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Health Law: SB 17 and State Regulation of Drug Pricing

Jaime S. King

Katherine L. Gudiksen

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Jaime S. King & Katherine L. Gudiksen

The California Drug Transparency Bill (SB-17), passed in October 2017, seeks to promote transparency in pharmaceutical pricing, enhance understanding about pharmaceutical pricing trends, and assist in managing pharmaceutical costs. This chapter examines the legal and regulatory aspects of SB-17, compares it to other state efforts to address rising drug prices, discusses how legal and political hurdles constrain the ability of states to pass significant legislation to rein in drug prices, and offers additional information relevant to California's efforts to control drug pricing.

I. Introduction

Prescription drug spending per capita is far higher in the United States than in other high-income countries, exceeding $1,000 per person in 2016.[2] While prescription drug spending has leveled off in recent years, prescription drug costs remain a significant financial burden for many. In a 2019 national survey, nearly 30% of adults reported not taking their medication as prescribed in the last year due to cost.[3] The same poll found broad, bipartisan support for many policy proposals to address rising drug costs, including allowing Medicare to negotiate drug prices, making it easier for generic drugs to come to market, and importing drugs from Canada.[4]

In response to this public outcry, the Trump Administration announced a Blueprint to Lower Drug Prices,[5] and Congress held

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1. Summarized and excerpted from Katherine L. Gudiksen, Timothy T. Brown, Christopher M. Whaley, & Jaime S. King, *California's Drug Price Transparency Law: Navigating the Boundaries of State Authority on Drug Pricing*, 37 HEALTH AFFAIRS 1503 (2018).

2. Micah Hartman et al., *National Health Care Spending In 2016: Spending And Enrollment Growth Slow After Initial Coverage Expansions*, 37 HEALTH AFFAIRS 150–60 (2018).

3. Ashley Kirzinger et al., KFF HEALTH TRACKING POLL – FEBRUARY 2019: PRESCRIPTION DRUGS – FINDINGS (2019).

4. *Id.*

5. American Patients First: President Donald J. Trump's Blueprint To Lower Drug Prices (May 2018).

hearings and introduced bills[6] attempting to make prescription drugs more affordable, all with negligible success. In the absence of federal action, states have recently proposed a variety of methods to regulate drug prices. In the past few years, nearly every state considered bills designed to increase the accessibility and affordability of prescription medications, including bills to increase price transparency, prevent "excessive" price increases, regulate pharmacy benefit managers (PBMs), and allow drug importation from Canada. In October 2017, California joined these states by passing SB-17, a bill that seeks to improve drug price transparency and enhance price negotiations by requiring specific disclosures from manufacturers and insurers.

Despite the magnitude of action by state legislatures, the boundaries of state power to regulate pharmaceutical prices remains opaque. The pharmaceutical industry has challenged state pharmaceutical-pricing laws in district and appellate courts around the country under a panoply of legal theories.[7] Therefore, any state that passes new legislation should expect a formidable legal challenge from the pharmaceutical industry. The uncertainty about the limits of state action means the precedents set in legal challenges to SB-17 may help resolve what power states have and may serve as a foundation for other states looking to pass meaningful legislation to address rising drug costs. This chapter examines specific provisions of SB-17 and discusses how SB-17, while carefully crafted to avoid many preemption issues, nonetheless faces the prospect of legal challenges from industry and thus may have limited impact unless coupled with other policies.

II. Provisions of SB-17

To promote transparency in pharmaceutical pricing, enhance understanding about pricing trends, and assist payers in the management of pharmaceutical costs, SB-17 requires insurers and manufacturers to disclose information on several aspects of pricing.

Disclosures by Insurers. Health plans that file rate information with the Department of Managed Health Care (DMHC) or California

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6. *E.g.*, The Creating and Restoring Equal Access To Equivalent Samples Act (CREATES) of 2017, H.R. 2212, 115th Cong. (2017); The Improving Access to Affordable Prescription Drugs Act of 2017, H.R. 1776 & S. 771, 115th Cong. (2017); The Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017, S. 637, 115th Cong. (2017).

7. *E.g.*, Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018).

Department of Insurance (CDI) must submit an additional report that names: (1) the 25 most frequently prescribed drugs; (2) the 25 most costly drugs by total annual spending; and (3) the 25 drugs with the highest increase in total annual spending.[8] In addition, large group plans must specify the portion of premiums attributable to prescription drugs and designate the proportion of any premium increase due to prescription costs versus other sources, such as inpatient care, outpatient care, and physician services. SB-17 also requires DMHC and CDI to report aggregated information to state legislators and the public and hold public meetings to discuss their findings. With the exception of reported aggregated information, however, the agencies must keep all other SB-17 disclosures confidential.

Disclosures by Pharmaceutical Manufacturers. SB-17 requires manufacturers to notify purchasers 60 days before any price increase that exceeds 16% over a two-year period for all drugs with a wholesale acquisition cost (WAC) greater than $40.[9] The WAC is a national price charged by the manufacturer to wholesalers. In addition, manufacturers must notify the California Offices of Statewide Health Planning and Development (OSHPD) about any new pharmaceutical with a WAC above the threshold WAC of a specialty drug under Medicare Part D (over $670 per month). Manufacturers must also provide OSHPD with information on the factors used to determine the WAC, usage, and marketing materials. Overall, these provisions will provide policymakers with information that already exists in the public domain but that might otherwise be difficult to collect and aggregate. The real value of these provisions, however, lies in their ability to help shape the scope of state legal boundaries surrounding drug pricing reform.

III. Challenges in State Regulation of Prescription Drug Prices

Despite state enthusiasm, the pharmaceutical industry has consistently challenged state attempts to promote price transparency and regulate price increases. A muddled web of federal laws, including the Employee Retirement Income Security Act of 1974 (ERISA), federal trade-secret law, the Dormant Commerce Clause, and the First and Fourteenth Amendments to the U.S. Constitution, constrain state authority to regulate prescription drug pricing. As a result, trade organizations representing the interests of the pharmaceutical industry have used all of these laws to challenge many new state laws including SB-17.

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8. CA HEALTH & SAFETY CODE § 1367.243.
9. *Id.* Div. 107 Part 2 § 127677.

A. ERISA Preemption

ERISA creates significant barriers to state health-reform efforts that affect employee benefit plans, including prescription drug coverage. With a goal of establishing uniformity across states, ERISA establishes minimum standards for employee pension and benefit plans and preempts the ability of states to pass laws that "relate to" employee benefit plans.[10] While ERISA exempts state insurance regulations from this preemption, it does not deem self-insured employer benefits to be insurance, and therefore ERISA preempts any state law that relates to self-insured employer plans, which cover approximately 60% of Americans with employer-based coverage.[11]

As a result, the recent expansion of ERISA preemption has had devastating consequences for state attempts to control healthcare costs and improve price transparency. In 2016, the Supreme Court ruled in *Gobeille vs. Liberty Mutual Insurance Co.* that Vermont could not require self-insured employers to report their healthcare claims data to the state all-payer claims database because such reporting impermissibly intrudes on central matters of ERISA plan administration.[12] This case represented a broad expansion in ERISA preemption which threatens much more than disclosure of health claims data. Indeed, citing *Gobeille*, the Eighth Circuit held that ERISA preempted an Iowa law requiring PBMs to report their generic pricing methodology from applying to PBMs that served ERISA plans.[13] ERISA has become a powerful barrier to several forms of healthcare price transparency legislation because states must choose between passing laws that will benefit only a small section of the population (because they exclude those with self-insured employer-based coverage) or risk being dragged through an uncertain, and currently unfavorable, legal battle over the scope of ERISA preemption.[14]

SB-17 attempted to avoid ERISA preemption by only requiring disclosures from plans regulated by DMHC or CDI, which includes large- and small-group employer plans, but not self-insured employer plans. As a result, lawmakers will not have pharmaceutical- spending

10. 29 U.S.C. § 1144(a).

11. Erin C. Fuse Brown & Ameet Sarpatwari, *Removing ERISA's Impediment to State Health Reform*, 378 NEW ENGL. J. MED. 5 (2018).

12. Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936 (2016).

13. Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722 (8th Cir. 2017).

14. Erin Fuse Brown & Jaime A. King, *The Consequences of* Gobeille v. Liberty Mutual *for Health Care Cost Control*, HEALTH AFFAIRS BLOG (Mar. 10, 2016).

data for employees of some of the largest employers in the state when considering other measures to address drug prices.

B. Trade Secrets

The pharmaceutical industry has also challenged state price transparency efforts for violating federal and state trade secret laws. In 2017, Nevada passed Senate Bill 539 (SB-539) which, among other provisions, requires manufacturers of "essential" diabetes drugs to provide information to the state, including the costs of manufacturing and marketing diabetes drugs, and the amount of profits attributed to the drug. Because manufacturers often claim trade secret protection for this type of information, the state legislature amended the state's definition of a trade secret to specifically exclude any information required by SB-539. Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization filed a civil suit[15] claiming the law was preempted by the federal Defend Trade Secrets Act (DTSA).[16] They further alleged that the law violated the Takings Clause of the Constitution because the state took trade secrets and disclosed them without proper compensation. To settle the lawsuit, the state agreed to a process by which the manufacturers will continue to report the required information, but the state will keep confidential any information it reasonably considers to meet the standards of a trade secret under the DTSA or Exemption 4 of the federal Freedom of Information Act.[17]

In contrast to the Nevada law, SB-17 attempts to avoid violating federal trade secret protections by limiting required disclosures to publically available information or requiring disclosures to agencies (like OSHPD) that must keep the information confidential. Advance notification of a WAC increase should not constitute a trade secret because the WAC is public information that cannot be kept confidential. Advance notification of an increase only speeds up the process of publicizing information and competitor reaction; it does not expose knowledge that would not otherwise become public.

15. Complaint, PhRMA v. Sandoval, 2:17-cv-02315 (Sept. 1, 2017).

16. Pub. L. 114-153, 130 Stat. 376 (May 11, 2016), codified at 18 U.S.C. § 1836, *et seq.*

17. 5 U.S.C. § 552(b)(4).

C. Dormant Commerce Clause

The Constitution gives Congress the power to regulate interstate commerce, and the Dormant Commerce Clause prohibits states from passing laws that discriminate against or excessively burden interstate commerce without sufficient offsetting local benefits.[18] In *Healy v. Beer Institute*, the Supreme Court held that the externality principle of the Dormant Commerce Clause forbids states from directly regulating commerce that occurs outside of the regulating state, "regardless of whether the statute's extraterritorial reach was intended by the legislature."[19]

Until recently, many courts narrowly interpreted the externality principle to only strike down laws that control prices or require price affirmation; link in-state prices to those charged elsewhere; or raise costs for out-of-state consumers or rival businesses.[20] In April 2018, however, the Fourth Circuit interpreted the principle more broadly to find that Maryland's law prohibiting price gouging for essential off-patent or generic drugs[21] violated the Dormant Commerce Clause. The court held that because the law applied to drugs "made available for sale within the state," the law could apply to drugs that were never actually sold in Maryland. Further, since the law required the state attorney general to review increases in the WAC for price gouging, the court held that the law regulated prices on transactions outside of the state. Specifically, the court reasoned that the law is "effectively a price control statute that instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland."[22] The court "acknowledge[d] that the Act does not establish a price schedule for prescription drugs, nor does it aim to tie the prices charged for prescription drugs in Maryland to the prices at which those drugs are sold in other states. But like the laws struck down in *Healy* and *Brown-Forman*, the Act attempts to dictate the price that may be charged elsewhere for a good. Any legitimate effects the Act may have in Maryland are insufficient to protect the law from invalidation."[23] But some scholars have contested the Fourth Circuit's conclusion by arguing that financial transactions

18. *See* Pike v. Bruce Church, Inc., 90 S. Ct. 844 (1970).

19. 491 U.S. 324, 336 (1989).

20. *See, e.g.*, Ene. & Env't Legal Inst. v. Epel, 793 F.3d 1169 (10th Cir. 2015).

21. MD. CODE, HEALTH-GEN. § 2-802(a).

22. Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664, 672 (4th Cir. 2018).

23. *Id.*

for pharmaceutical sales already differ based on where the product is made, where it will be sold, and to whom it will be sold. They assert, therefore, that Maryland's law imposes neither extra burden on interstate commerce nor meaningful restraints on out-of-state prices.[24] Since the Supreme Court denied certiorari for Maryland's appeal, the scope of state authority to regulate in state drug prices remains uncertain.

In contrast to Maryland's law, SB-17 only requires advance notice of price increases and allows increases of any size (with proper notification). However, under SB-17, a manufacturer must wait at least 60 days before increasing the WAC. Therefore, because contract prices with "wholesalers, hospitals, pharmacies, pharmacy benefit managers, payers, and others" are typically based on the WAC, a recent lawsuit by PhRMA challenging SB-17 argues that SB-17 effectively becomes an nationwide ban on price increases for certain drugs, unless California receives 60-day advance notification.[25]

PhRMA's challenge, if successful, will only further compound the inability of states to meaningfully protect their citizens from ever escalating drug prices. It will also increase the incentives for industries to create complicated business models that buy and sell products across state lines in an effort to escape state regulation. Thus, the outcome of court challenges to SB-17 will have significant implications for other drug pricing legislation and help shape the scope of judicial interpretation of the externality principle of the Domant Commerce Clause as applied to pharmaceutical legislation.

D. Free Speech and Due Process

In its lawsuit, PhRMA further argues that SB-17 violates the pharmaceutical manufacturers' First Amendment right to free speech and Fourteenth Amendment right to due process.[26] PhRMA contends that SB-17 violates the First Amendment when it singles out manufacturers as the only entity that must give advance notice of drug-price increases, when other entities, like PBMs, also affect prices. Because the First Amendment does not require that legislation target all potential market actors equally, it is unclear whether PhRMA's

24. Darien Shanske & Jane Horvath, *Maryland's Generic Drug Pricing Law is Constitutional: A Recent Decision Misunderstands the Structure of the Industry*, HEALTH AFFAIRS BLOG (June 22, 2018).

25. Complaint, PhRMA v. Brown, No. 2:17-at-01323 (Dec. 8, 2017).

26. *Id.*

argument has merit. PhRMA also argues that SB-17 restricts price increase justifications to a "change or improvement" in the drug—which does not consider other typical justifications for price increases, such as raising capital for research or providing increasing value to the health system by decreasing overall spending—essentially forcing a manufacturer to provide a false reason or abstain from supplying one. This argument's merit is also unclear because legislators may have just wanted to know if the justification for the price increase resulted from a change or improvement. Finally, PhRMA argues that SB-17 is unconstitutionally retroactive under the Due Process Clause by failing to specify whether WAC increases prior to January 1, 2018, would trigger SB-17's reporting requirements.[27] California could easily remedy this potential violation by agreeing to enforce the law only prospectively. The district court has yet to rule on PhRMA's lawsuit.

In order to pass effective legislation, states need clear signals from the courts and legislators regarding the bounds of state regulation of all healthcare prices, including pharmaceuticals. As such, SB-17 represents an important effort by a state looking to pass meaningful legislation that will withstand legal challenges by the pharmaceutical industry and help define the contours of permissible state action. Nonetheless, SB-17 will have minimal impact unless the state takes additional measures to address rising drug prices.

IV. In Isolation, SB-17 is Unlikely to Constrain Drug Prices

Shortly after its passage, SB-17 was dubbed "the most comprehensive law aimed at shining a light on prescription drug prices."[28] Nonetheless, the crafting of SB-17 to avoid preemption and constitutional pitfalls constrains its reach in several ways. First, the law will do little to directly reduce drug prices overall because pharmaceutical manufacturers can spread price increases out across drug categories and adjust rebates to maintain profits. Second, the law relies on the WAC to avoid trade secret issues but, as a result, may make the law more susceptible to constitutional challenges. Further, the law only requires disclosure of public information; rebates and price discounts provided to PBMs, which often dramatically alter the actual prices, can remain confidential. As a result, SB-17 leaves open several avenues of price manipulation.

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27. *Id.*

28. Tracy Seipel, *California assembly passes drug price transparency bill*, S.J. MERCURY NEWS (Sept. 11, 2017).

Finally, because transparency alone is insufficient to encourage patients to price shop, SB-17 is unlikely to reduce drug expenditures without additional measures. Research on online price transparency initiatives finds only modest changes in patient behavior,[29] but combining price transparency with targeted consumer incentives can lead to more sizable changes in price shopping behavior.[30] Supplementing price transparency information with a tangible financial incentive, such as reference pricing, has been found effective to reduce pharmaceutical spending and is a viable next step in drug pricing policy.[31]

Conclusion

California's SB-17 forms a critical part of a movement by states to reduce pharmacuetical prices and to clarify the scope of states' power to address healthcare prices more generally. While innovative, SB-17 is unlikely to have a significant impact on drug spending without additional incentives for consumers to use lower-priced drugs and additional measures to prevent market manipulation and cost-shifting. Nonetheless, the law remains a critical step in defining state authority and reflects California's status as a leader among states looking to control prescription drug prices.

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29. Christopher Whaley et al., *Association Between Availability of Health Service Prices and Payments for These Services*, 312 JAMA 1670 (2014); Sunita Desai et al., *Offering a Price Transparency Tool Did Not Reduce Overall Spending Among California Public Employees and Retirees*, 36 HEALTH AFFAIRS 1401 (2017).

30. Christopher Whaley et al., *Consumer Responses to Price Transparency Alone Versus Price Transparency Combined with Reference Pricing*, AM. J. HEALTH ECON. EPUB (2018).

31. James C. Robinson, et al., *Association of Reference Pricing with Drug Selection and Spending*, 377 NEW ENGL. J. MED. 568 (2017).

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