

WORK SESSION DOCUMENT

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

(Senate Bill 276 [2019])

September 9, 2020 (With Attachments)

INTRODUCTION

The chair and staff of the <u>Committee to Conduct an Interim Study Concerning the Costs of Prescription Drugs</u> prepared this "Work Session Document" (WSD) to assist the Committee in determining which topics it may wish to support as the legislative measures it will request for the 2021 Legislative Session, as well as other actions. The WSD contains a summary of recommendations presented during public hearings, through communication with individual Committee members, or through correspondence submitted to the Committee members or staff.

The members of the Committee do not necessarily support or oppose the recommendations in this WSD. Committee staff has compiled and organized the proposals so that Committee members can review them and decide whether they want to accept, reject, modify, or take no action on the recommendations. The WSD groups the proposals by topic and they are not preferentially ordered.

Pursuant to *Nevada Revised Statutes* (NRS) <u>218D.160</u>, the Committee may request up to five bill drafts for consideration by the 2021 Legislature. Additionally, the Committee may vote to: (1) pass resolutions to highlight a certain concern or issue; (2) include statements in the Committee's final report; and (3) send letters of recommendation or support.

At the direction of the chair, Legislative Counsel Bureau staff may coordinate with interested parties to obtain additional information for drafting purposes or for information to be included in the Committee's final report.

RECOMMENDATIONS

A. INTRA- AND INTERSTATE PURCHASING COALITIONS

Draft a bill to allow the establishment of intra- and interstate purchasing coalitions by the Department of Health and Human Services (DHHS), 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 from any state agency with a

pharmacy benefit program in a purchasing coalition. 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.

(Proposed by Barry Gold, Director of Government Relations, AARP Nevada, and Bobbette Bond, Director of Public Policy, Culinary Health Fund.)

B. LICENSURE OF PHARMACEUTICAL SALES REPRESENTATIVES

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.

(Proposed by the Committee to Conduct an Interim Study Concerning the Costs of Prescription Drugs.)

C. PHARMACEUTICAL DRUG PRICING TRANSPARENCY

Draft a bill to amend statutes <u>NRS 439B.600</u> through <u>439B.695</u> (see **Attachment A**) related to the reporting and tracking of information concerning the pricing of asthma and diabetes prescription drugs to (see certain sections of **Attachment B** [Draft Drug Transparency Model Legislation]):

- 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;
- 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 <u>NRS 439B.695</u> 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.

(Proposed by Barry Gold, Director of Government Relations, AARP Nevada, and Bobbette Bond, Director of Public Policy, Culinary Health Fund.)

(Attachment A was submitted by staff of the Legislative Counsel Bureau on September 1, 2020.)

(Attachment B—Draft Drug Transparency Model Legislation—was submitted to Committee staff by Beth Slamowitz, Pharm.D., Senior Advisor on Pharmacy, Division of Health Care Financing and Policy, DHHS, on July 29, 2020.)

D. PHARMACY BENEFIT MANAGERS

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;

(Proposed by Bobbette Bond, Director of Public Policy, Culinary Health Fund.)

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;

(Proposed by Barry Gold, AARP Nevada; Bobbette Bond, Director of Public Policy, Culinary Health Fund; and Asher Lisec, M.S.P.H., Deputy Vice President, State Policy, Pharmaceutical Research and Manufacturers of America.)

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

(Proposed by Bobbette Bond, Director of Public Policy, Culinary Health Fund.)

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.

(Proposed by Bobbette Bond, Director of Public Policy, Culinary Health Fund.)

ATTACHMENT A

REPORTING OF CERTAIN INFORMATION RELATING TO PRESCRIPTION DRUGS

NRS 439B.600 Definitions. As used in <u>NRS 439B.600</u> to <u>439B.695</u>, inclusive, unless the context otherwise requires, the words and terms defined in <u>NRS 439B.605</u> to <u>439B.620</u>, inclusive, have the meanings ascribed to them in those sections.

(Added to NRS by 2007, 3137; A 2017, 4301) — (Substituted in revision for NRS 439.900)

NRS 439B.605 "Manufacturer" defined. "Manufacturer" has the meaning ascribed to it in NRS 639.009.

(Added to NRS by 2017, 4297)

NRS 439B.610 "Pharmacy" defined. "Pharmacy" means every store or shop licensed by the State Board of Pharmacy where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed. The term does not include an institutional pharmacy as defined in NRS 639.0085.

(Added to NRS by <u>2017</u>, <u>4297</u>)

NRS 439B.615 "Pharmacy benefit manager" defined. "Pharmacy benefit manager" has the meaning ascribed to it in NRS 683A.174.

(Added to NRS by <u>2017</u>, <u>4297</u>)

NRS 439B.620 "Wholesale acquisition cost" defined. "Wholesale acquisition cost" means the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing data.

(Added to NRS by <u>2017</u>, <u>4297</u>)

NRS 439B.625 Organization representing interests of retail merchants to prepare and update list of most commonly prescribed drugs or generic equivalents. The organization with the largest membership in this State which represents the interests of retail merchants, as determined by the Department, shall:

- 1. Prepare a list of not less than the 100 brand name prescription drugs or generic equivalents most commonly prescribed to residents of this State; and
- 2. At least once each calendar year, update the list prepared pursuant to subsection 1 and transmit the list to the Department.

(Added to NRS by 2007, 3137) — (Substituted in revision for NRS 439.905)

NRS 439B.630 Department to annually compile lists of certain prescription drugs essential for treating asthma and diabetes. On or before February 1 of each year, the Department shall compile:

- 1. A list of prescription drugs that the Department determines to be essential for treating asthma and diabetes in this State and the wholesale acquisition cost of each such drug on the list. The list must include, without limitation, all forms of insulin and biguanides marketed for sale in this State.
- 2. A list of prescription drugs described in subsection 1 that have been subject to an increase in the wholesale acquisition cost of a percentage equal to or greater than:
- (a) The percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year; or
- (b) Twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years.

(Added to NRS by <u>2017</u>, <u>4297</u>; A <u>2019</u>, <u>1465</u>)

NRS 439B.635 Manufacturer of certain essential diabetes drugs to prepare and submit annual report. On or before April 1 of each year, the manufacturer of a prescription drug that appears on the most current list compiled by the Department pursuant to subsection 1 of NRS 439B.630 shall prepare and submit to the Department, in the form prescribed by the Department, a report which must include:

- 1. The costs of producing the drug;
- 2. The total administrative expenditures relating to the drug, including marketing and advertising costs;
- 3. The profit that the manufacturer has earned from the drug and the percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug;
- 4. The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;
- 5. The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs;
 - 6. The wholesale acquisition cost of the drug;
- 7. A history of any increases in the wholesale acquisition cost of the drug over the 5 years immediately preceding the date on which the report is submitted, including the amount of each

such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective and any explanation for the increase;

- 8. The aggregate amount of all rebates that the manufacturer has provided to pharmacy benefit managers for sales of the drug within this State; and
- 9. Any additional information prescribed by regulation of the Department for the purpose of analyzing the cost of prescription drugs that appear on the list compiled pursuant to subsection 1 of NRS 439B.630, trends in those costs and rebates available for such drugs.

(Added to NRS by <u>2017</u>, <u>4297</u>)

NRS 439B.640 Manufacturer of essential diabetes drug that has undergone significant price increase to submit report. On or before April 1 of a year in which a drug is included on the list compiled pursuant to subsection 2 of NRS 439B.630, the manufacturer of the drug shall submit to the Department a report describing the reasons for the increase in the wholesale acquisition cost of the drug described in that subsection. The report must include, without limitation:

- 1. A list of each factor that has contributed to the increase;
- 2. The percentage of the total increase that is attributable to each factor;
- 3. An explanation of the role of each factor in the increase; and
- 4. Any other information prescribed by regulation by the Department.

(Added to NRS by <u>2017</u>, <u>4298</u>)

NRS 439B.645 Pharmacy benefit manager to submit annual report concerning essential diabetes drugs.

- 1. Except as otherwise provided in subsection 2, on or before April 1 of each year, a pharmacy benefit manager shall submit to the Department a report which includes:
- (a) The total amount of all rebates that the pharmacy benefit manager negotiated with manufacturers during the immediately preceding calendar year for prescription drugs included on the list compiled by the Department pursuant to subsection 1 of NRS 439B.630;
- (b) The total amount of all rebates described in paragraph (a) that were retained by the pharmacy benefit manager; and
- (c) The total amount of all rebates described in paragraph (a) that were negotiated for purchases of such drugs for use by:
 - (1) Recipients of Medicare;

- (2) Recipients of Medicaid;
- (3) Persons covered by third parties that are governmental entities which are not described in subparagraph (1) or (2);
 - (4) Persons covered by third parties that are not governmental entities; and
- (5) Persons covered by a plan described in subsection 2 to the extent required by a contract entered into pursuant to subsection 3.
- 2. Except as otherwise provided in subsection 3, the requirements of this section do not apply to the coverage of prescription drugs under a plan that is subject to the Employee Retirement Income Security Act of 1974 or any information relating to such coverage.
- 3. A plan described in subsection 2 may, by contract, require a pharmacy benefit manager that manages the coverage of prescription drugs under the plan to comply with the requirements of this section.

(Added to NRS by <u>2017</u>, 4298)

NRS 439B.650 Department to compile report concerning price of essential asthma and diabetes drugs. On or before June 1 of each year, the Department shall analyze the information submitted pursuant to NRS 439B.635, 439B.640 and 439B.645 and compile a report on the price of the prescription drugs that appear on the most current lists compiled by the Department pursuant to NRS 439B.630, the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State. The report may include, without limitation, opportunities for persons and entities in this State to lower the cost of drugs for the treatment of asthma and diabetes while maintaining access to such drugs.

(Added to NRS by <u>2017</u>, <u>4299</u>; A <u>2019</u>, <u>1465</u>)

NRS 439B.655 Pharmacies to provide to Department contact information, electronic mail address and address of Internet website; exceptions.

- 1. Except as otherwise provided in subsections 2 and 3, each pharmacy shall, in accordance with the regulations adopted pursuant to NRS 439B.685, provide to the Department:
- (a) Information that a consumer may use to locate, contact or otherwise do business with the pharmacy, including, without limitation:
 - (1) The name of the pharmacy;
 - (2) The physical address of the pharmacy; and
 - (3) The phone number of the pharmacy;

- (b) If the pharmacy maintains an electronic mail address, the electronic mail address of the pharmacy; and
 - (c) If the pharmacy maintains an Internet website, the Internet address of that website.
- 2. If a pharmacy is not located within the State of Nevada, the pharmacy may, but is not required to, provide to the Department the information described in subsection 1.
- 3. If a pharmacy is part of a larger company or corporation or a chain of pharmacies or retail stores, the parent company or corporation may provide to the Department the information described in subsection 1.

(Added to NRS by 2007, 3137) — (Substituted in revision for NRS 439.910)

NRS 439B.660 Manufacturer required to provide list of its pharmaceutical sales representatives; electronic access to list; prohibition against unlisted person marketing prescription drugs; reports.

- 1. A manufacturer of a prescription drug shall provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs on behalf of the manufacturer to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS and update the list at least annually.
- 2. The Department shall provide electronic access to the most recent list provided by each manufacturer pursuant to subsection 1 to each provider of health care licensed, certified or registered in this State, operator of a pharmacy, operator of a medical facility or person licensed or certified under the provisions of title 57 for the purposes of ensuring compliance with the requirements of subsection 3. This subsection must not be construed to impose any duty on a provider of health care, operator of a pharmacy, operator of a medical facility or person licensed or certified under the provisions of title 57 to ensure such compliance.
- 3. A person who is not included on a current list submitted pursuant to subsection 1 shall not market prescription drugs on behalf of a manufacturer:
- (a) To any provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS; or
 - (b) For sale to any resident of this State.
- 4. On or before March 1 of each year, each person who was included on a list of pharmaceutical sales representatives submitted pursuant to subsection 1 at any time during the immediately preceding calendar year shall submit to the Department a report, which must include, for the immediately preceding calendar year:

- (a) A list of providers of health care licensed, certified or registered in this State, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of title 57 of NRS to whom the pharmaceutical sales representative provided:
 - (1) Any type of compensation with a value that exceeds \$10; or
 - (2) Total compensation with a value that exceeds \$100 in aggregate; and
- (b) The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS and the name of each such person to whom a free sample was provided.
- 5. The Department shall analyze annually the information submitted pursuant to subsection 4 and compile a report on the activities of pharmaceutical sales representatives in this State. Any information contained in such a report that is derived from a list provided pursuant to subsection 1 or a report submitted pursuant to subsection 4 must be reported in aggregate and in a manner that does not reveal the identity of any person or entity. On or before June 1 of each year, the Department shall:
 - (a) Post the report on the Internet website maintained by the Department; and
- (b) Submit the report to the Governor and the Director of the Legislative Counsel Bureau for transmittal to the Legislative Committee on Health Care and, in even-numbered years, the next regular session of the Legislature.
 - 6. As used in this section:
 - (a) "Medical facility" has the meaning ascribed to it in NRS 629.026.
- (b) "Pharmaceutical sales representative" means a person who markets prescription drugs to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS.
 - (c) "Provider of health care" has the meaning ascribed to it in NRS 629.031.

(Added to NRS by 2017, 4299)

NRS 439B.665 Report by certain nonprofit organizations that receive items of value from manufacturer.

1. On or before February 1 of each year, a nonprofit organization that advocates on behalf of patients or funds medical research in this State and has received a payment, donation, subsidy

or anything else of value from a manufacturer, third party or pharmacy benefit manager or a trade or advocacy group for manufacturers, third parties or pharmacy benefit managers during the immediately preceding calendar year shall:

- (a) Compile a report which includes:
- (1) For each such contribution, the amount of the contribution and the manufacturer, third party or pharmacy benefit manager or group that provided the payment, donation, subsidy or other contribution; and
- (2) The percentage of the total gross income of the organization during the immediately preceding calendar year attributable to payments, donations, subsidies or other contributions from each manufacturer, third party, pharmacy benefit manager or group; and
- (b) Except as otherwise provided in this paragraph, post the report on an Internet website that is maintained by the nonprofit organization and accessible to the public. If the nonprofit organization does not maintain an Internet website that is accessible to the public, the nonprofit organization shall submit the report compiled pursuant to paragraph (a) to the Department.
 - 2. As used in this section, "third party" means:
 - (a) An insurer, as that term is defined in NRS 679B.540;
- (b) A health benefit plan, as that term is defined in <u>NRS 687B.470</u>, for employees which provides coverage for prescription drugs;
- (c) A participating public agency, as that term is defined in <u>NRS 287.04052</u>, and any other local governmental agency of the State of Nevada which provides a system of health insurance for the benefit of its officers and employees, and the dependents of officers and employees, pursuant to <u>chapter 287</u> of NRS; or
- (d) Any other insurer or organization that provides health coverage or benefits in accordance with state or federal law.
- The term does not include an insurer that provides coverage under a policy of casualty or property insurance.

(Added to NRS by <u>2017</u>, <u>4300</u>; A <u>2019</u>, <u>1108</u>)

- NRS 439B.670 Department to place on Internet website certain information concerning pharmacies, nonprofit organizations and prescription drugs and certain reports by Department; additional or alternative procedures for obtaining information concerning pharmacies, nonprofit organizations and prescription drugs.
- 1. Except as otherwise provided in subsection 2 and subsection 3 of <u>NRS 439B.660</u>, the Department shall:

- (a) Place or cause to be placed on the Internet website maintained by the Department:
 - (1) The information provided by each pharmacy pursuant to NRS 439B.655;
- (2) The information compiled by a nonprofit organization pursuant to <u>NRS 439B.665</u> if such a report is submitted pursuant to paragraph (b) of subsection 1 of that section;
- (3) The lists of prescription drugs compiled by the Department pursuant to <u>NRS</u> 439B.630;
- (4) The wholesale acquisition cost of each prescription drug reported pursuant to <u>NRS</u> 439B.635; and
 - (5) The reports compiled by the Department pursuant to <u>NRS 439B.650</u> and <u>439B.660</u>.
- (b) Ensure that the information placed on the Internet website maintained by the Department pursuant to paragraph (a) is organized so that each individual pharmacy, manufacturer and nonprofit organization has its own separate entry on that website; and
- (c) Ensure that the usual and customary price that each pharmacy charges for each prescription drug that is on the list prepared pursuant to <u>NRS 439B.625</u> and that is stocked by the pharmacy:
- (1) Is presented on the Internet website maintained by the Department in a manner which complies with the requirements of NRS 439B.675; and
 - (2) Is updated not less frequently than once each calendar quarter.
- → Nothing in this subsection prohibits the Department from determining the usual and customary price that a pharmacy charges for a prescription drug by extracting or otherwise obtaining such information from claims reported by pharmacies to the Medicaid program.
- 2. If a pharmacy is part of a larger company or corporation or a chain of pharmacies or retail stores, the Department may present the pricing information pertaining to such a pharmacy in such a manner that the pricing information is combined with the pricing information relative to other pharmacies that are part of the same company, corporation or chain, to the extent that the pricing information does not differ among those pharmacies.
- 3. The Department may establish additional or alternative procedures by which a consumer who is unable to access the Internet or is otherwise unable to receive the information described in subsection 1 in the manner in which it is presented by the Department may obtain that information:
 - (a) In the form of paper records;
 - (b) Through the use of a telephonic system; or

- (c) Using other methods or technologies designed specifically to assist consumers who are hearing impaired or visually impaired.
- 4. As used in this section, "usual and customary price" means the usual and customary charges that a pharmacy charges to the general public for a drug, as described in 42 C.F.R. § 447.512.

(Added to NRS by 2007, 3138; A 2017, 4301) — (Substituted in revision for NRS 439.915)

NRS 439B.675 Manner of presentation of information.

- 1. Except as otherwise provided in this section, the Department shall ensure that the list of prescription drugs prepared pursuant to <u>NRS 439B.625</u> and the information that pharmacies and the Department provide and obtain pursuant to <u>NRS 439B.655</u> and <u>439B.670</u> are combined and presented to consumers in such a manner that a consumer may easily compare the prices for particular prescription drugs, and their generic equivalents, that are currently charged by:
- (a) Pharmacies located within the same city, county or zip code in which the consumer resides;
 - (b) Internet pharmacies; and
 - (c) Pharmacies that provide mail order service to residents of Nevada.
- → The requirements of paragraphs (b) and (c) apply only to the extent that information regarding such pharmacies is made available to the Department.
- 2. As used in this section, "Internet pharmacy" has the meaning ascribed to it in <u>NRS</u> 639.00865.

(Added to NRS by 2007, 3138) — (Substituted in revision for NRS 439.920)

NRS 439B.680 Immunity from civil and criminal liability. The Department and its members, officers and employees are not liable civilly or criminally for any act, omission, error or technical problem that results in:

- 1. The failure to provide to consumers information regarding a pharmacy, prescription drug or nonprofit organization, including, without limitation, the information made available on the Department's Internet website pursuant to NRS 439B.670; or
- 2. The providing to consumers of incorrect information regarding a pharmacy, prescription drug or nonprofit organization, including, without limitation, the information made available on the Department's Internet website pursuant to NRS 439B.670.

(Added to NRS by 2007, 3139; A 2017, 4302) — (Substituted in revision for NRS 439.925)

NRS 439B.685 Regulations. The Department shall adopt such regulations as it determines to be necessary or advisable to carry out the provisions of <u>NRS 439B.600</u> to 439B.695, inclusive. Such regulations must provide for, without limitation:

- 1. Notice to consumers stating that:
- (a) Although the Department will strive to ensure that consumers receive accurate information regarding pharmacies, prescription drugs and nonprofit organizations including, without limitation, the information made available on the Department's Internet website pursuant to NRS 439B.670, the Department is unable to guarantee the accuracy of such information;
- (b) If a consumer follows an Internet link from the Internet website maintained by the Department to an Internet website not maintained by the Department, the Department is unable to guarantee the accuracy of any information made available on that Internet website; and
- (c) The Department advises consumers to contact a pharmacy, manufacturer or nonprofit organization directly to verify the accuracy of any information regarding the pharmacy, a prescription drug manufactured by the manufacturer or the nonprofit organization, as applicable, which is made available to consumers pursuant to NRS 439B.600 to 439B.695, inclusive;
- 2. Procedures adopted to direct consumers who have questions regarding the program described in <u>NRS 439B.600</u> to <u>439B.695</u>, inclusive, to contact the Office for Consumer Health Assistance of the Department;
- 3. Provisions in accordance with which the Department will allow an Internet link to the information made available on the Department's Internet website pursuant to NRS 439B.670 to be placed on other Internet websites managed or maintained by other persons and entities, including, without limitation, Internet websites managed or maintained by:
- (a) Other governmental entities, including, without limitation, the State Board of Pharmacy and the Office of the Governor; and
 - (b) Nonprofit organizations and advocacy groups;
- 4. Procedures pursuant to which consumers, pharmacies, manufacturers and nonprofit organizations may report to the Department that information made available to consumers pursuant to NRS 439B.600 to 439B.695, inclusive, is inaccurate;
- 5. The form and manner in which pharmacies are to provide to the Department the information described in NRS 439B.655; and
- 6. The form and manner in which manufacturers are to provide to the Department the information described in NRS 439B.635, 439B.640 and 439B.660;
- 7. The form and manner in which pharmacy benefit managers are to provide to the Department the information described in NRS 439B.645;

- 8. The form and manner in which pharmaceutical sales representatives are to provide to the Department the information described in NRS 439B.660;
- 9. The form and manner in which nonprofit organizations are to provide to the Department the information described in NRS 439B.665, if required; and
- 10. Standards and criteria pursuant to which the Department may remove from its Internet website information regarding a pharmacy or an Internet link to the Internet website maintained by a pharmacy, or both, if the Department determines that the pharmacy has:
 - (a) Ceased to be licensed and in good standing pursuant to chapter 639 of NRS; or
- (b) Engaged in a pattern of providing to consumers information that is false or would be misleading to reasonably informed persons.

(Added to NRS by <u>2007</u>, <u>3139</u>; A <u>2011</u>, <u>977</u>; <u>2017</u>, <u>4302</u>) — (Substituted in revision for NRS 439.930)

NRS 439B.690 Suspension of components of program or duties of Department if sufficient money not available; acceptance of gifts and grants.

- 1. On or before July 1 of each odd-numbered year, the Department shall make a determination of whether sufficient money is available and authorized for expenditure to fund one or more components of the programs and other duties of the Department relating to NRS 439B.600 to 439B.695, inclusive.
- 2. The Department shall temporarily suspend any components of the program or duties of the Department for which it determines pursuant to subsection 1 that sufficient money is not available.
- 3. The Department may apply for and accept any available grants and may accept any bequests, devises, donations or gifts from any public or private source to carry out the provisions of NRS 439B.600 to 439B.695, inclusive.

(Added to NRS by 2007, 3140; A 2017, 4303) — (Substituted in revision for NRS 439.935)

NRS 439B.695 Penalty for failure to provide information to Department.

1. If a pharmacy that is licensed under the provisions of <u>chapter 639</u> of NRS and is located within the State of Nevada fails to provide to the Department the information required to be provided pursuant to <u>NRS 439B.655</u> or fails to provide such information on a timely basis, and the failure was not caused by excusable neglect, technical problems or other extenuating circumstances, the Department may impose against the pharmacy an administrative penalty of not more than \$500 for each day of such failure.

- 2. If a manufacturer fails to provide to the Department the information required by NRS 439B.635, 439B.640 or 439B.660, a pharmacy benefit manager fails to provide to the Department the information required by NRS 439B.645, a nonprofit organization fails to post or provide to the Department, as applicable, the information required by NRS 439B.665 or a manufacturer, pharmacy benefit manager or nonprofit organization fails to post or provide, as applicable, such information on a timely basis, and the failure was not caused by excusable neglect, technical problems or other extenuating circumstances, the Department may impose against the manufacturer, pharmacy benefit manager or nonprofit organization, as applicable, an administrative penalty of not more than \$5,000 for each day of such failure.
- 3. If a pharmaceutical sales representative fails to comply with the requirements of <u>NRS</u> <u>439B.660</u>, the Department may impose against the pharmaceutical sales representative an administrative penalty of not more than \$500 for each day of such failure.
- 4. Any money collected as administrative penalties pursuant to this section must be accounted for separately and used by the Department to establish and carry out programs to provide education concerning asthma and diabetes and prevent those diseases.

(Added to NRS by <u>2007, 3140</u>; A <u>2017, 4304</u>; <u>2019, 1465</u>) — (Substituted in revision for NRS 439.940)

ATTACHMENT B



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; 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 Section9.

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 subpoen aany 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].