HOUSE DOCKET, NO. 1646 FILED ON: 2/10/2021

HOUSE . . . . . No. 1272

The Commonwealth of Massachusetts

PRESENTED BY:

Kate Hogan

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to promote transparency in prescription drug prices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Kate Hogan	*3rd Middlesex*	*2/10/2021*

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HOUSE . . . . . No. 1272

By Ms. Hogan of Stow, a petition (accompanied by bill, House, No. 1272) of Kate Hogan relative to the pricing of prescription drugs. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. *1162* OF 2019-2020.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

An Act to promote transparency in prescription drug prices.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Chapter 6D is amended by adding the following new Sections:

Section 20- PHARMACEUTICAL COST TRANSPARENCY

(a) As used in this section:

(1) "Manufacturer" means the person that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or the license issued under section 351 of the Public Health Service Act, or who is responsible for setting the price for the drug.

(2) "Prescription drug" means a drug as defined in 21 U.S.C. § 321.

(b)(1) The Health Policy Commission, in collaboration with the Center for Health Information and Analysis, shall identify annually up to 15 prescription drugs on which the State

spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, or is a new drug whose price may have a significant impact on the cost benchmark.

The drugs identified shall represent different drug classes.

(2) The Commission shall provide to the Office of the Attorney General the list of prescription drugs developed pursuant to this subsection and the percentage of the wholesale acquisition cost increase for each drug and shall make the information available to the public on the Commission's website.

(c)(1) For each prescription drug identified pursuant to subsection (b) of this section, the Office of the Attorney General shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug in a format that the Attorney General determines to be understandable and appropriate. The manufacturer shall submit to the Office of the Attorney General all relevant information and supporting documentation necessary to justify the manufacturer's wholesale acquisition cost increase, which may include:

(A) all factors that have contributed to the wholesale acquisition cost increase;

(B) the percentage of the total wholesale acquisition cost increase attributable to each factor; and

(C) an explanation of the role of each factor in contributing to the wholesale acquisition cost increase.

(2) Nothing in this section shall be construed to restrict the legal ability of a prescription drug manufacturer to changes prices to the extent permitted under federal law.

(d) The Attorney General shall provide an Annual Prescription Drug Transparency Report to the Legislature, the Health Policy Commission and the Center for Health Information and Analysis on or before December 1 of each year based on the information received from manufacturers pursuant to this section. The Attorney General shall also post the report on the Office of the Attorney General's website.

(e) (2) In carrying out this section the Attorney General and the Health Policy Commission shall ensure the protection of confidential commercial information and trade secrets.

(f) The Attorney General may bring an action for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer that fails to provide the information required by subsection (c) of this section a civil penalty of no more than $10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate violation.

Section 21- REPORT ON PRICE INCREASES

(a) As used in this section:

(1) Average Manufacturer Price has the meaning given the term in section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)).

(2) "Manufacturer" means the person that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or the license issued under section 351 of the Public Health Service Act, or who is responsible for setting the price for the drug.

(b)(1) The manufacturer of a prescription drug shall submit a report to the Health Policy Commission for each price increase of a prescription drug that will result in an increase in the

average manufacturer price of that drug that is equal to 10 percent or more over a 12-month period or the introduction of a new drug whose price may threaten the cost benchmark.

(2) Each report described in paragraph (1) shall be submitted to the Health Policy Commission not later than 30 days prior to the planned effective date of such price increase.

(c) A report under subsection (b) shall, at a minimum, include:

(1) With respect to the prescription drug—

(A) the percentage by which the manufacturer will raise the average manufacturer price of the drug on the planned effective date of such price increase;

(B) a justification for, and description of, each manufacturer's price increase that occurred during the 12-month period described in subsection (b)(1);

(C) the identity of the initial developer of the drug;

(D) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or since the manufacturer acquired such approved application or license;

(E) the current list price of the drug;

(F) the total expenditures of the manufacturer on—

(i) materials and manufacturing for such drug; and

(ii) acquiring patents and licensing for such drug;

(G) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds;

(H) the total expenditures of the manufacturer on research and development for such drug that is used for—

(i) basic and preclinical research;

(ii) clinical research;

(iii) new drug development;

(iv) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act; and

(v) carrying out post market requirements related to such drug, including those under section 505(o)(3) of such Act;

(I) the total revenue and the net profit generated from the prescription drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or since the manufacturer acquired such approved application or license; and

(J) the total costs associated with marketing and advertising for the prescription drug;

(2) With respect to the manufacturer:

(A) the total revenue and the net profit of the manufacturer for the 12-month period described in subsection (b)(1);

(B) the amount the manufacturer has spent on dividends and stock repurchases and the specific metrics used by the manufacturer to determine executive compensation, including any stock-based performance metrics, for the 12-month period described in subsection (b)(1); and

(C) the amount the manufacturer has provided in funding to consumer and disease advocacy groups for the 12-month period described in subsection (b)(1);

(D) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

(i) drug research and development; or

(ii) clinical trials on drugs that failed to receive approval by the Food and Drug Administration; and

(3) such other related information as the Health Policy Commission considers appropriate.

(d) The Attorney General may bring an action for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer that fails to provide the information required by subsections (b) and (c) of this section a civil penalty of no more than $10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate violation.

(e)(1) Not later than 30 days after the submission of a report under subsection (b), the Health Policy Commission shall post the report on the public website of the Commission.

(2) In carrying out this section the Health Policy Commission shall ensure the protection of confidential commercial information and trade secrets.