LEGISLATIVE COUNSEL BUREAU

Committee to Conduct an Interim Study Concerning the Costs of Prescription Drugs

(SB 276 [Chapter 324, *Statutes of Nevada 2019*])

BULLETIN 21-9

JANUARY 2021

COMMITTEE TO CONDUCT AN INTERIM STUDY CONCERNING THE COSTS OF PRESCRIPTION DRUGS

Senate Bill 276
(Chapter 324, *Statutes of Nevada 2019*)

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Senate Bill 276
(Chapter 324, *Statutes of Nevada 2019*)

Section 25.

1. The Legislative Commission shall appoint a committee to conduct an interim study concerning the cost of prescription drugs in this State and the impact of rebates, reductions in price and other remuneration from manufacturers on prescription drug prices.

2. The interim committee must be composed of six Legislators as follows:

(a) Two members appointed by the Majority Leader of the Senate;

(b) Two members appointed by the Speaker of the Assembly;

(c) One member appointed by the Minority Leader of the Senate; and

(d) One member appointed by the Minority Leader of the Assembly.

3. The Legislative Commission shall appoint a Chair and Vice Chair from among the members of the interim committee.

4. In conducting the study, the interim committee shall consult with and solicit input from persons and organizations with expertise in matters relevant to the costs of prescription drugs and the impact of rebates, reductions in price and other remuneration from manufacturers on prescription drug prices.

5. The interim committee shall study and examine:

(a) The overall costs of prescription drugs in this State, including, without limitation, a comparison of those costs with other states;

(b) The impact of rebates, reductions in price and other remuneration from manufacturers on the overall costs of prescription drugs in this State; and

(c) Opportunities and options for lowering the costs of prescription drugs to make those drugs more affordable for the residents of this State.

6. The Legislative Commission shall submit a report of the results of the study, including any recommendations for legislation to:

(a) The Legislative Committee on Health Care; and

(b) The Director of the Legislative Counsel Bureau for transmittal to the 81st Session of the Nevada Legislature.

7. As used in this section, "manufacturer" has the meaning ascribed to it in NRS 639.009.

INTRODUCTION

The Legislative Commission established the Committee to Conduct an Interim Study Concerning the Costs of Prescription Drugs as directed by Senate Bill 276, which was passed during the 2019 Legislative Session. The Committee was comprised of six legislators, three from the Senate and three from the Assembly.

Pursuant to SB 276, the Committee was tasked to consult with and solicit input from persons and organizations with expertise in matters relevant to the costs of prescription drugs. Specifically, the Committee studied and examined:

1. The overall costs of prescription drugs in Nevada, including, without limitation, a comparison of those costs with other states;

2. The impact of rebates, price reductions, and other remuneration from manufacturers on the overall costs of prescription drugs in Nevada; and

3. Opportunities and options for lowering the costs of prescription drugs to make those drugs more affordable for Nevada residents.

The Committee held four meetings during the 2019–2020 Interim. The first two meetings were held in the Grant Sawyer State Office Building in Las Vegas, Nevada, with videoconferencing to the Legislative Building in Carson City, Nevada, and the last two meetings were conducted in a virtual format due to in-person meeting restrictions caused by the Coronavirus Disease of 2019 (COVID-19) pandemic. The pandemic also caused the Committee to meet past the August 31, 2020, deadline prescribed by *Nevada Revised Statutes* (NRS) 439B.210, after receiving a waiver from the Legislative Commission. The Committee concluded its work on September 9, 2020.

At each meeting, the Committee heard public testimony and received input from patients adversely affected by prescription drug prices and various other stakeholders. The Committee considered the following topics during the four meetings:

1. January 30, 2020—Overview of the Committee and its tasks; prescription drug pricing, rebates, and remuneration in Nevada; legislation from other states addressing the costs of prescription drugs; federal laws and regulations pertaining to prescription drug costs and pricing, as well as federal constraints on state action to control the costs of prescription drugs; and a review of prescription drug transparency efforts in Nevada;

2. February 28, 2020—Stakeholders' perspectives on the costs of prescription drugs, including perspectives from AARP Nevada, Association for Accessible Medicines, Biotechnology Innovation Organization (BIO), community pharmacies represented through the Retail Association of Nevada, Culinary Health Fund, Nevada Association of Health Plans, Pharmaceutical Care Management Association, and the Pharmaceutical Research and Manufacturers of America (PhRMA);

3. July 1, 2020—Overview of Nevada Medicaid's response to the COVID-19 pandemic, including future coverage of COVID-19-related treatment and vaccines, review of inter- and intrastate prescription drug purchasing coalitions, interaction between federal and state laws concerning prescription drugs, and state policy options; and

4. September 9, 2020—Overview of the impact of COVID-19 on communities of color in Nevada and the Committee's final work session.

At its work session on September 9, 2020, the Committee approved five proposals for bill draft requests (BDRs) to be transmitted to the Legislative Committee on Health Care and the director of the Legislative Counsel Bureau (LCB) for transmittal to the 2021 Legislative Session of the Nevada Legislature. The BDRs address the following topics:

1. Establishing intra- and interstate prescription drug purchasing coalitions;

2. Providing for the licensure of pharmaceutical sales representatives;

3. Expanding pharmaceutical drug pricing transparency;

4. Further regulating pharmacy benefit managers (PBMs); and

5. Requiring a certain percentage of health plans offered in Nevada to provide expanded coverage for prescription drugs.

The work of the Committee resulted in a multifaceted study regarding the costs of prescription drugs, including the prescription drug supply chain, underlying reasons for the high costs of drugs, current policy interventions on the federal and state levels, and feasible policy options to make drug prices more affordable and transparent to Nevadans.

Patients affected by the high costs of prescription drugs and representatives of Nevada's Department of Health and Human Services (DHHS), along with various stakeholders with expertise in matters relevant to the cost of prescription drugs, provided valuable information and recommendations to the Committee.

More information about the Committee's activities—including minutes, recordings of meetings, and copies of presentations and other exhibits—may be accessed on the Legislature's website for the 2019–2020 Interim.

BACKGROUND

According to testimony provided by numerous stakeholders, the costs of prescription drugs is considered an important issue nationwide. In the United States between 2008 and 2016, list prices for oral drugs, such as pills, rose by approximately 9 percent, and prices for injectable drugs, such as insulin injections, rose by over 15 percent. Overall pharmaceutical expenditures grew to almost $508 billion in 2019 alone. National projections of prescription drug expenditures predict an average increase of more than 6 percent per year for the next seven years. Increases are a result of certain factors, including price hikes of existing

medications, greater usage of prescription drugs (utilization), and costs for new drugs introduced on the markets.

In 2018, Americans paid an average of $1,229 for prescription drugs, the highest amount per capita in any developed country in the world. Increasing drug prices disproportionately affect uninsured and underinsured patients, while insured patients covered by high-deductible, commercial, or government-sponsored health insurance plans tend to pay more through premium and co-pay increases. Hence, even Nevada patients with full health insurance coverage are burdened by the costs of prescription drugs.

In recent years, Nevada has been one of the most innovative states pursuing drug pricing transparency efforts, while the federal government and other states have pursued various innovative approaches to keep prescription drugs affordable for patients. The most recent policies focus on the supply chain of pharmaceutical drugs, which offer different points of intervention for state legislatures, including Nevada.

A. Pharmaceutical Supply Chain: A Complex Distribution System

During the Committee meeting on January 30, 2020, representatives from DHHS provided testimony that gave an increased understanding of the complex pharmaceutical supply chain.

The pharmaceutical drug market consists of a complex distribution system. Pharmaceutical drug manufacturers conduct research and develop new prescription drugs, and patients are the consumers of prescription drugs. Generally, manufacturers can be differentiated between brand name drug manufacturers who develop and sell new prescription drugs and biologics and generic drug manufacturers who sell existing drugs and biosimilars of brand name manufacturers where patent protections have expired. Additionally, the supply chain consists of wholesalers, PBMs, pharmacies, and other providers such as hospitals or physicians. Due to the quantity of manufacturers, pharmacies and other providers usually purchase drugs from wholesale distributors who provide services such as warehousing, inventory management, and distribution of the different drugs produced by manufacturers.

Finally, about 266 million Americans have their prescription drug plan administered by PBMs. They provide prescription drug management for a multitude of providers, including commercial health plans, Medicaid, Medicare, self-insured employer plans, et cetera. Pharmacy benefit managers function as the primary connection between the drug manufacturers and wholesalers on one side and the health insurance provider and consumer on the other. The market players are active on the national and state level, including Nevada, and contribute to the costs of prescriptions drugs while the stakeholders are governed by federal laws and regulations, which may limit state actions.

B. Federal Constraints on State Action to Regulate the Prescription Drug Market

Federal law precedes state law, which limits policy options for states, including Nevada, to regulate the prescription drug market. A representative of Horvath Health Policy provided an introduction to this issue during the first Committee meeting on January 30, 2020. Additionally, during the Committee meeting on July 1, 2020, the Legal Division of the LCB presented information about certain legal constraints on state action concerning prescription drugs to the

Committee. This section provides a brief overview of some of the constraints that may preempt states, including Nevada, from enacting certain policies on the state level.

The Employee Retirement Income Security Act (ERISA) of 1974 (93rd Congress) was passed to create uniform, nationwide standards for retirement and other employee benefit plans, including health plans. Part of ERISA "supersede[s] any and all State laws as they . . . relate to any employee benefit plan . . . ." The objective of ERISA is to give employers a standard set of procedures as guidance, for instance, for processing claims, disbursing benefits, and establishing a grievance and appeals process for plan participants. The provisions of the Act prevent similar or conflicting state laws and regulations. Since health plans are often part of employee benefit plans, ERISA also applies to a health plans' prescription drug management, and states need to carefully draft legislation to avoid conflicts with ERISA plans. Past and current litigation shows that stakeholders of the pharmaceutical drug market, such as PBMs,[1] challenged state policies that potentially violated ERISA preemptions.

Additionally, the Dormant Commerce Clause of Article I, Section 8, Clause 3 of the *U.S. Constitution* and trade secret laws may preempt state policies that intend to regulate the pharmaceutical industry. The Dormant Commerce Clause is a judicial interpretation that prohibits states from enacting laws that discriminate against out-of-state competitors or unduly burden commerce between states. It implicitly applies to any state legislation related to prescription drug pricing. For example, PhRMA sued California over Senate Bill 17 (2017–2018) that would have required a manufacturer to wait 60 days before increasing the wholesale acquisition cost of a drug without facing a financial penalty. Similarly, Nevada was sued by PhRMA and BIO challenging its drug transparency law concerning diabetes drugs. The plaintiffs argued that state law violated federal trade secret law because the disclosure of confidential or proprietary data could destroy the value of trade secret property without proper recompense. After state regulators passed regulation (*Nevada Administrative Code* 439.735) that allowed manufacturers to request to keep certain disclosures confidential, PhRMA and BIO withdrew the lawsuit.

Finally, patent law applies in certain cases regarding pharmaceutical drugs. Patent law provides manufacturers with 12 years of guaranteed market exclusivity for biologics and 20 years for each conventional drug patent, among other provisions. During the period of patent and marketing exclusivity, brand drugs are priced and sold free from competition. After that period, generic drug and biosimilar manufacturers may produce the same medicine and the patent is no longer applicable. Once a generic drug or biosimilar enters the prescription drug market, prices usually drop substantially. For example, once a new oral generic drug enters the market, a price drop by two-thirds is common within the first year. Therefore, it is beneficial for brand drug manufacturers to maintain the exclusivity of its patented drugs to the longest extent possible, thereby recouping the costs for development of the drug and generating additional revenue. However, high costs of brand name drugs result in higher drug prices for health insurance plans and ultimately patients. Federal patent law may also preempt state laws, for instance, when state law prohibited selling a patented drug for an excessive price.

[1] See, for instance, *Rutledge v. Pharmaceutical Care Management Association*, Supreme Court of the US Blog.

Due to the complexity of the market, its underlying issues and relationships, and federal and state laws, regulations, and constraints, the Nevada Legislature has evaluated the various dimensions of the prescription drug realm.

C. Past Prescription Drug Legislation in Nevada

Innovative legislative efforts aim to assist patients in various ways. In recent years, the Nevada Legislature passed bills addressing or establishing drug pricing transparency, a statewide universal drug donation program, the Patient Protection Commission, and an interim study concerning the costs of prescription drugs, on which this report is based.

Prescription Drug Pricing Transparency

Continuous price increases for crucial prescription drugs may create hardships for patients who depend on medication for chronic conditions such as diabetes. Those patients often have no alternative but to pay the cost of medically necessary drugs; otherwise, they would risk an aggravation of their health condition.

Nevada was the first state in the nation to pass a bill on drug pricing transparency for the chronic condition diabetes, followed by similar legislation concerning asthma. It also followed many states in forbidding so called "gag" clauses for pharmacists and pharmacies.

In 2017, the Legislature passed SB 539 (NRS 439B.600 through 439B.695). The bill addressed costs and transparency for both drug manufacturers and PBMs concerning drug pricing of certain medication to treat diabetes. The law requires:

- DHHS to compile a list of essential diabetes drugs and a list of such drugs whose prices have increased significantly in recent years;
- Manufacturers of these drugs to submit information regarding drug costs and, for those drugs that have seen a price increase, the reasons for the increase; and
- PBMs to report certain information concerning essential diabetes drugs.

The law also increases transparency regarding formulary changes that affect diabetes drugs, requires drug manufacturers to identify their pharmaceutical sales representatives, and requires sales representatives to submit an annual report concerning their activities. The Department of Health and Human Services must compile and report all of the submitted information.

Senate Bill 262, which passed during the 2019 Legislative Session, is essentially the same bill passed for diabetes drug pricing in 2017, but this time for asthma drugs. That is, asthma drugs are now part of the list of essential prescription drugs that DHHS must compile in a list of drugs that have been subject to a significant price increase in the immediately preceding two calendar years. Asthma drugs must also be included in certain reports submitted by drug manufacturers and PBMs, as well as a report DHHS compiles regarding the reasons for and effects of the pricing of essential asthma drugs.

Two bills removed "gag" clauses on many pharmacists and pharmacies, allowing them to be transparent with consumers about less expensive drugs or other alternative payment options. Both SB 539 (2017) and Assembly Bill 141 (2019) forbid PBMs from prohibiting certain pharmacists or pharmacies from providing information about a less expensive alternative or generic drug to a person covered by a pharmacy benefits plan (NRS 683A.179). Additionally, PBMs are prohibited from penalizing such pharmacists or pharmacies for providing this information.

Prescription Drug Donation Program

While increasing transparency may eventually help reduce the cost of certain prescription drugs, another law, established by SB 91 (2017), created the Prescription Drug Donation Program (PDDP) (NRS 453B.060). It combined the existing HIV/AIDS Drug Donation Program and the Cancer Drug Donation Program. The bill aimed to increase access to prescription drugs—especially costly drugs—by ensuring that such usable, but unused, medications are redirected to patients who need them most. The PDDP allows a person or governmental entity to donate nearly any unopened prescription drug at a participating pharmacy, medical facility, health clinic, or other health care provider. An eligible recipient may receive donated drugs.

Patient Protection Commission

In 2019, the Legislature created the Patient Protection Commission (SB 544, NRS 439.902 through 439.918) with a mandate to systematically review issues related to the health care needs of Nevada residents and the accessibility, affordability, and quality of health care, including prescription drugs. The Commission must attempt to identify and facilitate collaboration between existing state governmental entities that study or address these issues, coordinate such entities to reduce duplication, and submit a report to the governor and the Legislature twice per year.

DISCUSSION OF TESTIMONY AND RECOMMENDATIONS

At its final meeting and work session on September 9, 2020, the Committee to Conduct an Interim Study Concerning the Costs of Prescription Drugs considered a total of five proposed actions for legislation. Additional information regarding all recommendations considered is available in the Committee's "Work Session Document" (WSD).

A. Intra- and Interstate Purchasing Coalitions

During its meeting on July 1, 2020, the Committee heard presentations from representatives of the Northwest Prescription Drug Consortium (NPDC) and the Division of Health Care Financing and Policy (DHCFP), DHHS, concerning intra- and interstate purchasing coalitions. Additionally, the Culinary Health Fund recommended during its presentation on February 28, 2020, to make purchasing coalitions available for all state-paid medication and to authorize nonprofit health insurance providers to join these coalitions.

The continued rise in prescription drug costs has a strong impact on state budgets and state policy decisions. Therefore, many states have adopted policies to consolidate the purchasing

power of multiple states (interstate purchasing coalition) or combine this power within a state from multiple state and local agencies (intrastate purchasing coalition) to buy prescription drugs in bulk in order to negotiate lower prices from wholesalers or directly from the drug manufacturers. This approach is also sometimes referred to as "pooling."

Generally, two types of interstate purchasing pools currently exist. The first type focuses on drug purchases for the states' respective Medicaid programs. For example, ten states and the District of Columbia participate in the National Medicaid Pooling Initiative. The average savings for a member state is approximately 3 to 5 percent.

Other purchasing interstate pools combine their purchasing power to also include non-Medicaid populations. For instance, the NPDC, initiated in 2006, is an interstate agreement between the states of Oregon and Washington. The NPDC objective is to pool drug purchasing and negotiate lower prices for program participants. According to testimony provided by representatives of NPDC, the NPDC provides full transparency in PBM services and offers multiple benefits and savings for participants and to anyone residing in Oregon or Washington through their discount drug card program.

The DHCFP provided testimony to the Committee regarding the difference of inter- and intrastate purchasing coalitions and the creation of an intrastate purchasing coalition or pool. Such as, a pool draws in the purchasing power of state, local, and commercial health plan providers within a state to create bulk purchasing power for pharmaceutical products. The Committee also evaluated the necessary steps to establish such a collaborative prescription drug program within the state.

Finally, the Committee received information on pharmaceutical bulk purchasing, including multistate and interagency plans, during testimony provided by a representative from the National Council of State Legislatures on January 30, 2020.

Recommendation

At its final meeting and work session, the Committee approved a proposal for legislation to:

> Allow DHHS to establish intra- and interstate purchasing coalitions, which consolidate the purchasing power of agencies within a state or different states to obtain prescription drugs in bulk in order to negotiate lower prices from wholesalers or directly from drug manufacturers. The intrastate purchasing coalition may consolidate purchasing power with any state or local agency with a pharmacy benefit program in a purchasing coalition. Commercial health plan providers are authorized to join an intrastate purchasing coalition as well. The state may also form a new or join an existing interstate purchasing coalition comprised of different states to combine the purchasing power of whole states to purchase pharmaceutical products at lower costs. **(BDR 40–443)**

B. Licensure of Pharmaceutical Sales Representatives

While pharmaceutical sales representatives may provide an informative service to health practitioners, their objective is the marketing of brand name prescription drugs to ultimately increase sales of a certain drug. Therefore, they have a significant impact on drug pricing. In

recent years, states have adopted laws to increase the accountability of these professionals through licensure and ethics education and to obligate sales representatives to inform health practitioners about less expensive brand name drug alternatives such as generic drugs.

Nevada acknowledged the importance of pharmaceutical sales representatives and included in SB 539 (2017) a requirement for pharmaceutical drug manufacturers to report a list of their active sales representatives to the state, which allows them to operate and market prescription drugs on behalf of the manufacturer within the state. Each representative on the list must also submit an annual report of certain activities.

During the final Committee meeting on September 9, 2020, Chair Cancela recommended to expand the current reporting requirements and require the licensure of pharmaceutical sales representatives. The Committee approved the following recommendation:

Recommendation

At its final meeting and work session, the Committee voted and approved to draft a bill to:

> Amend statutes related to the reporting of pharmaceutical sales representatives (NRS 439B.660) to require DHHS to license representatives who are operating within the state. **(BDR 54–444)**

C. Pharmaceutical Drug Pricing Transparency

Multiple states have enacted laws to better understand the factors behind the continuous increase in pharmaceutical drug prices. A common approach by states is to increase transparency on how drug manufacturers set prices for their products. Legislation often focuses on certain reporting requirements for manufacturers if a drug price exceeds a given percentage or amount. The manufacturers usually must report the reasons for the price increases. States may use this information to explore effective solutions to curb high costs of prescription drugs.

Nevada passed two bills on drug pricing transparency concerning asthma and diabetes medication during past legislative sessions as highlighted in the background section of this report. Throughout its four meetings, the Committee was presented with various policy options to expand transparency of prescription drug pricing. It finally decided to widen the scope of the existing laws on pharmaceutical drug pricing transparency using certain parts of the draft drug transparency model legislation from the National Academy for State Health Policy (see also Attachment A, "Draft Drug Transparency Model Legislation," in the Appendix).

Recommendation

At its final meeting and work session, the Committee voted and approved to draft a bill to:

> Amend statutes (NRS 439B.600 through 439B.695) related to the reporting and tracking of information concerning the pricing of asthma and diabetes prescription drugs to:
>
> 1. Expand NRS 439B.635 and 439B.640 to require the manufacturer of any prescription drug that has been subject to a price increase described in subsection 2 of

NRS 439B.630, in addition to essential diabetes and asthma medications, to report the information described in those sections;

2. Require wholesale drug distributors and insurers who cover prescription drugs to report the information described in Section 4 (pages 12 through 15) and Section 5 (pages 15 and 16), respectively, of the model legislation;

3. Modify the reporting requirements for PBMs set forth in NRS 439B.645 that, in addition to information about essential diabetes and asthma drugs, PBMs shall report the information for prescription drugs described in subsection 1 of Section 5 (page 15) of the model legislation;

4. Add Section 6 (page 16) and Section 7 (pages 16 and 17) of the model legislation, which require the reporting entities to register with DHHS and to be subject to annual assessments by DHHS;

5. Modify existing penalties set forth in NRS 439B.695 for failure to provide information to match the penalties provided in Section 8 (page 17) of the model legislation;

6. Require DHHS to make a report available on its website on emerging trends in prescription drug prices and conduct an annual public hearing based on the report findings as provided in subsection 1 of Section 9 (pages 17 and 18) of the model legislation; and

7. Keep all existing definitions in statutes; however, when adding new definitions use, to the extent possible, existing definitions in federal law, and, if not available, use the definitions provided in the model legislation. **(BDR 40–445)**

D. Pharmacy Benefit Managers

Representatives of the Culinary Health Fund provided testimony during a presentation on February 29, 2020, and recommended the licensure of PBMs, allowing for full audit rights of PBMs by their contractual health insurance partners (third-party payer), and establishing a fiduciary responsibility to a third-party payer. During the same meeting, AARP Nevada also recommended to prevent PBMs from spread pricing and pass rebates down to patients.

Pharmacy benefit managers usually function as the intermediary[2] between health insurance providers and pharmacies by managing the prescription drug coverage provided by the health care service plan. According to a report by PhRMA, PBMs process about two-thirds of all prescriptions every year in the United States. Three of the biggest PBMs—CVS Caremark, Express Scripts Holding Company, and OptumRx, Inc.—controlled about 66 percent of the

[2] This relationship may become blurry when PBMs also offer fulfillment of prescription drugs, for instance, by mail order, effectively taking over pharmacy functions.

market as of 2015. Overall, as of December 3, 2020, state lawmakers passed 95 bills concerning PBMs between 2017 and 2020. The following section provides an overview of policy options.

Spread Pricing

Spread pricing occurs when health plan providers contract with PBMs to manage their prescription drug benefits, and PBMs keep a portion of the amount paid to them by the health plans for prescription drugs. Specifically, a PBM retains the difference (spread) between the amount the PBM charges a health plan provider and the amount it reimburses the pharmacy when a patient purchases a drug through their health plan.

For instance, in 2018, Ohio state auditors discovered that PBMs contracting with the state's Medicaid managed care organizations (MCOs) had a spread of over 31 percent or $208 million for generic drugs.[3] In Kentucky, a study initiated by Kentucky Senate Bill 5 (2018) found that PBMs kept a spread of $123.5 million in 2018. The issue is so common among state MCOs that U.S Centers for Medicare and Medicaid Services issued new guidance on how to include spread amounts in its medical loss ratios.[4]

States addressed spread pricing in multiple ways. Following are some legislative measures passed during 2018 and 2019:

- Kentucky enacted SB 5, which prohibits pharmacy benefits in MCO contracts, and requires instead that Kentucky's Department for Medicaid Services directly administer all outpatient pharmacy benefits;
- Louisiana passed SB 41 (2019), which prohibits PBMs from participating in spread pricing in most circumstances. Additionally, this bill requires PBMs to be licensed when operating in the state, among other requirements; and
- Ohio's 2019 omnibus budget bill, House Bill 166, contains certain provisions addressing PBMs. Among others, the Ohio Department of Medicaid is required to contract with a single PBM to be used for all of the state's MCOs. The Medicaid director will determine the rate the state-contracted PBM is paid for its services. The state PBM will provide quarterly transparency reports to the director.

Licensing or Registration of Pharmacy Benefit Managers

State policymakers passed laws that require PBMs to be licensed or to register prior to operating within a state. The objectives are usually to enhance accountability of PBMs, protect the public's health and safety, ensure financial fidelity, and address prescription drug prices and the cost transparency of drugs and rebates administered by PBMs. For example, Mississippi requires PBMs to be licensed by its Board of Pharmacy and to file annual financial statements; PBMs

[3] Generic drugs comprised nearly 34 million (86 percent) of all prescriptions fulfilled by PBMs for Ohio MCOs in that one-year period.

[4] The medical loss ratio regulation stipulates that, at most, only 15 percent of the revenue for managed care plans can be used for administrative costs and profits. Eighty-five percent or more of premium revenue must go towards claims and activities that improve health care.

must register prior to conducting business in California; New Mexico licenses PBMs by the Office of Superintendent of Insurance; and Louisiana also licenses PBMs, as mentioned above.

Recommendation

At its final meeting and work session, the Committee voted to draft a bill to amend statutes related to PBMs to:

1. Require PBMs who are operating within the state to obtain a license from DHHS;

2. Prohibit PBMs from using spread pricing. Specify that a PBM shall agree to only enter into contracts with third-party payers, such as commercial, governmental, or nonprofit health insurance providers that are fully transparent for the contractual parties, including, but not limited to, the disclosure of all rebates, discounts, product pricing incentives, and fees collected by a PBM. The PBM's only source of income shall be from disclosed administration fees for services. All manufacturer discounts, product pricing incentives, and fees collected by a PBM must be reimbursed to the third-party payer; rebates shall be passed down to patients;

3. Require a PBM to allow a client—such as a health insurance provider contracting with a PBM to fulfill its prescription drug benefits—full audit rights, including, but not limited to, pharmacy claims, rebates, and similar information needed to assure compliance; and

4. Establish a fiduciary responsibility for a PBM to a third-party payer. The benefit of the payer is the primary and sole interest of the fiduciary and any conflict with that role must be disclosed and avoided. **(BDR 57–446)**

E. Cost Sharing Options

While health insurers provide coverage for health-related services including prescription drugs, patients often pay additional costs besides their health insurance premiums. Such cost sharing requirements may include a deductible, which is the amount patients must pay out-of-pocket before insurance plan payments begin. Once patients meet the deductible, many plans require them to pay additional specified dollar amounts (co-payments) or percentage contributions (coinsurance) when they receive covered services. Many plans also choose to combine these options. Patients usually pay under these cost sharing requirements until they meet a maximum out-of-pocket limit after which the health plan insurer covers 100 percent of the covered services.

As mentioned earlier, expensive prescription drugs may disproportionately affect patients with chronic conditions, such as asthma or diabetes, who continuously require filling their prescriptions. That is, these patients frequently meet their deductible or even their maximum out-of-pocket limit every plan year requiring them to often pay thousands of dollars. For example, for the 2020 Plan Year, health plans purchased from an Affordable Care Act marketplace have maximum out-of-pocket limits at $8,150 for an individual and $16,300 for a family.

To limit affordability issues for patients, several state legislatures placed caps on consumer co-pays for certain treatments and conditions. For example, California placed a cap of $250 on any filled prescription for a one-month supply. Other legislation focused on certain medication such as insulin. Colorado, for instance, placed a $100 cap on a 30-day supply of insulin, and Virginia limited its cap to $50 per 30-day supply. While such cap measures may assist patients to purchase medications at a predictable price, opponents argue they increase health insurance premiums for all of the insured since the plan provider still has to pay for the full price set by pharmaceutical manufacturers and wholesalers.

The Committee received testimony from a representative of PhRMA during a presentation on February 28, 2020, which explored different cost sharing options. The presentation focused on various solutions identified and supported by PhRMA to help lower the costs of prescription drugs and limit adverse outcomes for Nevadans.

Recommendation

At its final meeting and work session, the Committee voted and approved to draft a bill to require that at least half of the health plans offered by providers in Nevada have:

1. Prescription drug coverage with no deductibles from the first day the health plan coverage commences;

2. Fixed prescription co-payments that allow patients to pay a flat-dollar amount per prescription and is not percentage based; and

3. Limited co-payments of not more than one-twelfth of the patient's annual out-of-pocket spending maximum. **(BDR 57–442)**

SUGGESTED LEGISLATION

The following bill draft requests will be available during the 2021 Legislative Session at the following website: https://www.leg.state.nv.us/App/NELIS/REL/81st2021/Bdrs/List.

BDR	57–442	Imposes on health plans certain requirements relating to prescription drug coverage.
BDR	40–443	Authorizes the formation of purchasing coalitions for prescription drugs.
BDR	54–444	Requires licensing of pharmaceutical sales representatives.
BDR	40–445	Revises provisions relating to prescription drugs.
BDR	57–446	Revises provisions relating to pharmacy benefit managers.

APPENDIX

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Attachment A

Draft Drug Transparency Model Legislation.....15

(Related to the recommendation in Section C ["Pharmaceutical Drug Pricing Transparency"] on pages 8 and 9.)

DRAFT DRUG TRANSPARENCY MODEL LEGISLATION

AN ACT TO PROMOTE PRESCRIPTION DRUG PRICE TRANSPARENCY AND COST CONTROL

WHEREAS the cost of prescription drugs is rising rapidly, year over year;[1] and

WHEREAS, the cost of prescription drugs represents a significant challenge to the State budget for Medicaid and CHIP expenditures, state employee and retiree health insurance, corrections' health care, and the cost of coverage for the employees of public schools and institutions of public higher education for which the State shares the cost; and

WHEREAS the cost of prescription drugs represents 21 percent of spending for employer sponsored insurance, creating a significant challenge to employers that struggle to provide health insurance to employees and their dependents while maintaining a competitive and viable business concern in the State; and

WHEREAS the cost of prescription drugs represents a significant and daily challenge to thousands of the State's residents, who experience difficulty accessing affordable medications; and

WHEREAS the unpredictability of new, high cost drugs and significant price increases for older drugs can strain the ability of State agencies, private payers, and consumers to manage their budgets and access treatments;

WHEREAS the lack of transparency in health insurance issuer costs, and wholesaler and pharmacy benefits manager discounts and margins, prevents policymakers and the public from gaining a true understanding of the cost of the prescription drugs purchased;

WHEREAS providing pricing information across the prescription drug supply chain will help achieve pricing transparency;

WHEREAS a minimum data set in common with other States will minimize burden on entities that are required to report;

WHEREAS a minimum data set in common with other States will enable analyses and comparisons across states; and

WHEREAS the Legislature finds that greater transparency in the current opaque pricing and payment environment for prescription drugs will be a critical tool in developing strategies to address rising drug prices and managing State budgets in a responsible manner; now, therefore

Be it enacted by the People of the State of _____ as follows:

SECTION 1. DEFINITIONS

“Acquisition date” is the month and year that the manufacturer registered with the FDA as the labeler for the drug.

“Brand-name drug” is a prescription drug approved under 21 USC § 355(b) or 42 USC § 262.

“Current calendar year projections” are the amounts the manufacturer anticipates will occur in the current calendar year; or if so allowed by [the State Agency], has occurred in the current calendar year to date.

“Drug group” is as defined by [the State Agency] for the purpose of facilitating revenue and cost reporting by manufacturers.

“Drug grouper” is the name of the standard system the manufacturer is using to group drugs for the purpose of reporting, or a system designated by [the State Agency].

“Generic drug” is a prescription drug approved under 21 USC § 355(j).

“Ingredient cost” is the total amount that third parties pay to pharmacies or pharmacy networks for a drug or drug group.

“Insurance issuer” is a company or organization that is licensed by the Department of Insurance or equivalent agency or agencies in the State to issue coverage entitling a beneficiary to receive a defined set of health care benefits in exchange for a defined consideration such as a premium.

“Justification for current-year price increase” is the reason or reasons that the manufacturer increased the WAC of the drug or drug group compared with last year.

“Manufacturer” is any entity that holds the NDC for a prescription drug and is either engaged in the production, preparation, propagation, compounding, conversion, or processing of drug products; or is engaged in the packaging, repackaging, labeling, relabeling, or distribution of drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

“Manufacturer cost” is total costs directly related or allocated to the reported drug specifically for sales in the United States or the State as indicated. Such costs include the cost of goods sold and allocated operating expenses, consistent with Generally Accepted Accounting Principles (GAAP).

“Manufacturer sales volume” is the number of WAC units of the drug or drug group that the manufacturer has sold or expects to sell in the reference year, to any wholesaler or other direct purchaser in the United States or the State, as indicated.

“Market introduction” is the month and year in which the manufacturer acquired or first marketed the drug for sale in the United States.

“National drug code (NDC)” is the numerical code maintained by the FDA that includes the labeler code, product code, and package code.

“Nonproprietary name” is the generic name assigned by the United States Adopted Names (USAN) Council.

“Patient volume” is the number of patients expected to be prescribed the drug in the indicated year.

“Pharmacy benefits manager” is any entity that administers the prescription drug, prescription device, and pharmacist services portion of a health care plan on behalf of an issuer. This definition includes issuers that do not use a separate pharmacy benefits manager to administer their prescription drug programs.

“Pharmacy benefits manager net income” is revenue received from insurance issuers for the drug or drug group, after subtracting (i) the ingredient cost for the drug or drug group paid to pharmacies, pharmacy networks, or pharmacy services administrative organizations for the drug or drug group; and (ii) the pharmacy benefits manager’s operating expenses allocated specifically to the drug or drug group. Net revenue includes revenue from margin pricing, if used by the pharmacy benefits manager, plus any other revenue associated with or allocated to the drug or drug group. Net income is defined consistent with GAAP.

“Pharmacy dispensing fee” is the amount paid to a pharmacy or pharmacy network to cover charges for professional services and overhead costs.

“Pharmacy services administrative organization” is an entity that provides contracting and other administrative services to pharmacies to assist them in their interaction with third-party payers, pharmacy benefit managers, wholesale drug distributors, or other entities.

“Product cost” is the cost of material, direct labor, and overhead. Product cost is defined consistent with GAAP.

“Proprietary name” is the brand or trademark name of the drug reported to the FDA.

“Rebate” is a discount or concession that affects the price of a prescription drug manufactured by the pharmaceutical manufacturer, and that the pharmaceutical manufacturer directly provides to a (i)

health insurance issuer, (ii) pharmacy benefits manager after the manager processes a claim from a pharmacy or a pharmacist, or (iii) a wholesale drug distributor. "Rebate" does not mean a bona fide service fee, as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, as amended from time to time.

“Reporting entity” is any manufacturer, insurance issuer, pharmacy benefits manager, wholesale drug distributor, or any other entity required to report to [the State Agency] under this Act.

“Revenue” is the total gross revenue associated with the drug or drug group in the United States or the State, as indicated. Revenue is defined consistent with GAAP.

“Tax identification number” is the 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).

“Total spending” is the total of allowed amounts associated with payment for a specified drug or drug group, for all covered lives.

“Volume” is the total number of WAC units of each drug or summed across all drugs in a drug group.

“Wholesale acquisition cost (WAC)” is the manufacturer’s list price to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include prompt pay or other discounts, rebates or reductions in price. The current or proposed WAC is the amount that prompts reporting under this Act. If reported by drug group, it is the average WAC weighted by the relevant number of WAC units.

“Wholesale acquisition cost (WAC) Unit” is the lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. If reporting by drug group as indicated by [the State Agency], it is the total number of WAC units in the drug group.

"Wholesale drug distributor" is an entity engaged in the sale of prescription drugs to persons other than a consumer or patient, and licensed by the State Board of Pharmacy or equivalent agency or agencies, as the State requires.

"Wholesale drug distributor net income" is the amount received from all purchasers for the drug or drug group after subtracting the wholesale drug distributor's cost of goods sold and operating expenses allocated specifically to the drug or drug group. Net income includes revenue from margin pricing, if used by the wholesale drug distributor, plus any other revenue associated with or allocated to the drug or drug group. Net income is defined consistent with GAAP.

SECTION 2. PRICE INCREASE AND NEW DRUG PRICE JUSTIFICATION

(1) A manufacturer shall notify [the State Agency] if it is increasing the WAC of a brand-name drug by more than 20 percent per WAC unit during any 12-month period, or if it is increasing the WAC of a generic drug priced at $100 or more per WAC unit by 200 percent or more during the immediately preceding 12-month period. The notice shall be provided in writing at least 60 days prior to the planned effective date of the increase.

(2) A manufacturer shall notify [the State Agency] if it intends to introduce a new drug in the United States that has a WAC of $670 per WAC unit or more. The notice shall be provided in writing at least 60 days prior to market introduction.

(3) A manufacturer that must notify [the State Agency] under Paragraph 1 of this Section shall report to [the State Agency] the following minimum data, and other data that may be specified by [the State Agency], at least 30 days before the price increase:
    (a) Drug identification
        (i) National drug code
        (ii) Proprietary drug name
        (iii) Non-proprietary drug name
        (iv) WAC unit
        (v) Drug group code or name
        (vi) Drug grouper

(vii) Manufacturer tax identification number

(viii) Manufacturer name

(b) U.S. Sales volume by drug and drug group as specified by [the State Agency], in WAC units

(i) Projected current-year sales volume

(ii) Sales volume in the current year minus 1

(iii) Sales volume in the current year minus 2

(iv) Sales volume in the current year minus 3

(v) Sales volume in the current year minus 4

(c) Sales volume in this State for the drug and drug group as specified by [the State Agency], in WAC units:

(i) Projected current-year sales volume

(ii) Sales volume in the current year minus 1

(iii) Sales volume in the current year minus 2

(iv) Sales volume in the current year minus 3

(v) Sales volume in the current year minus 4

(d) Wholesale price and related information for the drug:

(i) Year of market introduction;

(ii) WAC at market introduction;

(iii) Current WAC;

(iv) WAC in the current year minus 1, year end

(v) WAC in the current year minus 2, year end

(vi) WAC in the current year minus 3, year end

(vii) WAC in the current year minus 4, year end

(viii) Justification for proposed current-year WAC increase

(e) Drug acquisition (if applicable):

(i) Acquisition date (MMYYYY)

(ii) Company from which acquired

(iii) WAC at acquisition, in U.S. dollars

(f) Revenue from the sale of the drug and (or) drug group in the United States by drug and drug group as specified by [the State Agency], in U.S. dollars per unit:

(i) Projected revenue in the current year

(ii) Revenue in the current year minus 1

(iii) Revenue in the current year minus 2;

(iv) Revenue in the current year minus 3;

(v) Revenue in the current year minus 4.

(g) Revenue from the sale of the drug and (or) drug group in the State by drug or drug group as specified by [the State Agency], in U.S. dollars per WAC unit:

(i) Projected revenue in the current year

(ii) Revenue in the current year minus 1

(iii) Revenue in the current year minus 2

(iv) Revenue in the current year minus 3

(v) Revenue in the current year minus 4

(h) Manufacturer cost associated with sales in the United States by drug or drug group as specified by [the State Agency]:

(i) Projected cost in the current year

(ii) Cost in the current year minus 1

(iii) Cost in the current year minus 2

(iv) Cost in the current year minus 3

(v) Cost in the current year minus 4

(i) Current calendar-year projections or incurred cost year to date, as [the State Agency] may indicate, related directly or allocated specifically to sales of this drug and drug group in the United States:

(i) Number of WAC units produced

(ii) Product cost;

(iii) Research and development costs

(iv) A description of research and development costs

(v) Other company-level capital expenditures allocated to the drug and drug group

(vi) A description of other capital expenditures and, if allocated, the rationale for allocation

(vii) Financial assistance provided in the United States through patient prescription assistance programs or coupons provided to consumers

(viii) Rebates to pharmacy benefits managers

(ix) Other rebates, discounts, and price concessions

(x) Marketing and advertising expense

(xi) Other administrative expense allocated to the drug or drug group

(xii) A description of other administrative expenditures and rationale for allocation

(4) A manufacturer that must notify [the State Agency] under Paragraph 2 of this Section shall report to the State the following minimum data and other data that may be specified by [the State Agency], at least 60 days before the date of market introduction:

(a) Drug identification

(i) National drug code

(ii) Proprietary drug name

(iii) Non-proprietary drug name

(iv) Manufacturer tax identification number

(v) Manufacturer name

(vi) Drug grouper

(vii) Drug group code or name

(viii) Date of market introduction

(IX) WAC unit

(X) Brand or generic

(b) Patient volume, revenue and price

(i) Projected patient volume in the current year for the drug and drug group in the United States

(ii) Projected patient volume in the current year for the drug and drug group in the State

(iii) Projected revenue for the drug and drug group in the current year in the United States

(iv) WAC at market introduction

(5) Disclosure of all information reported under this Section is subject to protections defined in Section 9.

SECTION 3. PHARMACY BENEFITS MANAGER DISCOUNTS AND NET INCOME

(1) Each pharmacy benefit manager shall, to the extent allowed by law, report annually to [the State Agency] the following minimum data, and other data that may be specified by [the State Agency], within 60 days after receiving notification by [the State Agency] indicating the specific drugs or drug groups for which reporting is required:

(a) Wholesale acquisition cost

(i) Minimum and maximum WAC for each indicated drug and drug group for which the pharmacy benefit manager has negotiated directly with the manufacturer in the last calendar year, related to prescriptions under an insurance policy issued in the State.

(ii) Minimum and maximum WAC for each indicated drug and drug group for which the pharmacy benefits manager has negotiated directly with the manufacturer in the current calendar year, related to prescriptions under an insurance policy issued in the State.

(b) Volume in WAC units of each indicated drug and drug group that the pharmacy benefit manager negotiated directly with the manufacturer in the last calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(c) Projected volume in WAC units of each indicated drug and drug group that the pharmacy benefit manager expects to negotiate directly with the manufacturer in the current calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(d) Total rebates, discounts, and price concessions received or negotiated directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid, before Federal and state rebates

(iv) Medicaid Federal and state rebates

(v) Medicare

(vi) Other payers

(e) Projected total rebates, discounts, or price concessions that the pharmacy benefit manager expects to receive or to negotiate directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid, before Federal and state rebates

(iv) Medicaid Federal and state rebates

(v) Medicare

(vi) Other payers

(f) Total discounts, dispensing fees, and other fees negotiated last year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(g) Projected total discounts, dispensing fees, or other fees that the pharmacy benefits manager expects to negotiate in the current calendar year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug

group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(h) Total net income received in the last calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(i) Projected net income that the pharmacy benefits manager expects to receive in the current calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(2) Disclosure of all information reported under this Section is subject to protections defined in Section 9.

SECTION 4. WHOLESALE DRUG DISTRIBUTOR DISCOUNTS AND NET INCOME

(1) Each wholesale drug distributor shall report annually to [the State Agency] the following minimum data, and other data that may be specified by [the State Agency], within 60 days after receiving

notification by [the State Agency] indicating the specific drugs or drug groups for which reporting is required:

(a) Wholesale acquisition cost
    (i) Minimum and maximum WAC for each indicated drug and drug group for which the wholesale drug distributor has negotiated directly with the manufacturer in the last calendar year, related to prescriptions under an insurance policy issued in the State.
    (ii) Minimum and maximum WAC for each indicated drug and drug group for which the wholesale drug distributor has negotiated directly with the manufacturer in the current calendar year, related to prescriptions under an insurance policy issued in the State.

(b) Volume in WAC units of each indicated drug and drug group that the wholesale drug distributor negotiated directly with the manufacturer in the last calendar year, for business in the State, in total and for each payer type as relevant.
    (i) Total
    (ii) Commercial insurance payers
    (iii) Medicaid
    (iv) Medicare
    (v) Other payers

(c) Projected volume (in WAC units) of each indicated drug and drug group that the wholesale drug distributor expects to negotiated directly with the manufacturer in the last calendar year, for business in the State, in total and for each payer type as relevant.
    (i) Total
    (ii) Commercial insurance payers
    (iii) Medicaid
    (iv) Medicare
    (v) Other payers

(d) Total rebates, discounts, and price concessions negotiated directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant
    (i) Total
    (ii) Commercial insurance payers
    (iii) Medicaid

(iv) Medicare

(v) Other payers

(e) Projected total rebates, discounts, or price concessions that the wholesale drug distributor expects to negotiate directly with the manufacturer for each drug and drug group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid, before Federal and state rebates

(iv) Medicaid Federal and state rebates

(v) Medicare

(vi) Other payers

(f) Total discounts, dispensing fees, and other fees negotiated last year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug group as indicated by [the State Agency] in the last calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(g) Projected total discounts, dispensing fees, or other fees that the wholesale drug distributor expects to negotiate in the current calendar year with pharmacies, prescription drug networks, or pharmacy services administrative organizations for each drug and drug group as indicated by [the State Agency] in the current calendar year, for business in the State, in total and for each payer type as relevant.

(i) Total

(ii) Commercial insurance payers

(iii) Medicaid

(iv) Medicare

(v) Other payers

(h) Total net income received in the last calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.
    (i) Total
    (ii) Commercial insurance payers
    (iii) Medicaid
    (iv) Medicare
    (v) Other payers
(i) Projected total margin that the wholesale drug distributor expects to receive in the current calendar year for each drug and drug group as indicated by [the State Agency], for business in the State, in total and for each payer type as relevant.
    (i) Total
    (ii) Commercial insurance payers
    (iii) Medicaid
    (iv) Medicare
    (v) Other payers

(2) Disclosure of all information reported under this section is subject to protections defined in Section 9.

SECTION 5. INSURANCE ISSUER COSTS

(1) Each insurance issuer designated by [the State Agency] as a reporting entity shall report annually to [the State Agency], to the extent allowed by law, spending on prescription drugs before enrollee cost sharing, in total and per prescription drug user, in total and for each of the top 25 prescription drugs and drug groups as defined by [the State Agency] in four categories, defined as: (i) the greatest total spending before enrollee cost sharing in the last calendar year; (ii) the greatest total spending per user of any drug in the drug group before enrollee cost sharing in the last calendar year; and (iii) highest year-over-year increase in total spending before enrollee cost sharing; and (iv) the highest year-over-year increase in total spending per user of any drug in the drug group before enrollee cost sharing.

(2) For each drug and drug group as indicated by [the State Agency], the insurance issuer shall report the following minimum data and other data that may be specified by [the State Agency] within 60 days of the close of each calendar year:

(a) Total spending

(i) Total issuer spending before enrollee cost sharing in the last calendar year.

(ii) Projected total issuer spending for each drug (as listed in Section 1) before enrollee cost sharing, in the current calendar year.

(b) Price concessions and fees paid to pharmacy benefits managers

(i) Margins and fees (for each drug listed in Section 1) paid directly to pharmacy benefits managers or pharmacy services administrative organizations in the last calendar year

(c) Other retail price concessions and fees

(i) Other retail discounts, price concessions, and fees (for each drug listed in Section 1) paid in the last calendar year

SECTION 6. REGISTRATION REQUIREMENTS

Each reporting entity shall register with [the State Agency] in a form and manner specified by [the State Agency] no later than January 31 of each calendar year.

SECTION 7: ASSESSMENTS

(1) Each reporting entity shall pay an annual assessment to support the operational costs of [the State Agency's] activities as required by this Act. Such costs will include staff salaries, administrative expenses, data system expenses, and consulting fees of [the State Agency] to effect this Act. Total annual assessments shall be based on the total annual allocation authorized by the [State] State Legislature for the operational costs of [the State Agency's] activities under this Act, as indicated in [the State Agency's] fiscal year budget. The amount to be assessed shall be reduced by the difference between the total annual authorized allocation for the next fiscal year and the beginning fund balance in [the State Agency's] account for the prior fiscal year. Any assessment reduction shall be applied proportionately to the categorical groups assessed. Annual assessments shall be at least $100 for each individual entity required to pay an assessment under this Act.

(2) Requests for payment of the final assessments shall be sent by [the State Agency] to all reporting entities under this Act. All assessments shall be due to [the State Agency] within 30 days of receipt of the request for payment.

SECTION 8. OVERSIGHT, CERTIFICATION, AND PENALTIES FOR NON-COMPLIANCE

(1) The reporting entity shall certify required reporting under this Act as accurate under the penalty of perjury.

(2) Failure of a reporting entity to comply with any Section of this Act may result in a civil penalty as determined by the Director of [the State Agency]. Civil penalties under this Act may not exceed $30,000 each day that the reporting entity is found to have not complied with any Section of this Act.

(3) [The State Agency] may audit the data submitted to [the State Agency] by a reporting entity pursuant to Section 2, Section 3, Section 4, and Section 5 of this Act, in a form and manner specified by [the State Agency]. The reporting entity shall pay all costs associated with the audit.

(4) [The State Agency] may require a reporting entity to submit a corrective action plan, in a form and manner specified by [the State Agency], to correct deficiencies in reporting pursuant to Section 2, Section 3, Section 4,and Section 5 of this Act.

(5) [The State Agency] may call one or more public hearings and may subpoena any reporting entity to explain its reporting pursuant to Section 2, Section 3, Section 4, and Section 5 of this Act.

SECTION 9. HEARING AND PUBLIC REPORTING

(1) [The State Agency] shall annually prepare and make available on its website a report on emerging trends in prescription drug prices, and conduct an annual public hearing based on the report findings. The report shall include, but may not be limited to, analysis of manufacturer prices and price increases as reported under this Act, and analysis of information as reported by issuers, pharmacy benefit managers, and wholesale drug distributors under this Act, so as to make clear the major components of prescription drug pricing along the supply chain, and the impacts on insurance

premiums and consumer cost sharing. The data in the report may not reveal information specific to any individual reporting entity.

(2) Except as provided in this Section, [the State Agency] shall keep confidential all information submitted by an individual reporting entity, and protect it from public disclosure. [The State Agency] may share such information with Department of Insurance or equivalent agency or agencies; such agency or agencies shall keep confidential any information shared by [the State Agency] under this Act and protect it from public disclosure.

SECTION 10. SEVERABILITY

(1) The provisions of this act are severable. If any part of this Act is declared invalid or unconstitutional, that declaration shall not affect the part which remains.

**Updated May 23, 2019*

[1] Total spending for prescription drugs increased at an average annual rate of 5.2 percent between 2012 and 2017, compared with an average increase of 4.5 percent for all other health care services, equipment, and supplies. Centers for Medicare & Medicaid Services. Table 2 - National Health Expenditures; Aggregate, Annual Percent Change, Percent Distribution and Per Capita Amounts, by Type of Expenditure: Selected Calendar Years 1960-2017 [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html].