SENATE DOCKET, NO. 923 FILED ON: 1/19/2017

SENATE . . . . . No. 652

The Commonwealth of Massachusetts

PRESENTED BY:

Mark C. Montigny

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 and prevent price gouging of pharmaceutical drug prices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	
Mark C. Montigny	*Second Bristol and Plymouth*	
Jason M. Lewis	*Fifth Middlesex*	*2/3/2017*
Jose F. Tosado	*9th Hampden*	*1/23/2017*
Diana DiZoglio	*14th Essex*	*1/24/2017*
Steven Ultrino	*33rd Middlesex*	*1/26/2017*
Kenneth I. Gordon	*21st Middlesex*	*1/26/2017*
Harriette L. Chandler	*First Worcester*	*2/22/2017*
Marjorie C. Decker	*25th Middlesex*	*1/26/2017*
James J. Dwyer	*30th Middlesex*	*1/26/2017*
Kay Khan	*11th Middlesex*	*1/27/2017*
Patricia D. Jehlen	*Second Middlesex*	*1/27/2017*
Michael D. Brady	*Second Plymouth and Bristol*	*1/27/2017*
James R. Miceli	*19th Middlesex*	*1/29/2017*
Robert M. Koczera	*11th Bristol*	*2/3/2017*
Colleen M. Garry	*36th Middlesex*	*1/31/2017*
William Smitty Pignatelli	*4th Berkshire*	*1/31/2017*
Antonio F. D. Cabral	*13th Bristol*	*1/31/2017*
John F. Keenan	*Norfolk and Plymouth*	*1/31/2017*

Patrick M. O'Connor	*Plymouth and Norfolk*	*2/1/2017*
Paul R. Heroux	*2nd Bristol*	*2/1/2017*
James M. Cantwell	*4th Plymouth*	*2/1/2017*
Angelo M. Scaccia	*14th Suffolk*	*2/2/2017*
James B. Eldridge	*Middlesex and Worcester*	*2/2/2017*
Mike Connolly	*26th Middlesex*	*2/2/2017*
Kevin G. Honan	*17th Suffolk*	*2/3/2017*
Joan B. Lovely	*Second Essex*	*2/3/2017*
Elizabeth A. Malia	*11th Suffolk*	*2/3/2017*
Denise Provost	*27th Middlesex*	*2/3/2017*
Anne M. Gobi	*Worcester, Hampden, Hampshire and Middlesex*	*2/3/2017*

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By Mr. Montigny, a petition (accompanied by bill, Senate, No. 652) of Mark C. Montigny, Jason M. Lewis, Jose F. Tosado, Diana DiZoglio and other members of the General Court for legislation to promote transparency and prevent price gouging of pharmaceutical drug prices. Health Care Financing.

The Commonwealth of Massachusetts

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

An Act to promote transparency and prevent price gouging of pharmaceutical 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. Section1 of chapter 12C of the General Laws, as appearing in the 2014 official edition, is hereby amended by inserting after the word "outcomes." in line 204 the following 3 definitions:-

"Pharmacy benefit manager", any person or entity that administers the (i) prescription drug, prescription device or pharmacist services or (ii) prescription drug and device and pharmacist services portion of a health benefit plan on behalf of plan sponsors, including, but not limited to, self-insured employers, insurance companies and labor unions. A health benefit plan that does not contract with a pharmacy benefit manager shall be considered a pharmacy benefit manager for the purposes of this section, unless specifically exempted.

"Pharmaceutical manufacturing company", any entity that participates in a commonwealth health care program and which is engaged in the production, preparation,

propagation, compounding, conversion or processing of prescription drugs, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity engaged in the 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 36A of chapter 112 or a retail pharmacist registered under section 37 of said chapter 112.

"Prescription drug", a drug as defined by 21 U.S.C. § 321.

Section1 of chapter 12C, as so appearing, is hereby further amended by inserting at the end thereof the following definition:-

"Wholesale acquisition cost", the cost of a prescription drug as defined by 42 U.S.C. §1395w-3a(c)(6)(B).

SECTION 2. Chapter 12C of the General Laws, as so appearing, is hereby amended by inserting after section 10 the following section:-

Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform reporting of prescription drug wholesale acquisition costs, discounts, rebates and other such data as the center may require of pharmacy benefit managers, pharmaceutical manufacturing companies and health care payers in order to better protect the public's interest in monitoring the overall effect of prescription drug spending on total health care expenditure growth. At a minimum, such reporting shall identify prescriptions drugs sold within the Commonwealth that are (i) the ten costliest drugs by total private health care payer spending; (ii) the ten prescription drugs with the highest annual increase in total private health care payer spending; (iii)

prescriptions drug introduced to the U.S. market within the past ten years at a wholesale acquisition cost of $10,000 or more annually or per course of treatment; and (iv) prescription drugs whose wholesale acquisition cost has increased by 50% or more within the past five years or by 15% or more within the past one year.

(b) For each prescription drug identified under (a), the center shall require each pharmaceutical manufacturing company of said drug to report each factor contributing to the drug's cost or cost increase and the percentage of cost or cost increase attributable to each factor. Such information shall include, but not be limited to (i) total cost of production per year; (ii) approximate cost of production per dose; (iii) research and development costs of the drug paid for by the manufacturer, including the cost of clinical trials and other regulatory costs; (iv) research and development costs paid with public funds, including any amount from federal, state, or other governmental programs or any form of subsidies, grants or other support; (v) research and development costs paid by third parties; (vi) the price paid by the manufacturer to acquire the drug, if not developed by such manufacturer; (vii) annual marketing and advertising costs for the drug, apportioned by marketing activities that are directed to consumers and prescribers in the Commonwealth and consumers and prescribers nationally, as well as expenses lobbying government entities; (viii) average rebates, discounts, and other price concessions offered from the drug's list price per year; (ix) prices charged for the drug to purchasers outside the United States, by country; (x) prices charged for the drug to direct purchasers in the Commonwealth; (xi) prices paid for the drug by the United States Veterans Administration, if such drug is purchased by such agency; (xii) the average profit margin of the drug over the most recent five-year period and the projected profit margin anticipated for such drug in the coming year; (xiii) any additional information the manufacturer chooses to provide related to drug pricing decisions,

such as total expenditures on drug research and development or clinical trials on similar drugs that failed to receive approval by the Food and Drug Administration; and (xiv) such other information as the center may require.

SECTION 3. Section 11 of chapter 12C of the General Laws, as so appearing, is hereby amended by striking out in its entirety and inserting the new text:-

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, pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable reporting deadlines. The center shall notify, in writing, a private health care payer, provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing company, which has failed to meet a reporting deadline and that failure to respond within 2 weeks of the receipt of the notice shall result in penalties. The center shall assess a penalty against a private payer, provider, provider organization, pharmacy benefit manager, 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 paragraph, of up to $5,000 per week for each week of delay after the 2 week period following receipt of said written notice; provided, however, that the maximum annual penalty against a private payer, provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing company under this section shall be $200,000. Amounts collected under this section shall be deposited in equal amounts to the Healthcare Payment Reform Fund, established under section 100 of 194 of the acts of 2011, and for the expenses of the center pursuant to this chapter.

Any payer, provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that fails to comply with this section shall not be eligible for grants, subsidies or tax credits, breaks or exemptions pursuant to chapters 23I, 62, 63, 64H, and 64I of the General Laws.

The center may promulgate regulations to define "just cause" for the purpose of this section.

SECTION 4. Section 12 of chapter 12C of the General Laws, as so appearing, is hereby amended by striking the words "8, 9 and 10" in line 2 and inserting in place thereof the following:- 8, 9, 10, and 10A.

SECTION 5. Section 16 of chapter 12C of the General Laws, as so appearing, is hereby amended by striking the first sentence and inserting in place thereof the following:-

The center shall publish an annual report based on the information submitted under sections 8, 9, 10 and 10A concerning health care provider, provider organization, pharmacy benefit manager, pharmaceutical manufacturer and private and public health care payer costs and cost trends, section 13 of chapter 6D relative to market power reviews and section 15 relative to quality data.

SECTION 6. Section 11 of chapter 133 of the Acts of 2016 is hereby repealed.

SECTION 7. Section 17 of chapter 12C of the General Laws, as so appearing, is hereby amended by striking out in its entirety and inserting thereof the following new text:-

The attorney general may review and analyze any information submitted to the center under sections 8, 9, 10 and 10A and the health policy commission under section 8 of chapter 6D.

The attorney general may require that any provider, provider organization, or payer produce documents, answer interrogatories and provide testimony under oath related to health care costs and cost trends, factors that contribute to cost growth within the commonwealth's health care system and the relationship between provider costs and payer premium rates. The attorney general may require that any pharmacy benefit manager, pharmaceutical manufacturing company or payer produce documents, answer interrogatories and provide testimony under oath related to prescription drug costs and cost trends, factors that contribute to cost growth within the commonwealth's health care system and the relationship between prescription drug costs and payer premium rates. The attorney general shall keep confidential all nonpublic information and documents obtained under this section and shall not disclose the information or documents to any person without the consent of the provider, pharmacy benefit manager, pharmaceutical manufacturing company or payer that produced the information or documents except in a public hearing under section 8 of chapter 6D, a rate hearing before the division of insurance or in a case brought by the attorney general, if the attorney general believes that such disclosure will promote the health care cost containment goals of the commonwealth and that the disclosure should be made in the public interest after taking into account any privacy, trade secret or anti-competitive considerations. The confidential information and documents shall not be public records and shall be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66.

SECTION 8. Section 8 of chapter 6D of said General Laws is hereby amended by inserting after the word “organization” in line 7 the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company

Said section 8 is hereby further amended by inserting after the word “payers” in line 15 the following words:- , pharmacy benefit managers, pharmaceutical manufacturing companies

Said section 8 is hereby further amended by striking the words “and (xi) any witness identified by the attorney general or the center” in line 32 and inserting in place thereof the following:-

(xi) at least 1 pharmacy benefit manager; (xii) at least 3 pharmaceutical manufacturing companies; and (xiii) any witness identified by the attorney general or the center.

Said section 8 is hereby further amended by inserting after the word “commission” in line 59 the following words:-

; and (iii) in the case of pharmacy benefit managers and pharmaceutical manufacturing companies, testimony concerning factors underlying prescription drug costs and price increases, the impact of manufacturer rebates, discounts and other price concessions on net pricing, the availability of alternative drugs or treatments and any other matters as determined by the commission.

Said section 8 is hereby further amended by striking the words “sections 8, 9 and 10” in line 100 and inserting in place thereof the following words:- sections 8, 9, 10 and 10A

SECTION 9. Chapter 6D of said General Laws is hereby amended by inserting after section 10 the following new section:-

Section 10A. (a) The commission, in consultation with the center, shall annually identify those critical prescription drugs whose cost is excessively higher than justified and jeopardizes the commonwealth’s ability to meet the statewide health care cost growth benchmark, as

established by section 9. The commission, in consultation with the center, may identify an individual drug, or grouping of similarly situated prescription drugs, when determining whether such costs jeopardize the ability to meet the said cost growth benchmark. The commission, in consultation with the center, shall examine cost data for each such drug, or grouping of drugs, reported under this chapter and section 10A of chapter 12C to determine whether such costs are excessively higher than justified. In determining whether a drug's cost is excessively higher than justified, the commission, in consultation with the center, shall examine (i) the prescription drug's medical benefits; (ii) the cost to develop and manufacture the prescription drug; (iii) the prescription drug's potential cost savings versus alternative drugs or treatments; (iv) independent evaluations by not-for-profit entities comparing a drug's clinical effectiveness and value; and (v) the prices charged by the manufacturer to the United States Veterans Administration, if applicable, and purchasers outside of the United States.

(b) If the commission determines pursuant to subsection (a) that a prescription drug's cost is excessively higher than justified and jeopardizes the commonwealth's ability to meet the statewide health care cost growth benchmark, the commission shall take the following actions:

(1) Provide notice to the manufacturer, or manufacturers, that the cost of its prescription drug exceeds the health care cost growth benchmark for the given year, jeopardizing the commonwealth's ability to meet future health care cost growth benchmarks. Such notice shall also state that the prescription drug price has been deemed excessively higher than justified, potentially subjecting it to further legal action pursuant to chapter 93A of the General Laws and notification to the attorney general, secretary of health and human services and registered providers and payers within the commonwealth; and

(2) Notify the attorney general and secretary of health and human services that the prescription drug's cost has been identified as excessively higher than justified, warranting further action by the commonwealth; and

(3) Notify registered providers and payers within the commonwealth that the prescription drug's cost has been identified as excessively higher than justified; and

(4) Recommending further actions to be taken by the attorney general or secretary of health and human services, including but not limited to:

(i) Entering into voluntary settlements with the identified manufacturer(s) to negotiate additional rebates or other price concessions;

(ii) In the case of a prescription drug not subject to patent protection under Article I, Section 8 of the U.S. Constitution or the Patent Act (35 U.S.C.), initiating action under chapter 93A of the General Laws to protect the commonwealth and consumers against unfair practices;

(iii) Reviewing the efficacy and cost effectiveness of preferred drug lists or formularies, prior authorization, generic substitutions, multi-state purchasing agreements, supplemental rebates, cost-sharing or copayment arrangements, out-of-pocket limits, and any other appropriate cost savings methods as determined by the secretary of health and human services.

SECTION 10. Section 2 of chapter 93A of the General Laws, as so appearing, is hereby amended by inserting after subsection (c) the following new subsection:-

(d) The attorney general may promulgate regulations to define prescription drug prices excessively higher than justified, under section 10A of chapter 6D, as an "unfair practice"

prohibited by this section. Such regulations shall not be inconsistent with the rules, regulations and decisions of the Federal Trade Commission and the Federal Courts interpreting the provisions of 15 U.S.C. 45(a)(1) (The Federal Trade Commission Act), as from time to time amended..

SECTION 11. Chapter 93A of the General Laws, as so appearing, is hereby amended by inserting after section 4 the following new section:-

Section 4A. For prescription drugs identified under section 10A of chapter 6D and not subject to patent protection under Article I, Section 8 of the U.S. Constitution or the Patent Act (35 U.S.C.), the attorney general may bring an action under section 4 or, in lieu of such action, negotiate a state excess drug cost rebate to be paid by the drug's manufacturer. Such excess drug cost rebates collected pursuant to this section shall be credited to the Vaccine Purchase Trust Fund, established under section 24N of chapter 111, the Prescription Advantage Senior Pharmacy Program, established under section 39 of chapter 19A, and any other preventative public health initiatives as recommended by the secretary of health and human services that support children, seniors, and low-income populations in the commonwealth.