



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,² 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

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

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

“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.

“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.

“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.

“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.

“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.

“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.

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 \$10 or more per WAC unit by more than 20 percent during any 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] all data elements specified in the National Academy for State Health Policy Model Act report template at least 30 days before the price increase.
- (4) A manufacturer that must notify [the State Agency] under Paragraph 2 of this Section shall report to [the State Agency] all data elements specified in the National Academy for State Health Policy Model Act report template at least 60 days before the date of 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] all data elements specified in the National Academy for State Health Policy Model Act report template within 60 days after receiving notification by [the State Agency] indicating the specific drugs or drug groups for which reporting is required.

- (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] all data elements specified in the National Academy for State Health Policy Model Act report template within 60 days after receiving notification by [the State Agency] indicating the specific drugs or drug groups for which reporting is required.
- (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 defined by [the State Agency], the insurance issuer shall report to [the State Agency] all data elements specified in the National Academy for State Health Policy Model Act report template, within 60 days of the close of each 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 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 parts that remain.

April 30, 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>].

² Cox, C. Rahab Kamal, Daniel McDermott. "What are the recent and forecasted trends in prescription drug spending?" Peterson-Kaiser Health System Tracker. February 20, 2019. Accessed online April 22, 2019.