sup>45</sup> Brannon P. Denning, *Extraterritoriality and the Dormant Commerce Clause: A Doctrinal Post-Mortem*, 73 La. L. Rev. 979 (2013) (citing *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)).

<sup>46</sup> *See Shanske & Hovarth, supra* note 44.

<sup>47</sup> H.F. 2414, 91st Leg. (2019) (as posted on May 1, 2019).

<sup>48</sup> States seeking additional guidance on crafting price gouging legislation may consult an upcoming paper from Michelle Mello and Rebecca Wolitz entitled “Legal Strategies for Reining in ‘Unconscionable’ Prices for Prescription Drugs.” 114 NW. U. L. REV. (forthcoming 2020), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3424300](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3424300).

<sup>49</sup> *See Connecticut, et. al., v. Teva Pharmaceuticals USA, Inc., et. al.*, No. 3:19-cv-00710 (D. Conn. May 10, 2019); *In Re Generic Pharmaceuticals Pricing Antitrust Litigation*, No. 2:16-md-02724 (E.D. Pa., May 29, 2019); Oregon

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v. Teva Pharmaceuticals USA, Inc., No. 3:19-cv-00657-KAD (D. Conn. April 30, 2019); State of Minnesota v. Sanofi-Aventis U.S. LLC, et al, No. 18-cv-14999 (D.N.J., Apr. 2, 2019).

<sup>50</sup> H.B. 768, 2019 Leg., Reg. Sess. (Md. 2019).

<sup>51</sup> *Id.*

<sup>52</sup> Many of these laws also require disclosures from PBMs or insurers. As discussed in the first part of this issue brief, mandated disclosures by PBMs may be voided by ERISA preemption. However, states generally have the legal authority to require disclosures to the state insurance commissioner from insurance plans regulated by the state.

<sup>53</sup> See also KATHERINE L. GUDIJKSEN, SAMUEL M. CHANG & JAIME S. KING, THE SECRET OF HEALTH CARE PRICES: WHY TRANSPARENCY IS IN THE PUBLIC INTEREST (Jul. 2019).

<sup>54</sup> S.B. 262, 80th Leg. (Nev. 2019).

<sup>55</sup> The legal theories include violation of federal trade secret laws, federal patent laws, the dormant commerce clause, the First Amendment (Free Speech), the Fifth Amendment (Due Process and Takings).

<sup>56</sup> Nev. Admin. Code §§ 439.730, 439.735, 439.740.

<sup>57</sup> Defend Trade Secrets Act of 2016, Pub. L. No. 114–153, 130 Stat. 376 (to be codified at 18 U.S.C. § 1836, et seq.) (2016). 18 U.S.C. § 1833(b) provides protection for “whistleblowers.” As long as the disclosures are filed under seal, this section protects individuals who disclose trade secrets to government officials, the individuals’ attorneys, or both, as part of a complaint or lawsuit alleging violation of a law or defensively when an employer claims that the individual has disclosed a trade secret.

<sup>58</sup> O’Grady v. Superior Court, 139 Cal. App. 4th 1423, 1475-76 (Cal. Ct. App. 2006).

<sup>59</sup> Applied Indus. Materials Corp. v. Brantjes, 891 F. Supp. 432, 434 (N.D. Ill. 1994).

<sup>60</sup> *Id.* at 438.

<sup>61</sup> Complaint at 2, Pharm. Research & Manufacturers of Am. v. Sandoval, 2017 WL 5158714 (D. Nev. Nov. 7, 2017) (No. 2:17-cv-02315).

<sup>62</sup> Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

<sup>63</sup> Beyond transparency laws, legal scholars also question whether the holding in *Biotechnology Industry Organization* should even apply to rate-setting legislation for pharmaceuticals. See ROBIN FELDMAN, ET. AL., STATES’ RIGHTS: A PATENT LAW ANALYSIS OF NASHP RATE-SETTING MODEL ACT at 4-5 (Mar. 2018).

<sup>64</sup> The law also requires disclosures from essential diabetes drugs for which the WAC increased by twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years. S.B. 539, 79th Leg. (Nev. 2017).

<sup>65</sup> Complaint at 24, 38, 43, Pharm. Research & Manufacturers of Am. v. Sandoval, 2017 WL 5158714 (D. Nev. Nov. 7, 2017) (No. 2:17-cv-02315).

<sup>66</sup> S.B. 17, 2017-2018 Leg., Reg. Sess. (Cal. 2017) (stating that “[a] manufacturer of a prescription drug with a wholesale acquisition cost of more than forty dollars (\$40) for a course of therapy shall notify each purchaser... if the increase in the wholesale acquisition cost of a prescription drug is more than 16 percent, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year.”)

<sup>67</sup> Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority, 476 U.S. 573 (1986).

<sup>68</sup> GUDIJKSEN ET. AL., *supra* note 52, at 10.

<sup>69</sup> NATIONAL ACADEMY FOR STATE HEALTH POLICY, DRAFT DRUG TRANSPARENCY MODEL LEGISLATION (2019), available at <https://nashp.org/wp-content/uploads/2019/05/Revised-comprehensive-Model-Legislation-5.24.19.pdf>

<sup>70</sup> See GUDIJKSEN ET. AL., *supra* note 52.

<sup>71</sup> O’Grady, 139 Cal. App. 4th at 1475-76.

<sup>72</sup> As updated on July 19, 2019.

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The National Academy for State Healthy Policy’s Center for State Rx Drug Pricing, with support from Arnold Ventures, commissioned this analysis from the following experts affiliated with *The Source on Healthcare Price & Competition* at the University of California, Hastings College of Law:

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**Acknowledgements:**

The Center for State Rx Drug Pricing is a project of the National Academy for State Health Policy (NASHP), an independent academy of state health policymakers working together to identify emerging issues, develop policy solutions, and improve state health policy and practice. This paper would not be possible without generous funding from Arnold Ventures. To learn more about the center, please contact Jennifer Reck at [jreck@nashp.org](mailto:jreck@nashp.org).