

An Act to Protect [Name of State] Consumers from Unsupported Price Increases on Prescription Drugs

Section 1. Statement of Legislative Intent; Purpose

The purpose of this Chapter is to protect the safety, health and economic well-being of [Name of State] people by guarding them from the negative and harmful impact of unsupported price increases for prescription drugs. In enacting this Act, the legislature finds that:

- 1) Access to prescription drugs is necessary for XXXXX people to maintain or acquire good health;
- 2) Unsupported price increases negatively impact the ability of XXXXX people to obtain prescription drugs and thereby endanger the health and safety of XXXXXX people to maintain or acquire good health;
- 3) Unsupported price increases for prescription drugs threaten the economic well-being of XXXXXX people and endanger their ability to pay for other necessary and essential goods and services including housing, food and utilities;
- 4) Unsupported price increases for prescription drugs contribute significantly to a dramatic and unsustainable rise in health care costs and health insurance that threaten the overall ability of XXXXXX people to obtain health coverage and maintain or acquire good health;
- 5) Unsupported price increases for prescription drugs contribute significantly to rising state costs for health care provided and paid for through a) state-funded medical assistance programs for XXXXX people who are older, living with disabilities or have low incomes; and b) 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;
- 6) Analysis of the increase in prices charged by manufacturers of prescription drugs demonstrates that many price increases for high-cost and high-volume prescription drugs are not supported by adequate evidence of improved clinical benefit or by significant increase in costs to the manufacturer related to the production or sale of the product; and
- 7) Based on findings (1) through (6) the legislature finds that unsupported price increases for prescription drugs threaten the safety and well-being of XXXXXX people and find it is necessary to act in order to protect XXXXXX people from the negative impact of unsupported price increases.

Section 2. Definitions

- (a) "Prescription Drug" has the same meaning stated in [Cite to State's Pharmacy Act]
- (b) "Unsupported Price Increase" is an increase in price for a Prescription Drug for which there was no, or inadequate, new clinical evidence to support the price increase. In order to determine whether a price increase for a Prescription Drug is unsupported by new clinical evidence, the state shall utilize and rely upon the analyses of Prescription Drugs prepared annually by the Institute for Clinical and Economic Review (ICER) and published in its annual Unsupported Price Increase Report.

- (c) "Identified Drug" is any Prescription Drug that has at any time been identified as having an Unsupported Price Increase
- (d) "Wholesale Acquisition Cost" has the meaning stated in 42 U.S.C. § 1395w-3a.
- (e) "Consumer Price Index" means the Consumer Price Index, Annual Average, for All Urban Consumers, CPI-U: US City Average, All items, reported by the United States Department of Labor, Bureau of Labor Statistics, or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "Consumer Price Index" means a comparable index chosen by the Bureau of Labor Statistics.

Section 3. Penalty Imposed

- (a) A penalty shall be assessed on the sales within the state of Identified Drugs and payable by the manufacturers of the Identified Drugs. The penalty shall be calculated as described in subsection 3(b) below
- (b) The penalty in any calendar year shall equal 80 percent of the difference between the revenue generated by sales within the state of the Identified Drugs and the revenue that would have been generated if the manufacturer had maintained the Wholesale Acquisition Cost from the previous calendar year, adjusted for inflation utilizing the Consumer Price Index.
- (c) In order to be subject to the penalty a manufacturer must have at least \$250,000 in total annual sales within the state in the calendar year for which the tax is assessed.
- (d) Within sixty (60) days of the annual publication by ICER of the Unsupported Price Increase Report, the Tax Assessor shall identify the manufacturers of Identified Drugs. The Tax Assessor shall notify each manufacturer that sales within the state of Identified Drugs shall be subject to the penalty assessed in this Section for a period of two calendar years following the Identified Drug's appearance in the annual publication by ICER.
- (e) Such penalty shall be collected annually. Any manufacturer notified by the assessor pursuant to subsection (d) of this section shall submit to the Tax Assessor a return on a form prescribed and furnished by the Tax Assessor and pay the penalty by the XXth day of XXXXX for the previous calendar year.
- (f) The form described in subsection (e) above shall contain information including but not limited to:
 - (i) The total amount of sales of the Identified Drug within the state
 - (ii) The total number of units sold of the Identified Drug within the state
 - (iii) The Wholesale Acquisition Cost of the Identified Drug during the tax period and any changes in the Wholesale Acquisition Cost during the calendar year
 - (iv) The Wholesale Acquisition Cost during the previous calendar year
 - (v) A calculation of the penalty owed
 - (vi) Any other information that the Tax Assessor determines is necessary to calculate the correct amount of the penalty owed

(g) The failure by any manufacturer to file the return required by subsection (e) shall result in an additional penalty of 10 percent or \$50,000, whichever is greater.

Section 4. Use of Revenue

- (a) Revenue generated as a result of the penalty described in Section 3 above must be segregated into a separate fund and made available to the Superintendent of Insurance to offset costs to consumers. The Superintendent of Insurance may work in cooperation with other state agencies to determine the most effective method of optimizing the consumer benefit.
- (b) Upon request from the Tax Assessor, the Superintendent of Insurance may make funds generated as a result of the penalty available to the Tax Assessor for the purpose of ensuring sufficient resources are available to 1) assess and collect the penalty; 2) audit manufacturers that are required to submit returns pursuant to Section 3(f) above; and 3) defend appeals from manufacturers. The Superintendent of Insurance may grant such request only upon finding that there will be no significant negative impact on the availability of funds to provide the consumer impact described in subsection (a) above.
- (c) The Superintendent of Insurance shall on an annual basis submit a report to the legislature describing 1) the amount of revenue that had been generated in the previous year on account of the penalty segregated by manufacturer and product; 2) the current amount available for use as a result of the tax; 3) how the tax revenue has been utilized to benefit consumers pursuant to subsection (a) above; and 4) funds made available to the Tax Assessor pursuant to subsection (b) above.
- (d) Any revenue in excess of the administrative costs described in subsection (a) above

Section 5. Prohibition on Withdrawal of Prescription Drugs for Sale

- (a) It shall be a prohibition of this Chapter for any manufacturer or distributor of an Identified Drug to withdraw that drug from sale or distribution within this state for the purpose of avoiding the penalty set forth in Section 3 above.
- (b) Any manufacturer who intends to withdraw an Identified Drug from sale or distribution from within the state in order to avoid a penalty as described in Section 3 of this part shall provide a notice of withdrawal in writing to the Board of Pharmacy and to the Attorney General 180 days prior to such withdrawal.
- (c) The Attorney General shall assess a penalty of \$500,000 on any entity, including any manufacturer or distributor of an Identified Drug, that it determines has withdrawn an Identified Drug from distribution or sale in the state in violation of subsection (a) or (b) of this Section.