HOUSE DOCKET, NO. 3101 FILED ON: 1/20/2017

HOUSE . . . . . No. 3223

The Commonwealth of Massachusetts

PRESENTED BY:

Christine P. Barber

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:
Christine P. Barber	*34th Middlesex*	*1/20/2017*
Jason M. Lewis	*Fifth Middlesex*	*12/20/2017*
Marjorie C. Decker	*25th Middlesex*	*12/20/2017*
Carmine L. Gentile	*13th Middlesex*	*12/20/2017*
Mike Connolly	*26th Middlesex*	*12/20/2017*
Kenneth I. Gordon	*21st Middlesex*	*12/20/2017*
Daniel Cullinane	*12th Suffolk*	*12/20/2017*
Carolyn C. Dykema	*8th Middlesex*	*12/20/2017*
Paul R. Heroux	*2nd Bristol*	*12/20/2017*
Michael S. Day	*31st Middlesex*	*12/20/2017*
Dylan Fernandes	*Barnstable, Dukes and Nantucket*	*12/20/2017*
Chris Walsh	*6th Middlesex*	*12/20/2017*
Patricia D. Jehlen	*Second Middlesex*	*12/20/2017*
Mary S. Keefe	*15th Worcester*	*12/20/2017*

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HOUSE . . . . . No. 3223

By Ms. Barber of Somerville, a petition (accompanied by bill, House, No. 3223) of Christine P. Barber and others relative to further regulating prescription drug price increases. Public Health.

The Commonwealth of Massachusetts

In the One Hundred and Ninetieth General Court
(2017-2018)

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. Chapter 6D of the General Laws is amended by adding the following new Sections:

Section X- 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) 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 attorneys' 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 XX- 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.

SECTION 2. Chapter 6D of the General Laws is amended by striking section 8 and replacing it with the following new sections:

Section 8.

(a) Not later than October 1 of every year, the commission shall hold public hearings based on the report submitted by the center for health information and analysis under section 16 of chapter 12C comparing the growth in total health care expenditures to the health care cost growth benchmark for the previous calendar year. The hearings shall examine health care provider, provider organization, prescription drug manufacturer and private and public health care payer costs, prices and cost trends, with particular attention to factors that contribute to cost growth within the commonwealth's health care system.

(b) The attorney general may intervene in such hearings.

(c) Public notice of any hearing shall be provided at least 60 days in advance.

(d) The commission shall identify as witnesses for the public hearing a representative sample of providers, provider organizations, prescription drug manufacturers, payers and others, including: (i) at least 3 academic medical centers, including the 2 acute hospitals with the highest level of net patient service revenue; (ii) at least 3 disproportionate share hospitals, including the 2 hospitals whose largest per cent of gross patient service revenue is attributable to Title XVIII and XIX of the federal Social Security Act or other governmental payers; (iii) community hospitals from at least 3 separate regions of the commonwealth; (iv) freestanding ambulatory surgical centers from at least 3 separate regions of the commonwealth; (v) community health centers from at least 3 separate regions of the commonwealth; (vi) the 5 private health care payers with the highest enrollments in the commonwealth; (vii) any managed care organization that provides

health benefits under Title XIX; (viii) the group insurance commission; (ix) at least 3 municipalities that have adopted chapter 32B; (x) at least 4 provider organizations, at least 2 of which shall be certified as accountable care organizations, 1 of which has been certified as a model ACO, which shall be from diverse geographic regions of the commonwealth; (xi) the prescription drug manufacturers whose drugs were identified in the latest Attorney General's Annual Prescription Drug Transparency Report and (xii) any witness identified by the attorney general or the center.

(e) Witnesses shall provide testimony under oath and subject to examination and cross examination by the commission, the executive director of the center and the attorney general at the public hearing in a manner and form to be determined by the commission, including, but not limited to: (i) in the case of providers and provider organizations, testimony concerning payment systems, care delivery models, payer mix, cost structures, administrative and labor costs, capital and technology cost, adequacy of public payer reimbursement levels, reserve levels, utilization trends, relative price, quality improvement and care-coordination strategies, investments in health information technology, the relation of private payer reimbursement levels to public payer reimbursements for similar services, efforts to improve the efficiency of the delivery system, efforts to reduce the inappropriate or duplicative use of technology and the impact of price transparency on prices; (ii) in the case of prescription drug manufacturers, testimony concerning all factors that have contributed to significant cost increases for their drugs, the percentage of cost increase attributable to each factor and an explanation of the role of each factor in contributing to such cost increases and their efforts in moving to value based drug pricing, and (iii) in the case of private and public payers, testimony concerning factors underlying premium cost and rate increases, the relation of reserves to premium costs, efforts by the payer to reduce

the use of fee-for-service payment mechanisms, the payer's efforts to develop benefit design, network design and payment policies that enhance product affordability and encourage efficient use of health resources and technology including utilization of alternative payment methodologies, efforts by the payer to increase consumer access to health care information, efforts by the payer to promote the standardization of administrative practices, the impact of price transparency on prices and any other matters as determined by the commission. The commission shall solicit testimony from any payer which has been identified by the center's annual report under subsection (a) of section 16 of chapter 12C as (1) paying providers more than 10 per cent above or more than 10 per cent below the average relative price or (2) entering into alternative payment contracts that vary by more than 10 per cent. Any payer identified by the center's report shall explain the extent of price variation between the payer's participating providers and describe any efforts to reduce such price variation.

(f) In the event that the center's annual report under subsection (a) of section 16 of chapter 12C finds that the percentage change in total health care expenditures exceeded the health care cost benchmark in the previous calendar year, the commission may identify additional witnesses for the public hearing. Witnesses shall provide testimony subject to examination and cross examination by the commission, the executive director of the center and attorney general at the public hearing in a manner and form to be determined by the commission, including, but not limited to: (i) testimony concerning unanticipated events that may have impacted the total health care cost expenditures, including, but not limited to, a public health crisis such as an outbreak of a disease, a public safety event or a natural disaster; (ii) testimony concerning trends in patient acuity, complexity or utilization of services; (iii) testimony concerning trends in input cost structures, including, but not limited to, the introduction of new

pharmaceuticals, medical devices and other health technologies; (iv) testimony concerning the cost of providing certain specialty services, including, but not limited to, the provision of health care to children, cancer-related health care and medical education; (v) testimony related to unanticipated administrative costs for carriers, including, but not limited to, costs related to information technology, administrative simplification efforts, labor costs and transparency efforts; (vi) testimony related to costs due the implementation of state or federal legislation or government regulation; and (vii) any other factors that may have led to excessive health care cost growth.

(g) The commission shall compile an annual report concerning spending trends and underlying factors, along with any recommendations for strategies to increase the efficiency of the health care system. The report shall be based on the commission's analysis of information provided at the hearings by providers, provider organizations and insurers, registration data collected under section 11, data collected by the center for health information and analysis under sections 8, 9 and 10 of chapter 12C and any other information the commission considers necessary to fulfill its duties under this section, as further defined in regulations promulgated by the commission. The report shall be submitted to the chairs of the house and senate committees on ways and means and the chairs of the joint committee on health care financing and shall be published and available to the public not later than December 31 of each year. The report shall include any legislative language necessary to implement the recommendations.