Introduction

The cost of prescription drugs is one of the leading health care issues in the United States. Prescription drug costs accounted for $335 billion of total health care spending in 2018 and over 23 percent of total health insurance premium costs. And the cost of prescription drugs is rising. According to the Centers for Medicare & Medicaid Services Office of the Actuary, prescription drug spending growth is projected to outpace all other major sectors of health care, averaging 6.3 percent per year for 2017-2026.

West Virginia has not been immune to the increasing costs of prescription drugs. Between 1991 and 2014, per capita spending on prescription drugs in West Virginia grew by an average of 6.8 percent per year, from $304 per capita to $1,377, faster than all other health care spending. Nationally, per capita prescription drug spending grew by 6.4 percent per year (Figure 1).

60 percent of Americans report taking at least one prescription medicine, and 79 percent say that the cost of prescription drugs is unreasonable. Beyond the financial impact, the high cost of prescription drugs can also have a health impact. 29 percent of Americans report that the costs of their medication have kept them from taking it as prescribed.

Both state governments and individuals have an interest in prescription drug costs. Prescription drug prices and reimbursement are major components of state Medicaid spending, and growing costs have generated interest in finding new ways to approach drug pricing. Several proposals focus on increasing visibility into how drug prices are set, and the decisions that lead to price increases. Proponents of prescription drug price transparency believe reform would not only expose inequities in the drug-pricing process, but also create a stronger element of competition that could drive down prices, relieving financial pressure on both individuals and states.

This brief examines the process behind prescription drug pricing, particularly the role of state budgets and Medicaid and how states have used drug price transparency reforms to improve the process.
Factors Controlling Prescription Drug Prices

For state governments, concern over drug prices largely stems from Medicaid costs. Medicaid payments for prescription drugs are determined by a complex set of policies, at both the federal and state levels, that draw on price benchmarks. State Medicaid agencies do not buy drugs directly from manufacturers. They instead reimburse retail pharmacies that fill prescriptions written for Medicaid patients. The amount the pharmacy receives is based on the ingredient cost of the drug and professional dispensing fees paid by Medicaid, plus any cost sharing paid by the beneficiary.

The ingredient cost reflects the price to the pharmacy of acquiring the drug from a manufacturer. Payment for ingredient cost is determined by federal regulations known as actual acquisition cost (AAC), which governs how states calculate pharmacy providers’ actual prices paid to obtain drug products marketed or sold by a specific manufacturer. To determine the AAC, states may survey pharmacies, use national survey data, or use data that manufacturers are already required to report. AAC is capped at the lower of federal upper limits (FULs) or state maximum allowable costs (MAC) for some drugs, both of which cap ingredient reimbursement.6

The dispensing fee is intended to cover costs associated with providing the drug to a Medicaid beneficiary. This includes the pharmacist’s services and the overhead associated with the pharmacy. States establish these fees, which typically range between $9 and $12 for each prescription.7

Cost sharing is the portion of Medicaid prescription drug costs paid for by the beneficiary. The amount is capped by federal law at $4 for preferred drugs and $8 for non-preferred drugs for individuals with incomes at or below 150 percent of the federal poverty level (FPL), with slightly higher caps for beneficiaries with higher incomes. 15 states do not impose cost sharing for prescription drugs.8

In 2017, approximately two-thirds of Medicaid gross drug spending was administered through managed care9, adding yet another layer to determining drug prices. As states enroll more beneficiaries into managed care organizations (MCOs), more states opt to include their pharmacy benefits under contracts with MCOs, which rely on pharmacy benefit managers (PBMs) for a variety of financial and clinical services, including drug price negotiation.

MCOs are not subject to the same drug payment rules as in traditional Medicaid. Federal rules state that MCOs must set payment rates sufficient to guarantee beneficiary access, but MCOs are not bound by rules regarding ingredient costs10, and may contract with a PBM that negotiates individual rates with pharmacies rather than a set payment rate.11 MCOs are also allowed to keep some pricing information proprietary in their negotiations with pharmacies, keeping the information from both states and individuals.

In 2017, West Virginia “carved out” prescription drug benefits from the state’s Medicaid managed care program, and now prescriptions drug benefits are managed directly by the state’s Bureau of Medical Services. This change saved the state’s Medicaid program $54.4 million in 2018, largely from reduced administrative costs.12

Drug Price Transparency

The many layers and factors that determine prescription drug pricing create a lack of transparency. Price benchmarks are collected, but not always accessible, and determining actual prices paid is difficult without access to a private database. Information on negotiated prices is often proprietary and kept from the public. Manufacturers frequently do not provide public information on how they set their list price.
and historically have not been required to explain changes in a product’s price. The prices paid by PBMs to manufacturers and the reimbursement they pay to pharmacies is also often unknown.

With drug prices increasing, straining state and personal budgets, many states have looked to reforms to create greater transparency on the way prices are set for prescription drugs. In 2018, 22 states introduced legislation promoting greater transparency from drug manufacturers around their drug pricing methods, with legislation passing in Oregon and Maine. California, Maryland, and Nevada passed similar laws in 2017.

The primary aim of drug transparency laws is to empower consumers, state health agencies, and health insurance providers with better information on drug prices. A fundamental tenant of economics is that providing buyers with better information regarding product quality and cost enables them to seek out and negotiate better prices.

In general, transparency laws would make information that may be available only to a state Medicaid agency or PBM available to the public and other state lawmakers. This helps policymakers better understand which prescription drugs and which parts of the supply chain are driving spending. The public highly favors drug pricing transparency, with a recent poll finding that 86 percent of Americans would like drug companies to publicly release information on how prices are set.

Drug price transparency laws can also act as a disincentive to overpricing drugs. When the development and production costs for particular medicines are publicly known, patients and the public can more easily identify examples of price gouging. And since some transparency laws require disclosures when certain price increase triggers are met, manufacturers may avoid pricing drugs at costs that would trigger disclosure requirements.

**Recent State Actions**

As mentioned above, several states have enacted drug price transparency legislation in recent years. These laws have two common elements. First, they require drug manufacturers to report drug pricing information for drugs that increase in price by a given percentage in a set period of time. Second, they require manufacturers to report on any drugs that have an estimated annual cost exceeding a certain amount. They often also require manufacturers to describe the reasons for those prices and increases.

For example, in 2017 California enacted SB 17, its drug price transparency law. The law required drug manufacturers to notify purchasers of prescription drugs at least 60 days in advance if they planned to increase a drug price by more than 16 percent in a 12 month period, or 32 percent in a 24 month period. The law applies to all drugs (brand-name and generic) with a wholesale acquisition cost of at least $40. The reporting requirements include detailed information regarding the reasons and justification for price increases. The law also requires justification of launch prices for new drugs.

Within months of the implementation of the California bill, several drug manufacturers notified the state that they were rescinding previously announced drug price increases.

Vermont has passed two drug price transparency laws, the first in 2016, followed by an expansion in 2018. The 2016 law required the state to identify 15 prescription drugs that it spends a significant amount on and for which wholesale acquisition price increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months. The manufacturers of those drugs were then required to provide a justification for the increase.
The 2018 law expanded the requirement, demanding all health insurers with coverage of more than 5,000 members to identify 10 prescription drugs with price increases of 50 percent or more over the past five years or 15 percent annually. The state then identifies which 15 drugs will require a justification from the manufacturer.\textsuperscript{17}

Nevada’s law, enacted in 2017, requires the state to identify drugs with price increases exceeding the medical consumer price index in the past 12 months or twice the increase in the previous 24 months, with justifications from the manufacturers. In addition, the costs of manufacturing and marketing for all essential diabetes medication must be reported annually. The law also requires the reporting of all free goods or compensation provided by each sales representative to Nevada-licensed health care providers.\textsuperscript{18}

Oregon’s 2018 law requires reporting on prices and costs associated with developing and marketing prescription drugs that are priced at $100 or more for a one-month supply or for a course of treatment lasting less than one month and had a net increase of 10 percent or more in the past 12 months. The law also requires manufacturers to report the reasons for the price increase.\textsuperscript{19}

**West Virginia’s Law**

During the 2020 legislative session, West Virginia became one of the latest states to pass a drug price transparency law. Senate Bill 689, which goes into effect in 2021, applies to prescription drugs with a wholesale acquisition cost of at least $100 for a 30-day supply that have had a price cost increase of 40 percent or greater over the preceding three calendar years, or 15 percent or greater in the previous calendar year. Drug manufacturers are required to report prices, research and development costs, and the reasoning for the price increase. In addition, all health plan insurers in the state are required to report the 25 most frequently prescribed prescription drugs, the percent increase in annual net spending for prescription drugs, and the percent increase in premiums that were attributable to prescription drugs.\textsuperscript{20}

The data from West Virginia’s transparency law will be available in a publicly accessible, searchable database maintained by the State Auditor’s office.\textsuperscript{21}

**Next Steps Beyond Transparency**

Some states have begun to look beyond drug price transparency to address the issue of drug affordability more directly. In 2019, seven states introduced legislation to create prescription drug affordability review boards. These boards would regulate the pharmaceutical industry much like a public utility.\textsuperscript{22}

These proposals create drug price review boards to review, approve, or adjust launch prices for all newly approved drugs or drugs with list prices above a certain dollar threshold. The review process could include holding open hearings, reviewing data submitted by manufacturers, and collecting other publicly available information. The boards could also direct new research to assess specific drug prices.\textsuperscript{23}

A prescription drug affordability review board would give West Virginia the ability to limit how much its residents pay for certain high-cost drugs. Because drug costs involve many complicated issues and affect numerous stakeholders, a drug affordability review board would bring the parties together, increase transparency, and set an upper payment limit for drugs.

For decades, states have set maximum payment levels for health care and other public utilities. States regulate insurers and other public goods and services in markets with little or no market competition. A drug affordability review board would build on the numerous regulatory precedents for drugs that have only a few suppliers.
Conclusion and Recommendations

Understanding how prescription drug prices are set will allow both patients and the state to make more informed decisions about whether prices are excessive, as well as introduce some rationality and evidence into the health care system.

West Virginia’s recently passed law is a good first step, incorporating some of the best policies from other states, which include covering both generic and patented drugs, research and development costs, and the rationale for price increases.

As the law is implemented, its impacts must be comprehensively analyzed. West Virginia should presume that all information related to prescription drug costs is public information that should be released, allowing company rebuttal only if they can demonstrate that a specific fact is a trade secret. West Virginia policymakers should also give the public the legal right to object to the withholding of specific information.

West Virginia could also consider expanding its law to cover pharmacy benefit managers (PBMs), including which rebates PBMs negotiate. Pharmaceutical companies, without disclosing research and development costs to PBMs, set the prices that PBMs then negotiate down. Laws that require disclosure of drug prices set by pharmaceutical companies would also help in evaluating the pricing practices of PBMs.

Finally, with the information from its price transparency law, West Virginia should explore more active roles in constraining prescription drug prices. For example, Maryland gives discretion to the Attorney General to prosecute drug companies that engage in excessive price increases for “essential generic drugs,” with a suggested threshold of, but not limited to, more than 50 percent over a two-year period. West Virginia could also consider a push for more drug affordability, as well as the creation of a prescription drug affordability review board with the power to regulate drug prices like a public utility.
4 Kaiser Family Foundation Health Tracking Poll, “Public opinion on prescription drugs and their prices: Poll findings from 2015-2019 KFF Health Tracking Polls”
5 Ibid.
8 Kaiser Family Foundation, State Health Facts, Medicaid Benefits: Prescription Drugs https://www.kff.org/medicaid/state-indicator/prescription-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22desc%22%7D
10 81 Federal Register 5169-5357, (February 1, 2016).
15 http://custom.statenet.com/public/resources.cgi?id=ID:bill:CA2017000S17&ciq=ncsl&md=a65467f7d7f716c5b58a6d93f3b894f4&mode=current_text
19 Oregon Legislative Assembly, 2018 Session, HB 4005 http://custom.statenet.com/public/resources.cgi?id=ID:bill:OR2018000H4005&ciq=ncsl&md=f7903f92c99b9b163267dfb4e6a1801a&mode=current_text
21 Ibid.