SENATE DOCKET, NO. 2517 FILED ON: 1/17/2025

SENATE . . . . . No.

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*

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SENATE . . . . . No.

[Pin Slip]

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. *783* OF 2023-2024.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

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 most recently amended by chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Alternative payment methodologies or methods" the following 2 definitions:-

"Biosimilar", a drug that is produced or distributed under a biologics license application approved under 42 U.S.C. 262(k)(3).

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (a) any drug approved through an application submitted under section 505(b)(2) of the federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c); (b) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services

under section 505(c) of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the federal Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or (c) an authorized generic drug as defined by 42 C.F.R. 447.502; (ii) produced or distributed pursuant to a biologics license application approved under 42 U.S.C. 262(a)(2)(C); or (iii) identified by the carrier as a brand name drug based on available data resources such as Medi-Span.

SECTION 2. Said section 1 of chapter 6D is hereby amended by inserting after the definition of "Physician" the following definition:-

"Pipeline drug", a prescription drug product 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 United States Food and Drug Administration.

SECTION 2. Said chapter 6D is hereby amended by inserting after section 15 the following section:-

Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or (iii) biosimilar drug. The commission shall provide nonconfidential information received under this section to the office of Medicaid, the division of insurance and the group insurance commission.

Early notice under this subsection shall be submitted to the commission in writing not later than 30 days after receipt of the United States Food and Drug Administration approval date.

For each pipeline drug, 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 date 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 United States Food and Drug Administration: (i) as an orphan drug; (ii) for fast track; (iii) as a breakthrough therapy; (iv) for accelerated approval; or (v) for priority review for a new molecular entity; provided, however, that notwithstanding clause (v), submissions for drugs in development that are designated as new molecular entities by the United States Food and Drug Administration shall be provided as soon as practical upon receipt of the relevant designations. For each generic drug, early notice shall include a copy of the drug label approved by the United States Food and Drug Administration.

(b) A pharmaceutical manufacturing company shall provide early notice to the commission if it plans to increase the wholesale acquisition cost of a: (i) brand-name drug by more than 15 per cent per wholesale acquisition cost unit during any 12-month period; or (ii) generic drug or biosimilar drug with a significant price increase as determined by the commission during any 12-month period. The commission shall provide non-confidential information received under this section to the office of Medicaid, the division of insurance and the group insurance commission.

Early notice under this subsection shall be submitted to the commission in writing not less than 60 days before the planned effective date of the increase.

A pharmaceutical manufacturing company required to notify the commission of a price increase under this subsection shall, not less than 30 days before the planned effective date of the increase, report to the commission any information regarding the price increase that is relevant to the commission including, but not limited to: (i) drug identification information; (ii) drug sales volume information; (iii) wholesale price and related information for the drug; (iv) net price and related information for the drug; (v) drug acquisition information, if applicable; (vi) revenue from the sale of the drug; and (vii) manufacturer costs.

(c) The commission shall conduct an annual study of pharmaceutical manufacturing companies subject to the requirements in subsections (a) and (b). The commission may contract with a third-party entity to implement this section.

(d) If a pharmaceutical manufacturing company fails to timely comply with the requirements under subsection (a) or subsection (b), or otherwise knowingly obstructs the commission's ability to receive early notice under this section, including, but not limited to, providing incomplete, false or misleading information, the commission shall 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. Amounts collected under this section shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

SECTION 3. Said chapter 6D is hereby further amended by adding the following 2 sections:-

Section 24. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Eligible drug", (i) a 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) a 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; (iii) a public health essential drug, as defined in subsection (f) of section 13 of chapter 17, 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; (iv) all drugs, continuous glucose monitoring system components, all components of the continuous glucose monitoring system of which the component is a part and, when applicable, delivery devices selected pursuant to section 17T of chapter 32A, section 10R of chapter 118E, section 47UU of chapter 175, section 8VV of chapter 176A, section 4VV of chapter 176B and section 4NN of chapter 176G; or (v) other prescription drug products that may have a direct and significant impact and create affordability challenges for the state's health care system and patients, as determined by the commission; provided, however, that the commission shall promulgate regulations to establish the type of prescription drug products classified under clause (v) prior to classification of any such prescription drug product under said clause (v).

"Public health essential drug", shall have the same meaning as defined in subsection (f) of section 13 of chapter 17.

(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 conducting a review of eligible drugs, the commission may request information relating to the pricing of an eligible drug from the pharmaceutical manufacturing company of said eligible drug. Upon receiving a request for information from the commission, a pharmaceutical manufacturing company shall disclose to the commission, within a reasonable time period, as determined by the commission, applicable 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 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 total amount of federal and state tax credits, incentives, grants and other subsidies provided to the pharmaceutical manufacturing company over the previous 10 calendar years that have been used to assist in the research and development of eligible drugs;

(iii) the pharmaceutical manufacturing company'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;

(iv) a narrative description, absent proprietary information and written in plain language, of factors that contributed to reported changes in wholesale acquisition cost during the previous 5 calendar years; and

(v) any other information that the pharmaceutical manufacturing company wishes to provide to the commission or that the commission requests.

(c) Based on the records provided 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 from the pharmaceutical manufacturing company and from other entities, including, but not limited to, payers and pharmacy benefit managers.

Any information, analyses or reports regarding an eligible drug review shall be provided to the pharmaceutical manufacturing company. The commission shall consider any clarifications or data provided by the pharmaceutical manufacturing company 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 and shall not employ a measure or metric that assigns a reduced value to the life extension provided by a treatment based on a pre-existing disability or chronic health condition of the individuals whom the treatment would benefit. If the commission relies upon a third party to provide cost-effectiveness analysis or research related to the proposed value of the eligible drug, such analysis or research shall also include, but not be limited to: (i) a description of the methodologies and models used in its analysis; (ii) any assumptions and potential limitations of research findings in the context of the results; and (iii) outcomes for affected subpopulations that utilize the drug, including, but not limited to, potential

impacts on individuals of marginalized racial or ethnic groups and on individuals with specific disabilities or health conditions who regularly utilize the eligible drug.

(d) If, after review of an eligible drug and after receiving information from the pharmaceutical manufacturing company under subsection (b) or subsection (e), the commission determines that the pharmaceutical manufacturing company's pricing of the eligible drug does not substantially exceed the proposed value of the drug, the commission shall notify the pharmaceutical manufacturing company, 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 pharmaceutical manufacturing company and other relevant stakeholders, including, but not limited to, patients, patient advocacy organizations, consumer 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 shall not be limited to: (i) an alternative payment plan or methodology; (ii) a bulk purchasing program; (iii) co-payment, deductible, co-insurance 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; provided, however, that the report shall be published on the website of the commission.

(e) If, after review of an eligible drug, the commission determines that the pharmaceutical manufacturing company's pricing of the eligible drug substantially exceeds the proposed value

of the drug, the commission shall request that the pharmaceutical manufacturing company provide further information related to the pricing of the eligible drug and the pharmaceutical manufacturing company'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 pharmaceutical manufacturing company under subsection (b) or subsection (e), the commission shall confidentially issue a determination on whether the pharmaceutical manufacturing company's pricing of an eligible drug substantially exceeds the commission's proposed value of the drug. If the commission determines that the pharmaceutical manufacturing company'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 may require the manufacturer to enter into an access and affordability improvement plan under section 25.

(g) Records disclosed by a pharmaceutical manufacturing company 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 under 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 under said chapter 66.

(h) The commission's proposed value of an eligible drug and the commission's underlying analysis of the eligible drug is not intended to be used to determine whether any individual patient meets prior authorization or utilization management criteria for the eligible drug. The proposed value and underlying analysis shall not be the sole factor in determining whether a drug is included in a formulary or whether the drug is subject to step therapy.

(i) If the pharmaceutical manufacturing company fails to timely comply with the commission's request for records under subsection (b) or subsection (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 shall impose appropriate sanctions against the pharmaceutical manufacturing company, 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. Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

(j) The commission shall adopt any written policies, procedures or regulations that the commission determines are necessary to effectuate the purpose of this section.

Section 25. (a) The commission shall establish procedures to assist manufacturers in filing and implementing an access and affordability improvement plan.

Upon providing written notice provided under subsection (f) of section 24, the commission may require that a pharmaceutical manufacturing company whose pricing of an

eligible drug substantially exceeds the commission's proposed value of the drug file an access and affordability improvement plan with the commission. Not later than 45 days after receipt of a notice under said subsection (f) of said section 24, a pharmaceutical manufacturing company shall: (i) file an access and affordability improvement plan; or (ii) provide written notice declining participation in the access and affordability improvement plan.

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

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

(d) If the commission determines that the proposed access and affordability 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 plan shall be proposed by the

pharmaceutical manufacturing company and the commission shall not require specific elements for approval.

(e) Upon approval of the proposed access and affordability improvement plan, the commission shall notify the pharmaceutical manufacturing company to begin immediate implementation of the access and affordability improvement plan. Public notice shall be provided by the commission on its website, identifying that the pharmaceutical manufacturing company is implementing an access and affordability improvement plan; provided, however, that upon the successful completion of the access and affordability improvement plan, the identity of the pharmaceutical manufacturing company shall be removed from the commission's website. All pharmaceutical manufacturing companies 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 pharmaceutical manufacturing company in the successful implementation of the access and affordability improvement plan.

(f) All pharmaceutical manufacturing companies shall work in good faith to implement the access and affordability improvement plan. At any point during the implementation of the access and affordability improvement plan, the pharmaceutical manufacturing company 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 and affordability improvement plan, the pharmaceutical manufacturing company shall report to the commission regarding the outcome of the access and affordability improvement plan. If the commission determines that the access and affordability improvement plan was unsuccessful, the commission

shall: (i) extend the implementation timetable of the existing access and affordability improvement plan; (ii) approve amendments to the access and affordability improvement plan as proposed by the pharmaceutical manufacturing company; (iii) require the pharmaceutical manufacturing company to submit a new access and affordability improvement plan; or (iv) waive or delay the requirement to file any additional access and affordability improvement plans.

(h) The commission shall 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 pharmaceutical manufacturing company with the implementation of access and affordability improvement plans or to otherwise ensure compliance with this section.

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

(j) The commission shall assess a civil penalty to a pharmaceutical manufacturing company of not more than $1,000,000, in each instance, if the commission determines that the pharmaceutical manufacturing company: (i) declined or willfully neglected to file an access and affordability improvement plan with the commission under subsection (a); (ii) failed to file an acceptable access and affordability improvement plan in good faith with the commission; (iii) failed to implement the access and affordability 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. Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

(k) If a pharmaceutical manufacturing company declines to enter into an access and affordability 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 pharmaceutical manufacturing company shall appear and testify at the public 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.

If a pharmaceutical manufacturing company is deemed to not be acting in good faith to develop an acceptable or complete access and affordability improvement plan, 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 pharmaceutical manufacturing company 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.

Before making a determination that the pharmaceutical manufacturing company is not acting in good faith, the commission shall send a written notice to the pharmaceutical

manufacturing company that the commission shall deem the pharmaceutical manufacturing company to not be acting in good faith if the pharmaceutical manufacturing company does not submit an acceptable access and affordability improvement plan within 30 days of receipt of notice; provided, however, that the commission shall not send a notice under this paragraph within 120 calendar days from the date that the commission notified the pharmaceutical manufacturing company of its requirement to enter into the access and affordability improvement plan.

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

SECTION 4. Section 13 of chapter 17 of the General Laws is hereby amended by adding the following subsection:-

(f) As used in this subsection, 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 United States 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 commission 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.

The commission shall identify and publish a list of public health essential drugs. The list shall be updated not less than annually and be made publicly available on the department's website; provided, however, that the commission may provide an interim listing of a public

health essential drug prior to an annual update. The commission shall notify and forward a copy of the list to the health policy commission established under chapter 6D.