SENATE DOCKET, NO. 2059 FILED ON: 1/18/2019

SENATE . . . . . No. 712

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*	
James B. Eldridge	*Middlesex and Worcester*	*1/30/2019*
Paul R. Feeney	*Bristol and Norfolk*	*1/25/2019*
Michael J. Barrett	*Third Middlesex*	*2/1/2019*
Anne M. Gobi	*Worcester, Hampden, Hampshire and Middlesex*	*1/30/2019*
Bruce E. Tarr	*First Essex and Middlesex*	*1/30/2019*
Christopher Hendricks	*11th Bristol*	*1/29/2019*
Patrick M. O'Connor	*Plymouth and Norfolk*	*1/29/2019*
Rebecca L. Rausch	*Norfolk, Bristol and Middlesex*	*1/30/2019*
Michael D. Brady	*Second Plymouth and Bristol*	*1/31/2019*
Diana DiZoglio	*First Essex*	*1/31/2019*
Donald F. Humason, Jr.	*Second Hampden and Hampshire*	*1/31/2019*
Michael O. Moore	*Second Worcester*	*2/1/2019*

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SENATE . . . . . No. 712

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 712) of Mark C. Montigny, James B. Eldridge, Paul R. Feeney, Michael J. Barrett and other members of the General Court for legislation to promote transparency and prevent price gouging of pharmaceutical drug prices. Health Care Financing.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. *652* OF 2017-2018.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-First General Court
(2019-2020)

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. Section 1 of chapter 6D of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Performance penalty" the following 2 definitions:-

"Pharmaceutical manufacturing company", an entity engaged in the production, preparation, propagation, conversion or processing of prescription drugs, 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 an 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 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

"Pharmacy benefit manager", a person or entity that administers: (i) a prescription drug, prescription device or pharmacist services; or (ii) a prescription drug and device and pharmacist services portion of a health benefit plan on behalf of a plan sponsor including, but not limited to, self-insured employers, insurance companies and labor unions; provided, however, that "Pharmacy benefit manager" shall include a health benefit plan that does not contract with a pharmacy benefit manager and administers its own: (a) prescription drug, prescription device or pharmacist services; or (b) prescription drug and device and pharmacist services portion, unless specifically exempted by the center.

SECTION 2. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by inserting after the definition of "Physician" the following definition:-

"Pipeline drugs", prescription drug products containing a new molecular entity for which the sponsor has submitted a new drug application or biologics license application and received an action date from the federal Food and Drug Administration.

SECTION 3. Section 6 of said chapter 6D, as so appearing, is hereby amended by adding the following paragraph:-

If the analysis of spending trends with respect to the pharmaceutical or biopharmaceutical products increases the expenses of the commission, the estimated increases in the commission's expenses shall be assessed fully to pharmaceutical manufacturing companies and pharmacy benefit managers in the same manner as the assessment under section 68 of chapter 118E. A pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and

administers its own prescription drug, prescription device or pharmacist services or prescription drug and device and pharmacist services portion shall not be subject to additional assessment under this paragraph.

SECTION 4. Section 8 of said chapter 6D, as so appearing, is hereby amended by striking out, in line 32, the words " and (xi) " and inserting in place thereof the following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least 1 pharmacy benefit manager; and (xiii).

SECTION 5. Said section 8 of said chapter 6D of the General Laws, as so appearing, is hereby amended by inserting after the word "commission", in line 59, the first time it appears, 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.

SECTION 6. Said chapter 6D is hereby further amended by inserting after section 15 the following section:-

Section 15A. (a) The commission shall conduct an annual study of pharmaceutical manufacturing companies with pipeline drugs, generic drugs or biosimilar drug products that may have a significant impact on statewide health care expenditures; provided, however, that the commission may issue interim studies if it deems it necessary. The commission may contract with a third-party entity to implement this section that has familiarity with the development and

approval of pharmaceuticals or biologics or studies and compares the clinical effectiveness and value of prescription drugs.

(b) A pharmaceutical manufacturing company shall, provide early notice to the commission for: (i) a pipeline drug; (ii) an abbreviated new drug application for generic drugs, upon submission to the federal Food and Drug Administration; or (iii) a biosimilar biologics license application upon the receipt of an action date from the federal Food and Drug Administration. The commission shall make early notice information available to the office of Medicaid or another agency in addition to acute hospitals, ambulatory surgical centers and surcharge payors, as deemed appropriate.

Early notice shall be submitted to the commission not later than 60 days after receipt of the federal Food and Drug Administration action date or after the submission of an abbreviated new drug application to the federal Food and Drug Administration action.

For each prescription drug product, early notice shall include a brief description of the: (i) primary disease, health condition or therapeutic area being studied and the indication; (ii) route of administration being studied; (iii) clinical trial comparators; and (iv) estimated year of market entry. To the extent possible, information shall be collected using data fields consistent with those used by the federal National Institutes of Health for clinical trials.

For each pipeline drug, early notice shall include whether the drug has been designated by the federal Food and Drug Administration: (i) orphan drug; (ii) fast track; (iii) breakthrough therapy; (iv) for accelerated approval; or (v) priority review for a new molecular entity.

Notwithstanding the foregoing, submissions for drugs in development that receive such a designation by the federal Food and Drug Administration for new molecular entities shall be provided as soon as practical upon receipt of the relevant designation.

(c) The commission shall assess pharmaceutical manufacturing companies for the implementation of this section in a similar manner to the annual registration fees and other assessments related to the annual marketing disclosure reports required under section 2A of chapter 111N.

(d) Notwithstanding any general or special law to the contrary, information provided under this section shall be protected as confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 or under chapter 66.

SECTION 7. Chapter 12 of the General Laws, as so appearing, is hereby amended by striking out section 11N and inserting in place thereof the following section:-

Section 11N. (a) The attorney general shall monitor trends in the health care market including, but not limited to, trends in provider organization size and composition, consolidation in the provider market, payer contracting trends, patient access and quality issues in the health care market and prescription drug cost trends. The attorney general may obtain the following information from a private health care payer, public health care payer, pharmaceutical manufacturing company, pharmacy benefit manager, provider or provider organization as any of those terms may be defined in section 1 of chapter 6D: (i) any information that is required to be submitted under sections 8, 9 10 and 10A of chapter 12C; (ii) filings, applications and supporting documentation related to any cost and market impact review under section 13 of said chapter 6D; (iii) filings, applications and supporting documentation related to a determination of need

application filed under section 25C of chapter 111; and (iv) filings, applications and supporting documentation submitted to the federal Centers for Medicare and Medicaid Services or the Office of the Inspector General for any demonstration project. Under section 17 of said chapter 12C and section 8 of said chapter 6D and subject to the limitations stated in those sections, the attorney general may require that any provider, provider organization, pharmaceutical manufacturing company, pharmacy benefit manager, private health care payer or public health care payer produce documents, answer interrogatories and provide testimony under oath related to health care costs and cost trends, pharmaceutical costs, pharmaceutical cost trends, the factors that contribute to cost growth within the commonwealth's health care system and the relationship between provider costs and payer premium rates and the relationship between pharmaceutical drug costs and payer premium rates.

(b) The attorney general may investigate any provider organization referred to the attorney general by the health policy commission under section 13 of chapter 6D to determine whether the provider organization engaged in unfair methods of competition or anticompetitive behavior in violation of chapter 93A or any other law and, if appropriate, take action under said chapter 93A or any other law to protect consumers in the health care market.

(c) The attorney general may investigate a pharmaceutical manufacturing company or pharmacy benefit manager referred to the attorney general by the center for health information and analysis under section 11 of chapter 12C to determine whether the pharmaceutical manufacturing company or pharmacy benefit manager engaged in unfair methods of competition or anticompetitive behavior in violation of chapter 93A or any other law and, if appropriate, take action under said chapter 93A or any other law to protect consumers in the health care market.

(d) The attorney general may intervene or otherwise participate in efforts by the commonwealth to obtain exemptions or waivers from certain federal laws regarding provider market conduct, including, from the federal Office of the Inspector General, a waiver or expansion of the safe harbors' provided for under 42 U.S.C. § 1320a-7b and obtaining from the federal Office of the Inspector General a waiver of or exemption from 42 U.S.C. § 1395nn subsections (a) to (e), inclusive.

(e) Nothing in this section shall limit the authority of the attorney general to protect consumers in the health care market under any other law.

SECTION 8. 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 analysis of information regarding pharmaceutical manufacturing companies and pharmacy benefit managers and that enable the center to analyze: (i) year-over-year wholesale acquisition cost changes; (ii) year-over-year trends in net expenditures; (iii) net expenditures on subsets of brand and generic pharmaceuticals identified by the center; (iv) research and development costs as a percentage of revenue, costs paid with public funds and costs paid by third parties, to the extent such costs are attributable to a specific product or set of products; (v) annual marketing and advertising costs, identifying costs for direct-to-consumer advertising; (vi) annual profits over the most recent 5-year period; (vii) information regarding trends of estimated aggregate drug rebates and other price reductions paid by a pharmaceutical manufacturing company in connection with utilization of all pharmaceutical drug products offered by the pharmaceutical manufacturing company; (viii) information regarding trends of estimated aggregate drug rebates

and other price reductions paid by a pharmacy benefit manager in connection with utilization of all drugs offered through the pharmacy benefit manager; (ix) information regarding pharmacy benefit manager practices in passing drug rebates or other price reductions received by the pharmacy benefit manager to a private or public health care payer or to the consumer; (x) information regarding discount or free product vouchers that a retail pharmacy provides to a consumer in connection with a pharmacy service, item or prescription transfer offer or to any discount, rebate, product voucher or other reduction in an individual's out-of-pocket expenses, including co-payments and deductibles under section 3 of chapter 175H; (xi) cost disparities between prices charged to purchasers in the commonwealth and purchasers outside of the United States and (xii) any other information deemed necessary by the center.

(b) The center shall require the submission of available data and other information from pharmaceutical manufacturing companies and pharmacy benefit managers including, but not limited to: (i) changes in wholesale acquisition costs for prescription drug products as identified by the center; (ii) aggregate, company-level and product-specific research and development to the extent attributable to a specific product or products 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) the price paid by the manufacturer to acquire the prescription drug product if not developed by the manufacturer; (iv) the 5-year history of any increases in the wholesale acquisition costs; (v) annual marketing and advertising expenditures apportioned by activities directed to consumers and prescribers for prescription drug products as identified by the center; and (vi) a description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition costs for prescription drug products as identified by the center.

SECTION 9. Section 11 of said chapter 12C is hereby amended by striking out in its entirety and inserting in place thereof the following:-

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 that it 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 health care 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 the written notice; provided, however, that the maximum annual penalty against a private health care 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 the Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

The center shall notify the attorney general of any pharmaceutical manufacturing company or pharmacy benefit manager that fails to comply with this section for further action pursuant to section 11N of chapter 12 or any other law.

For the purposes of this section, the center may promulgate regulations to define “just cause”.

SECTION 10. Said chapter 12C is hereby further amended by striking out section 17, as so appearing, and inserting thereof the following section:-

Section 17. The attorney general may review and analyze any information submitted to the center under sections 8, 9, 10, 10A and the health policy commission under section 8 of chapter 6D. The attorney general may require that any provider, provider organization, pharmaceutical manufacturing company, pharmacy benefit manager or payer produce documents, answer interrogatories and provide testimony under oath related to health care costs and cost trends, pharmaceutical 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 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, pharmaceutical manufacturing company, pharmacy benefit manager or payer that produced the information or documents except in a public hearing under said section 8 of said 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 shall be made in the public interest after taking into account any privacy, trade secret or anticompetitive 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.