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Client Alert

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State Initiatives to Control Drug Prices

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What You Need To Know:

- **States are more active than the federal government in proposing and taking action to influence drug prices.**
- **State drug price initiatives vary greatly in their approach and impact.**
- **The pharmaceutical industry is lobbying against enactment of many legislative proposals and challenging some enacted measures in court.**

Introduction

While the Trump administration and Congress have talked a lot about controlling drug prices, and the administration did recently float a much-criticized proposal to require drug companies to include list prices in TV ads, state governments have grown tired of waiting and seized the initiative in this area in imaginative ways. Over the past several years, numerous states have taken a broad variety of measures to control and influence prescription drug spending and prices. This trend shows no sign of abating, with one recent estimate showing 37 bills have been passed by at least one legislative chamber in 24 different states. Drug manufacturers are clearly on the defensive, spending aggressively to block pending legislation and challenging enacted laws in court. This client alert will broadly survey the different categories of price control legislation and outline some of the ongoing legal challenges to these laws.

Recent prescription drug price and cost-focused legislation can be placed into the following 11 categories.

Categories

1. Transparency/Reporting

Various states have enacted legislation requiring drug manufacturers to provide justifications for price increases that exceed specified thresholds. While these laws enable states to gain information and often make such information public, they do not limit the ability of drug companies to set prices. Pharmaceutical industry trade groups have fought vigorously against passage of these laws and have brought litigation challenging their constitutionality.

In 2016, Vermont became the first state to enact a drug price transparency law. Under the law, a state agency identifies prescription drugs on which the state spends significant health care dollars and whose wholesale acquisition cost (WAC) has increased by 50% or more over the past five years or by 15% or more over the past year. Each manufacturer of such drugs must then provide the state with a report justifying the WAC increase, and the report is made public on a state website.

In 2017, Nevada passed a transparency law that applies only to drugs "essential for treating diabetes." If a manufacturer increases WACs on these drugs by more than the prior year's inflation rate or twice the inflation rate of the past two years, it must report to the state information including profits, production costs, rebates provided and marketing spending. The state then publishes online an annual report based on the reported information. The industry trade groups Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO) challenged the law as an unconstitutional regulation of interstate commerce and claimed that the reporting requirements destroy federal and state trade secret and confidentiality protections. The case was voluntarily dismissed by PhRMA and

BIO after Nevada adopted regulations allowing manufacturers to request that certain information be kept confidential.

2. Notification

States have passed laws requiring drug manufacturers to provide notification prior to implementing price increases. For example, California enacted a law requiring, among other things, that prescription drug manufacturers notify purchasers at least 60 days prior to implementing a cumulative price increase of greater than 16% over a two-year period and providing the state with justifications for the price increase. PhRMA challenged the statute in federal court based on three theories: (1) it regulates interstate commerce in violation of the commerce clause, (2) it violates the First Amendment by compelling manufacturers to express views that are not content-neutral and (3) it is unconstitutionally vague. The case was dismissed without prejudice in August because at the time that the lawsuit was started no company had implemented price hikes that would have been affected by the law. PhRMA filed an amended complaint on September 28, 2018 that asserts that several companies have taken price increases that required them to make "justification" statements under the law.

3. Price Gouging

Certain state bills enable states to take legal action and impose penalties when drug manufacturers dramatically increase prices. In 2017, Maryland became the first state to enact such legislation.

The Maryland law prohibits a manufacturer or wholesale distributor from engaging in "price gouging" in the sale of an "essential off-patent or generic drug." A manufacturer that increases the price of such a drug by more than 50% in a year must provide justification and documents relevant to the price increase. If the price increase is deemed too steep, the state's attorney general is empowered to ask a state court to impose civil penalties and other remedies, including court orders reversing the price increase.

The Association for Accessible Medicines (AAM), an industry trade group, claimed that the law regulates interstate commerce in violation of the Constitution's dormant Commerce Clause and that the law is unconstitutionally vague. In April 2018, the 4th Circuit Court of Appeals ruled in favor of AAM and found the law unconstitutional.

4. Pharmacy Benefit Manager (PBM) Disclosure and Reporting

Certain states are requiring PBMs to make disclosures relating to drug costs. For example, Connecticut recently passed a law, scheduled to take effect in 2020, requiring PBMs to report information about rebates that they receive from drug companies. The Pharmaceutical Care Management Association (PCMA) trade group and Boehringer Ingelheim each submitted comments objecting to the legislation.

States have also taken administrative action to address PBM pricing issues. In August 2018, the Ohio Department of Medicaid issued a mandate requiring its managed care plans to renegotiate contracts with PBMs so that PBMs charge the plans exactly what they pay pharmacies for prescription drugs (plus a dispensing fee). In the existing contracts, PBMs charge plans a negotiated rate and can retain a portion of any rebates provided to the pharmacies.

5. Pharmacist Substitution and Disclosures

For decades, states have implemented legislation requiring generic substitution, when available, for higher-price prescription drugs. In the past few years, many states have enacted legislation addressing substitution for biosimilars as well. West Virginia, South Dakota, Wyoming, Idaho and Maryland each passed legislation enabling (but not requiring) a pharmacist to select a less expensive, interchangeable biological product under specified circumstances.

Many states have passed legislation prohibiting PBMs from contractually preventing pharmacists from discussing less-expensive drug options with patients, including whether their co-pay is higher than the actual cost of the drug. As of July 2018, nearly 20 states have passed laws with such requirements. For example, in 2018 Florida enacted legislation that requires a pharmacist to inform customers whether a less-expensive generic version of their prescribed drug exists and prohibits PBMs from using any mechanism to prevent a patient from paying the lowest available price for a particular drug.

6. Importation

In 2018, Vermont passed legislation creating a program for the wholesale importation of prescription drugs from Canada. Several other states, including New York, West Virginia, Missouri, Louisiana and Oklahoma, are considering similar legislation.

However, it is unknown whether a state drug importation program can actually be implemented. Federal law requires the Department of Health and Human Services (HHS) to certify to Congress that any such program poses no additional risk to public health and safety and will result in significant reduction in costs to the American consumer. HHS has never previously certified a state importation program, and it is not clear whether it has any intention of doing so in the future.

Previous state laws and programs that have attempted to circumvent the HHS certification requirement have been thwarted by the federal government or have otherwise failed. A 2013 Maine law enabled its residents to import drugs from licensed pharmacies in Australia, Canada, New Zealand and the United Kingdom. The U.S. District Court in Maine held that the law was preempted by the Federal Food, Drug and Cosmetic Act and therefore unconstitutional. In 2010, Minnesota discontinued a program that enabled residents and state employees to purchase drugs from Canadian pharmacies. The program suffered from low participation rates, exacerbated by repeated confiscation by U.S. Customs of imported mail-order medications.

7. Price Caps

Some states are considering legislation that sets limits on certain drug prices, although no such legislation has been passed. New Jersey, Maryland, Minnesota and Rhode Island each has pending legislation that would authorize the state to set a price for drugs with prices deemed to be excessively high.

8. Volume Purchasing

Various states are exploring ways to use volume purchasing power to lower drug costs. For example, Vermont has pending legislation that would require the state to explore ways to work with other states to create a public PBM program.

9. Studies

Several states have enacted legislation calling for studies to determine ways to lower drug price costs. For example, Montana passed a resolution requesting a study of specified factors impacting prescription drug pricing, and New Hampshire established a committee to study the impact of PBMs on the cost of drugs.

10. State Negotiation of Supplemental Rebates

New York has passed legislation authorizing the state to negotiate supplemental rebates for drugs determined to be overpriced when a state Medicaid drug-spending cap is reached. However, the law does not provide the state with any real power or require such negotiation. In April 2018, the state board recommended a supplemental rebate on Vertex's cystic fibrosis drug Orkambi, and Vertex simply responded by saying it does not intend to provide the state with any additional rebates.

11. Limitation on Coupons and Manufacturer Cost-Sharing

California has enacted legislation prohibiting the distribution of manufacturer-sponsored drug coupons when FDA-approved lower-cost generic drugs are available, are covered under the patient's health plan and are not otherwise contraindicated for the condition for which the prescription drug is approved. New Jersey is considering a similar requirement.

As this brief survey shows, the states are fertile ground for experimentation in controlling drug prices. In the absence of meaningful federal action, we anticipate that states will continue to take matters into their own hands by enacting a wide range of legislative measures intended to control excessive drug prices. We will continue to monitor developments in this area.

Contact

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