SENATE DOCKET, NO. 2055 FILED ON: 1/17/2025

SENATE . . . . . No.

The Commonwealth of Massachusetts

PRESENTED BY:

Edward J. Kennedy

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 in prescription drug prices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Edward J. Kennedy	*First Middlesex*

SENATE DOCKET, NO. 2055 FILED ON: 1/17/2025

SENATE . . . . . No.

[Pin Slip]

The Commonwealth of Massachusetts

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

An Act to promote transparency in prescription 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 is hereby amended by inserting after the definition of "ACO patient" the following definition:

"Affordability Challenge" means situations whereby the Board determines that a) the costs of appropriate utilization of a prescription drug, biologic or biosimilar exceed the therapeutic benefit; or b) the costs of appropriate utilization of the prescription drug, biologic or biosimilar are not sustainable to consumers or to public and private health care systems.

SECTION 2. Said section 1 of chapter 6D of the General Laws is hereby amended by inserting after the definition of "Alternative payment methodologies or methods" the following 4 definitions: -

"Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 USC § 1395w-3a(c)(6).

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

"Board" means the Prescription Drug Affordability Board established under Section 3B.

"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 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 3. Said section 1 of said chapter 6D is hereby further amended by inserting after the definition of "Disproportionate share hospital" the following definition: -

"Early notice", advanced notification by a pharmaceutical manufacturing company of a: (i) new drug, device or other product coming to market; or (ii) a price increase, as described in subsection (b) of section 15A.

SECTION 4. Said section 1 of said chapter 6D is hereby further amended by inserting after the definition of "Employer" the following definition: -

"ERISA Plan" means a plan qualified under the Employee Retirement Income Security Act of 1974.

SECTION 5. Said section 1 of said chapter 6D is hereby further amended by inserting after the definition of "Non-Acute Hospital" the following 2 definitions: -

"Participating ERISA Plan" means an ERISA Plan that has elected to participate in the requirements and restrictions of Section 24 of Chapter 6D.

"Pharmacy Wholesale Distributor" means a person engaged in wholesale distribution of prescription drugs or devices including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

SECTION 6. Said section 1 of said chapter 6D is hereby further amended by striking the definition of "pharmacy benefit managers" and replacing with the following definition: -

"Pharmacy benefit manager", a person, business or other entity, however organized, that directly or through a subsidiary provides pharmacy benefit management services for prescription drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit management services shall include, but not be limited to: (i) the processing and payment of claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii) drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x)

clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost ofc overed prescription drugs; “provided, however, that “pharmacy benefit manager” shall not include a health benefit plan sponsor that (i) contracts with a pharmacy benefit manager, (ii) manages a subset of pharmacy benefit management functions within its own organization, and (iii) is licensed as a carrier by the division.

SECTION 7. Said section 1 of said chapter 6D is hereby further amended by inserting after the definition of “Physician” the following 2 definitions: -

“Prescription Drug” means a. as defined under Section 1 of Chapter 94C b. A Biologic as defined in Section 1 of Chapter 6D. A Biosimilar as defined in Section 1 of Chapter 6D

“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 8. Said section 1 of said chapter 6D is hereby further amended by inserting after the definition of “Shared decision making” the following definition: -

“State Entity” means any agency of state government that purchases Prescription Drugs on behalf of the state for a person whose health care is paid for by the state, including any agent, vendor, fiscal agent, contractor, or other party acting on behalf of the state.

SECTION 9. Said chapter 6D is hereby further amended by striking out section 2A and inserting in place thereof the following section: -

Section 2A. The commission shall keep confidential all nonpublic clinical, financial, strategic or operational documents or information provided or reported to the commission in

connection with any care delivery, quality improvement process, performance improvement plan, early notification or access and affordability improvement plan activities authorized under sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under section 2GGGG of chapter 29 and shall not disclose the information or documents to any person without the consent of the entity providing or reporting the information or documents under said sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under said section 2GGGG of said chapter 29, except in summary form in evaluative reports of such activities or when the commission believes that such disclosure should 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 under chapter 66.

SECTION 10. Chapter 6D of the General Laws is further amended by inserting after section 3A the following new section:-

Section 3B. Establishment of the Prescription Drug Affordability Board.

a) There is hereby established within the commission's office for pharmaceutical policy and analysis, a Prescription Drug Affordability Board, hereinafter referred to as the Board.

i. The Board shall be constituted of five members, 1 appointed by the Governor, 1 appointed by the President of the Senate; 1 appointed by the Speaker of the House; 1 appointed by the Attorney General for the State of Massachusetts and 1 appointed jointly by the Senate President and the House Speaker to serve as chair of the board. The Board shall include members who have demonstrated expertise in health policy, health care economics, or clinical medicine.

ii. Board members shall serve for a term of five years and members may be reappointed for additional terms.

iii. The Commission shall have the authority to hire an Executive Director and staff necessary to conduct the Board's activity as described in this Act.

iv. The Board shall have the authority to enter into a contract with a third party for any service necessary to carry out the powers and duties of the Board described in sub-sections b) and c)

v. No Board member may be an employee of a board member of, or consultant to a Manufacturer, Pharmacy Benefit Manager, Health Plan, Pharmacy Wholesale Distributor, or related trade association.

vi. Board members, staff members, and contractors providing services on behalf of the Board shall recuse themselves from any Board activity in which they have a conflict of interest. For the purposes of this section, a conflict of interest means an association, including a financial or personal association, that has the potential to bias or appear to bias an individual's decisions in matters related to the Board or the activities of the Board.

vii. The Board may establish advisory groups consisting of relevant stakeholders.

viii. The Board, in consultation with the Commission, has the authority to promulgate and adopt rules to allow it to carry out its duties and obligations.

ix. A simple majority of the Board's membership constitutes a quorum for the purpose of conducting business. Decisions of the Board shall be determined by majority vote of members present.

x. All meetings of the Board shall be open and public, except that the Board may hold executive sessions to the extent permitted by the Commission.

xi. The Board shall meet at least quarterly and hold its first meeting by July 31, 2026.

b) Identification of Drugs Subject to Review: The Board shall select Prescription Drugs for Affordability Review based on the following criteria:

i. By December 31, 2026, and yearly thereafter, the Board shall identify:

a. Prescription Drugs that: i. have a Wholesale Acquisition Cost of three thousand dollars or more; or ii. have a Wholesale Acquisition Cost increase of three hundred dollars or more in the preceding twelve months; or iii. have a Wholesale Acquisition Cost increase of one hundred percent or more in the preceding twelve months.

b. Biosimilars with an initial Wholesale Acquisition Cost that is not at least fifteen percent below the Wholesale Acquisition Cost of the referenced brand biologic product at the time the biosimilar is launched.

c. Other drugs identified by the Board as posing potential Affordability Challenges.

ii. Prescription Drugs referred to the Board by any advisory group created by the Board; and

iii. Prescription Drugs included in the following reports, which shall be reported annually to the Board from each payor:

a. The fifty prescription drugs most frequently dispensed by pharmacies for claims paid by a payor and the total number of paid claims for each such drug;

b. The 50 highest costing prescription drugs by total annual spending accounting for rebates and other price concessions;

c. The 50 prescription drugs with the greatest increase in unit price over the preceding the plan year and for each such drug, the change in amounts expended by the plan or coverage in each such plan year after rebates and other price concessions;

d. The 50 drugs with the highest cost to consumers based on the average out-of-pocket cost per utilizer;

e. Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers, with respect to prescription drugs prescribed to participants or beneficiaries in the plan, including:

i. the amounts paid by manufacturers for each therapeutic class of drugs; and

ii. the amounts paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan from drug manufacturers during the plan year; and

f. Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration described in subsection (b).

iv. The reports described in subsection (b) shall include the following information for each Prescription Drug:

a. Total annual spending by payor after rebate and other price concessions;

b. Total annual spending by participants, beneficiaries, and enrollees enrolled in the plan or coverage, as applicable;

c. The number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim;

d. Total dosage units dispensed; and

e. The number of paid claims.

c) Information to the Board.

i. In performing an affordability review of a prescription drug, the board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to life-cycle management; the average cost of the prescription drug; market competition and context; projected revenue; the estimated cost-effectiveness of the prescription drug; off-label usage of the prescription drug; development and manufacturing costs; and information regarding any consumer assistance programs funded by the manufacturer.

ii. To the extent practicable, the Board may access pricing information for prescription drugs through: publicly available pricing information from a state to which manufacturers report pricing information or information acquired through a data-sharing agreement with another state; available pricing information from state entities and data assets that have access to cost and pricing information; pricing information that is available from other countries; and any other sources available to the Board.

d) Affordability Review.

i. The Board may conduct an affordability review of any prescription drug identified pursuant to subsection (b). The purpose of the affordability review is to determine whether the cost of the prescription drug poses an Affordability Challenge.

ii. When conducting a review, the Board may consider any of the following criteria a) the relevant factors contributing to the price paid for the prescription drug, including the Wholesale Acquisition Cost, discounts, rebates, or other price concessions; b) the average patient co-pay or other cost-sharing for the drug; the effect of the price on consumers' access to the drug in the state; c) whether the cost of the drug contributes to inequities in the availability of health care to underserved communities in the state; d) the dollar value and accessibility of patient assistance programs offered by the manufacturer for the drug; e) the price and availability of therapeutic alternatives; f) input from patients affected by the condition or disease treated by the drug and individuals with medical or scientific expertise related to the condition or disease treated by the drug; g) the average cost of the drug in the state; h) market competition; i) projected manufacturer revenue, if available; j) off-label usage of the drug; and k) any other relevant factors as determined by the Board.

iii. Before commencing a review, the Board shall publish which drugs are subject to an affordability review and shall notify in writing the manufacturer of any Prescription Drug subject to review.

iv. At the conclusion of its affordability review, the Board shall determine whether the cost of a reviewed prescription drug presents an affordability challenge.

e) Upper Payment Limits.

i. Prior to setting any upper payment limits, the Board shall establish by rule a methodology for setting upper payment limits.

ii. The Board may set an upper payment limit for each prescription drug for which it determines there is an affordability challenge.

iii. The methodology may take into consideration: a) the cost of administering the prescription drug; b) the cost of delivering the Prescription Drug to patients; c) the status of the prescription drug on the drug shortage list published by the United States Food and Drug Administration; d) the differential in price between the price of the drug in the commonwealth, nationally, and the price of the drug in other countries; e) other relevant administrative costs related to the production and delivery of the prescription drug; and f) other relevant criteria the Board, accounting for any stakeholder input, determines is necessary.

iv. The methodology determined by the Board shall consider whether an upper payment limit may help alleviate health disparities and inequitable outcomes for (a) underserved communities, (b) people with disabilities, (c) older adults, or (d) any other socially, economically, or environmentally disadvantaged group.

v. An upper payment limit for a Prescription Drug established by the Board applies to all purchases of the Prescription Drug and reimbursements for a claim for the drug when the Prescription Drug is dispensed or administered to an individual in the state in person, by mail, or by other means. An upper payment limit does not include a pharmacy dispensing fee and nothing in this Chapter shall be interpreted to prevent a retail pharmacy from receiving a payment that includes a dispensing fee above the upper payment limit.

vi. A health plan governed by the Employee Retirement Income Security Act may elect to be subject to the upper payment limits as established by the Board.

vii. The Board shall publish a list of Prescription Drugs for which it has set an upper payment limit.

viii. Unless the Board prescribes a specific effective date, upper payment limits established by the Board shall become effective six months after the adoption of the upper payment limit and apply only to purchases, contracts, and plans that are issued on or renewed after the effective date.

f) Any savings generated by a payor that are attributable to the implementation of an upper payment limit established by the Board shall be used to reduce costs to consumers. No later than April 1 of each calendar year, each payor shall submit to the Board a report describing the savings achieved as a result of implementing upper payment limits and how those savings were used to reduce costs to consumers.

g) No manufacturer shall withdraw the sale or distribution of a prescription drug within the commonwealth, a prescription drug for which the Board has established an upper payment limit.

h) The Board shall assess a penalty not to exceed five hundred thousand dollars if the Board finds that a manufacturer withdrew the sale or distribution of a prescription drug within the commonwealth, a prescription drug for which the Board has established an upper payment limit

i) On or before December 1 of each year, the Board shall submit a report to the governor and the joint committees on health care financing summarizing the activities of the Board during the preceding calendar year. The report shall include, but is not limited to, the following:

i. Publicly available data concerning price trends for prescription drugs;

ii. A list of the prescription drugs that were subjected to an affordability review by the Board pursuant to section, including the results of each affordability review;

iii. A list of each prescription drug for which the Board established an upper payment limit pursuant to subsection (e), including the amount of the upper payment limit;

iv. With respect to each drug for which the Board conducted an affordability review how the Board determined whether the cost of the drug contributes to inequities in the availability of health care to communities of color or other underserved communities in the state;

v. With respect to each drug for which the Board set an upper payment limit how the Board assessed the impact to communities of color, people with disabilities, and older adults;

vi. The known impact of any upper payment limits established by the Board pursuant to sub-section (e) on health care providers, pharmacies, and patients' ability to access any prescription drugs for which the Board has established upper payment limits;

vii. Any recommendations the Board may have for legislative and regulatory policy changes to increase the affordability of prescription drugs and reduce the effects of costs on consumers and the health care systems in the state.

SECTION 11. Said chapter 6D is hereby further amended by striking out section 6, most recently amended by section 5 of Senate Bill 3012, and inserting in place thereof the following section:

Section 6. (a) For the purposes of this section, "non-hospital provider organization" shall mean a provider organization required to register under section 11 that is: (i) a non-hospital based physician practice with not less than $500,000,000 in annual gross patient service revenue; (ii) a clinical laboratory; (iii) an imaging facility; or (iv) a network of affiliated urgent care centers.

(b) Each acute hospital, ambulatory surgical center, non-hospital provider organization, pharmaceutical manufacturing company and pharmacy benefit manager shall pay to the commonwealth an amount for the estimated expenses of the commission

(c) The assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations shall be 25 percent of the amount appropriated by the general court for the expenses of the commission minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the commission; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies; provided, however, that, to the maximum extent permissible under federal law, non hospital provider organizations shall be assessed not less than 3 per cent nor more than 8 per cent of the total assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay such assessed amount multiplied by the ratio of the acute hospital's, ambulatory surgical center's or non-hospital provider organization's gross patient service revenues to the total gross patient

service revenues of all such hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall make a preliminary payment to the commission on October 1 of each year in an amount equal to 1/2 of the previous year's total assessment. Thereafter, each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay, within 30 days' notice from the commission, the balance of the total assessment for the current year based upon its most current projected gross patient service revenue. The commission shall subsequently adjust the assessment for any variation in actual and estimated expenses of the commission and for changes in acute hospital, ambulatory surgical center and non-hospital provider organization gross patient service revenue. Such estimated and actual expenses shall include an amount equal to the cost of fringe benefits and indirect expenses, as established by the comptroller under section 5D of chapter 29. In the event of late payment by any such acute hospital, ambulatory surgical center or non-hospital provider organization, the treasurer shall advance the amount of due and unpaid funds to the commission prior to the receipt of such monies in anticipation of such revenues up to the amount authorized in the then current budget attributable to such assessments and the commission shall reimburse the treasurer for such advances upon receipt of such revenues. This section shall not apply to any state institution or to any acute hospital which is operated by a city or town.

(d) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmaceutical manufacturing companies shall be 25 per cent of the amount appropriated by the general court for the expenses of the commission minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the commission; and (iii) federal matching

revenues received for these expenses or received retroactively for expenses of predecessor agencies. Each pharmaceutical manufacturing company shall pay such assessed amount multiplied by the ratio of MassHealth's net spending for the manufacturer's prescription drugs used in the MassHealth rebate program to MassHealth's total pharmacy spending.

(e) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmacy benefit managers shall be 25 per cent of the amount appropriated by the general court for the expenses of the commission minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the commission; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies. Each pharmacy benefit manager shall pay such assessed amount multiplied by the ratio of the claims paid by the pharmacy benefit manager attributed to residents of the commonwealth for whom it manages pharmaceutical benefits on behalf of carriers to the total of all such claims paid by all pharmacy benefit managers attributed to residents of the commonwealth for whom they manage pharmaceutical benefits on behalf of carriers.

(f) Each pharmaceutical manufacturing company and each pharmacy benefit manager shall make a preliminary payment to the commission annually on October 1 in an amount equal to 1/2 of the previous year's total assessment. Thereafter, each pharmaceutical manufacturing company and each pharmacy benefit manager shall pay, within 30 days of receiving notice from the commission, the balance of the total assessment for the current year as determined by the commission.

SECTION 12. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “commission”, in line 60, 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 changes including, but not limited to, the initial prices of drugs coming to market and subsequent price changes, changes in industry profit levels, marketing expenses, reverse payment patent settlements, the impact of manufacturer rebates, discounts and other price concessions on net pricing, the availability of alternative drugs or treatments, corporate ownership organizational structure and any other matters as determined by the commission.

SECTION 13. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the second sentence and inserting in place thereof the following 2 sentences: - The report shall be based on the commission’s analysis of information provided at the hearings by witnesses, providers, provider organizations, payers, pharmaceutical manufacturing companies and pharmacy benefit managers, registration data collected under section 11, data collected or analyzed by the center under sections 8, 9, 10,10A and 10B of chapter 12C and any other available information that the commission considers necessary to fulfill its duties under this section as defined in regulations promulgated by the commission. To the extent practicable, the report shall not contain any data that is likely to compromise the financial, competitive or proprietary nature of the information.

SECTION 14. Said chapter 6D is hereby further 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 may impose appropriate sanctions against the manufacturer, including reasonable monetary penalties not to exceed

$500,000, 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 section shall be deposited into the Health Safety Net Trust Fund.

SECTION 15. 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 199 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).

"Manufacturer", a pharmaceutical manufacturer of an eligible drug, or, when applicable, the manufacturer of a delivery device 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.

"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 and shall refer these eligible drugs to the Board established under the commission's office or pharmaceutical policy and analysis to consider for affordability review.

In conducting a review of eligible drugs, the commission may request information relating to the pricing of an eligible drug from the manufacturer of said eligible drug. Upon receiving a request for information from the commission, a manufacturer 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 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 total amount of federal and state tax credits, incentives, grants and other subsidies

provided to the manufacturer over the previous 10 calendar years that have been used to assist in the research and development of eligible drugs; (iii) 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; (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 manufacturer 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 manufacturer and from other entities, including, but not limited to, pharmacy benefit managers.

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 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 manufacturer under subsection (b) or subsection (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, 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 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 subsection (b) or subsection (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 may require the manufacturer to enter into an access and affordability improvement plan under section 24.

(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 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 manufacturer 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 may impose appropriate sanctions against the manufacturer, including reasonable monetary penalties not to exceed $500,000, 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 section shall be deposited into the Health Safety Net Trust Fund.

(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 21, the commission may require that a manufacturer 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 21, a manufacturer 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 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 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 manufacturer 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 manufacturer 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 manufacturer 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 manufacturer shall be removed from the commission's website. 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 and affordability improvement plan.

(f) All manufacturers 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 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 and affordability improvement plan, the manufacturer 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 manufacturer;

(iii) require the manufacturer 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 manufacturers 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 may assess a civil penalty to a manufacturer of not more than $500,000, in each instance, if the commission determines that the manufacturer: (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

Amounts collected under this section shall be deposited into the Health Safety Net Trust Fund.

(k) If a manufacturer 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 manufacturer 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 manufacturer 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 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.

Before making a determination that the manufacturer is not acting in good faith, the commission shall send a written notice to the manufacturer that the commission shall deem the manufacturer to not be acting in good faith if the manufacturer 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 manufacturer of its requirement to enter into the access and affordability improvement plan.

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

SECTION 16. Section 1 of chapter 12C of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by inserting after the definition of "Ambulatory surgical center services" the following 3 definitions:-

"Average manufacturer price", the average price paid to a manufacturer for a drug in the commonwealth by a: (i) wholesaler for drugs distributed to pharmacies; and (ii) pharmacy that purchases drugs directly from the manufacturer.

"Biosimilar", a drug that is produced or distributed pursuant to 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 17. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by inserting after the definition of “Patient-centered medical home” the following definition: -

“Pharmacy benefit manager”, a person, business or other entity, however organized, that, directly or through a subsidiary, provides pharmacy benefit management services for prescription drugs and devices on behalf of a health benefit plan sponsor, including, but not limited to, a self-insurance plan, labor union or other third-party payer; provided, however, that pharmacy benefit management services shall include, but not be limited to: (i) the processing and payment of claims for prescription drugs; (ii) the performance of drug utilization review; (iii) the processing of drug prior authorization requests; (iv) pharmacy contracting; (v) the adjudication of appeals or grievances related to prescription drug coverage contracts; (vi) formulary administration; (vii) drug benefit design; (viii) mail and specialty drug pharmacy services; (ix) cost containment; (x) clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of covered prescription drugs; “provided, however, that “pharmacy benefit manager” shall not include a health benefit plan sponsor that (i) contracts with a pharmacy benefit manager, (ii) manages a subset of pharmacy benefit management functions within its own organization, and (iii) is licensed as a carrier by the division.

SECTION 18. The first paragraph of section 7 of said chapter 12C, as so appearing, is hereby amended by adding the following sentence: - Each pharmaceutical and biopharmaceutical manufacturing company and pharmacy benefit manager shall pay to the commonwealth an amount for the estimated expenses of the center and for the other purposes described in this chapter.

SECTION 19. Said chapter 12C is hereby further amended by striking out section 7, most recently amended by section 21 of Senate Bill 3012, and inserting in place thereof the following section:

Section 6. (a) For the purposes of this section, "non-hospital provider organization" shall mean a provider organization required to register under section 11 that is: (i) a non-hospital-based physician practice with not less than $500,000,000 in annual gross patient service revenue; (ii) a clinical laboratory; (iii) an imaging facility; or (iv) a network of affiliated urgent care centers.

(b) Each acute hospital, ambulatory surgical center, non-hospital provider organization, pharmaceutical manufacturing company and pharmacy benefit manager shall pay to the commonwealth an amount for the estimated expenses of the commission

(c) The assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations shall be 25 percent of the amount appropriated by the general court for the expenses of the commission minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the commission; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies; provided, however, that, to the maximum extent permissible under federal law, non hospital provider organizations shall be assessed not less than 3 per cent nor more than 8 per cent of the total assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay such assessed amount multiplied by the ratio of the acute hospital's, ambulatory surgical center's or non-hospital provider organization's gross patient service revenues to the total gross patient

service revenues of all such hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall make a preliminary payment to the commission on October 1 of each year in an amount equal to 1/2 of the previous year's total assessment. Thereafter, each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay, within 30 days' notice from the commission, the balance of the total assessment for the current year based upon its most current projected gross patient service revenue. The commission shall subsequently adjust the assessment for any variation in actual and estimated expenses of the commission and for changes in acute hospital, ambulatory surgical center and non-hospital provider organization gross patient service revenue. Such estimated and actual expenses shall include an amount equal to the cost of fringe benefits and indirect expenses, as established by the comptroller under section 5D of chapter 29. In the event of late payment by any such acute hospital, ambulatory surgical center or non-hospital provider organization, the treasurer shall advance the amount of due and unpaid funds to the commission prior to the receipt of such monies in anticipation of such revenues up to the amount authorized in the then current budget attributable to such assessments and the commission shall reimburse the treasurer for such advances upon receipt of such revenues. This section shall not apply to any state institution or to any acute hospital which is operated by a city or town.

(d) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmaceutical manufacturing companies shall be 25 per cent of the amount appropriated by the general court for the expenses of the commission minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the commission; and (iii) federal matching

revenues received for these expenses or received retroactively for expenses of predecessor agencies. Each pharmaceutical manufacturing company shall pay such assessed amount multiplied by the ratio of MassHealth's net spending for the manufacturer's prescription drugs used in the MassHealth rebate program to MassHealth's total pharmacy spending.

(e) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmacy benefit managers shall be 25 per cent of the amount appropriated by the general court for the expenses of the commission minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the commission; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies. Each pharmacy benefit manager shall pay such assessed amount multiplied by the ratio of the claims paid by the pharmacy benefit manager attributed to residents of the commonwealth for whom it manages pharmaceutical benefits on behalf of carriers to the total of all such claims paid by all pharmacy benefit managers attributed to residents of the commonwealth for whom they manage pharmaceutical benefits on behalf of carriers.

(f) Each pharmaceutical manufacturing company and each pharmacy benefit manager shall make a preliminary payment to the commission annually on October 1 in an amount equal to 1/2 of the previous year's total assessment. Thereafter, each pharmaceutical manufacturing company and each pharmacy benefit manager shall pay, within 30 days of receiving notice from the commission, the balance of the total assessment for the current year as determined by the commission.

SECTION 20. Said chapter 12C is hereby further amended by striking out section 10A, most recently amended by section 22 of Senate Bill 3012, and inserting in place thereof the following section:

Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform reporting of information from pharmaceutical manufacturing companies to enable the center to analyze: (i) year-over-year changes in wholesale acquisition cost and average manufacturer price or prescription drug products; (ii) year-over-year trends in net expenditures; (iii) net expenditures on subsets of biosimilar, brand name and generic drugs identified by the center; (iv) trends in estimated aggregate drug rebates, discounts or other remuneration paid or provided by a pharmaceutical manufacturing company to a pharmacy benefit manager, wholesaler, distributor, health carrier client, health plan sponsor or pharmacy in connection with utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing company; (v) discounts provided by a pharmaceutical manufacturing company to a consumer in connection with utilization of the pharmaceutical drug products offered by the pharmaceutical manufacturing company, including any discount, rebate, product voucher, coupon or other reduction in a consumer's out-of-pocket expenses including co-payments and deductibles under section 3 of chapter 175H; (vi) research and development costs as a percentage of revenue; (vii) annual marketing and advertising costs, identifying costs for direct-to-consumer advertising; (viii) annual profits over the most recent 5-year period; (ix) disparities between prices charged to purchasers in the commonwealth and purchasers outside of the United States; and (x) any other information deemed necessary by the center. The center shall require the submission of available data and other information from pharmaceutical manufacturing companies including, but not limited to: (i) wholesale acquisition costs and average manufacturer prices for prescription drug

products as identified by the center; (ii) true net typical prices charged to pharmacy benefits managers by payor type for prescription drug products identified by the center, net of any rebate or other payments from the manufacturer to the pharmacy benefits manager and from the pharmacy benefits manager to the manufacturer; (iii) aggregate, company-level research and development costs to the extent attributable to a specific product and other relevant capital expenditures for the most recent year for which final audited data is available for prescription drug products as identified by the center; (iv) annual marketing and advertising expenditure; (v) the total amount of federal and state tax credits, incentives, grants and other subsidies provided to the manufacturer over the previous 10 calendar years that have been used to assist in the research and development of eligible drugs; and (vi) a description, absent proprietary information and written in plain language, of factors that contributed to reported changes in wholesale acquisition costs, net prices and average manufacturer prices for prescription drug products as identified by the center.

(b) The center shall promulgate regulations necessary to ensure the uniform reporting of information from pharmacy benefit managers to enable the center to analyze: (i) trends in estimated aggregate drug rebates and other drug price reductions, if any, provided by a pharmacy benefit manager to a health carrier client or health plan sponsor or passed through from a pharmacy benefit manager to a health carrier client or health plan sponsor in connection with utilization of drugs in the commonwealth offered through the pharmacy benefit manager and a measure of lives covered by each health carrier client or health plan sponsor in the commonwealth; (ii) pharmacy benefit manager practices with regard to drug rebates and other drug price reductions, if any, provided by a pharmacy benefit manager to a health carrier client or health plan sponsor or to consumers in the commonwealth or passed through from a pharmacy

benefit manager to a health carrier client or health plan sponsor or to consumers in the commonwealth; and (iii) any other information deemed necessary by the center. The center shall require the submission of available data and other information from pharmacy benefit managers including, but not limited to: (i) true net typical prices paid by pharmacy benefits managers for prescription drug products identified by the center, net of any rebate or other payments from the manufacturer to the pharmacy benefit manager and from the pharmacy benefit manager to the manufacturer; (ii) the amount of all rebates that the pharmacy benefit manager received from all pharmaceutical manufacturing companies: (A) for all health carrier clients in the aggregate; (B) for each health carrier client or health plan sponsor individually; and (C) by drug, for 30 of the most utilized drugs in the commonwealth as determined by the center; (iii) the administrative fees that the pharmacy benefit manager received from all health carrier clients or health plan sponsors in the aggregate and for each health carrier client or health plans sponsors individually; (iv) the aggregate amount of rebates a pharmacy benefit manager: (A) retains based on its contractual arrangement with each health plan client or health plan sponsor individually; and (B) passes through to each health care client individually; (v) the aggregate amount of all retained rebates that the pharmacy benefit manager received from all pharmaceutical manufacturing companies and did not pass through to each pharmacy benefit manager's health carrier client or health plan sponsor individually; (vi) the percentage of contracts that a pharmacy benefit manager holds where the pharmacy benefit manager: (A) retains all rebates; (B) passes all rebates through to the client; and (C) shares rebates with the client; and (vii) other information as determined by the center, including, but not limited to, pharmacy benefit manager practices related to spread pricing, administrative fees, claw backs and formulary placement.

(c) Except as specifically provided otherwise by the center or under this chapter, data collected by the center pursuant to this section from pharmaceutical manufacturing companies and pharmacy benefit managers shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 or under chapter 66.

Section 21. Said chapter 12C is hereby further amended by inserting after section 10A the following section:-

Section 10B:

(a) Definitions - For the purposes of this section,

(i) Applicable group purchasing organization. The term “applicable group purchasing organization” means a group purchasing organization (as defined by the Center) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the Massachusetts, or in a territory, possession, or commonwealth of the Massachusetts.

(ii) Applicable manufacturer. The term “‘applicable manufacturer” means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the Massachusetts, or in a territory, possession, or commonwealth of the Massachusetts.

(iii) Clinical investigation. The term “clinical investigation” means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(iv) Covered device. The term “covered device” means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(v) Covered drug, device, biological, or medical supply. The term "covered drug, device, biological, or medical supply" means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(vi) Covered recipient. The term "covered recipient" means the following, physician; teaching hospital; physician assistant; nurse practitioner, or clinical nurse specialist; certified registered nurse anesthetist; certified nurse-midwife; and Patient Advocacy Organizations. Such term does not include a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, or certified nurse-midwife who is an employee of the applicable manufacturer that is required to submit information under subsection (b).

(vii) Manufacturer of a covered drug, device, biological, or medical supply. The term "manufacturer of a covered drug, device, biological, or medical supply" means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

(viii) Payment or other transfer of value. The term "payment or other transfer of value" means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered

recipient. An applicable manufacturer shall not be required to submit information under subsection (b) with respect to the following:

(1) A transfer of anything the value of which is less than $$13.07, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $130.66. For calendar years after 2025, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(2) Product samples that are not intended to be sold and are intended for patient use.

(3) Educational materials that directly benefit patients or are intended for patient use.

(4) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(5) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(6) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(7) Discounts (including rebates).

(8) In-kind items used for the provision of charity care.

(9) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund

(10) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(11) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.

(12) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

(b) Payments or other transfers of value

(i) On March 31, 2027 and on the 90th day of each calendar year thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Center, in such electronic form as the Center shall require, the following information with respect to the preceding calendar year:

(1) The name of the covered recipient.

(2) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.

(3) The amount of the payment or other transfer of value.

(4) The dates on which the payment or other transfer of value was provided to the covered recipient.

(5) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) cash or a cash equivalent;

(II) in-kind items or services;

(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

(IV) any other form of payment or other transfer of value (as defined by the Center).

(6) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) consulting fees;

(II) compensation for services other than consulting;

(III) honoraria;

(IV) gift;

(V) entertainment;

(VI) food;

(VII) travel (including the specified destinations);

(VIII) education;

(IX) research;

(X) charitable contribution;

(XI) royalty or license;

(XII) current or prospective ownership or investment interest;

(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;

(XIV) grant; or

(XV) any other nature of the payment or other transfer of value (as defined by the Center).

(7) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

(8) Any other categories of information regarding the payment or other transfer of value the Center determines appropriate.

(ii) Special rule for certain payments or other transfers of value.—In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(iii) Physician ownership. On March 31, 2027, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Center, in such electronic form as the Center shall require, the following information regarding any ownership or investment interest held by a physician or an immediate family member of such physician in the applicable manufacturer or applicable group purchasing organization during the preceding year:

(1) The dollar amount invested by each physician holding such an ownership or investment interest.

(2) The value and terms of each such ownership or investment interest.

(3) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (1) through (8) of paragraph (b(i), except that in applying such clauses, “physician” shall be substituted for “covered recipient” each place it appears.

(4) Any other information regarding the ownership or investment interest the Center determines appropriate.

(c) (i) The Center shall establish procedures for applicable manufacturers and applicable group purchasing organizations to submit information to the Center under subsection (b); and for the Center to make such information submitted available to the public.

(ii) Except as provided in subparagraph (e) the procedures established under subparagraph (c)(i) shall ensure that, not later than September 30, 2027, and on June 30 of each

calendar year beginning thereafter, the information submitted under subsection (b) with respect to the preceding calendar year is made available to public at CHIA website that

(1) is searchable and is in a format that is clear and understandable;

(2) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate), the nature of the payment or other transfer of value, indicated (as appropriate), and the name of the covered drug, device, biological, or medical supply, as applicable;

(3) contains information that is able to be easily aggregated and downloaded;

(4) contains a description of any enforcement actions taken to carry out this section.

(5) contains background information on industry-physician relationships;

(6) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (e)(i), lists such information separately from the other information submitted under subsection (b) and designates such separately listed information as funding for clinical research;

(7) contains any other information the Center determines would be helpful to the average consumer;

(8) subject to subparagraph (d), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to

the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

(d) Clarification of time period for review and corrections. In no case may the 45-day period for review and submission of corrections to information under subparagraph (c)(ii)(8) prevent such information from being made available to the public.

(e) Delayed publication for payments made pursuant to product research or development agreements and clinical investigations.

(i) In general.—In the case of information submitted under subsection (b) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under subparagraph (b)(ii) shall provide that such information is made available to the public on the first date described in the matter preceding clause (i) in subparagraph (C) after the earlier of the following:

(I) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(II) Four calendar years after the date such payment or other transfer of value was made.

(ii) Confidentiality of information prior to publication.—Information described in clause (i) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

(2) Consultation. In establishing the procedures under paragraph (1), the Center shall consult with the Secretary of Executive Office of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

SECTION 22. Said chapter 12C is hereby further amended by striking out section 11, as appearing in the 2022 Official Edition, and inserting in place thereof the following section: - Section 11. The center shall ensure the timely reporting of information required under sections 8, 9, 10,10A and 10B. The center shall notify private health care payers, providers, provider organizations, pharmacy benefit managers, pharmaceutical manufacturing companies and their parent organization and other affiliates 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 and their parent organization and other affiliates, that has failed to meet a reporting deadline of such failure 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 and their parent organization and other affiliates, that fails, without just cause, to provide the requested information, including subsets of 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 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. The center may promulgate regulations to define “just cause” for the purpose of this section.

SECTION 23. Section 12 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 2, the words “and 10” and inserting in place thereof the following words:-, 10,10A and 10B.

SECTION 24. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence: - The center shall publish an annual report based on the information submitted under: (i) sections 8, 9, 10,10A and 10B concerning health care provider, provider organization, private and public health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii) section 15 of said chapter 6D relative to quality data.

SECTION 25. Said section 16 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 18, the words: - “in the aggregate”.

SECTION 26. Said section 16 of said chapter 12C, as so appearing, is hereby further amended by inserting after the second paragraph the following paragraph:- As part of its annual report, the center shall report on prescription drug utilization and spending for pharmaceutical drugs provided in an outpatient setting or sold in a retail setting for private and public health care payers, including, but not limited to, information sufficient to show the: (i) highest utilization drugs; (ii) drugs with the greatest increases in utilization; (iii) drugs that are most impactful on

plan spending, net of rebates; and (iv) drugs with the highest year-over-year price increases, net of rebates. The report shall not contain any data that is likely to compromise the financial, competitive or proprietary nature of the information contained in the report. The report shall be published on the website of the center.

SECTION 27. Prohibition on the Use of Utilization Management Criteria in Supplemental Rebate Negotiations.

Said Sub-section (b) of section 12A of said chapter 118E, as so appearing, is hereby further amended by inserting after the second paragraph the following paragraph:- The executive office of health and human services, managed care entities, pharmacy benefit managers, and any other entities involved in the administration of MassHealth benefits shall not condition, require, or utilize any form of utilization management criteria, including but not limited to prior authorization, step therapy, or quantity limits, as a negotiation tactic or requirement for the provision of supplemental rebates by manufacturers of prescription drugs. Negotiations for supplemental rebates shall be conducted in good faith, based solely on considerations of cost-effectiveness, clinical efficacy, and affordability, without tying such rebates to the imposition or removal of utilization management criteria. Nothing in this section shall preclude the application of utilization management criteria based solely on clinical guidelines or best practices aimed at improving patient outcomes, provided that such criteria are not used as a condition for supplemental rebate negotiations.

SECTION 28. Prohibition on the Use of Utilization Management Criteria in Supplemental Rebate Negotiations.

Said sub-section 8 of Section 3 of said chapter 176D as so appearing, is hereby further amended by inserting after the second paragraph the following paragraph:- The health plans, pharmacy benefit managers, and any other entities involved in the administration of health and pharmacy benefits shall not condition, require, or utilize any form of utilization management criteria, including but not limited to prior authorization, step therapy, or quantity limits, as a negotiation tactic or requirement for the provision of supplemental rebates by manufacturers of prescription drugs. Negotiations for supplemental rebates shall be conducted in good faith, based solely on considerations of cost-effectiveness, clinical efficacy, and affordability, without tying such rebates to the imposition or removal of utilization management criteria. Nothing in this section shall preclude the application of utilization management criteria based solely on clinical guidelines or best practices aimed at improving patient outcomes, provided that such criteria are not used as a condition for supplemental rebate negotiations.

SECTION 29. Section 27 and 28 shall take effect January 1, 2026, and shall apply to all contracts and negotiations initiated or renewed on or after such date.