HOUSE DOCKET, NO. 3326 FILED ON: 1/20/2023

HOUSE . . . . . No. 1201

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*	*1/18/2023*

HOUSE DOCKET, NO. 3326 FILED ON: 1/20/2023

HOUSE . . . . . No. 1201

By Representative Hogan of Stow, a petition (accompanied by bill, House, No. 1201) of Kate Hogan relative to the pricing of prescription drugs. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. *1272* OF 2021-2022.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court
(2023-2024)

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:

SECTION 1. Section 1 of Chapter 6D of the General Laws is hereby amended by inserting after the definition of "Performance penalty" the following definition: -

"Pharmaceutical manufacturing company", an entity engaged in the: (i) production, preparation, propagation, compounding, conversion or processing of prescription drugs, directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that "pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

SECTION 2. Section 8 of said chapter 6D, as so appearing, is further amended by inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmaceutical manufacturing company.

SECTION 3. Said section 8 of said chapter 6D, as so appearing, is further amended by inserting after the word “organizations”, in line 14, the following words:- , pharmaceutical manufacturing companies.

SECTION 4. Said section 8 of said chapter 6D, as so appearing, is further amended by inserting after the word “commission”, in line 59, the first time it appears, the following words:- ; and (iii) in the case of pharmaceutical manufacturing companies, testimony concerning factors underlying prescription drug costs and price increases including, but not limited to, the initial prices of drugs coming to market and subsequent price increases, changes in industry profit levels, marketing expenses, reverse payment patent settlements, the availability of alternative drugs or treatments and any other matters as determined by the commission

SECTION 5. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the second sentence and inserting in place thereof the following sentence:- The report shall be based on the commission’s analysis of information provided at the hearings by witnesses, providers, provider organizations, payers, and pharmaceutical manufacturing companies, registration data collected under section 11, data collected or analyzed by the center under sections 8, 9, 10, and 10A of chapter 12C and any other available information that the commission considers necessary to fulfill its duties under this section as defined in regulations promulgated by the commission.

SECTION 6. Section 9 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “organization”, in line 72, the following words:- , pharmaceutical manufacturing company.

SECTION 7. Said chapter 6D is further amended by inserting after section 19 the following new section:-

SECTION 20. Pharmaceutical Cost Transparency

(a) As used in this section, the following terms shall have the following meanings:-

Pharmaceutical manufacturing company”, an entity engaged in the: (i) production, preparation, propagation, compounding, conversion or processing of prescription drugs, directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that “pharmaceutical manufacturing company” shall not include a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

“Prescription 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 25 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 growth

benchmark. When determining whether a drug price may have a significant impact on the cost growth benchmark, the commission shall consider both the volume of prescriptions issued in the commonwealth and single dose wholesale acquisition cost.

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 commission shall require the drug's pharmaceutical manufacturing company to provide a justification for the increase in the wholesale acquisition cost of the drug in a format that the commission determines to be understandable and appropriate. The pharmaceutical manufacturing company shall submit to the commission 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 pharmaceutical manufacturing company to changes prices to the extent permitted under federal law.

(d) The commission shall publish an Annual Prescription Drug Transparency Report on or before December 1 of each year based on the information received from pharmaceutical manufacturing companies pursuant to this section.

(e) In carrying out this section, the commission shall ensure the protection of confidential commercial information and trade secrets.

(f) The commission shall promulgate regulations to implement and enforce this section and may impose financial penalties on a pharmaceutical manufacturing company that fails to provide the information required by subsection (c) of this section in an amount not to exceed $10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate violation.

SECTION 8. Said chapter 6D, as so appearing, is further amended by inserting after section 20 the following new section:-

SECTION 20A. Transparency in Patient Advocacy

The commission shall require a pharmaceutical manufacturing company to annually disclose payments and other transfers of value provided to a patient advocacy organization, consumer advocacy organization, voluntary health agency, or a coalition of such organizations, including a disease-specific advocacy organization. The commission shall issue an annual report identifying the payments or other transfers of value made by manufacturers to a patient advocacy

organization, consumer advocacy organization, voluntary health agency, or a coalition of such organizations, including a disease-specific advocacy organization and analyzing the impact of such payments or transfers of value on health care public policy in the commonwealth.

SECTION 9. Said chapter 6D is further amended by inserting after section 20 the following new section:-

SECTION 21. Early Notice of High Cost Drugs

(a) As used in this section, the following terms have the following meanings:-

"Average Manufacturer Price", as defined in section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)).

"Pharmaceutical manufacturing company", an entity engaged in the: (i) production, preparation, propagation, compounding, conversion or processing of prescription drugs, directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that "pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

(b)(1) A pharmaceutical manufacturing company shall submit a report to the commission notifying the commission of 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

either due to anticipated volume of prescriptions filled in the commonwealth or the increase in the average manufacturer price for a single dose.

(2) Each report described in paragraph (1) shall be submitted to the 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 pharmaceutical manufacturing company 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 pharmaceutical manufacturing company’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 pharmaceutical manufacturing company '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 pharmaceutical manufacturing company acquired such approved application or license;

(E) the current list price of the drug;

(F) the total expenditures of the pharmaceutical manufacturing company 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 pharmaceutical manufacturing company on research and development for such drug that was derived from Federal funds;

(H) the total expenditures of the pharmaceutical manufacturing company 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 pharmaceutical manufacturing company 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 pharmaceutical manufacturing company:

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

(B) the amount the pharmaceutical manufacturing company has spent on dividends and stock repurchases and the specific metrics used by the pharmaceutical manufacturing company 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 pharmaceutical manufacturing company 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 commission considers appropriate.

(d) The commission shall promulgate regulations to implement and enforce this section and may impose financial penalties on a pharmaceutical manufacturing company that fails to provide the information required by subsection (c) of this section in an amount not to exceed $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 commission shall post the report on the public website of the commission.

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

SECTION 10. Section 1 of chapter 12C of the General Laws, as so appearing, is hereby amended by inserting after the definition of “Patient-centered medical home” the following definition:-

“Pharmaceutical manufacturing company”, an entity engaged in the: (i) production, preparation, propagation, compounding, conversion or processing of prescription drugs, directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that “pharmaceutical manufacturing company” shall not include a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

SECTION 11. Section 3 of said chapter 12C, as so appearing, is hereby amended by inserting after the word “organizations”, in lines 13 and 14, the following words:- , pharmaceutical manufacturing companies.

SECTION 12. Said section 3 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 24, the words “and payer” and inserting in place thereof the following words:- , payer, and pharmaceutical manufacturing company.

SECTION 13. Section 5 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 15, the words “and affected payers” and inserting in place thereof the following words:- affected payers, and affected pharmaceutical manufacturing companies.

SECTION 14 Said chapter 12C is hereby further amended by inserting after section 10 the following new section:-

Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform reporting of information from pharmaceutical manufacturing companies that enables the center to analyze: (i) year-over-year changes in wholesale acquisition cost and average manufacturer price for prescription drug products; (ii) year-over-year trends in net expenditures; (iii) net expenditures on subsets of biosimilar, brand name and generic drugs identified by the center; (iv) trends in estimated aggregated drug rebates, discounts or other remuneration paid or provided by a pharmaceutical manufacturing company to a pharmacy benefit manager, wholesaler, distributor, health carrier client, health plan sponsor or pharmacy in connection with utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing company; (v) discounts provided by a pharmaceutical manufacturing company to a consumer in connection with utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing company, including any discount, rebate, product voucher, coupon or other reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii) annual marketing and advertising costs, identifying costs for direct-to-consumer advertising; (viii) annual profits over the most recent 5-year period; (ix) cost disparities between prices charged to purchasers in the commonwealth and purchasers outside of the United States; and (x) any other information deemed necessary by the center.

The center shall require the submission of available data and other information from pharmaceutical manufacturing companies including, but not limited to: (i) changes in wholesale

acquisition costs and average manufacturer prices for prescription drug products as identified by the center; (ii) aggregate, company-level research and development costs to the extent attributable to a specific product and other relevant capital expenditures for the most recent year for which final audited data are available for prescription drug products as identified by the center; (iii) annual marketing and advertising expenditures; and (iv) a description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition costs and average manufacturer prices for prescription drug products as identified by the center.

(b) Except as specifically provided otherwise by the center or under this chapter, data collected by the center pursuant to this section from pharmaceutical manufacturing companies shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 or under chapter 66.

SECTION 15. Said chapter 12C is hereby further amended by striking out section 11, as appearing in the 2018 Official Edition, and inserting in place thereof the following section:-

Section 11. The center shall ensure the timely reporting of information required under sections 8, 9, 10 and 10A. The center shall notify payers, providers, provider organizations, and pharmaceutical manufacturing companies of any applicable reporting deadlines. The center shall notify, in writing, a private health care payer, provider, provider organization, or pharmaceutical manufacturing company that it has failed to meet a reporting deadline and that failure to respond within 2 weeks of the receipt of the notice may result in penalties. The center may assess a penalty against a private health care payer, provider, provider organization, or pharmaceutical manufacturing company that fails, without just cause, to provide the requested information within 2 weeks following receipt of the written notice required under this section of not more

than $1,000 per week for each week of delay after the 2-week period following receipt of the written notice. Amounts collected under this section shall be deposited in the Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

SECTION 16. Section 12 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- ,

10 and 10A.

SECTION 17. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:-

The center shall publish an annual report based on the information submitted under: (i) sections 8, 9, 10 and 10A concerning health care provider, provider organization, private and public health care payer, and pharmaceutical manufacturing company costs, and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii) section 15 of said chapter 6D relative to quality data.

SECTION 18. The General Laws are hereby amended by inserting after chapter 63B the following new chapter: -

Chapter 63D. Penalty on drug manufacturers for excessive price increases

Section 1. As used in this section, the following terms shall have the following meanings:- “Commissioner”, the commissioner of revenue.

“Consumer price index”, the consumer price index for all urban consumers for Boston, as most recently reported by the federal Bureau of Labor Statistics.

"Drug", any medication, as identified by a National Drug Code, approved for sale by the U.S. Food and Drug Administration.

"Excessive price," the price of a drug if it exceeds the sum of (a) the reference price of that drug, as adjusted for any increase or decrease in the consumer price index since the reference price was determined, and (b) an additional two percent of the reference price for each twelve-month period that has elapsed since the date on which the reference price was determined. The two percent increment provided in (b) of the preceding sentence shall compound annually on the first day of the first calendar quarter commencing after the end of each 12-month period described therein.

"Excessive price increase", the amount by which the price of a drug exceeds the sum of (a) the reference price of that drug, as adjusted for any increase or decrease in the consumer price index since the reference price was determined, and (b) an additional two percent of the reference price for each twelve-month period that has elapsed since the date on which the reference price was determined. The two percent increment provided in (b) shall compound annually on the first day of the first calendar quarter commencing after the end of each twelve-month period described therein.

"Person", any natural person or legal entity.

"Price", the wholesale acquisition cost of a drug, per unit, as reported to the First Data Bank or other applicable price compendium designated by the commissioner.

"Reference price", the price of a drug as of October 1, 2019, or in the case of any drug first commercially marketed in the United States after October 1, 2019, the price of the drug on the date when first marketed.

"Related party", an entity is a related party with respect to a person if that entity belongs to the same affiliated group as that person under section 1504 of the Internal Revenue Code, as amended and in effect for the taxable year, or if the entity and the person are otherwise under common ownership and control.

"Unit", the lowest dispensable amount of a drug.

Section 2. (a) Any person who manufactures and sells drugs, directly or through another person, for distribution in the commonwealth and who establishes an excessive price for any such drug directly or in cooperation with a related party, shall pay a per unit penalty on all units of the drug ultimately dispensed or administered in the commonwealth. The penalty for each unit shall be 80 percent of the excessive price increase for each unit, determined at the beginning of the calendar quarter.

(b) A person who establishes an excessive price for a drug as described in subsection (a) shall file a return as provided in section 4 declaring all units of excessively priced drug sold for distribution in the commonwealth during the quarter. In the event that a person filing such a return pays a penalty with regard to one or more units of drug that are ultimately dispensed or administered outside of the commonwealth, the person may claim a credit for such penalty amounts on the return for the tax period during which such units are ultimately dispensed or administered.

Section 3. The penalty under section 2 shall apply for any calendar quarter only to a person who maintains a place of business in the commonwealth or whose total sales of all products, directly or through another person, for distribution in the commonwealth were more

than $100,000 in the prior twelve-month period. The penalty shall not apply more than once to any unit of drug sold.

Section 4. Any person subject to the penalty under section 2 shall file a return with the commissioner and shall pay the penalty by the fifteenth day of the third month following the end of each calendar quarter, subject to such reasonable extensions of time for filing as the commissioner may allow. The return shall set out the person's total sales subject to penalty in the immediately preceding calendar quarter and shall provide such other information as the commissioner may require.

Section 5. The penalty imposed under this chapter shall be in addition to, and not a substitute for or credit against, any other penalty, tax or excise imposed under the General Laws.

Section 6. The commissioner may disclose information contained in returns filed under this chapter to the department of public health for purposes of verifying that a filer's sales subject to penalty are properly declared and that all reporting is otherwise correct. Return information so disclosed shall remain confidential and shall not be public record.

Section 7. To the extent that a person subject to penalty under section 2 fails to pay amounts due under this chapter, a related party of such person that directly or indirectly distributes in the commonwealth any drug whose sales are subject to this chapter shall be jointly and severally liable for the penalty due.

Section 8. The commissioner may promulgate regulations or issue other guidance for the implementation of this chapter.