An Act to Reduce the Cost of Prescription Drugs

by Establishing a Prescription Drug Affordability Board

Section 1. Statement of Legislative Intent; Purpose

The purpose of this Title is to protect the safety, health, and economic well-being of Name of State people by taking to steps to increase access to affordable Prescription Drugs. In enacting this, the legislature finds that:

(1) Access to Prescription Drugs is necessary for Name of State people to maintain or acquire good health;

(2) Excessive costs negatively impact the ability of Name of State people to obtain Prescription Drugs and costs that exceed reasonable levels endanger the health and safety of Name of State people to maintain or achieve good health;

(3) Lack of affordability of Prescription Drugs threaten the economic well-being of Name of State people and endanger their ability to afford other necessary and essential goods and services including housing, food, and utilities;

(4) Excessive costs for Prescription Drugs contribute significantly to health care costs and health insurance that threaten the overall ability of Name of State people to obtain health coverage and maintain or achieve good health;

(5) The high cost of Prescription Drugs contributes significantly to rising state costs for health care provided and paid for through health insurance programs for public employees, including employees of the state, municipalities and counties, school districts, institutions of higher education, and retirees whose health care costs are funded by public programs, thereby threatening the ability of the state to fund those programs adequately

and further threatening the ability of the state to fund other programs necessary for the public good and safety, such as public education and public safety; and

(6) The costs to consumers, health plans, and the state for Prescription Drug coverage is higher than the costs in other countries because the prices charged by manufacturers and distributors of drugs in Name of State are higher.

Based on findings (1) through (6), the legislature finds that high costs of Prescription Drugs threaten the safety and well-being of Name of State people and find it is necessary to act in order to protect Name of State people from the negative impact of excessive costs for Prescription Drugs.

Section 2. Definitions. The definitions in this section apply throughout this Title:

(1) "Affordability Challenge" means situations whereby the Board determines that a) the costs of appropriate utilization of a Prescription Drug, Biologic or Biosimilar exceed the therapeutic benefit; or b) the costs of appropriate utilization of the Prescription Drug, Biologic or Biosimilar are not sustainable to consumers or to public and private health care systems.

(2) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 USC § 1395w-3a(c)(6).

(3) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(k)(3).

(4) "Board" means the Prescription Drug Affordability Board established under this Title.

(5) "ERISA Plan" means a plan qualified under the Employee Retirement Income Security Act of 1974.

(6) "The Fund" is the Prescription Drug Affordability Fund established in Section XX of this Title.

(7) "Health Plan" means State's definition of health plan as defined in insurance statute.

(8) "Manufacturer" means an entity that (a)(i) engages in the manufacture of a Prescription Drug, Biologic or Biosimilar product; or (ii) enters into an agreement with another manufacturer to market and distribute a Prescription Drug, Biologic or Biosimilar product

under the entity's own name; and (b) sets or changes the Wholesale Acquisition Cost of the Prescription Drug, Biologic or Biosimilar product it manufactures or markets.

(9) "Participating ERISA Plan" means an ERISA Plan that has elected to participate in the requirements and restrictions of this subchapter as described in Section 6 below.

(10) "Pharmacy Benefits Manager" means Define under state law.

(11) "Pharmacy Wholesale Distributor" means Define under state law.

(12) "Prescription Drug" means:

a. Cite to State's Pharmacy Act Definition

b. A Biologic as defined in Section 2(2) above

c. A Biosimilar as defined in Section 2(3) above

(13) "State Entity" means any agency of state government that purchases Prescription Drugs on behalf of the state for a person whose health care is paid for by the state, including any agent, vendor, fiscal agent, contractor, or other party acting on behalf of the state.

(14) "Wholesale Acquisition Cost" has the meaning stated in 42 U.S.C. § 1395w-3a(6).

Section 3. Establishment of the Prescription Drug Affordability Board.

(1) The Board is established as an independent unit of state government.

(2) The Board shall be constituted of five members, appointed by the Governor and confirmed by the Senate. The Board shall include members who have demonstrated expertise in health policy, health care economics, or clinical medicine.

(3) Board members shall serve for a term of five years and members may be reappointed by the Governor for additional terms.

(4) The Board shall have the authority to hire an Executive Director and staff necessary to conduct the Board's activity as described in this Act.

(5) The Board shall assess and collect an annual assessment on Manufacturers, Health Plans, Pharmacy Benefits Managers, and Pharmacy Wholesale Distributors that sell or offer for sale Prescription Drug products to persons in the state.

a. The Board shall assess and collect the annual assessment in accordance with regulations promulgated and adopted by the Board. The regulations shall specify the methodology for determining the amount of the assessment and the methodology and timeline for collecting the assessment.

b. Amounts generated and collected as a result of annual assessments shall be deposited in the Fund described in Section 10 of this Title and utilized by the Board to fund its operations.

(6) The Board shall have the authority to enter into a contract with a third party for any service necessary to carry out the powers and duties of the Board described in Sections 4 and 5 of this Title.

(7) No Board member may be an employee of, a board member of, or consultant to a Manufacturer, Pharmacy Benefit Manager, Health Plan, Pharmacy Wholesale Distributor, or related trade association.

(8) The Board, may seek, accept, and expend gifts, grants, and donations from private or public sources for the purposes of this Title. The Board shall not accept any gift, grant, or donation that creates a conflict of interest, or the appearance of any conflict of interest, for any board member.

(9) Board members, staff members, and contractors providing services on behalf of the Board shall recuse themselves from any Board activity in which they have a conflict of interest. For the purposes of this section, a conflict of interest means an association, including a financial or personal association, that has the potential to bias or appear to bias an individual's decisions in matters related to the Board or the activities of the Board.

(10) The Board may establish advisory groups consisting of relevant stakeholders.

(11) The Board has the authority to promulgate and adopt rules to allow it to carry out its duties and obligations.

(12) A simple majority of the Board's membership constitutes a quorum for the purpose of conducting business. Decisions of the Board shall be determined by majority vote of members present.

(13) All meetings of the Board shall be open and public, except that the Board may hold executive sessions to the extent permitted by Cite to state's open meetings law.

(14) The Board shall meet at least quarterly and hold its first meeting by XXXXXXX.

Section 4. Identification of Drugs Subject to Review.

The Board shall select Prescription Drugs for Affordability Review based on the following criteria:

(1) By XXXXX _____, XX _____ 20XX___, and yearly thereafter, the Board shall identify:

a. Prescription Drugs that:
    i. Have a Wholesale Acquisition Cost of three thousand dollars or more; or
    ii. Have a Wholesale Acquisition Cost increase of three hundred dollars or more in the preceding twelve months; or
    iii. Have a Wholesale Acquisition Cost increase of two hundred percent or more in the preceding twelve months.
b. Biosimilars with an initial Wholesale Acquisition Cost that is not at least fifteen percent below the Wholesale Acquisition Cost of the referenced brand biologic product at the time the biosimilar is launched.
c. Other drugs referred to the Board as posing potential Affordability Challenges.

(2) Prescription Drugs referred to the Board by any advisory group created by the Board pursuant to Section 3(10) above; and

(3) Prescription Drugs included in the following reports, which shall be reported annually to the Board from each Health Plan:

a. The 50 Prescription Drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug;
b. The 50 most costly Prescription Drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug after rebates and other price concessions;
c. The 50 Prescription Drugs with the greatest increase in plan or coverage expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year after rebates and other price concessions;
d. The 50 most costly Prescription Drugs with respect to consumers based on average out-of-pocket cost per utilizer;
e. Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers, with respect to Prescription Drugs prescribed to participants or beneficiaries in the plan, including:

i. the amounts paid by manufacturers for each therapeutic class of drugs; and
ii. the amounts paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan from drug manufacturers during the plan year; and

f. Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration described in Section 4(3)€.

(4) The reports described in Section 4(3)(a)-(f) shall include the following information for each Prescription Drug:

a. Total annual spending by the plan or coverage after rebate and other price concessions;
b. Total annual spending by participants, beneficiaries, and enrollees enrolled in the plan or coverage, as applicable;
c. The number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim;
d. Total dosage units dispensed; and
e. The number of paid claims.

Section 5. Information to the Board.

(1) In performing an affordability review of a Prescription Drug, the Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the Prescription Drug, including documents and information relating to:

a. Life-cycle management;
b. The average cost of the Prescription Drug;
c. Market competition and context;
d. Projected revenue;
e. The estimated cost-effectiveness of the Prescription Drug;
f. Off-label usage of the Prescription Drug;
g. Development and manufacturing costs; and
h. Information regarding any consumer assistance programs funded by the manufacturer.

(2) To the extent practicable, the Board may access pricing information for Prescription Drugs through:

a. Publicly available pricing information from a state to which manufacturers report pricing information or information acquired through a data-sharing agreement with another state;
b. Available pricing information from state entities and data assets that have access to cost and pricing information;
c. Pricing information that is available from other countries; and
d. Any other sources available to the Board.

Section 6. Affordability Review.

(1) The Board may conduct an affordability review of any Prescription Drug identified pursuant to Section 4 of this Title. The purpose of the affordability review is to determine whether the cost of the Prescription Drug poses an Affordability Challenge.
(2) When conducting a review, the Board may consider any of the following criteria:

a. The relevant factors contributing to the price paid for the Prescription Drug, including the Wholesale Acquisition Cost, discounts, rebates, or other price concessions;
b. The average patient co-pay or other cost-sharing for the drug;
c. The effect of the price on consumers' access to the drug in the state;
d. Whether the cost of the drug contributes to inequities in the availability of health care to underserved communities in the state;
e. The dollar value and accessibility of patient assistance programs offered by the manufacturer for the drug;
f. The price and availability of therapeutic alternatives;
g. Input from any advisory groups established by the Board as described in Section 3(9) above;
h. Input from patients affected by the condition or disease treated by the drug and individuals with medical or scientific expertise related to the condition or disease treated by the drug;

i. Life cycle management;
j. The average cost of the drug in the state;
k. Market competition and context;
l. Projected manufacturer revenue, if available;
m. Off-label usage of the drug;
n. Any other relevant factors as determined by the Board.

(3) Before commencing a review, the Board shall publish which drugs are subject to an affordability review and shall notify in writing the manufacturer of any Prescription Drug subject to review.

(4) At the conclusion of its affordability review, the Board shall determine whether the cost of a reviewed Prescription Drug presents an Affordability Challenge.

Section 7. Upper Payment Limits.

(1) Prior to setting any upper payment limits, the Board shall establish by rule a methodology for setting upper payment limits.

(2) The Board may set an upper payment limit for each Prescription Drug for which it determines there is an Affordability Challenge.

(3) The methodology may take into consideration:

a. The cost of administering the Prescription Drug;
b. The cost of delivering the Prescription Drug to patients;
c. The status of the Prescription Drug on the drug shortage list published by the United States Food and Drug Administration;
d. The differential in price between the price of the drug in _____ and the price of the drug in other countries;
e. Other relevant administrative costs related to the production and delivery of the Prescription Drug;
f. Other relevant criteria the Board, accounting for any stakeholder input, determines is necessary.

(4) The methodology determined by the Board shall consider whether an upper payment limit may help alleviate health disparities and inequitable outcomes for (a) underserved

communities, (b) people with disabilities, (c) older adults, or (d) any other socially, economically, or environmentally disadvantaged group.

(5) The Board may not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a pre-existing disability or chronic health condition of the individuals whom the treatment would benefit.

(6) The Board may suspend an upper payment limit if it determines that there is a shortage of the drug in the state, unless the Board determines that the shortage was caused by a Manufacturer or its agent.

(7) An upper payment limit for a Prescription Drug established by the Board applies to all purchases of the Prescription Drug and reimbursements for a claim for the drug when the Prescription Drug is dispensed or administered to an individual in the state in person, by mail, or by other means. An upper payment limit does not include a pharmacy dispensing fee and nothing in this Chapter shall be interpreted to prevent a retail pharmacy from receiving a payment that includes a dispensing fee above the upper payment limit.

(8) An ERISA plan may elect to be subject to the upper payment limits as established by the Board.

(9) The Board shall publish a list of Prescription Drugs for which it has set an upper payment limit.

(10) Unless the Board prescribes a specific effective date, upper payment limits established by the Board shall become effective six months after the adoption of the upper payment limit and apply only to purchases, contracts, and plans that are issued on or renewed after the effective date.

(11) The establishment of an upper payment limit shall constitute final agency action for the purpose of this Title and any person or entity alleging to be aggrieved by a decision of the Board to establish an upper payment limit may request an appeal within thirty days of the Board's decision. The Board shall consider the appeal and issue a final decision concerning the appeal within sixty days after the Board receives the appeal.

(12) Final decisions as a result of such appeals are subject to judicial review.

Section 8. Use of Savings.

Any savings generated by a Health Plan, State Entity or Participating ERISA plan that are attributable to the implementation of an upper payment limit established by the Board shall be used to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs for Prescription Drugs. No later than April 1 of each calendar year, each State Entity, Health Plan and Participating ERISA Plan shall submit to the Board and to the Superintendent of Insurance a report describing the savings achieved as a result of implementing upper payment limits and how those savings were used to reduce costs to consumers.

Section 9. Manufacturer Withdrawal of a Drug from the State.

(1) Any manufacturer that intends to withdraw from sale or distribution within the state a Prescription Drug for which the Board has established an upper payment limit shall provide a notice of withdrawal in writing at least six months before the withdrawal to the Board, the Insurance Commissioner, the Attorney General, and any entity in the state with which the manufacturer has a contract for the sale or distribution of the drug.

(2) The Board shall assess a penalty not to exceed five hundred thousand dollars if the Board determines that a manufacturer failed to provide the notice required by subsection (1) of this section before withdrawing from sale or distribution within the state a Prescription Drug for which the Board has established an upper payment limit pursuant.

Section 10. Establishment of the Prescription Drug Affordability Fund.

(1) There is established the Prescription Drug Affordability Fund. The Fund is a non-lapsing account. The purpose of the fund is to provide resources to the Board to carry out the purpose of this Title.

(2) In addition to amounts generated as a result of the assessment required in Section 3(5) of this Title, the Fund shall also receive any other appropriations to the Fund by the legislature and any grants received by the Board.

(3) The legislature shall appropriate the sum of $_____ in in a non-lapsing fund for the purpose of funding initial operations of the Board.

Section 11. Report to the Governor and the Legislature.

On or before December 1 of each year, the Board shall submit a report to the Governor and the Legislature summarizing the activities of the Board during the preceding calendar year. The report shall include, but is not limited to, the following criteria:

(1) Publicly available data concerning price trends for Prescription Drugs;
(2) A list of the Prescription Drugs that were subjected to an affordability review by the Board pursuant to section, including the results of each affordability review;
(3) A list of each Prescription Drug for which the Board established an upper payment limit pursuant to Section 7, including the amount of the upper payment limit;
(4) With respect to each drug for which the Board conducted an affordability review how the Board determined whether the cost of the drug contributes to inequities in the availability of health care to communities of color or other underserved communities in the state;
(5) With respect to each drug for which the Board set an upper payment limit how the Board assessed the impact to communities of color, people with disabilities, and older adults;
(6) The known impact of any upper payment limits established by the Board pursuant to Section 7 on health care providers, pharmacies, and patients' ability to access any Prescription Drugs for which the Board has established upper payment limits;
(7) A summary of any appeals of decisions that were considered by the Board including a summary of the outcome of any such appeal;
(8) A description of each conflict of interest that was disclosed to the Board during the preceding year;
(9) A description of any violations of any of the provisions of the Title, including an indication of any enforcement action taken in response to any such violation; and
(10) Any recommendations the Board may have for the executive branch or the legislature concerning legislative and regulatory policy changes to increase the affordability of Prescription Drugs and reduce the effects of costs on consumers and the health care systems in the state.

Section 12. Severability.

If any provision of this Chapter or the application thereof is determined to be invalid, the invalidity does not affect other provisions or applications of this subchapter which can be given effect without the invalid provision or application, and to this end the provisions of this Chapter are severable.