State Policy Options for Controlling Prescription Drug Prices and Spending

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It is imperative that West Virginia start to identify and implement tools that can hold down prescription drug costs in Medicaid, CHIP, PEIA, and for all public and private payers. For West Virginia, it is a key strategy to help the state meet growing gaps between revenue and spending in the state budget. For West Virginia consumers who pay for prescription drugs directly or through premiums and cost-sharing payments, the increase in prescription drug costs is taking a toll on family budgets. Addressing prescription drug cost growth is a vital part of increasing quality while controlling health care costs in the state.

Polls show that rising prescription drug prices are a top health care concern among Americans across all political affiliations.[1] While federal initiatives to control drug costs have been discussed, the concrete legislative action on prescription drug costs have been happening at the state-level.[2] First, states are working within federal limits to reduce prescription drug spending in Medicaid and West Virginia has been among those states. Second, states are moving forward to look at state policy tools to address prescription drug costs across all sectors and purchasers. With regard to cross-sector efforts, West Virginia has an opportunity to learn from other states' progress addressing prescription drug costs. This white paper highlights some of the recent legislation and strategies that states are pursuing.

Trends in U.S. Prescription Drug Expenditures

For years spending on prescription drugs by both public and private payers in the United States and in West Virginia has outpaced growth in other health care services subsets. However, in 2016 the long-term trend in high prescription drug spending increases appeared to change. According to the most recent National Health Expenditure (NHE) data available, overall national health care costs grew 4.3 percent to $3.3 trillion in 2016, or $10,348 per person, and accounted for 17.9 percent of Gross Domestic Product (GDP). Hospital expenditures grew 4.7 percent, physician and clinical service expenditures grew 5.4 percent, and total retail prescription drug spending increased by only 1.3 percent. The significantly slower growth in 2016 followed two years of strong growth in prescription drug spending in 2014 and 2015, 12.4 percent and 8.9 percent, respectively. Growth slowed in 2016 primarily due to fewer new drug approvals, slower growth in brand-name drug spending (including spending for

hepatitis C drugs), and a decline in spending for generic drugs as price growth slowed.[3] Nonetheless, prescription drug spending accounted for about 10 percent of total health care spending in 2016.

However, projections for 2017 through 2025 expect a 5.7 to 6.4 percent annual growth increase from the previous year in retail drug expenditures. Some of the drug spending growth will be driven by the opioid addiction crisis – certainly a factor in West Virginia. [4]

Prescription Drug Use in West Virginia

Annually, West Virginians have almost 36 million retail prescriptions filled at pharmacies[5] at a cost of more than $2.750 billion.[6] West Virginians use more, and spend more, per capita on prescription drugs than the average for the nation. This is true regardless of age.

Retail Prescription Drugs Filled at Pharmacies – Annual Per Capita[7]

United States	12.6
West Virginia	20.0

Retail Prescription Drugs Filled at Pharmacies – Annual Per Capita by Age[8]

	Ages 0-18	Ages 19-64	Ages 65+
United States	4.3	12.7	23.9
West Virginia	6.1	20.2	30.1

An important question is "Why do West Virginians use more prescription drugs on average? Very little recent empirical evidence is available to explain higher prescription drug use in West Virginia, with the exception of recent literature on misuse of opioids. Clearly, the misuse of prescription painkillers is one contributing factor.[9] Also the aging of the state population is a factor. The overall health of the population and more limited access to alternative treatments to prescription drugs are also factors, including lack of geographic proximity to these treatments as well as economic barriers (cost, lack of insurance coverage, and inability to take time off work to pursue alternative routes of treatment for pain and other conditions).

Impact of Rising Prescription Drug Costs

In 2017, approximately 22 percent of consumers – 27 million – experienced a price hike for one or more of their medications. About one third of those people paid at least $50 per month extra for one or more prescriptions.[10]

A 2017 *Consumer Reports* survey of consumers who have had a prescription drug cost increase of at least one drug in the last 12 months provides a window into the strategies people use to cope with rising drug costs, often for drugs that are lifesaving or life-prolonging medications. Consumers who reported

an increase were more likely (as compared to consumers who did not) to resort to using coping strategies that included not filling a prescription, cutting pills in half without doctor approval, not taking a drug as scheduled, taking an expired medication, switching to a supplement, over-the-counter drug, or non-drug treatment, or putting off a doctor's visit, medical test, or procedure. People also reported that they spent less on groceries, used a credit card more often, postponed paying other bills, postponed retirement to maintain coverage, and took a second job.[11]

Kaiser Health Tracking Polls in 2015, 2016, and 2017 confirm that prescription drug spending growth is an important issue for consumers. More than one in four consumers taking prescription drugs report difficulty affording them,[12] and one in eight report that they or a family member have cut pills in half or skipped doses due to high drug costs.[13] Two-thirds of consumers across political parties believe that lowering the cost of prescription drugs should be a top policy priority. More than 80 percent of Americans support requiring drug companies to release information to the public about how they set drug prices and want government to limit what companies charge for high-cost drugs for illnesses like cancer or hepatitis. [14]

West Virginia Medicaid Prescription Drug Program

Federal Requirements

State Medicaid prescription drug coverage must comply with the requirements of Section 1927 of the Social Security Act. Under Section 1927, states generally must include on their Preferred Drug Lists all Food and Drug Administration (FDA)-approved drugs of a pharmaceutical manager, so long as the manufacturer has entered into a rebate agreement under which the manufacturer offers rebates to state Medicaid programs. These rebates are subject to complicated formulas but typically must be at least 23.1 percent for brand-name drugs and 13 percent for generics.

States can take certain steps to control costs, such as requiring prior authorization for non-preferred drugs and for prescriptions beyond certain quantity/duration limits. States may choose to layer individually negotiated supplemental rebates over the federal Medicaid drug rebates. States leverage their ability to subject certain drugs within classes to prior authorization and Preferred Drug List (PDL) status to drive deeper rebate supplements from manufacturers looking for a competitive edge. [15] But states cannot label a drug as "non-covered" except under very limited circumstances – impacting a states' ability to negotiate discounts from manufacturers. Some states have joined multi-state purchasing pools to increase their ability to negotiate supplemental rebates,[16] including West Virginia as discussed later in this paper.

In reaction to this limit of price negotiating power, Massachusetts and Arizona have requested a 1115 Medicaid waiver that would allow the Medicaid program to use a "closed formulary" that would not include every FDA-approved drug. A consumer appeal process would allow some Medicaid enrollees to have coverage of a drug off the formulary. President Trump's FY2019 proposed budget also proposed a five-state demonstration program that would allow states to have closed formularies and negotiate

more favorable drug prices from manufacturers. It is not clear if this demonstration would require legislative authority or could be one done through administrative rule-making.

One criticism of both federal and state supplemental Medicaid drug rebate programs is that forcing manufacturers to deliver high rebates to Medicaid programs may lead to higher costs for the same drugs for other public purchasers and for the private sector.

West Virginia's New Approach to Medicaid Prescription Drugs

The West Virginia Medicaid program saw rising prescription drug costs in State Fiscal Year (SFY) 2016 in Medicaid managed care plans that forced the state to adjust managed care rates up approximately $120 million. While rising prescription drug costs were built into the SFY 2017 Medicaid managed care rates, again an upward adjustment was needed to cover prescription drug costs beyond projected increases in 2017. Looking to SFY 2018, the state projected yet another rate increase. Responding to this situation, the West Virginia Department of Health and Human Resources (DHHR) contracted with Optum and Lewin Actuaries to provide an independent analysis of options to help reduce Medicaid prescription drug costs.

After reviewing options to reduce prescription drug costs in SFY 2018, DHHR decided to transition the prescription drug benefit for Medicaid managed care enrollees from the Managed Care Organizations (MCOs) back to traditional Medicaid Fee-For-Service (FFS) coverage, effective July 1, 2017. The DHHR Bureau for Medical Services (BMS) is the designated single state agency responsible for the administration of the State's overall Medicaid program. The prescription drug benefit "carve out" from managed care would be managed by the Bureau's Office of Pharmacy Services (OPS) supported by a claims processor, Molina Medicaid Solutions. The Bureau's Office of Pharmacy Services is its own Pharmacy Benefits Manager (PBM). Molina also serves as the claims processor for Fee for Service medical and dental claims and is the system of record for Medicaid enrollment.

At the start of implementation, the Office of Pharmacy Services (OPS) honored all prior authorizations obtained from the four Medicaid MCOs. OPS manages the prior authorization process for all new prescription drugs provided at retail pharmacies for Medicaid managed care enrollees, eliminating the need to intervene on issues between multiple MCOs and their contracted PBMS with pharmacies regarding prior authorization approval. Although a single state managed Preferred Drug List had been in effect for both MCOs and Fee for Service Pharmacy Programs, the OPS also standardized preferred diabetic testing supplies with the transition back to Fee for Service Pharmacy for all members by creating a Preferred Diabetes Supply List (PDSL).

Before the implementation date of July 1, 2017 DHHR projected that the transition to FFS with a single pharmacy benefit manager would generate approximately $30 million in prescription drug savings annually due to administrative cost savings and modifications to the ingredient and dispensing cost formulas. Looking at the first six months of data, DHHR revised projections of savings upward to closer to $70 million, in part due to increased compliance to the Preferred Drug List, management of

therapeutic and ingredient duplications of prescription drugs, and the application of dosing limits by the OPS.[17] These clinical interventions are done in conjunction with the OPS Drug Utilization Review Program and an advisory board of healthcare practitioners. More data is needed to determine if the transition back to Fee for Service is reducing the overall number of prescriptions and the impact on enrollees.

PEIA Prescription Drug Benefit Strategies

The Public Employees Insurance Agency (PEIA) provides health insurance to 230,000 people in West Virginia who work for state agencies, local governments, county schools, higher education, as well as for these workers when they retire and their survivors. About 27 percent of enrollees are retired, and spending on retirees is about 30 percent of total PEIA spending.

PEIA offers 4 PEIA Preferred Provider Benefit plans and 3 Managed Care Organization plans to its currently working members. There are 10 salary tiers with deductibles and out-of-pocket maximums varying by salary. All members have an 80/20 percent premium split requirement. For retirees, premiums are based on years of service.

In state fiscal year 2016, PEIA increased the copayment for generic drugs for a 30-day supply from $5 to $10 and for 90-day supply (maintenance only) from $10 to $20. PEIA increased the copayment for a Preferred Brand drug for a30-day supply from $15 to $25 and for 90-day supply (maintenance only) from $30 to $50. There is a mandatory 90-day fill required for maintenance prescriptions. Maintenance drugs are medications prescribed for chronic, long-term conditions and are taken on a regular, recurring basis. Examples of chronic conditions that may require maintenance drugs are: high blood pressure, high cholesterol, and diabetes.

In state fiscal year 2017, PEIA contracted with CVS Health for pharmacy benefit management. PEIA is evaluating the formulary and network through CVS on an on-going basis. PEIA also has a “Specialty Drug” program developed specifically for PEIA that covers over 480 specialty medications. Specialty drugs are a recent designation of pharmaceuticals that are classified as high-cost, high complexity and/or high touch. Specialty drugs are often biologics—"drugs derived from living cells" that are injectable or infused (although some are oral medications). Specialty drugs costs are a significant portion of overall drug spending – averaging about 30 percent. Under the Specialty Drug program, specialty pharmacy contracts are negotiated to secure better discounts and pricing, as well as drug rebates. There is a medical appropriateness review on all drugs, and members are directed to copayment assistance programs. PEIA pays $.79 per member per month in administrative costs for the program (total annual cost $737,000) and the program has saved $10.9 million on the cost of specialty drugs to PEIA and $6.6 million through copayment assistance.

In addition to these measures to reduce prescription drug costs, PEIA uses prior authorization and medical appropriateness review for many drugs. PEIA encourages generic drug use through education

and reduced copayments. Members are also educated about strategies such as discussing choice of drugs with providers and pill splitting.

State Level Cross-Sector Policies to Impact Prescription Drug Costs

Over the last several years, states have begun to look beyond state Medicaid program and public employee program levers to address rising prescription drug costs. In 2015, the National Academy of State Health Policy convened a Pharmacy Costs Work Group to explore state policies to control rising prescription drug costs across additional public and private sectors. This Work Group is providing additional resources to states including an October 2016 report that outlines 11 policy options for states to consider that range from regulatory interventions to more market-oriented approaches.[18] The Work Group also is developing model state legislation to address rising prescription drug prices and has a prescription drug resource center on the internet and a state prescription drug legislation tracker.[19]

In 2017, more than 80 prescription drug pricing bills were proposed in over 30 states around the country.[20] Recently, ground-breaking drug pricing legislation has passed in Maryland, New York, and Nevada that have the potential to impact prescription drug prices across sectors. Highlights of these state actions and other recent state action are described below, organized under five headings:

1) Direct Regulation of Drug Prices;
2) Drug Price Transparency;
3) Biosimilar Substitution;
4) Purchasing Pools and Preferred Drug Lists; and,
5) Importation.

<u>Direct Regulation of Drug Prices</u>

Recent state laws that directly regulate prescription drug prices are built on states' authority to regulate public utilities and to set payment rates in Medicaid and state employee health programs. States have traditionally regulated goods and services that are essential to the public health and well-being, and that tend to be sold by only one or a small number of producers; electric and gas are both examples of state-regulated industries . Like utilities, prescription drugs are essential to the public well-being. Both require significant upfront investments – utilities in infrastructure and pharmaceutical manufacturers invest in costly research, development, safety testing and approval. Both utilities and pharmaceuticals are often provided by a limited number of suppliers. States already engage in health care rate setting – how much the state will pay for health care is a routine state function in Medicaid, state employee benefits, and

corrections. Rate setting is routine in the commercial health market as well – private insurance companies and some large health facilities set payment rates for brand and generic drugs.

Traditionally, generic drugs have been a cheaper, safe alternative to expensive brand name prescription drugs and have been key to consumer access to affordable medications. In recent years decreasing competition among the generic market manufacturers and wide-spread anti-competitive practices within the generic drug industry has led to significant generic drug price increases.[21] With this trend in mind, the stage was set for Maryland to pass a "drug price-gouging bill" in May 2017. Maryland's new law gives the Attorney General authority to investigate large generic drug price increases and to use the courts to sanction drug manufacturers or compel them sell a drug at a lower price.

Maryland's new generic price control law, HB 631, as described by the state:

> "…prohibits a manufacturer or wholesale distributor from engaging in "price gouging" in the sale of an "essential off-patent or generic drug." Medicaid may notify the Attorney General when specified price increases occur. On request of the Attorney General, the manufacturer of an essential off-patent or generic drug must submit a specified statement. The Attorney General may require a manufacturer or wholesale distributor to produce any records or documents relevant to determining if a violation of the prohibition on price gouging has occurred. On petition of the Attorney General, a circuit court may issue specified orders, including compelling a manufacturer or wholesale distributor to provide certain statements or records, restraining or enjoining a violation, requiring restitution, and imposing a civil penalty of up to $10,000 for each violation." (Fiscal and Policy Note for HB 631)[22]

The new Maryland law only applies to generic or off-patent drugs that are manufactured by three or fewer manufacturers. The law suggests that the Attorney General can request detailed information justifying the price increase and pursue legal action in the event that a manufacturer raises the "Wholesale Acquisition Cost" (WAC) of certain higher-cost generic or off-patent drug by more than 50 percent in a year, or the price paid by the Maryland state Medicaid program increases by more than 50 percent in a year. In addition to the $10,000 civil penalty, a circuit court may require manufacturers to provide the drug to Maryland state programs at the price prior to the increase. The Maryland law went into effect on October 1, 2017; it currently faces court challenges. The 4th Circuit federal appeals court, in a 2-1 ruling, found on April 13, 2018 that the law violated the commerce clause of the U.S. Constitution. The court found that the law regulates trade that happens beyond Maryland's borders and is therefore prohibited. The Maryland Attorney General's office has not decided if the state's lawyers will seek another review by all the judges in the 4th Circuit, or take the case to the Supreme Court. [23]

Similar bills to Maryland have been proposed in **Massachusetts, Montana, Rhode Island, and Tennessee**.[24]

A 2017 proposed bill in **Oregon** requires prescription drug manufacturers to report to the state's Department of Consumer and Business Services prices and price increases for any drug sold in Oregon

for a total of 36 months or more. Manufacturers must provide a justification for any increase in price greater than 3.4 percent. If the Department finds a price increase to be excessive and unjustified, the Department is required to issue an order for the manufacturer to refund to all purchasers of the drug the portion of the price increase that the Department finds excessive.[25]

A recent bill that passed in **New York** in 2017 allows for state sanctions for price increases on both brand and generic prescription drug increases, but is limited to the Medicaid program.[26] The bill requires that the state Department of Health set annual projected spending caps for Medicaid prescription drug spending and assess on a quarterly basis if the caps will be met. If spending is expected to exceed these caps, the Department is authorized to negotiate additional manufacturer supplemental Medicaid rebates for specific drugs. The cap for 2017-2018 is the ten-year rolling average of the medical component of the consumer price index plus 5 percent and minus a prescription drug savings target of $55 million. If an agreement on supplemental rebates cannot be reached, the prescription drug may be referred to a New York Drug Utilization Review Board for additional review of pricing factors, further negotiations, and possible sanctions including requiring prior authorization and being taken off the preferred drug list for Medicaid managed care.

Four prescription drug bills were introduced in the **Pennsylvania** legislature in 2017, including one to establish a Pharmaceutical Transparency Commission to determine whether retail drug prices are reasonable. Insurers or PBMs would not be required to pay the price of a prescription that is more than 20 percent higher than the "reasonable cost." The Commission would also determine a reasonable reimbursement to hospitals, health providers, and physicians for costs associated with dispensing medicine. To determine reasonable cost, manufacturers would be required to report various financial data (including R&D, marketing costs, consumer rebates) to the Commission annually for drugs sold in state.[27]

A drug price standards initiative – Measure 26 - will be on the November 2018 ballot in **South Dakota**. South Dakotans for Lower Drug Prices submitted over 22,000 signatures; 13,871 were needed. The measure would require state agencies to pay no more for prescription drugs than the prices paid by the U.S. Department of Veterans Affairs (VA). The VA typically receives a 24 percent discount for prescription drugs. The measure would apply in any case in which the state ultimately funds the purchase of drugs, even if the drugs were not purchased directly by a state government agency. Measure 26 is the third effort to tie drug prices paid by state agencies to the prices paid by the VA. Voters in California and Ohio defeated similar measures in 2016 and 2017.

The **NASHP Pharmacy Costs Work Group** has developed a drug rate setting model bill that includes elements from the new Maryland law. The NASHP Drug Rate Setting Model Act creates a new state Drug Cost Review Commission. The Commission sets standards for drug price increases that trigger information submissions from the makers of both brand name and generic prescription drugs. This information is used to determine the reasonableness of the drug price and increase through a public process that accepts data and analysis from manufacturers, payers, consumers, as well as Commission staff and contractors to determine if the price is inappropriately excessive and whether the drug is

affordable to state residents. Proprietary information can be shared with the public for analysis in a de-identified manner. The Commission is authorized to establish a payment rate for the drug to which all state programs, local governments, state-licensed commercial health plans (including state marketplace plans), and state-licensed pharmacies, and others must abide. These entities are prohibited from paying more for the drugs than the Commission-established rate. The prohibition would be enforced by the state attorney general.[28]

Drug Price Transparency

Prescription drug pricing is a complex process involving manufacturers, wholesalers, pharmacies, state and federal governments, and consumers, with various rebates along the pricing and payment chain. There are many factors that affect drug pricing, and many are hidden or proprietary. However, the starting point for drug pricing is a manufacturer-set "list" price for a drug (wholesale acquisition cost – WAC – or the Average Wholes Price – AWP). Manufacturers have not been required to explain how they calculate these prices even though they are the basis for drug pricing throughout the payment chain. Moving down the payment chain, information about rebates such as the federal Medicaid rebate, state supplemental rebates, and rebates from private Prescription Benefit Managers (PBMs) are not released to the public. It is often unknown how much of these rebates are passed on to consumers or other payers. In some cases a consumer's copay for a drug may be higher than the cost of the drug to a PBM.

State transparency laws can help provide the data to understand how drug prices are set and what levers can help control prices. Transparency laws can provide information only to regulators, or they can provide information to the public as well. Transparency laws can address manufacturer and/or PBM pricing. While drug pricing transparency laws do not directly lower prescription drug costs, they are a foundation to address costs by a wide range of payers and can be the necessary foundation for direct regulation of drug prices and increases. They also can be a tool to educate the public and build support for direct drug price regulation.

Drug transparency legislation is popular with the public. A Kaiser Family Foundation poll found that 86 percent of Americans "favor requiring drug companies to release information to the public on how they set drug prices."[29]

State drug pricing transparency legislation was the most common policy approach to addressing drug price increases in 2016 and 2017. **Vermont** passed a law in June 2016 that directed the state to identify up to 15 costly drugs from separate drug classes with large manufacturer WAC increases. The manufacturers must provide justification for their price increases to the Attorney General and the state General Assembly. The information is posted on-line.[30]

In 2017, **California, Connecticut, Louisiana, and Nevada** passed prescription drug pricing laws. The **California** law requires drug manufacturers to provide advance notice (60 days) of any significant WAC increases and justification for the increase. Health care plans are also required to report annually on the

25 most prescribed, the 25 most costly, and the 25 drugs with the highest price increase in spending. All of this information will be summarized and available to the public.[31]

The **Nevada** law specifically targets the high-cost diabetes medication insulin, and addresses both manufacturer and PBM rebate transparency. The Nevada law requires manufacturers to provide annual WAC list prices, data about the costs of producing the drug, and data about profits for all diabetes drugs to the Nevada Department of Health and Human Services. Manufacturers must provide information about factors contributing to price increases for diabetes drugs that had significant price increases over a two-year period. PBMs must report all discounts and rebates for these diabetes drugs and how these discounts and rebates were distributed among different payers, including Medicaid. The Department will provide annually a report to the public based on this information.[32]

The 2017 **Connecticut** law prohibits PBMs from inserting "gag clauses" into their pharmacy network contracts that would bar pharmacists from informing consumers when their copay is actually more than the price of the drug, and then "clawing back" the excess money paid.[33]

On May 31, 2018, **Connecticut** Governor Malloy signed Public Act 18-41. This new law requires drug companies to justify prescription drug price increases when the price of a drug increases by 20 percent in one year or by 50 percent over three years. The bill also requires Pharmacy Benefit Managers (PBMs) to disclose rebates they received from drug companies and the amount of rebate they passed on to consumers versus the amount they retained. [34]

The **NASHP Pharmacy Costs Work Group** developed a comprehensive prescription drug transparency model bill that addresses both manufacturer list pricing and the role various rebates or discounts in the prescription drug pricing and payment chain to see what discounts benefit consumers, including PBM discounts and discounts through patient assistance programs. It also addresses the Medicaid discounts provided to 340B safety net providers and hospitals. The NASHP Pharmacy Costs Work Group states that the model bill:

- Requires pharmaceutical companies to provide information about how a drug is priced.
- Identifies the size and volume of discounts in the state health care market, as well as whether and how those discounts reach the consumer.
- Requires a report on how many pharmacies may not inform consumers when the price of a drug is less than the cost sharing they are required to pay.
- Includes penalties for pharmaceutical manufacturers and certain 340B entities that do not comply with the law's provisions.
- Protects proprietary discount information but requires a state agency to aggregate the data, report annually on drug price trends and hold a hearing for public review and comment.
- Publishes price justification documents obtained from pharmaceutical manufacturers.
- Determines and reports on whether coupons help or hurt consumers
- Does *not* require disclosure of manufacturer research and development costs because these are not built into the pricing of any one drug.[35]

Biosimilar Substitution

Biologics are drugs made from complex, large molecules manufactured using living microorganisms, plants, or animal cells as compared to traditional small molecules which are chemically synthesized in labs.[36] Common biologics include injectable treatments for arthritis, medicines for cancer, diabetes, Crohn's disease, psoriasis, macular degeneration, the Hepatitis B vaccine, and stem cell therapies.[37]

With traditional prescription drugs, once the Federal Food and Drug Administration (FDA) approves a generic drug as "therapeutically equivalent" a pharmacist usually can substitute a generic for a brand name drug unless the prescribing doctor or provider has explicitly requested a brand drug. In some states, including West Virginia, pharmacists are *required* to substitute a generic for a brand name prescription drug unless the provider instructs otherwise. Like other state laws, the West Virginia law only requires substitution if a generic drug has been approved by the FDA as "therapeutically equivalent."[38]

Biosimilars – the term used for generic biologic drugs - are interchangeable with biologics, but do not necessarily meet the state legislative and FDA definitions of "therapeutically equivalent. Because the process of making biologics is more complex – often using DNA recombinant technology – the FDA process of certifying biosimilars as "interchangeable" with biologics is not the same process as the approval of traditional generic drugs as therapeutically equivalent to brand drugs. As a result, even though biosimilars can be safely substituted for branded biologic drugs, the difference in FDA terminology and approval requires new state legal authority to permit or require biosimilar substitution.[39]

While the FDA has been slow to approve biosimilars, the current FDA Commissioner has recognized that the promotion of the use of biosimilars could generate significant savings across all payers.[40] Scott Gottlieb, U.S. Food and Drug Administration (FDA) Commissioner**,** stated on March 7, 2018: "….biosimilars not only present opportunities for significant cost savings, they can dramatically expand patient access to therapies….For instance, in an FDA analysis of the market for white-blood cell stimulating biologics – which can help cancer patients fight off infections when they are taking chemotherapy – we've seen pricing relative to the incumbent biologic, Neupogen, decline by 34 percent after the approval of two competitors, with the competitors capturing nearly 50 percent of the market share, and saving payers $150 million annually."[41]

States have been leaders in recognizing these potential savings and passing laws that provide the legal authority for biosimilar substitution. From 2013 to 2018, **44 states** and **Puerto Rico** have passed biosimilar substitution laws.[42] West Virginia passed a biosimilar substitution law in March 2018 (House Bill 4524).[43]

Purchasing Pools and Preferred Drug Lists (PDLs)

States can join with other states to leverage greater prescription drug purchasing power. States also can leverage better prescription drug prices within the state by bringing the purchasing power of Medicaid,

state public employees, educational institutions, other public purchasers, and even private insurers together.

As 2017, there were five major operating multi-state bulk buying pools, including one that West Virginia participates in - the **Sovereign States Drug Consortium (SSDC)** that is focused on state Medicaid drug supplemental rebates and has a total of thirteen state participants. Each state manages its own PDL. The SSDC negotiates directly with drug manufacturers for supplemental drug rebates on behalf of all participating states. Each state independently decides which supplemental rebate bids they will accept in constructing their PDLs. West Virginia also joined the TOP$ State Medicaid Purchasing Pool in 2005 and withdrew in 2008 to join the SSDC.

The **Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)** combines agencies and clinics in 49 states including West Virginia (only Massachusetts is not represented) but does not serve Medicaid or public employee programs. It is operated by the state of Minnesota and offers cooperative multistate contracting agreements for health-care related supplies, equipment and services to participating states and facilities (over 5,000 separate facilities were listed as part of MMCAP as of January 2017). MMCAP permits "*any entity recognized by another state's statutes as authorized to use that state's commodity or service contracts*" to enter into the bulk purchasing consortium. A prime vendor administers the program, handles inventory and delivers awarded contract items. Participating states and facilities reserve the right to utilize or not utilize any MMCAP contracted agreements. According to program staff, MMCAP achieves average savings of approximately 23.7 percent below AWP for brand name pharmaceuticals and 65 percent below AWP for generics.[44]

With a grant from NASHP, in 2018 **Delaware** is developing a common Preferred Drug List (PDL) across in-state purchasers and hospitals for selected categories of drugs. Partners in this collaborative approach include the Delaware Division of Medicaid and Medical Assistance, the Delaware Statewide Benefits Office, the Delaware Department of Correction, and major hospitals. The partnership's first task will be to identify the drug categories that promise the most savings. The goal is to lower the net cost per patient, per year for all categories included in the common PDL by 1 percent in the first year, and by 5 percent by the second year.[45]

<u>Importation</u>

Some prescription drugs are available at significantly lower prices in Canada as compared to the United States.[46] Traditionally, prescription drug importation legislation has been viewed as a possible federal policy strategy. However, **Utah** passed a law that authorized a state study of the possibility of a program to import lower-cost prescription drugs from Canada. In January 2017, a Republican state legislator introduced legislation to create a state-run prescription drug importation program that would import high-cost drugs from Canada.[47] The proposal for a whole-sale importation program of select, higher-cost drugs that are already licensed for sale in Canada would be among the first in the nation and is based on a model law developed by the NASHP Pharmacy Costs Work Group.

Vermont is the first state in the nation to approve a wholesale program to import lower-cost prescription drugs from Canada/ Vermont now begins the task of winning approval from the secretary of the US Department of Health and Human Services (HHS) and implementing its program. The new importation law must show that any imported drugs will be tested regularly for safety and purity; that the new program will not put consumers at a greater health risk than they are under the current drug supply system; and, the program will yield significant savings to the state's consumers. Opioids cannot be imported. Vermont's Agency for Human services is applying to HHS for approvals and plans to begin implementation with six months of getting state funding and federal approval.[48]

The **NASHP Pharmacy Costs Work Group** model state prescription drug importation bill is designed to meet the standards set by federal law that allow the U.S. Secretary of Health and Human Services (HHS) to approve personal and wholesale importation of prescription drugs from Canada. Basically the federal law allows HHS to certify a drug importation program if consumer safety protections are equal to those in the U.S. and significantly lower drug prices can be obtained. The model bill establishes a state-administered system of wholesale importation that can purchase drugs for public program only or expand to include commercial health plans.

- Select a Canadian supplier that is licensed and regulated under Canadian law;
- Select the drugs to be imported that are approved for the Canadian market;
- Solicit the voluntary participation of distributors, pharmacies and other dispensers, and health plans. Participants would agree to purchase and reimburse drugs at the import price and patient cost sharing would be based on the import price as well.
- Publicly post the imported products and the acquisition costs;
- Ensure that the imported products are distributed in-state only; and
- Monitor/audit the system for compliance, safety and savings.[49]

Conclusion

Rising prescription drug costs are negatively impacting the West Virginia state budget and West Virginia consumers. While prescription drug cost initiatives are under discussion in Washington, it does not appear that any significant solutions will advance in the near future. Therefore, it is imperative that prescription drug costs are addressed at the state level. West Virginia has already made progress addressing rising prescription drug spending in the Medicaid program by transitioning the drug benefit for Medicaid managed care enrollees from Managed Care Organizations back to traditional Medicaid Fee-For-Service coverage and using a single Pharmacy Benefit Manager. West Virginia Medicaid also participates in a multi-state bulk purchasing cooperative to help leverage better drug prices. PEIA also has undertaken a number of strategies to reduce the growth in prescription drug expenditures.

Moving forward, West Virginia can look at policy tools that go beyond Medicaid and PEIA alone. West Virginia can join other states that are moving forward with new laws that would impact prescription drug prices for all purchasers in the state. To spur necessary discussion, this White Paper offers a menu of brief summaries of what other states have been doing in the last several years. While West Virginia

has policy options, any serious effort to address prescription drug costs will take political leadership, bipartisan will, and public support.

Endnotes

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