State drug pricing laws

Overview of state price transparency and other legislative trends
Introduction

The drug pricing debate was front and center during the 2016 presidential election, with Donald Trump calling for significant changes to current US drug pricing policy. Voters continue to identify the high cost of pharmaceuticals as a top health care concern, with 80% of the public perceiving prescription drug costs as “unreasonable” according to a Kaiser Health Tracking Poll. Measures intended to rein in costs also poll very favorably among voters of both political parties, with half of the public saying that passing legislation to bring down the price of prescription drugs should be a “top priority” for President Trump and Congress. The Administration has begun the process of rolling out new proposals to address high drug costs, with Health and Human Services Secretary Alex Azar suggesting action influencing various problems that plague drug markets. This includes solutions aimed at addressing high list prices, seniors and government programs overpaying for drugs due to lack of negotiating tools, rising out-of-pocket costs for consumers and foreign governments ‘free-riding’ off of American investment in innovation. Yet, despite all of the attention, change has been slow at the federal level. Federal legislators and regulators continue to struggle to find the right balance between creating affordability without limiting access or stifling innovation. Only 39% of the public is confident that President Trump and his administration will be able to deliver on the promise that Americans will pay less for prescription drugs than they pay now. The complexity and range of challenges, from high-cost generic and specialty drugs to aggressive use of patent protections, the role of insurers and pharmacy benefit managers (PBMs) and the complex supply chain, mean that there is no single policy solution that can address all consumer pricing concerns.

In the face of federal uncertainty, consumer pressure has spurred states into the policy void. Since 2016, hundreds of drug pricing proposals have been introduced in state legislatures across the US. State legislatures have focused their drug pricing proposals in several key areas. Emerging legislative themes include efforts to address: price transparency, so-called price gouging, spending targets, PBM and rebate practices, out-of-pocket spending, utilization management and biosimilar substitution. Pharmaceutical companies have raised concerns about the fairness, efficacy and challenges of complying with new legislation. This patchwork of state efforts is challenging for pharmaceutical companies and other stakeholders to navigate and monitor. Listed below are samples of enacted and proposed state legislation arranged by theme.

Sample enacted legislation, by theme

1. **Price transparency and price gouging bills**: Price transparency bills require manufacturers, PBMs and others in the drug supply chain to report to the state information aimed at explaining certain manufacturer price increase or launch price decisions. Some bills also impose penalties on manufacturers for price increases over a certain amount over a specified period of time.

   Vermont passed the first drug price transparency law in 2016, and since then several other states have taken steps to require pharmaceutical manufacturers and others across the supply chain to disclose price increases and prohibit price gouging practices. Such bills often require drug companies to justify price increases over a certain threshold, and some require manufactures, PBMs and others across the pharmaceutical supply chain to report detailed information about outlays that may impact pricing, such as R&D and marketing costs, profits, rebate disclosures and more. While many states do not have the power to cap or reduce the drugs’ prices, they do have the power to impose various fines and civil penalties, or mandate other rebates or refunds from manufacturers and others. Several states also require the development of reports that detail their findings as well as public forums and other vehicles to explore the impact of high drug prices. States hope that exposing price increases to the public will work to drive drug prices downward.

   In April of 2018, a federal appeals court handed the generic drug industry a major win by ruling against Maryland's first-in-the-nation price gouging law. The appeals court raised concerns that a move by other states to enact laws similar to Maryland’s would cause a significant burden on interstate commerce involving prescription drugs. The court ruled that Maryland’s law violates the dormant Commerce Clause, as legal action under the state law is predicated on initial sales of drugs to wholesalers operating outside of Maryland, not the price Marylanders ultimately pay. The ruling could end up being appealed to the US Supreme Court and may have a major impact on efforts by a dozen of other states pursuing similar legislation.
## Recent drug price transparency and price gouging legislation

<table>
<thead>
<tr>
<th>State</th>
<th>Bill (year)</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT</td>
<td>216 (2016)</td>
<td>Requires the state to do an annual identification of up to 15 state-purchased prescription drugs for which the wholesale acquisition cost (WAC) has increased by 50% or more over the past five years or by 15% or more over the past 12 months. The state Attorney General (AG) will then require the manufacturer to provide justification for the increase. It also mandates rules be adopted for certain insurers to provide information about the State Health Benefit Exchange plan’s drug formularies, and develop reports on drug dispensing fees and out-of-pocket drug limits.</td>
</tr>
<tr>
<td>CA</td>
<td>SB 2017 (2017)</td>
<td>Requires manufacturers to notify all purchasers at least 90 days prior to the planned effective date of a price increase for prescription drugs currently on the market. Manufacturers are required to provide information justifying these increases, as well as when launch prices of new drugs that exceed the threshold set for a specialty drug under the Medicare Part D program. All insurers must include in their yearly report specified drugs which make up the highest share of spending. PBMs who receive a notice of an increase in WAC must notify their public and private purchasers of the increase.</td>
</tr>
<tr>
<td>NV</td>
<td>SB 539 (2017)</td>
<td>Requires the Nevada Department of Health and Human Services to compile lists of prescription drugs that are used to treat diabetes, and requires manufacturers and PBMs that sell these drugs to provide specified information to the department. Requires manufacturers to submit a list of each sales representative who markets prescription drugs in Nevada and prohibits sales from representatives not included on such a list. Certain nonprofit organizations or patient assistance programs are required to report specified information concerning contributions and benefits received from drug manufacturers, insurers and PBMs or the trade and advocacy groups for such entities. Authorizes the Department to impose penalties for certain violations.</td>
</tr>
<tr>
<td>MD</td>
<td>HB 631 and SB 415 (2017)</td>
<td>Authorizes the AG to require manufacturer records or documents relevant to determining whether the price increase of a generic or off-patent brand drug was excessive or unconscionable and thus a violation of law. The state Medicaid program can notify the AG when the WAC increases by more than 50% within one year and the drug’s WAC exceeds $80 for a 30-day supply or full course of treatment. The AG may ask the state court to impose civil penalties up to $10,000 and other remedies in the event of a violation.</td>
</tr>
<tr>
<td>OR</td>
<td>HB 4005 (2018)</td>
<td>Requires drug manufacturers to annually report prices of prescription drugs and costs associated with developing and marketing prescription drugs to the Oregon Department of Consumer and Business Services. Imposes penalties on manufacturers for failure to comply with reporting requirements. Also requires health insurers that offer prescription drug benefits to report to the department information about prescription drug prices and the impact on premium rates. Authorizes the department to adopt by rule fees on manufacturers and requires the department to conduct annual public hearings on prescription drug prices reported by manufacturers.</td>
</tr>
</tbody>
</table>
2. **Spending targets**: Bills allow states to set annual spending targets for prescription drugs and to negotiate additional rebates with manufacturers if they exceed the target amount.

Directly limiting state spending on prescription drugs in Medicaid is one approach that states are targeting to drive down costs. While Medicaid has some built-in cost controls, high-cost specialty drugs continue to drive increases in spending. In April 2017, New York passed a Medicaid drug expenditure provision in its fiscal year 2018 budget that allows the state Department of Health to set an annual projected spending target for prescription drugs. New rules are triggered if the combination of price increases and use of drugs is forecast to push spending to exceed an annual spending growth cap, which could include multiple layers of review regarding profit margins and drug effectiveness, along with referral to the state's Drug Utilization Review Board. New York expects to save $55 million this fiscal year (FY18) and $85 million the next under the law. However, some advocates fear the law could hinder access to needed medications. Ohio failed to advance a similar ballot measure in November 2017, the Ohio Drug Price Relief Act, which was aimed at capping the amount state agencies pay for prescription drugs at the rate paid by the Department of Veteran Affairs.

<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>NY</td>
<td>AB 3007 and SB 2007 (2017)</td>
<td>Imposes a Medicaid drug spending cap as a separate component within the Medicaid global cap. The Department and the Division of the Budget shall assess on a quarterly basis the projected total amount to be expended in the year on a cash basis by the Medicaid program for each drug, and the projected annual amount of drug expenditures for all drugs. The Drug Utilization Review Board will determine whether to recommend a supplemental rebate for a drug considering the actual cost of the drug to the Medicaid program including (1) the drug’s impact on spending, (2) any significant and unjustified price increases of the drug, and (3) whether the drug may be priced disproportionately to its therapeutic benefits.</td>
</tr>
</tbody>
</table>

States are also exploring ways to rein in drug costs through the Medicaid waiver process. Massachusetts, for example, is requesting a waiver from the Centers for Medicare and Medicaid Services (CMS) to use a “closed” Medicaid drug formulary, limited pharmacy network and tiered copays for prescription drugs. Currently, drug companies are required to discount drugs 23% for Medicaid and in return, states must cover them. A shift to a closed formulary is meant to drive down costs and would in turn only cover certain drugs in each therapeutic class. While the waiver would be a drastic departure from Medicaid policy and face likely opposition in the state legislature, stakeholders are monitoring the issue closely. CMS is said to be exploring the potential to let states use restricted Medicaid formularies in order to give them more leverage in price negotiations. Drug makers and patient advocates, however, question the legality of the waiver and express concern about the safety of patients who rely on specific medications.
3. **PBM and rebate practices**: Bills regulating PBMs focus on greater transparency and new standards for pharmacy reimbursement, customer charges, rebate revenue and limitations on pharmacist communication with customers about costs (i.e., “gag clauses”). Other bills are aimed at tamping down practices that reduce patient incentives to choose lower-cost drugs through rebates.

Some policymakers have suggested that PBMs’ intermediary position in the pharmaceutical supply chain may exacerbate drug spending, seeking to limit certain PBM practices to tamp down rising pharmaceutical costs. Several states, for example, have passed legislation prohibiting PBMs and/or health plans from restricting pharmacists from informing customers about cheaper options at the pharmacy counter. Others have passed legislation prohibiting PBMs from engaging in ‘claw back’ practices that require a pharmacy to charge a patient more in cost-sharing than what the PBM pays the pharmacy for the drug, or more than the cash price of the drug if the patient filled the prescription without insurance coverage. The plan or PBM can then “claw back” these amounts periodically through the year. California also passed a bill prohibiting manufacturers from offering reductions in an insured patient’s out-of-pocket costs if a therapeutically equivalent, lower-cost generic drug is available. This is intended to tamp down practices that reduce patient incentives to choose lower-cost products.

<table>
<thead>
<tr>
<th>State</th>
<th>Bill (year)</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>SB 445 (2017)</td>
<td>Prohibits PBM contracts that prevent pharmacists from disclosing specified information to an individual purchasing a drug (i.e., the availability of any alternative, less-expensive medications). Prohibits a health carrier or PBM from requiring an individual to pay for a covered prescription in an amount greater than the lesser of the (1) applicable copayment, (2) allowable claim amount (i.e., the amount the health carrier or PBM agreed to pay the pharmacy), or (3) amount an individual would pay for the drug if he or she had no insurance plan, benefits or discounts.</td>
</tr>
<tr>
<td>GA</td>
<td>HV 276 and SB 103 (2017)</td>
<td>Authorizes the Georgia Commissioner of Insurance to promulgate rules and regulations to prohibit PBMs from requiring the use of mail-order pharmacies. Bans the PBM practice that prohibits a pharmacist or pharmacy from providing an insured patient information regarding the amount of the patient’s prescription drug cost share and the clinical efficacy of a lower-priced alternative drug if one is available. Also prohibits PBMs charging or collecting from an insured a copayment that exceeds the total submitted charges by the network pharmacy for which the pharmacy is paid.</td>
</tr>
<tr>
<td>NC</td>
<td>H 466 and S 384 (2017)</td>
<td>Bans the PBM practice that prohibits a pharmacist or pharmacy from providing an insured patient information regarding the amount of the patient’s prescription drug cost share and the clinical efficacy of a lower-priced alternative drug if one is available. Also prohibits PBMs charging cost sharing that exceeds what the PBM pays the pharmacy for the drug.</td>
</tr>
<tr>
<td>TX</td>
<td>HB 2360 and SB 1076 (2017)</td>
<td>Prevents a health benefit plan issuer that covers prescription drugs from requiring an enrollee to make a payment for a prescription drug at the point of sale in an amount greater than the lesser of: (1) the applicable copayment, (2) the allowable claim amount for the prescription drug, or (3) the amount an individual would pay for the drug if purchasing the drug without using a health benefit plan or any other source of drug benefits or discounts.</td>
</tr>
<tr>
<td>CA</td>
<td>AB 265 (2017)</td>
<td>Prohibits the distribution of manufacturer-sponsored drug coupons when other FDA-approved lower-cost generic drugs are available, are covered under the individual’s health plan and are not otherwise contraindicated for the condition for which the prescription drug is approved.</td>
</tr>
</tbody>
</table>
4. **Out-of-pocket spending**: Bills that impose limits on the amount that a person must pay in copayment, coinsurance or other out-of-pocket spending through a health benefit plan, often focused on specialty drugs.

In 2016, the District of Columbia passed legislation that imposes a limit on the amount that a person must pay in copayment or coinsurance through a health benefit plan for a specialty drug prescription. Additionally, California has a proposed bill (SB 1021) which would eliminate the sunset of a law that caps a person's out-of-pocket costs for prescriptions at $250 every 30 days and prohibits the formulary or formularies for outpatient prescription drugs maintained by a health care service plan or health insurer from discouraging the enrollment and reducing the generosity of benefits of individuals with certain health conditions. It would also make permanent formulary standards that keep insurers from routinely placing specialty drugs in their highest pricing tiers.

<table>
<thead>
<tr>
<th>State</th>
<th>Bill (year)</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>DC</td>
<td>21-32 (2016)</td>
<td>Prohibits public and private insurers, with few exceptions, from setting patient out-of-pocket costs (copayments and coinsurance) for specialty drugs at more than $150 for a 30-day supply or $300 for a 90-day supply.</td>
</tr>
</tbody>
</table>

5. **Utilization management**: Bills to regulate how health plans implement utilization management tools to control costs and ensure appropriate prescription drug use.

Several states have moved to regulate how health plans implement utilization management tools to control costs and ensure appropriate prescription drug use, passing laws that ban or restrict insurers’ use of step therapy (which requires patients to try a less expensive drug before insurance will cover a more expensive therapy) for certain populations, which limits their ability to control costs.

<table>
<thead>
<tr>
<th>State</th>
<th>Bill (year)</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>H 740 (2017)</td>
<td>Prohibits insurers, nonprofit health service plan or health maintenance organizations from imposing a step therapy or fail-first protocol on an insured or an enrollee for a certain prescription drug used in the treatment of a certain cancer.</td>
</tr>
<tr>
<td>CO</td>
<td>S 203 (2017)</td>
<td>Prohibits carriers from requiring a covered person to undergo step therapy and requires them to provide coverage for the drug prescribed as long as the drug is on the carrier’s prescription drug formulary, when the patient has tried the required drugs while under his or her current or previous health insurance plan and it was discontinued due to lack of efficacy.</td>
</tr>
<tr>
<td>WV</td>
<td>H 2300 (2017)</td>
<td>Provides access to a clear and convenient process to request a step therapy exception determination that should be granted if the drug is contraindicated or could cause adverse reaction or harm, the patient has tried the drug previously and was discontinued due to lack of efficacy, the patient is stable on a prescription drug selected by their provider, or it is otherwise not in the best interest of the patient.</td>
</tr>
</tbody>
</table>
6. **Biosimilar substitution**: Bills to regulate pharmacists’ substitution of biosimilar drugs.

Due to the high costs of some biological products and the proliferation of biosimilar versions, some states are implementing policies to allow pharmacists’ substitution of these products, which the FDA has yet to deem “interchangeable,” without prior approval from the prescriber. Some of these laws require that pharmacists notify prescribers if an interchangeable biosimilar substitution has been made while others allow prescribers to prevent interchangeable biosimilar substitutions by including “dispense as written” or similar language on the prescription.

<table>
<thead>
<tr>
<th>State</th>
<th>Bill (year)</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>SB 2022 (2017)</td>
<td>Authorizes a pharmacist to substitute an interchangeable biologic product for a prescribed product under specified circumstances. Except when specified, the pharmacist must inform consumers of the availability of an interchangeable biologic product and the approximate cost difference as compared to the prescribed drug.</td>
</tr>
<tr>
<td>MN</td>
<td>HF 712 and SF 1184 (2017)</td>
<td>Allows pharmacists to substitute a generic in place of a brand-name drug when there is a therapeutically equivalent product. Substitution not permitted when a prescriber personally writes “dispense as written” or “DAW.” The pharmacist would be required to inform the customer and within five days communicate electronically to the prescriber.</td>
</tr>
<tr>
<td>SC</td>
<td>H 3428 (2017)</td>
<td>Changes the definition of substitute to include interchangeable biological products and allows pharmacists to substitute with a biosimilar product when appropriate. Includes details on prescriber notification upon interchangeable biosimilar substitutions.</td>
</tr>
</tbody>
</table>
Sample proposed legislation, by theme

1. **Importation:** Bills that seek to allow the importation of prescription drugs from Canada.

Several states (including Utah, West Virginia, Vermont and Oklahoma) have proposed legislation seeking permission from the Trump Administration to import drugs from Canada. The states are aiming to set up wholesale programs through their state health departments that buy drugs from Canada and resell them to local pharmacies and hospitals. Each state also would be responsible for ensuring the medications are safe and cost-effective. The legislation follows a model developed by the National Academy for State Health Policy and draws on a framework put in place by the 2003 federal law that created Medicare Part D, which says HHS can approve drug importation plans if it will save money and not create public health concerns (which has never been acted upon).

An analysis in Utah suggests the state could save $70 million in the private sector and another $20 million-$30 million in state-funded insurance programs through an importation program that features 15%-20% discounts on imports for drugs like insulin, along with other expensive drugs such as those for hepatitis C or HIV. While opponents of the legislation are concerned about drug safety, proponents argue that Canadian drugs are made by reputable companies and often in the same facilities as US drugs.

2. **Manufacturer gifts:** Bills that seek to place restrictions on gifts from manufacturers to physicians.

A proposed bill in California (SB 790) would prohibit a manufacturer of a prescribed product from offering or giving gifts to health care providers, designed to operate in conjunction with the Federal Physician Payments Sunshine Act, aimed at increasing transparency of financial relations. It would further prohibit a manufacturer of a prescribed product (or entity acting on behalf of a manufacturer) from providing a fee, payment, subsidy or other economic benefit to a health care provider in connection with the provider’s participation in research.

3. **Group purchasing:** These bills would instruct state agencies to explore different approaches to drug purchasing and drug price negotiations, often through multiagency collaboration and/or through the work of task forces.

In Oregon, there is a bill under consideration (HB 4151) that would require state agencies to purchase prescription drugs through the Oregon Prescription Drug Program. The bill would appoint an administrator and authorize the administrator to handle select responsibilities including but not limited to negotiating price discounts and rebates on prescription drugs with prescription drug manufacturers or group purchasing organizations. California also has a bill (AB 587) that would require certain state agencies to convene a California Pharmaceutical Collaborative to meet regularly to identify ways to address rising drug costs and negotiate with manufacturers for discounts on pharmaceuticals for the state, requiring various state entities to participate in the bulk purchasing arrangements.
Conclusion

State experimentation with drug pricing proposals is expected to continue, and early lessons from state efforts are beginning to emerge amid concerns from pharmaceutical stakeholders about the effects on access, cost containment and incentive for innovation. The Trump Administration continues to announce efforts to address the challenge of high drug cost at the federal level, but most observers are not expecting eminent congressional action. The Administration’s early efforts focused on the supply chain and the roles that insurers, PBMs and hospitals play in the challenge of rising drug prices. These moves raise questions about how far the Administration will go in its next steps to address the public’s concerns about the high cost of pharmaceuticals.

This leaves companies, stakeholders and consumers watching to see which state and federal proposals move forward, how compliance and enforcement will be managed, what lessons have been learned, and what effect (if any) these state initiatives will have on pharmaceutical pricing trends and patient access.

Sources:

About EY
EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit ey.com.

Ernst & Young LLP is a client-serving member firm of Ernst & Young Global Limited operating in the US.

© 2018 Ernst & Young LLP.
All Rights Reserved.
SCORE No. 02995-181US
CSG No. 1804-2672924
ED None
This material has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax or other professional advice. Please refer to your advisors for specific advice.

ey.com

Contacts
For assistance or more information please contact your Ernst & Young LLP professional, or:

Heather Meade
Partner
Washington Council Ernst & Young
Ernst & Young LLP
+1 202 467 8414
heather.meade@ey.com

Tara Bradshaw
Senior Manager
Washington Council Ernst & Young
Ernst & Young LLP
+1 202 467 4306
tara.bradshaw@ey.com

Laura Dillon
Manager
Washington Council Ernst & Young
Ernst & Young LLP
+1 202 467 4308
laura.dillon@ey.com