HOUSE DOCKET, NO. 3583 FILED ON: 1/17/2025

HOUSE . . . . . No.

The Commonwealth of Massachusetts

PRESENTED BY:

Christine P. Barber

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to ensure affordable prescription medications through accountability standards.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Christine P. Barber	*34th Middlesex*	*1/17/2025*

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HOUSE . . . . . No.

[Pin Slip]

The Commonwealth of Massachusetts

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

An Act to ensure affordable prescription medications through accountability standards.

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, 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 pursuant to a biologics license application approved under 42 U.S.C. 262(k)(3).

SECTION 2. Said chapter 6D, as so appearing, is hereby further amended by adding the following section:-Section 22. (a) For the purposes of this section, "Manufacturer" shall mean an entity that manufactures a pharmaceutical drug.

(b) The commission may require a manufacturer specified in subsection (c) to disclose to the commission within a reasonable time information relating to the manufacturer's pricing of that drug, on a standard reporting form developed by the commission with the input of the manufacturers, which includes, but shall not be limited to, the following:

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

(2) 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;

(3) 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

(4) Any other information that the manufacturer wishes to provide to the commission.

Based on the records furnished, the commission may identify a proposed value for a prescribed drug specified in subsection (c). The Commission may request additional relevant information that it deems necessary.

(c) A manufacturer of a drug for which the commission has received a referral from the center under subsection (b) of section 25 of chapter 12C shall comply with the requirements set forth in this section; provided that the commission may select or prioritize a subset of the referred drugs for the commission's review.

(d) 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 section 7 of chapter 4 or chapter 66; and (iii) remain confidential; provided, however, that the commission may produce reports summarizing any findings; provided 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.

(e) If, after review of any records furnished to the commission under subsection (b), the commission determines that the manufacturer's pricing of the drug is potentially unreasonable or excessive in relation to the commission's proposed value under subsection (b), the commission shall require that the manufacturer provide within 30 days further information related to the pricing of the prescribed drug and the manufacturer's justification for the pricing. In addition to the manufacturer, the commission may identify other relevant parties including but not limited to patients, providers, provider organizations and payers who may provide information to the commission.

(f) The commission shall provide to the manufacturer for review and input any information, analyses or reports regarding a particular drug reviewed or relied on by the commission in assessing the proposed value of the drug shall be provided to the manufacturer. The commission shall consider any clarifications or data provided by the manufacturer with respect to its drug. The commission may not rely solely on the analysis or research of an outside third party in reaching its determination regarding the proposed value or the reasonableness of the drug pricing.

(g) If the commission relies upon a third party to provide cost-effectiveness analysis or research related to the proposed value, such analysis or research shall also provide, without limitation (i) a description of the methodologies and models used by the third party 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 minority racial or ethnic groups, and on individuals with specific disabilities or health conditions who regularly utilize the eligible drug.

(h) Not later than 60 days after receiving information from the manufacturer, as required under subsections (b) or (e), the commission shall issue a determination on whether the manufacturer's pricing of a drug is unreasonable or excessive in relation to the commission's proposed value of the drug. Following the determination, the commission shall issue recommendations on measures to reduce the cost of the drug and to improve the affordability of the drug for patients. Recommendations may include, but not be limited to: (i) an alternative purchasing plan or value-based payment methodology; (ii) a bulk purchasing program; (iii) changes to co-pay, deductibles, coinsurance or other cost-sharing requirements; or (iv) a reinsurance program to subsidize the cost of the eligible drug. The commission shall make its determination and recommendations public and shall post them on its website and shall provide them to private and public health care payers.

(i) 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 (h), including, but not limited to, providing incomplete, false or misleading information, the commission may assess a civil penalty to a manufacturer of not more than $500,000. A civil penalty assessed under this subsection shall be deposited into the Payment Reform Fund established pursuant to section 100 of chapter 194 of the acts of 2011. The commission shall seek to promote compliance with this section and shall only impose a civil penalty on the manufacturer as a last resort.

(j) Neither the proposed value, nor the analysis produced via the process to determine a proposed value, is intended to be used by MassHealth, health insurance carriers, managed care organizations, accountable care organizations, hospitals or pharmacies to determine whether a treatment should be approved for an individual patient, whether any individual patient should be subjected to step therapy or other utilization management methodology,

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

SECTION 3. Section 11N of chapter 12 of the General Laws, as so appearing, is hereby amended by striking out subsection (a) and inserting in place thereof the following subsection:-

(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 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.

SECTION 4. Said chapter 12C is hereby further amended by striking out section 11, as so appearing, and inserting in place thereof the following section:-

Section 11. The center shall ensure the timely reporting of information required under sections 8, 9, 10. 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 may result in penalties. The center may 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 section of not more than $2,000 per week for each week of delay after the 2-week period following receipt of the written notice. 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.

SECTION 5. Said chapter 12C is hereby further amended by adding the following section:-

Section 25. (a) The center shall analyze data on Massachusetts drug utilization and spending, including but not limited to data reported under Sections 10. Annually, the center shall refer drugs to the health policy commission for review under section 8A of chapter 6D that meet any of the following criteria: (i) a current average annual gross cost per utilizer for public and private health care payers in Massachusetts of greater than $50,000; (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; or (iii) among the 25 drugs determined by the center to have the most impact on health care spending in the most recent year of available data, based upon utilization, price, utilization and price growth, patient cost sharing amounts, net spending and other factors as determined by the center. The center shall provide notice of the referral to the manufacturer of the drug.

(b) Not later than May 1, the center shall publish an annual report detailing, at minimum, each drug referred to the health policy commission under subsection (a).

(c) The center shall adopt any written policies, procedures or regulations necessary to implement this section.

SECTION 6. Section 2 of Chapter 176O of the General Laws, as so appearing, is hereby amended by adding the following subsection:-

(i) At least annually, a carrier that contracts with a pharmacy benefit manager shall coordinate an audit of the operations of the pharmacy benefit manager to ensure compliance with

this chapter and to examine the pricing and rebates applicable to prescription drugs that are provided to the carrier's covered persons.

SECTION 7. Said chapter 176O of the General Laws is hereby further amended by inserting after section 22 the following section:-

Section 22A. Notwithstanding any other general or special law to the contrary, each carrier shall require that a pharmacy benefit manager receive a license from the division under chapter 176O as a condition of contracting with that carrier.