SENATE DOCKET, NO. 2130 FILED ON: 1/20/2023

SENATE . . . . . No. 783

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*	
Michael J. Barrett	*Third Middlesex*	*1/30/2023*

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SENATE . . . . . No. 783

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 783) of Mark C. Montigny and Michael J. Barrett 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. *804* OF 2021-2022.]

The Commonwealth of Massachusetts

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

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 2020 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. Said chapter 6D is hereby further amended by adding the following 2 sections:-

Section 20. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Eligible drug", a (i) brand name drug or biologic, not including a biosimilar, that has a launch wholesale acquisition cost of $50,000 or more for a 1-year supply or full course of treatment; (ii) biosimilar drug that has a launch wholesale acquisition cost that is not at least 15 per cent lower than the referenced brand biologic at the time the biosimilar is launched; or (iii) public health essential drug, as defined in section 239 of chapter 111, with a significant price increase over a defined period of time as determined by the commission by regulation or with a wholesale acquisition cost of $25,000 or more for a 1-year supply or full course of treatment.

"Manufacturer", a pharmaceutical manufacturer of an eligible drug.

"Public health essential drug", shall have the same meaning as defined in section 239 of chapter 111.

(b) The commission shall review the impact of eligible drug costs on patient access; provided, however, that the commission may prioritize the review of eligible drugs based on potential impact to consumers.

In order to conduct a review of eligible drugs, the commission may require a manufacturer to disclose to the commission within a reasonable time period information relating to the manufacturer's pricing of an eligible drug. The disclosed information shall be on a standard reporting form developed by the commission with the input of the manufacturers and shall include, but not be limited to:

(i) a schedule of the drug's wholesale acquisition cost increases over the previous 5 calendar years;

(ii) the manufacturer's aggregate, company-level research and development and other relevant capital expenditures, including facility construction, for the most recent year for which final audited data are available;

(iii) a written, narrative description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition cost during the previous 5 calendar years; and

(iv) any other information that the manufacturer wishes to provide to the commission or that the commission requests.

(c) Based on the records furnished under subsection (b) and available information from the center for health information and analysis or an outside third party, the commission shall identify a proposed value for the eligible drug. The commission may request additional relevant information that it deems necessary.

Any information, analyses or reports regarding an eligible drug review shall be provided to the manufacturer. The commission shall consider any clarifications or data provided by the manufacturer with respect to the eligible drug. The commission shall not base its determination on the proposed value of the eligible drug solely on the analysis or research of an outside third party.

(d) If, after review of an eligible drug and after receiving information from the manufacturer under subsections (b) or (e), the commission determines that the manufacturer's pricing of the eligible drug does not substantially exceed the proposed value of the drug, the commission shall notify the manufacturer, in writing, of its determination and shall evaluate other ways to mitigate the eligible drug's cost in order to improve patient access to the eligible drug. The commission may engage with the manufacturer and other relevant stakeholders, including, but not limited to, patients, patient advocacy organizations, providers, provider organizations and payers, to explore options for mitigating the cost of the eligible drug. Upon the conclusion of a stakeholder engagement process under this subsection, the commission shall issue recommendations on ways to reduce the cost of the eligible drug for the purpose of improving patient access to the eligible drug. Recommendations may include, but not be limited to: (i) an alternative payment plan or methodology; (ii) a bulk purchasing program; (iii) co-pay, deductible, coinsurance or other cost-sharing restrictions; and (iv) a reinsurance program to subsidize the cost of the eligible drug. The recommendations shall be publicly posted on the

commission's website and provided to the clerks of the house of representatives and senate, the joint committee on health care financing and the house and senate committees on ways and means.

(e) If, after review of an eligible drug, the commission determines that the manufacturer's pricing of the eligible drug substantially exceeds the proposed value of the drug, the commission shall request that the manufacturer provide further information related to the pricing of the eligible drug and the manufacturer's reasons for the pricing not later than 30 days after receiving the request.

(f) Not later than 60 days after receiving information from the manufacturer under subsections (b) or (e), the commission shall confidentially issue a determination on whether the manufacturer's pricing of an eligible drug substantially exceeds the commission's proposed value of the drug. If the commission determines that the manufacturer's pricing of an eligible drug substantially exceeds the proposed value of the drug, the commission shall confidentially notify the manufacturer, in writing, of its determination and require the manufacturer to enter into an access improvement plan under section 21.

(g) Records disclosed by a manufacturer under this section shall: (i) be accompanied by an attestation that all information provided is true and correct; (ii) not be public records under clause Twenty-sixth of section 7 of chapter 4 or chapter 66; and (iii) remain confidential; provided, however, that the commission may produce reports summarizing any findings; provided further, that any such report shall not be in a form that identifies specific prices charged for or rebate amounts associated with drugs by a manufacturer or in a manner that is likely to compromise the financial, competitive or proprietary nature of the information.

Any request for further information made by the commission under subsection (e) or any determination issued or written notification made by the commission under subsection (f) shall not be public records under said clause Twenty-sixth of said section 7 of said chapter 4 or said chapter 66.

(h) If the manufacturer fails to timely comply with the commission's request for records under subsections (b) or (e), or otherwise knowingly obstructs the commission's ability to issue its determination under subsection (f), including, but not limited to, by providing incomplete, false or misleading information, the commission may impose appropriate sanctions against the manufacturer, including reasonable monetary penalties not to exceed $1,000,000, in each instance. The commission shall seek to promote compliance with this section and shall only impose a civil penalty on the manufacturer as a last resort.

(i) The commission shall adopt any written policies, procedures or regulations that the commission determines are necessary to implement this section.

Section 21. (a) The commission shall establish procedures to assist manufacturers in filing and implementing an access improvement plan.

Upon providing written notice provided under subsection (f) of section 20, the commission shall require that a manufacturer whose pricing of an eligible drug substantially exceeds the commission's proposed value of the drug file an access improvement plan with the commission. Not later than 45 days after receipt of a notice under subsection (g) of section 20, a manufacturer shall: (i) file an access improvement plan; or (ii) provide written notice declining the commission's request.

(b) An access improvement plan shall: (i) be generated by the manufacturer; (ii) identify the reasons for the manufacturer's drug price; and (iii) include, but not be limited to, specific strategies, adjustments and action steps the manufacturer proposes to implement to address the cost of the eligible drug in order to improve patient access to the eligible drug. The proposed access improvement plan shall include specific identifiable and measurable expected outcomes and a timetable for implementation. The timetable for an access improvement plan shall not exceed 18 months.

(c) The commission shall approve any access improvement plan that it determines: (i) is reasonably likely to address the cost of an eligible drug in order to substantially improve patient access to the eligible drug; and (ii) has a reasonable expectation for successful implementation.

(d) If the commission determines that the access improvement plan is unacceptable or incomplete, the commission may provide consultation on the criteria that have not been met and may allow an additional time period of not more than 30 calendar days for resubmission; provided, however, that all aspects of the access improvement plan shall be proposed by the manufacturer and the commission shall not require specific elements for approval.

(e) Upon approval of the proposed access improvement plan, the commission shall notify the manufacturer to begin immediate implementation of the access improvement plan. All manufacturers implementing an approved access improvement plan shall be subject to additional reporting requirements and compliance monitoring as determined by the commission. The commission shall provide assistance to the manufacturer in the successful implementation of the access improvement plan.

(f) All manufacturers shall work in good faith to implement the access improvement plan. At any point during the implementation of the access improvement plan the manufacturer may file amendments to the access improvement plan, subject to approval of the commission.

(g) At the conclusion of the timetable established in the access improvement plan, the manufacturer shall report to the commission regarding the outcome of the access improvement plan. If the commission determines that the access improvement plan was unsuccessful, the commission shall: (i) extend the implementation timetable of the existing access improvement plan; (ii) approve amendments to the access improvement plan as proposed by the manufacturer; (iii) require the manufacturer to submit a new access improvement plan; or (iv) waive or delay the requirement to file any additional access improvement plans.

(h) The commission may submit a recommendation for proposed legislation to the joint committee on health care financing if the commission determines that further legislative authority is needed to assist manufacturers with the implementation of access improvement plans or otherwise ensure compliance with this section.

(i) An access improvement plan under this section shall remain confidential in accordance with section 2A.

(j) The commission shall assess a civil penalty to a manufacturer of not more than $1,000,000, in each instance, if the commission determines that the manufacturer: (i) willfully neglected to file an access improvement plan with the commission under subsection (a); (ii) failed to file an acceptable access improvement plan in good faith with the commission; (iii) failed to implement the access improvement plan in good faith; or (iv) knowingly failed to provide information required by this section to the commission or knowingly falsified the

information,. The commission shall seek to promote compliance with this section and shall only impose a civil penalty as a last resort.

(k) If a manufacturer fails to enter into an access improvement plan under this section, the commission may publicly post the proposed value of the eligible drug, hold a public hearing on the proposed value of the eligible drug and solicit public comment. The manufacturer shall appear and testify at any hearing held on the eligible drug's proposed value. Upon the conclusion of a public hearing under this subsection, the commission shall issue recommendations on ways to reduce the cost of an eligible drug for the purpose of improving patient access to the eligible drug. The recommendations shall be publicly posted on the commission's website and provided to the clerks of the house of representatives and senate, the joint committee on health care financing and the house and senate committees on ways and means.

(l) Amounts collected under this section shall be deposited in to the Prevention and Wellness Trust Fund established in section 2G of chapter 111.

(m) The commission shall promulgate regulations necessary to implement this section.

SECTION 8. 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 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.

(c) 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.

(d) 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 9. 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 10. 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 $20,000 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 $1,000,000. 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 11. 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.

SECTION 12. Chapter 111 of the General Laws is hereby amended by adding the following section:-

Section 239. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Public health essential drug", a prescription drug, biologic or biosimilar approved by the federal Food and Drug Administration that: (i) appears on the Model List of Essential Medicines most recently adopted by the World Health Organization; or (ii) is deemed an essential medicine by the commissioner due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living or because limited access to a certain population would pose a public health challenge.

(b) The department shall identify and publish a list of public health essential prescription drugs. The list shall be updated not less than annually and be made publicly available on the department's website; provided, however, that the department may provide an interim listing of a public health essential drug prior to an annual update. The department shall also notify and forward a copy of the list to the health policy commission established under chapter 6D.