SENATE DOCKET, NO. 1910 FILED ON: 1/17/2025

SENATE . . . . . No.

The Commonwealth of Massachusetts

PRESENTED BY:

Cindy F. Friedman

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 enhancing health care market oversight and pharmaceutical access.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Cindy F. Friedman	*Fourth Middlesex*

SENATE DOCKET, NO. 1910 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 enhancing health care market oversight and pharmaceutical access.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Section 1 of chapter 6D of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by inserting after the definition of "Alternative payment methodologies or methods" the following 3 definitions:-

"Benchmark cycle", a period of 2 consecutive calendar years during which the projected annualized growth rate in total health care expenditures in the commonwealth is calculated pursuant to section 9 and monitored pursuant to section 10.

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

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

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

SECTION 2. Said section 1 of said chapter 6D, as so appearing, 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 3. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by striking out the definition of "Health care cost growth benchmark" and inserting in place thereof the following definition:-

"Health care cost growth benchmark", the projected annualized growth rate in total health care expenditures in the commonwealth during a benchmark cycle, as established in section 9.

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

"Pipeline 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 5. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by striking out the definition of "Provider organization" and inserting the following definition:-

"Provider organization", a corporation, partnership, business trust, association or organized group of persons that is in the business of health care delivery or management, whether incorporated or not that represents 1 or more health care providers in contracting with carriers, third party administrators or public payers for the payments of health care services; provided, however, that "provider organization" shall include, but not be limited to, physician organizations, physician-hospital organizations, management services organizations, independent practice associations, provider networks, accountable care organizations, providers that are owned or controlled, fully or partially, by for-profit entities including, but not limited to, significant equity investor, and any other organization that contracts with carriers, third party administrators or public payers for payment for health care services.

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

"Total medical expenses", the total cost of care for the patient population associated with a provider organization based on allowed claims for all categories of medical expenses and all non-claims related payments to providers.

SECTION 7. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by adding the following definition:-

"Wholesale acquisition cost", the cost of a prescription drug as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

SECTION 8. Said chapter 6D, as so appearing, is hereby further amended by striking out section 2A, as so appearing, 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, 24 or 25 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, 24 or 25 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 9. Section 4 of said chapter 6D, as so appearing, is hereby amended by inserting after the words "biotechnology industry", in line 7, the following words:- , at least 2 pharmacists, one of whom shall be an independent pharmacist.

SECTION 10. Section 5 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “growth”, in line 3, the following words:- and affordability.

SECTION 11. Section 6 of chapter 6D, as amended by section 5 of chapter 342 of the acts of 2024, is hereby amended by striking out subsection (d) and inserting in place thereof the following subsection:-

(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 not less than 5 per cent nor more than 10 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 the pharmaceutical manufacturing company’s gross sales of outpatient prescription drugs dispensed in the commonwealth to the total gross sales of outpatient prescription drugs dispensed in the commonwealth.

SECTION 12. Subsection (a) of section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:- Not later than October 1 of every year, the commission shall hold public hearings based on the report submitted by the center pursuant to section 16 of chapter 12C comparing: (i) the average of the annual growth in total health care expenditures during each year of the most recently concluded benchmark cycle to the health care cost growth benchmark for that benchmark cycle;

and (ii) the growth in the affordability index pursuant to said section 16 of said chapter 12C to the affordability benchmark.

SECTION 13. Subsection (f) of said section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:- If the center's annual report pursuant to subsection (a) of section 16 of chapter 12C finds that the average of the annual percentage changes in total health care expenditures during a benchmark cycle exceeded the health care cost growth benchmark for that benchmark cycle or the percentage change in the affordability index exceeded the affordability benchmark, the commission may identify additional witnesses for the public hearing.

SECTION 14. Said chapter 6D, as so appearing, is hereby further amended by striking out sections 9 and 10 and inserting in place thereof the following 3 sections:-

Section 9. (a) Not later than April 15 of every year, the board shall establish the health care cost growth benchmark for a benchmark cycle consisting of the 2 calendar years beginning after the year in which the April 15 date occurs.

(b) The health care cost growth benchmark shall be equal to the average of the growth rate of potential gross state product established under section 7H½ of chapter 29 for each of the 2 calendar years that comprise the benchmark cycle. The commission shall establish procedures to prominently publish the health care cost growth benchmark on the commission’s website.

(c) For all benchmark cycles through the cycle containing the calendar years 2039 and 2040, if the commission determines that an adjustment in the health care cost growth benchmark is reasonably warranted, having first considered any testimony at a public hearing as required under subsection (d), the board of the commission may recommend a modification of the health

care cost growth benchmark, in any amount as determined by the commission. The board shall submit notice of its recommendation for any modification to the joint committee on health care financing. Within 30 days of such filing, the joint committee may hold a public hearing on the board's proposed modification to the health care cost growth benchmark. Within 30 days of the public hearing, the joint committee may report its findings and proposed legislation, including its recommendation on whether to affirm or reject the boards' recommendation, to the general court and provide a copy of its findings and proposed legislation to the board.

(d) Prior to making any recommended modification to the health care cost growth benchmark under subsection (c), the board shall hold a public hearing on any such recommended modification. The public hearing shall be based on the report submitted by the center pursuant to section 16 of chapter 12C comparing the average of the annual growth in total health care expenditures during each year of the most recently concluded benchmark cycle to the health care cost growth benchmark, any other data provided by the center and such other pertinent information or data as may be available to the board. The hearing shall examine the costs, prices and cost trends of health care provider, provider organization and private and public health care payer and any relevant impact of significant equity investors, health care real estate investment trusts, management services organizations, pharmaceutical manufacturing companies and pharmacy benefit managers on such costs, prices and cost trends, with particular attention to factors that contribute to cost growth within the commonwealth's health care system and whether, based on the testimony, information and data presented at the hearing, a modification in the health care cost growth benchmark is appropriate. The commission shall provide public notice of such hearing not less than 45 days prior to the date of the hearing, including notice to the joint committee on health care financing. The joint committee on health care financing may

participate in the hearing. The commission shall identify as witnesses for the public hearing a representative sample of providers, provider organizations, payers, significant equity investors, health care real estate investment trusts, management services organizations, pharmaceutical manufacturing companies, pharmacy benefit managers and such other interested parties as the commission may determine. Any other interested parties may testify at the hearing.

(e) Any recommendation of the commission to modify the health care cost growth benchmark under subsection (c) of this section shall be approved by a two-thirds vote of the board.

Section 9A. Not later than April 15 of every year, the board shall establish a health care affordability benchmark for the following calendar year. The commission shall establish procedures to prominently publish the annual affordability benchmark on the commission's website.

Section 10. (a) For the purpose of this section, “Health care entity” shall mean any health care entity identified by the center pursuant to section 18 of chapter 12C.

(b) The commission shall provide notice to a health care entity that the commission may analyze the health care spending performance of such health care entity and that such health care entity shall perform certain actions as provided in subsection (c); provided, however, that at the discretion of the commission, the commission may publicly identify the identities and performance results of such health care entity.

(c) The commission may require a performance improvement plan to be filed with the commission for a health care entity that is identified by the center under section 18 of chapter 12C.

(d) In addition to the notice provided under subsection (b), the commission shall provide written notice to a health care entity that it determines must file a performance improvement plan. Within 45 days of receipt of such written notice, the health care entity shall either:

(1) file a performance improvement plan with the commission; or

(2) file an application with the commission to waive or extend the requirement to file a performance improvement plan.

(e) The health care entity may file documentation or supporting evidence with the commission to support the health care entity's application to waive or extend the requirement to file a performance improvement plan. The commission shall require the health care entity to submit any other relevant information it deems necessary in considering the waiver or extension application; provided, however, that such information shall be made public at the discretion of the commission.

(f) The commission may waive or delay the requirement for a health care entity to file a performance improvement plan in response to a waiver or extension request filed under subsection (d) in light of all information received from the health care entity, based on a consideration of the following factors:

(1) the spending, price and utilization trends of the health care entity over time, independently and as compared to similar entities, and any demonstrated improvement to reduce spending or total medical expenses;

(2) any ongoing strategies or investments that the health care entity is implementing to improve future long-term efficiency and reduce spending growth;

(3) whether the factors that led to increased spending for the health care entity can reasonably be considered to be unanticipated and outside of the control of the entity. Such factors may include, but shall not be limited to, age and other health status adjusted factors and other cost inputs such as pharmaceutical expenses, medical device expenses and labor costs;

(4) the overall financial condition of the health care entity;

(5) a significant difference between the growth rate of potential gross state product and the growth rate of actual gross state product, as determined under section 7H½ of chapter 29; and

(6) any other factors the commission considers relevant.

(g) If the commission declines to waive or extend the requirement for the health care entity to file a performance improvement plan, the commission shall provide written notice to the health care entity that its application for a waiver or extension was denied and the health care entity shall file a performance improvement plan.

(h) A health care entity shall file a performance improvement plan: (1) within 45 days of receipt of a notice under subsection (d); (2) if the health care entity has requested a waiver or extension, within 45 days of receipt of a notice that such waiver or extension has been denied; or (3) if the health care entity is granted an extension, on the date given on such extension. The performance improvement plan shall identify the causes of the entity's excessive spending, and shall include, but not be limited to, specific strategies, adjustments and action steps the entity proposes to implement to improve spending performance. The proposed performance improvement plan shall include specific identifiable and measurable expected outcomes and a timetable for implementation. The timetable for a performance improvement plan shall not exceed 18 months.

(i) The commission shall approve any performance improvement plan that it determines is reasonably likely to address the underlying cause of the health care entity's excessive spending and has a reasonable expectation for successful implementation.

(j) If the board determines that the performance 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.

(k) Upon approval of the proposed performance improvement plan, the commission shall notify the health care entity to begin implementation of the performance improvement plan. Public notice shall be provided by the commission on its website, identifying that the health care entity is implementing a performance improvement plan. Health care entities implementing an approved performance improvement plan shall be subject to additional reporting requirements and compliance monitoring, as determined by the commission. The commission shall assist the health care entity with the successful implementation of the performance improvement plan.

(l) Health care entities subject to a performance improvement plan shall, in good faith, work to implement such plan and may file amendments to the performance improvement plan at any point during the implementation of the performance improvement plan, subject to approval of the commission.

(m) At the conclusion of the timetable established in the performance improvement plan, the health care entity shall report to the commission regarding the outcome of the performance improvement plan. If the commission finds that the performance improvement plan was unsuccessful, the commission shall either: (i) extend the implementation timetable of the existing performance improvement plan; (ii) approve amendments to the performance improvement plan

as proposed by the health care entity; (iii) require the health care entity to submit a new performance improvement plan under subsection (c), including requiring specific elements for approval; or (iv) waive or delay the requirement to file any additional performance improvement plans.

(n) Upon the successful completion of the performance improvement plan, the identity of the health care entity shall be removed from the list of entities currently implementing a performance improvement plan on the commission's website.

(o) The commission may submit a recommendation for proposed legislation to the joint committee on health care financing if the commission determines that further legislative authority is needed to achieve the commonwealth's health care quality and spending sustainability objectives, assist health care entities with the implementation of performance improvement plans or otherwise ensure compliance with the provisions of this section.

(p)(1) If the commission determines that a health care entity has: (i) willfully neglected to file a performance improvement plan with the commission within 45 days as required under subsection (d); (ii) failed to file an acceptable performance improvement plan in good faith with the commission; (iii) failed to implement the performance improvement plan in good faith; or (iv) knowingly failed to provide or falsified information required by this section to the commission, the commission may: (A) assess a civil penalty to the health care entity of not more than $500,000 for a first violation, not more than $750,000 for a second violation and not more than the amount of spending attributable to the health care entity that is in excess of the health care cost growth benchmark for a third or subsequent violation; provided, however, that a civil penalty assessed pursuant to one of the above clauses shall be a first offense if a previously

assessed penalty was assessed pursuant to a different clause; (B) stay consideration of any material change notice submitted under section 13 of this chapter by the health care entity or any affiliates until the commission determines that the health care entity is in compliance with this section; and (C) notify the department of public health that the health care entity, if applying for a notice of determination of need, is not in compliance with this section. A civil penalty assessed under this subsection shall be deposited into the Healthcare Payment Reform Fund established under section 100 of chapter 194 of the acts of 2011. Except as otherwise expressly authorized under this section, the commission shall seek to promote compliance with this section and shall only impose a civil penalty as a last resort.

(q) The commission shall promulgate regulations necessary to implement this section; provided, however, that notice of any proposed regulations shall be filed with the joint committee on state administration and regulatory oversight and the joint committee on health care financing not less than 180 days before adoption.

SECTION 15. Section 11 of said chapter 6D, as so appearing, is hereby amended by striking out, in line 3, the words “2 years” and inserting in place thereof the following words:- 1 year.

SECTION 16. Said section 11 of said chapter 6D, as so appearing, is hereby further amended by striking out subsection (b) and inserting in place thereof the following subsection:-

(b) The commission shall require that all provider organizations report information detailed in section 9 of chapter 12C. The commission may specify additional data elements in a given reporting year to support the development of the state health plan or the focused assessments defined in section 22 of chapter 6D.

SECTION 17. Said section 11 of said chapter 6D, as so appearing, is hereby further amended by striking out subsection (d) and inserting in place thereof the following subsection:-

(d) The commission may enter into interagency agreements with the center and other state agencies to effectuate the goals of this section.

SECTION 18. Said chapter 6D, as so appearing, is hereby further amended by striking out section 12 and inserting in place thereof the following section:-

Section 12. (a) The commission shall ensure the timely reporting of information required under section 11. The commission shall notify provider organizations of any applicable reporting deadlines; provided, that the commission shall notify, in writing, a provider organization that 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 commission may assess a penalty against a provider organization that fails, without just cause, to provide the requested information within 2 weeks following receipt of the written notice required under this subsection of up to $10,000 per week for each week of delay after the 2-week period following provider organization's receipt of the written notice; provided, however, that the maximum annual penalty against a provider organization under this section shall be $500,000 per registration cycle. Amounts collected under this section shall be deposited in the Healthcare Payment Reform Fund established under section 100 of chapter 194 of the Acts of 2011.

(b) Notwithstanding any general or special law to the contrary, any material change notice submitted under section 13 and any determination of need application submitted under sections 25B to 25G, inclusive, of chapter 111 by a provider organization that has failed to

provide required information pursuant to section 9 and section 11 of chapter 12C shall be incomplete until such time as the provider organization has provided such required information.

(c) Nothing in this chapter shall require a provider organization which represents providers who collectively receive, less than $25,000,000 in annual net patient service revenue to be registered if such provider or provider organization is not a risk-bearing provider organization or is not owned or controlled, whether fully or partially, directly or indirectly, by a significant equity investor.

SECTION 19. Subsection (a) of section 13 of said chapter 6D, as amended by section 24 of chapter 343 of the acts of 2024, is hereby amended by striking out the second paragraph and inserting in place thereof the following paragraph:-

Within 30 days of receipt of a completed notice filed under the commission's regulations, the commission shall conduct a preliminary review to determine whether the material change is likely to result in: (i) a significant impact on the commonwealth's ability to meet the health care cost growth benchmark established in section 9; (ii) a significant impact on the competitive market; or (iii) a significant negative impact on Massachusetts health care consumers, including, not limited to: (A) significantly increased costs; (B) significantly reduced quality; or (C) significantly impaired access to health care services, including for at-risk, underserved an government payer patient populations. If the commission finds that the material change is likely to result in a significant impact on the commonwealth's ability to meet the health care cost growth benchmark, on the competitive market, or on Massachusetts health care consumers, the commission may conduct a cost and market impact review under this section.

SECTION 20. Said section 13 of said chapter 6D, as amended by section 24 of chapter 343 of the acts of 2024, is hereby amended by striking out subsection (b) and inserting in place thereof the following subsection:-

(b) In addition to the grounds for a cost and market impact review set forth in subsection (a), if the commission finds, based on the center's benchmark cycle report under section 16 of chapter 12C, that the average of the annual percentage changes in total health care expenditures during each year of the benchmark cycle exceeded the health care cost growth benchmark for that benchmark cycle, the commission may conduct a cost and market impact review of any provider organization identified by the center under section 18 of said chapter 12C.

SECTION 21. Said section 13 of said chapter 6D, as amended by section 24 of chapter 343 of the acts of 2024, is hereby amended by striking out subsection (e) through subsection (l), inclusive, and inserting in place thereof the following subsections:

(e)(1) The commission shall make factual findings and issue a preliminary report on the cost and market impact review.

(2) In the report, the commission shall identify whether the proposed material change is likely to have a significant negative impact on Massachusetts health care consumers, including through significantly increased costs, significantly reduced quality, or significantly impaired access to health care services, including for at-risk, underserved and government payer patient populations. The commission's report shall identify the specific significant negative impacts anticipated and recommend modifications to the proposed material change to mitigate such impacts.

(3) In the report, the commission shall identify any provider or provider organization that meets all of the following criteria: (i) the provider or provider organization has, or likely will have as a result of the proposed material change, a dominant market share for the services it provides; (ii) the provider or provider organization charges, or likely will charge as a result of the proposed material change, prices for services that are materially higher than the median prices charged by comparable providers for the same services in the same market; and (iii) the provider or provider organization has, or likely will have as a result of the proposed material change, a health status adjusted total medical expense that is materially higher than the median total medical expense of comparable providers in the same market.

(f)(1) Within 30 days after issuance of a preliminary report, the provider or provider organization may respond in writing to the findings in the report. In its response, the provider or provider organization may identify any modifications it will make to the proposed material change to address any significant negative impacts on consumers identified in the commission's report. The commission shall then issue its final report.

(2) The commission shall refer to the attorney general its report on any proposed material change likely to result in significant harm to Massachusetts health care consumers.

(3) The commission shall refer to the attorney general its report on provider or provider organization that meets all 3 criteria under paragraph (3) of subsection (e).

(4) The commission shall issue its final report on the cost and market impact review within 185 days from the date that the provider or provider organization has submitted a completed notice to the commission; provided, that the provider or provider organization has certified substantial compliance with the commission's requests for data and information

pursuant to subsection (c) within 21 days of the commission's notice, or by a later date set by mutual agreement of the provider or provider organization and the commission.

(g) Nothing in this section shall prohibit a proposed material change under subsection (a); provided, however, that any proposed material change shall not be completed: (i) until at least 30 days after the commission has issued its final report; or (ii) if the attorney general brings an action under chapter 93A or any other law related to the material change, while such action is pending and prior to a final judgment being issued by a court of competent jurisdiction, whichever is later.

(h)(1) A material change with a significant negative impact on Massachusetts health care consumers, including through significantly increased costs, significantly reduced quality, or significantly impaired access to health care services, including for at-risk, underserved and government payer patient populations, shall constitute an unfair method of competition or unfair trade practice under chapter 93A subject to challenge pursuant to section 4 but not sections 9 or 11 of said chapter 93A. When the commission, under paragraph (2) of subsection (f), refers a report on a provider or provider organization to the attorney general, the report shall create a presumption that the provider or provider organization through the material change addressed in the report will have a significant negative impact on Massachusetts health care consumers and therefore through the material change will engage in an unfair practice in violation of chapter 93A. The attorney general may take action under chapter 93A or any other law to protect consumers in the health care market, including by bringing an action seeking to restrain such violation of chapter 93A. The commission's report shall be evidence in any such action brought by the attorney general.

(2) A provider or provider organization that meets the criteria in paragraph (3) of subsection (e) and makes a material change has engaged in an unfair method of competition or unfair and deceptive trade practice subject to challenge pursuant to section 4, but not sections 9 or 11, of chapter 93A. When the commission, under paragraph (3) of subsection (f), refers a report on a provider or provider organization to the attorney general, the report shall create a presumption that the provider or provider organization has met or through the material change addressed in the report will meet the 3 criteria in paragraph (3) of subsection (e) and therefore through a material change will engage in an unfair method of competition or unfair and deceptive trade practice in violation of chapter 93A. The attorney general may take action under chapter 93A or any other law to protect consumers in the health care market, including by bringing an action seeking to restrain such violation of chapter 93A. The commission's final report shall be evidence in any such action brought by the attorney general.

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

(j) The commission shall adopt regulations for conducting cost and market impact reviews and for administering this section. These regulations shall include definitions of material change and non-material change, primary service areas, dispersed service areas, dominant market share, materially higher prices and materially higher health status adjusted total medical expenses, and any other terms as necessary to provide market participants with appropriate notice. These regulations may identify filing thresholds in connection with this section; provided, however, that any financial threshold identified by the commission shall be adjusted annually based on any inflation index established by the United States Department of Health and Human

Services or similarly reliable national index, as set forth by the commission. All regulations promulgated by the commission shall comply with chapter 30A.

(k) Nothing in this section shall limit the application of other laws or regulations that may be applicable to a provider or provider organization, including laws and regulations governing insurance.

(l) Upon issuance of its final report pursuant to subsection (f), the commission shall provide a copy of said final report to the department of public health. The final report shall be included in the written record and considered by the department of public health during its review of an application for determination of need and considered where relevant in connection with licensure or other regulatory actions involving the provider or provider organization.

SECTION 22. Said chapter 6D, as so appearing, 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. Amounts collected under this section shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

SECTION 23. Section 22 of said chapter 6D, as inserted by section 24 of chapter 343 of the acts of 2024, is hereby amended by striking out subsection (c) and inserting in place thereof the following subsection:-

(c) The office shall provide direction to the center to establish and maintain on a current basis an inventory of all such health care resources together with all other reasonably pertinent

information concerning such resources. Agencies of the commonwealth that license, register, regulate or otherwise collect cost, quality or other data concerning health care resources shall cooperate with the office and the center in coordinating such data and information collected pursuant to this section and section 9 of chapter 12C. The inventory compiled pursuant to this section and said section 9 of said chapter 12C and all related information shall be maintained in a form usable by the general public and shall constitute a public record; provided, however, that any item of information which is confidential or privileged in nature under any other law shall not be regarded as a public record pursuant to this section.

SECTION 24. Said chapter 6D, as so appearing, is hereby further amended by adding the following 3 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 17Z of chapter 32A, section 10Z

of chapter 118E, section 47CCC of chapter 175, section 8DD of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G; or (v) other prescription drug products that may have a direct and significant impact on, and create affordability challenges for, the state's health care system and patients, by contributing to increased premiums, patient out-of-pocket costs, or for similar reasons, 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 17Z of chapter 32A, section 10Z of chapter 118E, section 47CCC of chapter 175, section 8DD of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G.

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

(b)(1) The commission shall review: (i) the impact of eligible drug costs on patient access, such as by significantly contributing to high patient out-of-pocket costs compared to other drugs, increased utilization management compared to other drugs, lack of coverage by payers, or similar factors as determined by the commission; and (ii) the extent to which eligible drug costs have created or likely will create affordability challenges for the state's health care system and patients, such as by contributing significantly to increased premiums or patient out-of-pocket costs compared to other drugs, or similar factors, as determined by the commission; provided, however, that the commission may prioritize the review of eligible drugs based on the significance of the potential impact to patients.

(2) In conducting a review of eligible drugs, the commission shall consider:

(i) the relevant factors contributing to the price paid in the state for the drug, including the wholesale acquisition cost, discounts, rebates, or other price concessions;

(ii) the average patient co-pay or other cost-sharing for the drug in the state;

(iii) whether the cost of the drug contributes to inequities in health care access or outcomes;

(iv) the price and availability of therapeutic alternatives in the state;

(v) 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;

(vi) input from other stakeholders, which may include, but shall not be limited to: patient advocacy organizations, consumer advocacy organizations, providers, provider organizations and payers; and

(vii) any other factors the commission deems relevant.

(3) In conducting a review of eligible drugs, the commission may request relevant information 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.

(4) 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;

(v) information regarding the drug's prices, net of rebates, internationally, nationally, and in Massachusetts; and

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

(c)(1) Based on the records and information provided under subsection (b), available information from the center, from an outside third party, or that is otherwise available to the commission or any of its subdivisions, the commission shall identify a proposed value for the eligible drug. In identifying proposed values for eligible drugs, the commission may prioritize

drugs based on the commission's determination of the significance of the drug cost's impact on patient access or the extent to which the drug's cost have created or likely will create affordability challenges for the state's health care system or patients.

(2) The commission shall base the proposed value on:

(i) the cost of delivering and administering the drug;

(ii) the status of the drug on the drug shortage list published by the Food and Drug Administration;

(iii) the drug's status as an orphan drug; and

(iv) other factors the commission deems relevant in determining a drug's value.

(3) The commission may request additional relevant information from the manufacturer and from other entities, including, but not limited to, pharmacy benefit managers and payers, and may base the proposed value on this additional information.

(4) 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 the commission determines that the cost 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; provided, however, that the commission shall determine a threshold establishing how much more a drug must cost than the proposed value to substantially exceed the proposed value; and provided further, that the threshold shall require the cost to be at least 15 per cent above the proposed value. 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 cost 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. The commission shall also notify the manufacturer that the manufacturer may agree to undertake actions that will lower the cost of the drug for units of the drugs that are dispensed or administered to an individual in the state in person, by mail, or by other means. The manufacturer shall respond with such actions within 30 days of receiving the notification.

(f) The commission may revise the proposed value for an eligible drug based on the information provided pursuant to subsection (e). Not later than 60 days after receiving information from the manufacturer under subsection (b) or subsection (e), if any, and actions agreed to by the manufacturer to lower the cost of the drug under subsection (e), if any, the commission shall publicly issue a determination on whether the cost of an eligible drug substantially exceeds the commission's proposed value of the drug. If the commission determines that the cost 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 set an upper payment limit for the drug under section 25. (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.

In issuing public determinations under subsection (f), the commission shall not identify 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. Such prices or rebates 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) The commission shall be permitted to request relevant information to effectuate the purposes of this section. This information may include, but shall not be limited to, drug pricing, utilization, and other relevant information from manufacturers, pharmacy benefit managers, wholesalers, payers, providers, provider organizations, and third parties. To the extent practicable, in collecting said information the commission shall collaborate with the center to

avoid collecting duplicative information and reduce the administrative burden on the entities providing the information.

If a 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 subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

The failure of any entity to provide any requested information to the commission or the center, or the failure of a manufacturer to agree to undertake actions to lower the cost of a drug pursuant to subsection (e), shall not impair the commission's ability to exercise the commission's authority under this section or section 25.

(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) Upon providing written notice provided under subsection (f) of section 24, the commission may set an upper payment limit for an eligible drug if the cost of the eligible drug substantially exceeds the commission's proposed value of the drug.

(b) The upper payment limit shall be based on the proposed value for the eligible drug; provided, however, that if the commission revised the proposed value pursuant to subsection (f)

of section 24, the upper payment limit shall be based on the drug's revised proposed value. The commission may annually raise a drug's upper payment limit to account for inflation. An upper payment limit does not include a pharmacy dispensing fee and nothing in this section shall be interpreted to prevent a retail pharmacy from receiving a payment that includes a dispensing fee above the upper payment limit.

(c) The upper payment limit applies to all purchases of the drug and reimbursements for a claim for the drug when the drug is dispensed or administered to an individual in the state in person, by mail, or by other means. The commission shall adopt regulations to ensure that the upper payment limit does not apply to transactions or entities that federal law prohibits states from regulating.

(d) Upper payment limits shall become effective six months after the commission has issued a public determination under subsection (f) of section 24 and shall apply only to purchases, contracts, and plans that are issued on or renewed after the upper payment limit goes into effect.

(e) A self-insured plan governed by the Employee Retirement Income Security Act of 1974 may elect to be subject to the upper payment limits.

(f) The commission may suspend an upper payment limit if the commission determines that there is a shortage of the drug in the state, unless the commission determines that the shortage was caused by a manufacturer or the manufacturer's agent due to the commission establishing an upper payment limit for the drug.

(g) Any manufacturer or wholesaler that intends to withdraw from sale or distribution within the state a drug for which the commission has established an upper payment limit shall

provide a notice of withdrawal in writing at least 6 months before the withdrawal to the commission, the commissioner of the division of insurance, the attorney general, and any entity in the state with which the manufacturer or wholesaler has a contract for the sale or distribution of the drug. The commission shall assess a penalty not to exceed one year's worth of the manufacturer's revenue attributable to use of the drug in the commonwealth, as determined by the commission, if the commission determines that a manufacturer or wholesaler failed to provide said notice. This subsection shall not apply in instances where the drug is being withdrawn due to a recall or revocation of the drug's approval by the Food and Drug Administration, or similar reasons as determined by the commission.

(h) Any savings that a carrier, a participating self-insured plan, or the group insurance commission generates due to the implementation of an upper payment limit shall be used to reduce costs to consumers, prioritizing the reduction of premiums or out-of-pocket costs for prescription drugs. Annually, each carrier, participating self-insured plan, the group insurance commission, and the division of medical assistance shall submit to the commission 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.

(i) The attorney general shall be permitted to enforce this subsection.

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

Section 26. (a) A private equity company shall not engage in a transaction involving a provider or provider organization that the private equity company directly or indirectly owns or controls if the transaction has a reasonable likelihood of causing or materially contributing to the

provider or provider organization's financial distress due to placing an excessively high level of debt on the provider or provider organization or for similar reasons.

A private equity company that directly or indirectly owns or controls a provider or provider organization shall not cause or otherwise take actions that would reasonably likely lead the provider or provider organization to: (i) issue debt-funded dividends; (ii) pay to the private equity company management fees or similar fees or costs; or (iii) issue dividends at a time or in an amount, or perform any other action or exceed any other metric, that has a reasonable likelihood of causing the provider or provider organization to become financially distressed.

(b) A provider or provider organization that a private equity company directly or indirectly owns or controls shall not engage in a transaction if the transaction has a reasonable likelihood of causing or materially contributing to the provider or provider organization's financial distress due to placing an excessively high level of debt on the provider or provider organization or for similar reasons.

A provider or provider organization that a private equity company directly or indirectly owns or controls shall not: (i) issue debt-funded dividends; (ii) pay to the private equity company management fees or similar fees or costs; or (iii) issue dividends at a time or in an amount, or perform any other action or exceed any other metric, that has a reasonable likelihood of causing the provider or provider organization to become financially distressed.

(c) A health care real estate investment trust and a provider or provider organization shall not engage in a transaction if the transaction has a reasonable likelihood of causing or materially contributing to the provider or provider organization's financial distress.

(d) A violation of this section shall constitute an unfair method of competition or unfair trade practice under chapter 93A, and the attorney general may take action under said chapter 93A or any other law to protect consumers in the health care market. Upon becoming aware of a violation the commission shall notify the attorney general and any labor organization representing workers who work or worked for the provider or provider organization or in the provider or provider organization's facilities. Only the attorney general or said labor organizations may bring an action under said chapter 93A for a violation of this section. If an action is brought against a provider or provider organization under said chapter 93A, only injunctive relief and reasonable attorney's fees and costs may be obtained.

(e) To effectuate the purposes of this section, the commission may consider all publicly available data and documents, including information submitted to the commission and the center under any authority. The commission may also solicit additional non-public information from providers or provider organizations to the extent necessary to achieve the purposes of this section. The commission shall keep confidential all nonpublic information and documents obtained under this section, and such information shall not be public records and shall be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66.

(f) The commission shall promulgate regulations to effectuate the purposes of this section. Prior to making any notifications pursuant to subsection (d), the commission shall promulgate regulations defining financial distress and the metrics used to measure financial distress.

SECTION 25. Section 5A of chapter 12 of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by striking out, in line 39, the words “an individual” and inserting in place thereof the following words:- a person.

SECTION 26. Said section 5A of said chapter 12, as amended by section 27 of chapter 343 of the acts of 2024, is hereby further amended striking out the words “or (3) interest held by a pool of funds by investors, including a pool of funds managed or controlled by private limited partnerships, if those investors or management of that pool or private limited partnership employ investment strategies of any kind to earn a return on that pool of funds” and inserting in place thereof the following words:- (3) interest held by a pool of funds by investors, including a pool of funds managed or controlled by private limited partnerships, if those investors or the management of that pool or private limited partnership employ investment strategies of any kind to earn a return on that pool of funds; or (4) interest held by a health care real estate investment trust.

SECTION 27. Said section 5A of said chapter 12, as appearing in the 2022 Official Edition, is hereby further amended by striking out, in line 56, the words “an individual” and inserting in place thereof the following words:- a person.

SECTION 28. Section 5C of said chapter 12, as so appearing, is hereby amended by striking out, in line 7, the words “an individual” and inserting in place thereof the following words:- a person.

SECTION 29. Section 5G of said chapter 12, as so appearing, is hereby amended by striking out, in line 7, the words “an individual” and inserting in place thereof the following words:- a person.

SECTION 30. Section 11N of said chapter 12, as amended by section 30 of chapter 343 of the acts of 2024, is hereby amended by striking out the words “or management services organization” and inserting in place thereof the following words:- , management services organization, pharmaceutical manufacturing company and pharmacy benefit manager.

SECTION 31. Said section 11N of said chapter 12, as so appearing, is hereby further amended by striking out subsection (b) and inserting in place thereof the following subsection:-

(b) The attorney general may investigate any provider organization referred to the attorney general by the health policy commission under chapter 6D to determine whether the provider organization engaged in unfair methods of competition, unfair or deceptive trade practices or anti-competitive behavior in violation of chapter 93A or any other law, and, if appropriate, take action under said chapter 93A or any other law to protect consumers in the health care market, including, but not limited to, an action for injunctive relief.

SECTION 32. 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 4 definitions:-

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

“Benchmark cycle”, a period of 2 consecutive calendar years during which the projected annualized growth rate in total health care expenditures in the commonwealth is calculated pursuant to section 9 of chapter 6D and monitored pursuant to section 10 of said chapter 6D.

"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 33. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by inserting after the definition of "General health supplies, care or rehabilitative services and accommodations" the following definition:-

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962 that was not originally marketed under a new drug application; or (iv) identified by the carrier as a generic drug based on available data resources such as Medi-Span.

SECTION 34. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by striking out the definition of “Health care cost growth benchmark” and inserting in place thereof the following 2 definitions:-

“Health care cost growth benchmark”, the projected annualized growth rate in total health care expenditures in the commonwealth during a benchmark cycle as established in section 9 of chapter 6D.

“Health care entity”, as defined in section 1 of chapter 6D.

SECTION 35. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by striking out the definition of “Provider organization” and inserting in place thereof the following definition:-

“Provider organization”, any corporation, partnership, business trust, association or organized group of persons, which is in the business of health care delivery or management, whether incorporated or not, that represents at least 1 health care providers in contracting with carriers, third party administrators or public payers for the payments of health care services; provided, that "provider organization" shall include, but not be limited to, physician organizations, physician-hospital organizations, independent practice associations, provider networks, accountable care organizations, management services organizations, providers that are owned or controlled, fully or partially, by for-profit entities, including, but not limited to, significant equity investors, and any other organization that contracts with carriers, third party administrators or public payers for payment for health care services.

SECTION 36. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by inserting after the definition of “Total health care expenditures” the following definition:-

“Total medical expenses”, the total cost of care for the patient population associated with a provider organization based on allowed claims for all categories of medical expenses and all non-claims related payments to providers.

SECTION 37. Section 3 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 11, the word “benchmark” and inserting in place thereof the following words:- and affordability benchmarks.

SECTION 38. Said section 3 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 12, the words “section 9” and inserting in place thereof the following words:- sections 9 and 9A.

SECTION 39. Section 7 of chapter 12C, as amended by section 21 of chapter 342 of the acts of 2024, is hereby amended by striking out subsection (d) and inserting in place thereof the following subsection:-

(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 not less than 5 per cent of nor more than 10 per cent the amount appropriated by the general court for the expenses of the center minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the center; 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 the pharmaceutical manufacturing company's gross sales of outpatient prescription drugs dispensed in the commonwealth to the total gross sales of outpatient prescription drugs dispensed in the commonwealth.

SECTION 40. Section 9 of said chapter 12C, as so appearing, is hereby amended by striking out subsections (d) and (e) and inserting in place thereof the following subsections:-

(d) Notwithstanding the annual reporting requirements under this section, the center may require in writing, at any time, such additional information as it deems reasonable and necessary to determine the organizational structure, business practices, clinical services, market share or financial condition of a registered provider organization, including information related to its total adjusted debt and total adjusted earnings. The center shall also collect and analyze such data as it considers necessary to monitor compliance with section 26 of chapter 6D, and shall refer to the commission any provider, provider organization or private equity company that the center reasonably believes has violated section 26 of chapter 6D. The center may: (i) modify uniform reporting requirements; (ii) require registered provider organizations with private equity investment to report required information quarterly or upon request from the center; or (iii) require the disclosure of relevant information from any significant equity investor associated with a registered provider organization.

The information shall be analyzed on an industry-wide and provider-specific basis and shall include, but not be limited to: (i) gross and net patient service revenues; (ii) sources of revenue; (iii) total payroll as a per cent of operating expenses and the salary and benefits of the top 10 highest compensated employees, identified by position description and specialty; and (iv) other relevant measures of financial health or distress.

The center shall publish annual reports and establish a continuing program of investigation and study of financial trends among registered provider organizations, including an analysis of systemic instabilities or inefficiencies that contribute to financial distress. The reports shall include an identification and examination of registered provider organizations that the center considers to be in financial distress, including any at risk of closing or discontinuing essential health services, as defined by the department of public health under section 51G of chapter 111, as a result of financial distress.

(e) The center shall develop and maintain an inventory of health care resources on its website in a form usable by the public; provided, that the extracts must include information on the geographic distribution of clinicians, facilities, equipment or any other health care resources. Such inventory shall be derived from all available data, including, but not limited to, data collected under this section and data collected by other state agencies. Agencies that license, register, regulate or otherwise collect cost, quality or other data concerning health care resources shall provide the center and the commission such data and information necessary to develop and maintain the inventory required by this this section.

(f) The center may enter into interagency agreements with the commission and other state agencies to effectuate the goals of this section.

SECTION 41. Section 10 of said chapter 12C, as so appearing, is hereby amended by inserting after the word “of”, in line 21, the following words:- communities and purchaser.

SECTION 42. Subsection (b) of said section 10 of said chapter 12C, as so appearing, is hereby further amended by striking out clause (8) and inserting in place thereof the following clause:-

(8) relative prices paid to every hospital or physician group in the payer's network, by type of provider, with hospital inpatient and outpatient prices listed separately and product type, including health maintenance organization and preferred provider organization products.

SECTION 43. Said subsection (b) of said section 10 of said chapter 12C, as so appearing, is hereby further amended by striking out, in lines 56 to 61, inclusive, the words "and (11) a comparison of relative prices for the payer's participating health care providers by provider type which shows the average relative price, the extent of variation in price, stated as a percentage, and identifies providers who are paid more than 10 per cent, 15 per cent and 20 per cent above and more than 10 per cent, 15 per cent and 20 per cent below the average relative price" and inserting in place thereof the following words:- (11) information about prescription drug utilization and spending for all covered drugs, including for generic drugs, brand-name drugs and specialty drugs provided in an inpatient or outpatient setting or sold in a retail setting, 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; (iv) drugs with the highest year-over-year price increases, net of rebates; (v) drugs with the highest out-of-pocket costs including, but not limited to, coinsurances, copayments and deductibles expended by patients; and (vi) drugs with the highest cost per prescription both gross and net of rebates; (12) information on clinical quality, care coordination and patient referral practices; and (13) a comparison of relative prices for the payer's participating health care providers by provider type, which shows the average relative price and the extent of variation in price and identifies providers who are paid more than 10 per cent, 15 per cent and 20 per cent above and more than 10 per cent, 15 per cent and 20 per cent below the average relative price.

SECTION 44. Subsection (c) of said section 10 of said chapter 12C, as so appearing. is hereby amended by striking out clause (8) and inserting in place thereof the following clause:-

(8) relative prices paid to every hospital or physician group in the payer's network, by type of provider, with hospital inpatient and outpatient prices listed separately and product type, including health maintenance organization and preferred provider organization products.

SECTION 45. Said subsection (c) of said section 10 of said chapter 12C, as so appearing, is hereby further amended by striking out, in lines 99 to 104, inclusive, the words "and (11) a comparison of relative prices for the payer's participating health care providers by provider type which shows the average relative price, the extent of variation in price, stated as a percentage and identifies providers who are paid more than 10 per cent, 15 per cent and 20 per cent above and more than 10 per cent, 15 per cent and 20 per cent below the average relative price" and inserting in place thereof the following words:- (11) information about prescription drug utilization and spending for all covered drugs, including for generic drugs, brand-name drugs and specialty drugs provided in an inpatient or outpatient setting or sold in a retail setting, 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, (v) drugs with the highest year-over-year price increases, net of rebates, and (v) drugs with the highest cost per prescription, both gross and net of rebates; (12) information on clinical quality, care coordination and patient referral practices; and (13) a comparison of relative prices for the payer's participating health care providers by provider type, which shows the average relative price and the extent of variation in price and identifies providers who are paid more than 10 per cent, 15 per cent and 20 per cent above and more than 10 per cent, 15 per cent and 20 per cent below the average relative price.

SECTION 46. Section 10A of said chapter 12C, as inserted by section 22 of chapter 342 of the acts of 2024, is hereby amended by striking out subsection (c) and adding the following subsections:-

(c) 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 for 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.

(d) Except as specifically provided otherwise by the center or under this chapter, data collected by the center pursuant to this section shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 and section 10 of chapter 66. No such data shall be disclosed in a manner that is likely to compromise the financial, competitive or proprietary nature of such data and other information, or that may identify specific prices charged for drugs, the value of any rebate amounts, individual drugs, or any pharmaceutical manufacturing company.

SECTION 47. Section 12 of said chapter 12C, as so appearing, is hereby amended by adding the following subsection:-

(c) Notwithstanding any general or special law to the contrary, a provider, private health care payer, public health care payer, agency, department, division, commission, board, authority or other public or quasi-public entity in the commonwealth that collects patient information, including personal data as defined in section 1 of chapter 66A, shall, upon a request from the center, provide such data to the center for any purpose consistent with this chapter; provided, however, that the disclosure of such information shall be in compliance with federal law.

SECTION 48. Section 16 of said chapter 12C, as so appearing, is hereby amended by inserting after the word “publish”, in line 1, the following words:- , for the most recently concluded benchmark cycle.

SECTION 49. Said section 16 of said chapter 12C, as so appearing, is hereby further amended by inserting after the word “submitted”, in line 2, the following words:- for that benchmark cycle.

SECTION 50. Said section 16 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 7, the word “benchmark” and inserting in place thereof the following words:- and affordability benchmarks.

SECTION 51. Said section 16 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 8, the words “section 9” and inserting in place thereof the following words:- sections 9 and 9A.

SECTION 52. Said section 16 of said chapter 12C, as appearing in the 2022 Official Edition, is hereby further amended by striking out, in the second sentence, the words “in the aggregate”.

SECTION 53. Said section 16 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 43, the words “and (12)” and inserting in place thereof the following words:- (12) a standard set of measures of health care affordability in the commonwealth, including family health care expenditures and an annual index of how such health care costs compare to the health care affordability benchmark set under section 9A of chapter 6D; and (13).

SECTION 54. Subsection (a) of 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 55. Said section 16 of said chapter 12C, as so appearing, is hereby further amended by adding the following subsection:-

(d) The center shall evaluate and report on individual private and public health care payer data metrics submitted to the center pursuant to clauses (1) to (5), inclusive, of subsection (b) of section 10 and data submitted to the division of insurance pursuant to section 21 of chapter 176O. The center shall include information on payer data in its annual report required under this

section; provided, however, that such information shall be reported on an industry-wide, payer-specific basis and shall include, but not be limited to: (i) operating margins; (ii) total margins; (iii) reserves in dollars and as a percentage of risk-based capital; (iv) enrollment and member months; (v) total premiums and premiums on a per member per month basis; (vi) total medical expenses and medical expenses on a per member per month basis; and (vii) total administrative expenses and administrative expenses on a per member per month basis; and provided further, that the center shall report this information by type of business, where possible.

SECTION 56. Section 17 of said chapter 12C, as amended by section 49 of chapter 343 of the acts of 2024, is hereby amended by inserting after the words “provider organization” the following words:- , pharmaceutical manufacturing company, pharmacy benefit manager.

SECTION 57. Said chapter 12C, as so appearing, is hereby further amended by striking out section 18 and inserting in place thereof the following section:-

Section 18. (a) The center shall perform ongoing analysis of data it receives under this chapter to identify any health care entity whose: (1) contribution to health care spending levels and growth, including but not limited to, spending levels and growth as measured by health-status adjusted total medical expense or total medical expense, is considered excessive and who threaten the ability of the state to meet the health care cost growth benchmark established by the commission under section 9 of chapter 6D; provided further, that the center shall identify cohorts for similar health care entities and establish differential standards for excessive growth rates within the health care cost growth benchmark established by the commission under section 9 of chapter 6D, based on factors which may include, but are not limited to, a health care entity’s

spending, pricing levels and payer mix; or (2) data is not submitted to the center in a proper, timely or complete manner.

(b) The center shall confidentially provide a list of the health care entities to the commission such that the commission may pursue further action under section 10 of chapter 6D. Confidential referrals under this section shall not preclude the center from using its authority to assess penalties for noncompliance under section 11.

SECTION 58. Section 13 of chapter 17 of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by adding the following subsection:-

(f) As used in this subsection, the following words shall have the following meanings unless the context clearly requires otherwise:

"Public health essential drug", a prescription drug, biologic or biosimilar approved by the United States Food and Drug Administration that: (i) appears on the Model List of Essential Medicines most recently adopted by the World Health Organization; (ii) is selected pursuant to section 17Z of chapter 32A, section 10Z of chapter 118E, section 47CCC of chapter 175, section 8DDD of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G; or (iii) is deemed an essential medicine by the commission due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living or because limited access to a certain population would pose a public health challenge. "Public health essential drug" shall also include all continuous glucose monitoring system components, all components of the continuous glucose monitoring system of which the component is a part and delivery devices selected pursuant to

section 17Z of chapter 32A, section 10Z of chapter 118E, section 47CCC of chapter 175, section 8DDD of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G.

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

SECTION 59. Chapter 29 of the General Laws, as so appearing, is hereby amending by inserting after section 2DDDDDD the following section:-

2EEEEEE. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The secretary of health and human services shall administer the fund and shall make expenditures from the fund, without further appropriation, to provide financial assistance to residents of the commonwealth for the cost of prescription drugs through the prescription drug costs assistance program established under section 246 of chapter 111. For the purpose of this section, "prescription drug" shall include the prescription drug and any drug delivery device needed to administer the drug that is not included as part of the underlying drug prescription.

The fund shall consist of: (i) revenue from appropriations or other money authorized by the general court and specifically designated to be credited to the fund; and (ii) funds from public or private sources, including, but not limited to, gifts, grants, donations, rebates and settlements received by the commonwealth that are specifically designated to be credited to the fund. Money remaining in the fund at the close of a fiscal year shall not revert to the General Fund and shall be available for expenditure in the following fiscal year.

(b) Annually, not later than March 1, the secretary shall report on the fund's activities detailing expenditures from the previous calendar year. The report shall include: (i) the number of individuals who received financial assistance from the fund; (ii) the breakdown of fund recipients by race, gender, age range, geographic region and income level; (iii) a list of all prescription drugs that were covered by money from the fund; and (iv) the total cost savings received by all fund recipients and the cost savings broken down by race, gender, age range and income level. The report shall be submitted to the clerks of the senate and house of representatives, senate and house committees on ways and means and the joint committee on health care financing; provided, however, that annually, not later than March 1, the report shall be published on the website of the executive office of health and human services.

(c) The secretary shall promulgate regulations or issue other guidance for the expenditure of the funds under this section.

SECTION 60. Subsection (b) of section 7H½ of chapter 29 of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:- Annually, not later than January 15, the secretary of administration and finance shall meet with the house and senate committees on ways and means and shall jointly develop a growth rate of potential gross state product for the calendar year that will begin 2 years following the calendar year in which the January 15 date occurs, which shall be agreed to by the secretary and the committees.

SECTION 61. Subsection (a) of section 17Z of chapter 32A of the General Laws, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Brand name drug" the following 3 definitions:-

"Continuous glucose monitoring system", a system to continuously sense, transmit and display blood glucose levels.

"Delivery device", a device that: (i) is used to deliver a brand name drug or a generic drug; and (ii) an individual can obtain with a prescription.

"Diabetes treatment supplies", supplies for the treatment of diabetes including, but not limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips, lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose monitors for use by the legally blind and visual magnifying aids for use by the legally blind; provided, however, that "diabetes treatment supplies" shall not include a brand name drug, a generic drug, a continuous glucose monitoring system component, or a delivery device.

SECTION 62. Said subsection (a) of said section 17Z of said chapter 32A, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby further amended by inserting after the definition of "Generic drug" the following definition:-

"Separate delivery device", a device that is used to deliver a brand name drug or a generic drug and that can be obtained with a prescription separate from, or in addition to, the brand name drug or generic drug that the device delivers.

SECTION 63. Subsection (b) of said section 17Z of said chapter 32A, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby amended by striking out the figure "2" and inserting in place thereof the following figure:- 3.

SECTION 64. Subsection (d) of said section 17Z of said chapter 32A, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby amended by adding the following 3 paragraphs:-

If use of a brand name drug or generic drug that the commission selects requires a separate delivery device, the commission shall select a delivery device for that drug in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the extent possible. The commission shall provide coverage for the delivery device; provided, however, that the delivery device shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The commission shall select a continuous glucose monitoring system in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs. The commission shall provide coverage for the continuous glucose monitoring system and all components thereof; provided, however, that the continuous glucose monitoring system and all components thereof shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The commission shall provide coverage for necessary diabetes treatment supplies. Such supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

SECTION 65. Subsection (e) of said section 17Z of said chapter 32A, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices, in the same manner in which the subsection applies to drugs.

SECTION 66. Subsection (f) of said section 17Z of said chapter 32A, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 67. Subsection (g) of said section 17Z of said chapter 32A, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 68. Said section 17Z of said chapter 32A, as inserted by section 26 of chapter 342 of the acts of 2024, is hereby amended by adding the following subsection:-

(h) A member and their prescribing health care provider shall have access to a clear, readily accessible and convenient process to request to use a different brand name drug or generic drug of the same pharmacological class in place of a brand name drug or generic drug selected under subsection (b). Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs selected under subsection (b) are contraindicated or will likely cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs and generic drugs selected under subsection (b) are expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to the commission establishing that the member has previously tried the brand name drugs and generic drugs selected under subsection (b); and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or prescribing health care provider has provided documentation to the commission establishing that the member: (A) is stable on a prescription drug prescribed by the

health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the member. This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices.

SECTION 69. Subsection (a) of section 21C of chapter 94C of the General Laws, as inserted by section 27 of chapter 342 of the acts of 2024, is hereby amended by striking out the definition of "Cost-sharing" and inserting in place thereof the following definition:-

"Cost-sharing", an amount owed by an individual under the terms of the individual's health benefit plan or, to the extent permissible under federal law, self-insurance plan.

SECTION 70. Subsection (c) of said section 21C of said chapter 94C, as inserted by section 27 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "carrier" the following words:- or pharmacy benefit manager.

SECTION 71. Section 25A of chapter 111 of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by striking out the first 5 paragraphs.

SECTION 72. Said chapter 111, as so appearing, is hereby further amended by inserting after section 244 the following 2 sections:-

Section 245. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Private equity company", as defined in section 1 of chapter 6D.

"Provider", as defined in section 1 of chapter 6D.

"Provider Organization", as defined in section 1 of chapter 6D.

(b) A private equity company engaging in a transaction that will lead to the private equity company obtaining direct or indirect ownership or control of a provider or provider organization shall deposit, upon submission of a notice of material change pursuant to section 13 of chapter 6D, a bond with the department. The private equity company shall not use the provider or provider organization or the provider or provider organization's assets or property as security for the bond, pay for the bond by placing debt on the provider or provider organization, permit the provider or provider organization to pay the bond on the private equity company's behalf, or allow the provider or provider organization to otherwise be liable or indemnify the private equity company firm for the bond.

(c) Until such bond has been deposited, the department shall not issue a license to such provider or provider organization under this chapter, the department of mental health shall not issue a license to such provider or provider organization under chapter 19, and any determination of need application submitted under sections 25B to 25G, inclusive, of said chapter 111 or material change notice submitted under section 13 of chapter 6D shall be deemed incomplete. If the bond has not been deposited, but the department would otherwise be permitted to collect the bond, the department shall be permitted to collect from the private equity company the amount the department would have been able to collect had the bond been deposited.

(d) The department, in consultation with the health policy commission, shall determine the amount of the bond, which shall equal 1 year of the provider or provider organization's average or estimated operating expenses, plus the estimated cost of hiring an independent supervisor and reasonable staff to supervise and facilitate collecting and spending the bond. The private equity company shall maintain the bond for as long as the private equity company

directly or indirectly owns or controls the provider or provider organization, and for 7 years thereafter.

(e) The department may collect the bond if the provider or provider organization declares bankruptcy, is at imminent risk of closure, or closes a majority of the essential services the provider or provider organization provides, as determined by the department. The department, in consultation with the health policy commission and the center for health information and analysis, shall use the bond proceeds to support the continued provision of health services to patients served by the provider or provider organization. Prior to spending the bond, the department shall seek input from the public, including, but not limited to, providers, provider organizations and patients in the affected region, regarding how to spend the bond. The department may, in consultation with the health policy commission and center for health information and analysis, select an independent supervisor and reasonable staff to supervise and facilitate collecting and spending the bond. This section does not provide the department with the authority to petition for the appointment of a receiver for the provider or provider organization.

(f) The department shall promulgate regulations necessary to implement this section.

Section 246. (a) The department shall establish and administer a prescription drug cost assistance program, which shall be funded by the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29. The program shall provide financial assistance for prescription drugs used to treat: (i) chronic respiratory conditions, including, but not limited to, chronic obstructive pulmonary disease and asthma; (ii) chronic heart conditions, including, but not limited to, those heart conditions that disproportionately impact a particular demographic group, including people of color; (iii) diabetes; and (iv) any other chronic condition identified by

the department that disproportionately impacts a particular demographic group, including people of color; provided, however, that "prescription drug" shall include the prescription drug and any drug delivery device needed to administer the drug that is not included as part of the underlying drug prescription. Financial assistance shall cover the cost of any copayment, coinsurance and deductible for the prescription drug for an individual who is eligible for the program.

(b) An individual shall be eligible for the program if the individual: (i) is a resident of the commonwealth; (ii) has a current prescription from a health care provider for a drug that is used to treat a chronic condition listed in subsection (a); (iii) has a family income of not more than 500 per cent of the federal poverty level; and (iv) is not enrolled in MassHealth.

(c) The department shall create an application process, which shall be available electronically and in hard copy form, to determine whether an individual meets the program eligibility requirements under subsection (b). The department shall determine an applicant's eligibility and notify the applicant of the department's determination within 10 business days of receiving the application. If necessary for its determination, the department may request additional information from the applicant; provided, however, that the department shall notify the applicant within 5 business days of receipt of the original application as to what specific additional information is being requested. If additional information is requested, the department shall, within 3 business days of receipt of the additional information, determine the applicant's eligibility and notify said applicant of the department's determination.

If the department determines that an applicant is not eligible for the program, the department shall notify the applicant and shall include in said notification the specific reasons

why the applicant is not eligible. The applicant may appeal this determination to the department within 30 days of receiving such notification.

If the department determines that an applicant is eligible for the program, the department shall provide the applicant with a prescription drug cost assistance program identification card, which shall indicate the applicant's eligibility; provided, however, that the program identification card shall include, but not be limited to, the applicant's full name and the full name of the prescription drug that the applicant is eligible to receive under the program without having to pay a co-payment, co-insurance or deductible. An applicant's program identification card shall be valid for 12 months and shall be renewable upon a redetermination of program eligibility.

(d) An individual with a valid program identification card may present such card at any pharmacy in the commonwealth and, upon presentation of such card, the pharmacy shall fill the individual's prescription and provide the prescribed drug to the individual without requiring the individual to pay a co-payment, co-insurance or deductible; provided, however, that the pharmacy shall be reimbursed by the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29 in a manner determined by the department, in an amount equal to what the pharmacy would have received had the individual been required to pay a co-payment, co-insurance or deductible.

(e) The department, in collaboration with the division of insurance, board of registration in pharmacy and stakeholders representing consumers, pharmacists, providers, hospitals and carriers, shall develop and implement a plan to educate consumers, pharmacists, providers, hospitals and carriers regarding eligibility for and enrollment in the program under this section. The plan shall include, but not be limited to, appropriate staff training, notices provided to

consumers at the pharmacy and a designated website with information for consumers, pharmacists and other health care professionals.

(f) The department shall compile a report detailing information about the program from the previous calendar year. The report shall include: (i) the number of applications received, approved, denied and appealed; (ii) the total number of applicants approved, and the number of applicants approved broken down by race, gender, age range and income level; (iii) a list of all prescription drugs that qualify for the program under subsection (b) and a list of prescription drugs for which applicants actually received financial assistance; and (iv) the total cost savings received by all approved applicants and the cost savings broken down by race, gender, age range and income level. The report shall be submitted annually, not later than March 1, to the clerks of the senate and house of representatives, the house and senate committees on ways and means and the joint committee on health care financing; provided, however, that annually, not later than March 1, the report shall be published on the website of the department.

(g) The department shall promulgate regulations or issue guidance for the implementation and enforcement of this section.

SECTION 73. Section 1 of chapter 112 of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by inserting after the third paragraph the following paragraph:-

The commissioner of occupational licensure and the commissioner of public health shall by regulation define the words “good moral character”, establish a standardized assessment of “good moral character” for applicants for certification or licensure. Each of the boards of registration and examination under supervision of the commissioner of occupational licensure

and the commissioner of public health shall apply said standard definition and assessment of "good moral character" for applicants of certification or licensure. The commissioners shall hold at least 1 public hearing seeking input on the standard definition and assessment of "good moral character" for applicants of certification or licensure. In developing the standard definition and assessment of "good moral character", the commissioners shall consider factors including, but not limited to: (i) the nature and gravity of any conduct that would cause concerns about an applicant's moral character, including whether the conduct demonstrates a disregard for the welfare, safety or rights of another or disregard for honesty, integrity or trustworthiness; (ii) the nature of the job; (iii) the length of time that has passed since the conduct; (iv) the circumstances surrounding the conduct, including the age of the offender and contributing social conditions and biases; (v) evidence of rehabilitation, including subsequent work history and character references; and (vi) racial, ethnic and other inequities in the criminal justice system.

SECTION 74. Said chapter 112 is hereby further amended by inserting after section 4 the following 3 sections:-

Section 4A. (a) For the purposes of this section through section 4C, the following words shall have the following meanings unless the context clearly requires otherwise:

"Clinician with independent practice authority", a physician or nurse practitioner, psychiatric nurse mental health clinical specialist or nurse anesthetist who has independent practice authority pursuant to sections 80E, 80H and 80J.

"Health care practice", a business, regardless of form, through which a registered practicing clinician offers health services; provided, however, that "health care practice" shall not include any entity that holds a license to operate a facility issued by the department of public

health or the department of mental health or that is conducted by the federal government or the commonwealth.

"Hospital health system", an entity that directly or indirectly owns or controls at least 1 hospital licensed by the department of public health pursuant to chapter 111.

"Licensed independent clinical social worker," a licensed independent clinical social worker who is licensed to practice in the commonwealth pursuant to sections 130 to 137, inclusive.

"Management services organization", a business that provides management or administrative services to a provider or provider organization for compensation.

"Nurse anesthetist", an advanced practice registered nurse who registered to practice advanced nursing practice in the commonwealth pursuant to sections 74, 80B and 80H.

"Nurse-midwife", a nurse-midwife who is registered to practice nurse-midwifery in the commonwealth pursuant to sections 74, 80B, 80C and 80G.

"Nurse practitioner", an advanced practice registered nurse who is registered to practice advanced nursing practice in the commonwealth pursuant to sections 74, 80B and 80E.

"Physician", a doctor of medicine or doctor of osteopathy who is registered to practice medicine in the commonwealth pursuant to section 2.

"Physician assistant", a physician assistant who is registered to practice in the commonwealth pursuant to sections 9F and 9I.

"Psychiatric nurse mental health clinical specialist", an advanced practice registered nurse who is registered to practice advanced nursing practice in the commonwealth pursuant to sections 74, 80B, 80E and 80J.

"Psychologist", a psychologist licensed to practice psychology in the commonwealth pursuant to sections 118 to 129B, inclusive.

"Registered practicing clinician", a physician, physician assistant, nurse practitioner, psychiatric nurse mental health clinical specialist or nurse anesthetist.

(b) Nothing in this section shall be deemed to restrict registered practicing clinicians from employment in a setting that does not constitute a health care practice.

(c) Health care facilities or entities that hold a license issued by the department of public health or the department of mental health and management services organizations shall not directly or indirectly interfere with, control or otherwise direct the professional judgment or clinical decisions of health care practices or registered practicing clinicians, nurse-midwives, psychologists or licensed independent clinical social workers who provide health care services at or through said facilities or entities or at or through a health care practice.

(d) Conduct prohibited under this section shall include, but not be limited to, controlling, either directly or indirectly, through discipline, punishment, threats, adverse employment actions, coercion, retaliation, or excessive pressure: (i) the amount of time spent with patients or the number of patients seen in a given time period, including but not limited to the time permitted to triage patients in the emergency department or evaluate admitted patients; (ii) the time period within which a patient must be discharged; (iii) decisions involving the patient's clinical status, including, but not limited to, whether the patient should be kept in observation status, whether

the patient should receive palliative care and where the patient should be placed upon discharge; (iv) the diagnosis, diagnostic terminology or codes that are entered into the medical record; (v) the appropriate diagnostic test for medical conditions; or (vi) any other conduct the department of public health determines by regulation would interfere with, control or otherwise direct the professional judgement or clinical decisions of registered practicing clinicians, nurse-midwives, psychologists or licensed independent clinical social workers; provided, however, that the department may establish exceptions to subsections (i) to (vi), inclusive, for the appropriate clinical supervision of those who are not clinicians with independent practice authority. Such health care facilities or entities or management services organizations shall not limit the range of clinical orders available to registered practicing clinicians either directly or by configuring the medical record to prohibit or significantly limit the clinical order options available.

(e) Nondisclosure or non-disparagement agreements regarding subsections (i) to (vi), inclusive, to which registered practicing clinicians are a party shall be void and unenforceable.

(f) Any policy or contract that has the effect of violating this subsection shall be void and unenforceable and shall be considered the unauthorized practice of medicine in violation of section 6 or the unauthorized practice of nursing in violation of section 80E, 80H or 80J. If a court of competent jurisdiction finds a policy, contract or contract provision void and unenforceable pursuant to this subsection, the court shall award the plaintiff reasonable attorney’s fees and costs. Nothing in this section shall limit the ability of any person to bring any action relating to defamation, disclosure of confidential or proprietary information or trade secrets or similar torts.

(g) The department of public health, in consultation with the health policy commission, shall promulgate regulations to effectuate the purposes of this section.

Section 4B. (a) This section shall apply only to health care practices that are not owned or controlled by hospitals licensed by the department of public health under chapter 111 or nonprofit hospital health systems.

(b) It shall be a violation of this section for a management services organization or other entity that is not a health care practice to exercise control over clinical decisions of a health care practice. A management services organization, or any other organization that is not a health care practice, that does the following shall be considered to have control over the clinical decisions of the health care practice: (i) managing, supervising, evaluating or recommending promotion or discipline of any owner of or registered practicing clinician associated with the health care practice; (ii) negotiating with third-party payers on behalf of a health care practice without first obtaining informed consent from the health care practice's owners; (iii) advertising or otherwise presenting as a health care practice or provider of health care services; or (iv) performing any other functions that the department of public health determines, by regulation, confers to a management services organization or any other entity that is not a health care practice the ability to control the clinical decisions of the health care practice or its registered practicing clinicians.

(c) A health care practice shall maintain ultimate decision-making authority over: (i) personnel decisions involving registered practicing clinicians, including, but not limited to, employment status, compensation, hours or working conditions; (ii) coding or billing decisions; (iii) the selection and use of property, including, but not limited to, real property, medical equipment or medical supplies; (iv) the number of patients seen in a given period of time or the

amount of time spent with each patient; (v) the appropriate diagnostic test for medical conditions; (vi) the use of patient medical records; (vii) referral decisions; or (viii) any other function or decision that the department of public health determines, by regulation, confers to a management services organization or any other entity that is not a health care practice the ability to control the clinical decisions of a health care practice or its registered practicing clinicians.

(d) It shall be a violation of this section for a management services organization or any other entity that is not a health care practice to include in an agreement with any health care practice provisions that would: (i) restrict the ability of the health care practice or practice owner to exercise complete, unfettered control and discretion over the finances or capital of the health care practice, including, but not limited to, restricting the ability to create, buy or sell stock, issue dividends or sell the health care practice; (ii) restrict the ability of a person who owns stock in the health care practice to transfer, alienate or otherwise exercise unfettered discretion and control over their stock; (iii) restrict, in any way, the ability of the health care practice or clinicians with independent practice authority associated with the health care practice to provide health care services in any place, for any entity or in any form otherwise permitted by law; (iv) restrict the ability of the health care practice to contract with another management services organization for management or administrative services upon expiration of the current contract; (v) limit the ability of the health care practice or the practice's owners, employees or agents to publicly discuss the business relationship between the health care practice and the management services organization; provided, however, that this provision shall not limit the ability of any person to bring any action relating to defamation, disclosure of confidential or proprietary information or trade secrets or similar torts; (vi) limit access to, take control from or otherwise obscure from any registered practicing clinicians providing services in connection with the health

care practice, the price, rate or amount of the charges for their services; (vii) establish, supervise, manage or otherwise control the health care practice's officers or directors; or (viii) create any other situation the department of public health determines, by regulation, could create the possibility of allowing the management services organization to control the clinical decisions of the health care practice or registered practicing clinicians.

(e) A violation of this section shall constitute the unauthorized practice of medicine in violation of section 6 or the unauthorized practice of nursing in violation of section 80E, 80H or 80J. Any provision of a contract or agreement that has the effect of violating this section shall be void and unenforceable. If a court of competent jurisdiction finds a policy, contract or contract provision void and unenforceable pursuant to this section, the court shall award the plaintiff reasonable attorney's fees and costs.

(f) The department of public health, in consultation with the health policy commission, shall promulgate regulations to effectuate the purposes of this section.

Section 4C. (a) Health care practices shall file with the department of public health a registration application containing such information as the department may reasonably require, including, but not limited to: (i) the identity of the applicant and of the registered practicing clinicians that constitute the practice; (ii) any management services organization under contract with the health care practice; (iii) a certified copy of the health care practice's certificate of organization, if any, as filed with the secretary of the commonwealth, or any applicable partnership agreement; (iv) the address of the health care practice; (v) the services provided by the health care practice; and (vi) any information the department, in consultation with the health policy commission and the center for health information and analysis, deems relevant for the

state health plan and focused assessments pursuant to section 22 of chapter 6D and the health care resources inventory pursuant to section 9 of chapter 12C. The application shall be accompanied by a fee in an amount to be determined pursuant to section 3B of chapter 7. All health care practices registered in the commonwealth shall renew their certificates of registration with the department every 2 years. The department shall share information relevant to the state health plan and focused assessments pursuant to said section 22 of said chapter 6D with the commission and information relevant to the health care resources inventory pursuant to said section 9 of said section 12C with the center.

(b) The department of public health may promulgate regulations to establish minimum requirements for the conduct of a health care practice, including, but not limited to: (i) compliance with this section; (ii) maintenance and access to medical records; and (iii) in the event of a planned closure of the health care practice or an unplanned event that prevents the health care practice from continuing operations, the development of a continuity plan to: (A) ensure access to medical records, (B) provide notice to patients, and (C) assist patients with transitioning to a new provider.

SECTION 75. Section 9A of chapter 118E of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by adding the following paragraph:-

(17)(a) Residents of the commonwealth who are under the age of 19 and enrolled in MassHealth shall qualify for not less than 12 months of continuous eligibility; provided, however, that continuous eligibility shall not apply to: (i) residents who are 19 years of age or older, unless MassHealth provides continuous eligibility to such residents; (ii) individuals who are under the age of 19 and no longer reside in the commonwealth; (iii) residents under the age

of 19 who requests voluntary disenrollment or whose representative requests such disenrollment on behalf of said resident; or (iv) residents under the age of 19 whose eligibility is determined to have been erroneously granted because of agency error or fraud, abuse or perjury attributed to said resident or their representative.

(b) The executive office of health and human services shall maximize federal financial participation for the coverage and benefits provided under this section; provided, however, that continuous eligibility under subparagraph (a) shall not result in any reduction of federal financial participation; and provided further, that coverage and benefits provided under this paragraph shall not be contingent upon the availability of federal financial participation.

SECTION 76. Subsection (a) of section 10Z of chapter 118E of the General Laws, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of “Brand name drug” the following 3 definitions:-

“Continuous glucose monitoring system”, a system to continuously sense, transmit and display blood glucose levels.

“Delivery device”, a device that: (i) is used to deliver a brand name drug or a generic drug; and (ii) an individual can obtain with a prescription.

“Diabetes treatment supplies”, supplies for the treatment of diabetes including, but not limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips, lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose monitors for use by the legally blind and visual magnifying aids for use by the legally blind;

provided, however, that diabetes treatment supplies shall not include a brand name drug, a generic drug, a continuous glucose monitoring system component or a delivery device.

SECTION 77. Said subsection (a) of said section 10Z of said chapter 118E, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby further amended by inserting after the definition of "Generic drug" the following definition:-

"Separate delivery device", a device that is used to deliver a brand name drug or a generic drug and that can be obtained with a prescription separate from, or in addition to, the brand name drug or generic drug that the device delivers.

SECTION 78. Subsection (b) of said section 10Z of said chapter 118E, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby amended by striking out the figure "2" and inserting in place thereof the following figure:- 3.

SECTION 79. Subsection (d) of said section 10Z of said chapter 118E, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby amended by adding the following 3 paragraphs:-

If use of a brand name drug or generic drug that the division selects requires a separate delivery device, the division shall select a delivery device for that drug in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the extent possible. The division shall provide coverage for the delivery device; provided, however, that the delivery device shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The division shall select a continuous glucose monitoring system in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs. The division shall provide coverage for the continuous glucose monitoring system and all components thereof; provided, however, that the continuous glucose monitoring system and all components thereof shall be not subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The division shall provide coverage for necessary diabetes treatment supplies. Such supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

SECTION 80. Subsection (f) of said section 10Z of said chapter 118E, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:-

This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices, in the same manner in which the subsection applies to drugs.

SECTION 81. Subsection (g) of said section 10Z of said chapter 118E, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 82. Subsection (h) of said section 10Z of said chapter 118E, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 83. Said section 10Z of said chapter 118E, as inserted by section 28 of chapter 342 of the acts of 2024, is hereby amended by adding the following subsection:-

(i) An enrollee and their prescribing health care provider shall have access to a clear, readily accessible and convenient process to request to use a different brand name drug or generic drug of the same pharmacological class in place of a brand name drug or generic drug selected under subsection (b). Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs selected under subsection (b) are contraindicated or will likely cause an adverse reaction in or physical or mental harm to the enrollee; (ii) the brand name drugs and generic drugs selected under subsection (b) are expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics of the prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to the division establishing that the enrollee has previously tried the brand name drugs and generic drugs selected under subsection (b) while covered by the division or by a previous health insurance carrier or a health benefit plan; and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the enrollee or prescribing health care provider has provided documentation to the division establishing that the enrollee: (A) is stable on a prescription drug prescribed by the health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the enrollee. This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices.

SECTION 84. Said chapter 118E, as so appearing, is hereby amended by striking out section 40 and inserting in place thereof the following section:-

Section 40. Any person or entity who directly or indirectly furnishes items or services for which payment may be made under this chapter, even if no items or services are provided, who: (1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this chapter; (2) knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment; (3) having knowledge of the occurrence of any event affecting his or her initial or continued right to any such benefit or payment, or the benefit of any other individual in whose behalf he or she has applied for or is receiving such benefit or payment, conceals or fails to disclose such an event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized; or (4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefits or payment other than for the use and benefit of such person or entity, shall, if the amount is equal to or less than $50,000, be punished by a fine of not more than ten one hundred thousand dollars, or by imprisonment in the state prison for not more than five years or in a jail or house of correction for not more than two and one-half years, or by both such fine and imprisonment; or, if the amount is greater than $50,000, be punished by a fine of not more than two hundred and fifty thousand dollars, or by imprisonment in the state prison for not more than ten years or in a jail or house of correction for not more than two and one-half years, or by both such fine and imprisonment.

Any person or entity who does not furnish items of services for which payment may be made under this chapter, who violates any of the provisions of clauses (1) to (4), inclusive, shall, if the amount is equal to or less than $50,000, be punished by imprisonment in a jail or house of

correction for not more than two and one-half years or by a fine of not more than five fifty thousand dollars or by both such fine and imprisonment; or, if the amount is greater than $50,000, be punished by a fine of not more than one hundred thousand dollars, or by imprisonment in the state prison for not more than five years or in a jail or house of correction for not more than two and one-half years, or by both such fine and imprisonment.

SECTION 85. Section 1 of chapter 175 of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by inserting after the definition of "Foreign company" the following definition:-

"Health insurance company", a company that engages in the business of health insurance.

SECTION 86. Said section 1 of said chapter 175, as so appearing, is hereby further amended by inserting after the definition of "Net value of policies" the following definition:-

"Party of record", for the purpose of a review by the commissioner of a written agreement for a merger or consolidation of 2 or more health insurance companies, the health policy commission, the center for health information and analysis, the attorney general, the center for health information and analysis and any government agency with relevant oversight or licensure authority over the proposed project or components therein.

SECTION 87. Section 19A of said chapter 175, as so appearing, is hereby amended by adding the following 2 sentences:-

A party of record may review a written agreement for a merger or consolidation of 2 or more health insurance companies submitted to the commissioner for written approval, as well as provide written comment or specific recommendations for consideration by the commissioner. If

a party of record sends a written communication or submits written materials concerning a written agreement, the commissioner shall provide copies of such communication or materials to all other parties of record.

SECTION 88. Subsection (a) of section 47CCC of chapter 175 of the General Laws, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Brand name drug" the following 3 definitions:-

"Continuous glucose monitoring system", a system to continuously sense, transmit and display blood glucose levels.

"Delivery device", a device that: (i) is used to deliver a brand name drug or a generic drug; and (ii) an individual can obtain with a prescription.

"Diabetes treatment supplies", supplies for the treatment of diabetes including, but not limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips, lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose monitors for use by the legally blind and visual magnifying aids for use by the legally blind; provided, however, that diabetes treatment supplies shall not include a brand name drug, a generic drug, a continuous glucose monitoring system component or a delivery device.

SECTION 89. Said subsection (a) of said section 47CCC of said chapter 175, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby further amended by inserting after the definition of "Generic drug" the following definition:-

“Separate delivery device”, a device that is used to deliver a brand name drug or a generic drug and that can be obtained with a prescription separate from, or in addition to, the brand name drug or generic drug that the device delivers.

SECTION 90. Subsection (b) of said section 47CCC of said chapter 175, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby amended by striking out the figure “2” and inserting in place thereof the following figure:- 3.

SECTION 91. Subsection (d) of said section 47CCC of said chapter 175, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby amended by adding the following 3 paragraphs:-

If use of a brand name drug or generic drug that the carrier selects requires a separate delivery device, the carrier shall select a delivery device for that drug in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the extent possible. The carrier shall provide coverage for the delivery device; provided, however, that the delivery device shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall select a continuous glucose monitoring system in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs. The carrier shall provide coverage for the continuous glucose monitoring system and all components thereof; provided, however, that the continuous glucose monitoring system and all components thereof shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall provide coverage for necessary diabetes treatment supplies. Such supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

SECTION 92. Subsection (e) of said section 47CCC of said chapter 175, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices, in the same manner in which the subsection applies to drugs.

SECTION 93. Subsection (f) of said section 47CCC of said chapter 175, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 94. Subsection (g) of said section 47CCC of said chapter 175, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 95. Said section 47CCC of said chapter 175, as inserted by section 31 of chapter 342 of the acts of 2024, is hereby amended by adding the following subsection:-

(h) A member and their prescribing health care provider shall have access to a clear, readily accessible and convenient process to request to use a different brand name drug or generic drug of the same pharmacological class in place of a brand name drug or generic drug selected under subsection (b). Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs selected under subsection (b) are contraindicated or will likely cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs and generic drugs selected under subsection (b) are expected to be ineffective based on the

known clinical characteristics of the member and the known characteristics of the prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to the carrier establishing that the member has previously tried the brand name drugs and generic drugs selected under subsection (b); and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or prescribing health care provider has provided documentation to the carrier establishing that the member: (A) is stable on a prescription drug prescribed by the health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the member. This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices.

SECTION 96. Said chapter 175 of the General Laws is hereby further amended by inserting after section 47CCC, as inserted by section 31 of chapter 342 of the acts of 2024, the following section:-

Section 47DDD. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"340B drug", a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a 340B grantee as defined in this section.

"340B grantee", a federally qualified health center, a non-state, government public safety net hospital system established pursuant to chapter 147 of the acts of 1996 or a non-profit acute care hospital in the commonwealth that received not less than 60 per cent of its gross patient service revenue in fiscal year 2021 from government payers, including Medicare, MassHealth

and the Health Safety Net Trust Fund based on the hospital's fiscal year 2021 cost report and that is also authorized to participate in the federal drug discount program under 42 U.S.C 256b, including its pharmacies or any contracted pharmacy.

"Distributor", a person engaged in the sale, distribution or delivery, at wholesale, of drugs or medicines within the commonwealth, including entities operating outside of the commonwealth that cause deliveries of drugs or medicines to be made within the commonwealth.

"Federally qualified health center", an entity receiving a grant under 42 U.S.C. 254(b).

"Manufacturer", an entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs.

"Pharmacy", an entity engaged in the drug business, as defined in section 37 of chapter 112, or engaged in the practice of compounding to fulfill a practitioner prescription.

(b)(1) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B grantee and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(2) A manufacturer or distributor shall not interfere with a contract between a pharmacy and a 340B grantee.

(3) A 340B grantee shall have sole discretion of the type and quantity of 340B drugs acquired or delivered by a manufacturer or distributor to a pharmacy that is under contract with or otherwise authorized by a 340B grantee to receive and dispense 340B drugs on behalf of the 340B grantee unless prohibited by federal or state law.

(c) A manufacturer or distributor, agent, or affiliate of such manufacturer or distributor shall not, either directly or indirectly, require a 340B grantee, or a pharmacy that is under contract with a 340B grantee or is otherwise authorized by a 340B grantee to receive and dispense 340B drugs on behalf of the 340B grantee, to submit any claims, utilization, purchasing, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B grantee or a pharmacy that is under contract with a 340B grantee, unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

(d) The commission of any act prohibited under subsections (b) and (c) of this section shall constitute an unfair or deceptive practice within the meaning of section 2 of chapter 93A. Each commission of a prohibited act shall constitute a separate violation.

(e) The attorney general shall have jurisdiction, consistent with the provisions of chapter 93A, to enforce the provisions of this section. The attorney general shall issue regulations to implement this chapter.

(f) The board of registration in pharmacy shall promulgate regulations to implement and enforce of this section and may investigate any complaint of a violation of this section by an

individual or entity licensed by the board and may impose discipline, suspension or revocation of any such license.

(g) Nothing in this section shall be construed or applied to be less restrictive than any federal law as to any person or entity regulated by this section or to conflict with: (i) any applicable federal law and related regulations; and (ii) any other general law that is compatible with applicable federal law.

(h) Limited distribution of a drug required under 21 U.S.C. 355-1 shall not be a violation of this section.

SECTION 97. Subsection (a) of section 8DDD of chapter 176A of the General Laws, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Brand name drug" the following 3 definitions:-

"Continuous glucose monitoring system", a system to continuously sense, transmit and display blood glucose levels.

"Delivery device", a device that: (i) is used to deliver a brand name drug or a generic drug; and (ii) an individual can obtain with a prescription.

"Diabetes treatment supplies", supplies for the treatment of diabetes including, but not limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips, lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose monitors for use by the legally blind and visual magnifying aids for use by the legally blind;

provided, however, that diabetes treatment supplies shall not include a brand name drug, a generic drug, a continuous glucose monitoring system component, or a delivery device.

SECTION 98. Said subsection (a) of said section 8DDD of said chapter 176A, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby further amended by inserting after the definition of “Generic drug” the following definition:-

“Separate delivery device”, a device that is used to deliver a brand name drug or a generic drug and that can be obtained with a prescription separate from, or in addition to, the brand name drug or generic drug that the device delivers.

SECTION 99. Subsection (b) of said section 8DDD of said chapter 176A, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby amended by striking out the figure “2” and inserting in place thereof the following figure:- 3.

SECTION 100. Subsection (d) of said section 8DDD of said chapter 176A, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby amended by adding the following 3 paragraphs:-

If use of a brand name drug or generic drug that the carrier selects requires a separate delivery device, the carrier shall select a delivery device for that drug in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the extent possible. The carrier shall provide coverage for the delivery device; provided, however, that the delivery device shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall select a continuous glucose monitoring system in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs. The carrier shall provide coverage for the continuous glucose monitoring system and all components thereof; provided, however, that the continuous glucose monitoring system and all components thereof shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall provide coverage for necessary diabetes treatment supplies. Such supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

SECTION 101. Subsection (e) of said section 8DDD of said chapter 176A, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices, in the same manner in which the subsection applies to drugs.

SECTION 102. Subsection (f) of said section 8DDD of said chapter 176A, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 103. Subsection (g) of said section 8DDD of said chapter 176A, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 104. Said section 8DDD of said chapter 176A, as inserted by section 33 of chapter 342 of the acts of 2024, is hereby amended by adding the following subsection:-

(h) A member and their prescribing health care provider shall have access to a clear, readily accessible and convenient process to request to use a different brand name drug or generic drug of the same pharmacological class in place of a brand name drug or generic drug selected under subsection (b). Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs selected under subsection (b) are contraindicated or will likely cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs and generic drugs selected under said subsection (b) are expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to the carrier establishing that the member has previously tried the brand name drugs and generic drugs selected under subsection (b); and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or prescribing health care provider has provided documentation to the carrier establishing that the member: (A) is stable on a prescription drug prescribed by the health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the member. This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices.

SECTION 105. The fifth paragraph of section 4 of chapter 176B of the General Laws, as appearing in the 2022 Official Edition, is hereby amended striking out the first sentence and inserting in place thereof the following sentences:- Under such a group medical service agreement, subscription certificates and the rates charged by the corporation to the subscribers shall be filed with the commissioner within thirty days after their effective date. The commissioner shall approve, modify or disapprove any proposed changes to rates; provided,

however, that the commissioner shall only modify or disapprove any proposed changes to rates that are excessive, inadequate or unfairly discriminatory; provided, further, that group plan contracts issued and rates charged by a nonprofit medical service corporation to its subscribers providing supplemental coverage to medicare shall be subject to the provisions of chapter one hundred and seventy-six K if the subscribers, and not their employer, employers or representatives, are billed directly for such contracts. No classification of risk may be established on the basis of age.

SECTION 106. Subsection (a) of section 4DDD of chapter 176B of the General Laws, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Brand name drug" the following 3 definitions:-

"Continuous glucose monitoring system", a system to continuously sense, transmit and display blood glucose levels.

"Delivery device", a device that: (i) is used to deliver a brand name drug or a generic drug; and (ii) an individual can obtain with a prescription.

"Diabetes treatment supplies", supplies for the treatment of diabetes including, but not limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips, lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose monitors for use by the legally blind and visual magnifying aids for use by the legally blind; provided, however, that diabetes treatment supplies shall not include a brand name drug, a generic drug, a continuous glucose monitoring system component or a delivery device.

SECTION 107. Said subsection (a) of said section 4DDD of said chapter 176B, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby further amended by inserting after the definition of "Generic drug" the following definition:-

"Separate delivery device", a device that is used to deliver a brand name drug or a generic drug and that can be obtained with a prescription separate from, or in addition to, the brand name drug or generic drug that the device delivers.

SECTION 108. Subsection (b) of said section 4DDD of said chapter 176B, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby amended by striking out the figure "2" and inserting in place thereof the following figure:- 3.

SECTION 109. Subsection (d) of said section 4DDD of said chapter 176B, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby amended by adding the following 3 paragraphs:-

If use of a brand name drug or generic drug that the carrier selects requires a separate delivery device, the carrier shall select a delivery device for that drug in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the extent possible. The carrier shall provide coverage for the delivery device; provided, however, that the delivery device shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall select a continuous glucose monitoring system in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs. The carrier shall provide coverage for the continuous glucose monitoring system and all components thereof; provided, however, that the continuous glucose monitoring system and all components

thereof shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall provide coverage for necessary diabetes treatment supplies. Such supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

SECTION 110. Subsection (e) of said section 4DDD of said chapter 176B, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices, in the same manner in which the subsection applies to drugs.

SECTION 111. Subsection (f) of said section 4DDD of said chapter 176B, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 112. Subsection (g) of said section 4DDD of said chapter 176B, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 113. Said section 4DDD of said chapter 176B, as inserted by section 34 of chapter 342 of the acts of 2024, is hereby amended by adding the following subsection:-

(h) A member and their prescribing health care provider shall have access to a clear, readily accessible and convenient process to request to use a different brand name drug or generic drug of the same pharmacological class in place of a brand name drug or generic drug selected under subsection (b). Such request for an exception shall be granted if: (i) the brand

name drugs and generic drugs selected under said subsection (b) are contraindicated or will likely cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs and generic drugs selected under said subsection (b) are expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to the carrier establishing that the member has previously tried the brand name drugs and generic drugs selected under said subsection (b) while covered by the carrier or by a previous health insurance carrier or a health benefit plan; and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or prescribing health care provider has provided documentation to the carrier establishing that the member: (A) is stable on a prescription drug prescribed by the health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the member. This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices

SECTION 114. Said section 3B of said chapter 176D, as appearing in the 2022 Official Edition, is hereby further amended by striking out the fifth paragraph and inserting in place thereof the following paragraph:-

A carrier shall not prohibit a network pharmacy from offering and providing mail delivery services to an insured; provided, however, that the network pharmacy agrees to the reimbursement terms and conditions and discloses to the insured any delivery service fee associated with the delivery service.

SECTION 115. Subsection (a) of section 4VV of chapter 176G of the General Laws, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Brand name drug" the following 3 definitions:-

"Continuous glucose monitoring system", a system to continuously sense, transmit and display blood glucose levels.

"Delivery device", a device that: (i) is used to deliver a brand name drug or a generic drug; and (ii) an individual can obtain with a prescription.

"Diabetes treatment supplies", supplies for the treatment of diabetes including, but not limited to, syringes, needles, blood glucose monitors, blood glucose monitoring strips for home use, strips to calibrate continuous blood glucose monitors, urine glucose strips, ketone strips, lancets, adhesive skin patches, insulin pump supplies, voice-synthesizers for blood glucose monitors for use by the legally blind and visual magnifying aids for use by the legally blind; provided, however, that diabetes treatment supplies shall not include a brand name drug, a generic drug, a continuous glucose monitoring system component, or a delivery device."

SECTION 116. Said subsection (a) of said section 4VV of said chapter 176G, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby further amended by inserting after the definition of "Generic drug" the following definition:-

"Separate delivery device", a device that is used to deliver a brand name drug or a generic drug and that can be obtained with a prescription separate from, or in addition to, the brand name drug or generic drug that the device delivers.

SECTION 117. Subsection (b) of said section 4VV of said chapter 176G, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby amended by striking out the figure “2” and inserting in place thereof the following figure:- 3.

SECTION 118. Subsection (d) of said section 4VV of said chapter 176G, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby amended by adding the following 3 paragraphs:-

If use of a brand name drug or generic drug that the carrier selects requires a separate delivery device, the carrier shall select a delivery device for that drug in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs, to the extent possible. The carrier shall provide coverage for the delivery device; provided, however, that the delivery device shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall select a continuous glucose monitoring system in accordance with the criteria established in subsection (c) for selecting brand name drugs and generic drugs. The carrier shall provide coverage for the continuous glucose monitoring system and all components thereof; provided, however, that the continuous glucose monitoring system and all components thereof shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

The carrier shall provide coverage for necessary diabetes treatment supplies. Such supplies shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible.

SECTION 119. Subsection (e) of said section 4VV of said chapter 176G, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices, in the same manner in which the subsection applies to drugs.

SECTION 120. Subsection (f) of said section 4VV of said chapter 176G, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby amended by inserting after the words "drugs" the following words:- , continuous glucose monitoring systems and delivery devices.

SECTION 121. Subsection (g) of said section 4VV of said chapter 176G, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby amended by inserting after the word "drugs" the following words:- , continuous glucose monitoring systems and delivery device.

SECTION 122. Said section 4VV of said chapter 176G, as inserted by section 35 of chapter 342 of the acts of 2024, is hereby amended by adding the following subsection:-

(h) A member and their prescribing health care provider shall have access to a clear, readily accessible and convenient process to request to use a different brand name drug or generic drug of the same pharmacological class in place of a brand name drug or generic drug selected under subsection (b). Such request for an exception shall be granted if: (i) the brand name drugs and generic drugs selected under said subsection (b) are contraindicated or will likely cause an adverse reaction in or physical or mental harm to the member; (ii) the brand name drugs and generic drugs selected under said subsection (b) are expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the prescription drug regimen; (iii) the member or prescribing health care provider: (A) has provided documentation to the carrier establishing that the member has previously tried the brand name

drugs and generic drugs selected under said subsection (b); and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the member or prescribing health care provider has provided documentation to the carrier establishing that the member: (A) is stable on a prescription drug prescribed by the health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the member. This subsection shall apply to continuous glucose monitoring systems and, when applicable, delivery devices.

SECTION 123. The first paragraph of section 16 of chapter 176G of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by inserting after the second sentence the following sentence:- The commissioner shall approve, modify or disapprove rates; provided, however, that the commissioner shall only modify or disapprove rates that are excessive, inadequate or unreasonable in relation to the benefits charged.

SECTION 124. Subsection (c) of section 6 of chapter 176J of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by striking out the second sentence and inserting in place thereof the following sentence:- The commissioner shall approve, modify or disapprove any proposed changes to base rates; provided, however, that the commissioner shall only modify or disapprove any proposed changes to base rates that are excessive, inadequate or unreasonable in relation to the benefits charged.

SECTION 125. The first paragraph of subsection (d) of section 7 of chapter 176K of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by striking out the second sentence and inserting in place thereof the following sentence:- The commissioner shall approve, modify or disapprove the proposed rates; provided, however, that the commissioner

shall only modify or disapprove any proposed rates that are excessive, inadequate or unreasonable in relation to the benefits charged.

SECTION 126. Section 2 of chapter 176O of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by adding the following subsection:-

(i) Every 3 years, a carrier that contracts with a pharmacy benefit manager shall conduct 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 127. Section 21 of said chapter 176O, as appearing in the 2022 Official Edition, is hereby amended by adding the following subsection:-

(f) The commissioner shall make all information submitted to the division pursuant to this section available to the center for health information and analysis.

SECTION 128. Said chapter 176O, as so appearing, 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 176Y as a condition of contracting with that carrier.

SECTION 129. Section 30 of said chapter 176O, as inserted by section 36 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- This section shall also apply to selected continuous glucose monitoring systems and, when applicable, delivery devices.

SECTION 130.Chapter 176Y of the General Laws, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by striking out the title and inserting in place thereof the following title:- LICENSING AND REGULATION OF PHARMACY BENEFIT MANAGERS AND PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS.

SECTION 131. Section 1 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Center" the following 3 definitions:-

"Clean claim", a claim that has no defect or impropriety, including a lack of any required substantiating documentation, or other circumstance requiring special treatment that prevents timely payment from being made on the claim.

"Covered individual", an individual covered by insurance through a carrier or, to the extent permissible under federal law, a self-insurance plan.

"Generic equivalent", a drug listed as therapeutically equivalent and pharmaceutically equivalent A or B rated in the United States Food and Drug Administration's most recent version of the Orange Book or Green Book or has an NR or NA rating by Medi-Span, Gold Standard, or a similar rating by a nationally recognized reference.

SECTION 132. Said section 1 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby further amended by striking out the definition of "Health benefit plan" and inserting in place thereof the following definition:-

"Health benefit plan", a contract, certificate or agreement entered into, offered or issued by a carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care

services; provided, however, that the commissioner may by regulation define other health coverage as a "health benefit plan" for the purposes of this chapter; provided, however, that health benefit plan shall include a self-insurance plan to the extent permissible under federal law.

SECTION 133. Said section 1 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of "Mail-order pharmacy" the following 6 definitions:-

"Maximum allowable cost", the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a generic or multiple source prescription drugs, excluding dispensing fees and copayments, coinsurance, or other cost-sharing amounts, if any.

"National Drug Code", the numerical code assigned to a prescription drug by the United States Food and Drug Administration.

"Net price", a price for a prescription drug that takes into account all rebates received or expected to be received in connection with the dispensing or administration of the prescription drug.

"Network pharmacy", a pharmacy that contracts with a pharmacy benefit manager to participate in a pharmacy network.

"Person", a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

“Pharmaceutical wholesaler”, any person, partnership, corporation, or business licensed under section 36B of chapter 112 that purchases prescription drugs from a pharmaceutical manufacturer for the purpose of distributing to persons other than an individual.

SECTION 134. Said section 1 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by striking out the definition of “Pharmacy” and inserting in place thereof the following 2 definitions:-

“Pharmacy”, a physical or electronic facility under the direction or supervision of a registered pharmacist that is authorized to dispense prescription drugs and has entered into a network contract with a pharmacy benefit manager or a carrier, or to the extent permissible under federal law, a self-insurance plan.

“Pharmacy acquisition cost”, the amount a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy’s billing invoice.

SECTION 135. Said section 1 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by inserting after the definition of “Pharmacy benefit manager” the following 4 definitions:-

“Pharmacy benefit manager affiliate pharmacy”, a pharmacy that directly or indirectly, through 1 or more intermediaries, owns or controls, is owned or controlled by or is under common ownership or control with a pharmacy benefit manager.

“Pharmacy network”, a group of pharmacies under contract with a pharmacy benefit manager to provide pharmacy services.

"Pharmacy services administrative organization", an entity that provides a contracted pharmacy with administrative, contracting, or payment services relating to prescription drug benefits.

"Rebate", any: (i) negotiated price concessions, whether described as a rebate or otherwise, including, but not limited to, base price concessions and reasonable estimates of any price protection rebates and performance-based price concessions that may accrue, directly or indirectly, to a carrier, pharmacy benefit manager or other party on a carrier's behalf during a carrier's plan year from a pharmaceutical manufacturing company, dispensing pharmacy or other party to the transaction based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter; and (ii) reasonable estimates of any price concessions, fees and other administrative costs that are passed through, or are reasonably anticipated to be passed through to the carrier, pharmacy benefit manager or other party on the carrier's behalf, and that serve to reduce the carrier's prescription drug liabilities for the plan year based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter.

SECTION 136. Subsection (d) of section 2 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by striking out the words "or (ii) limiting the activities in which the license holder may be engaged" and inserting in place thereof the following words:- (ii) limiting the activities in which the license holder may be engaged; or (iii) addressing conflicts of interest between pharmacy benefit managers and health plan sponsors.

SECTION 137. Subsection (g) of said section 2 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

SECTION 138. Subsection (h) of said section 2 of said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by adding the following sentence:- Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

SECTION 139. Said chapter 176Y, as inserted by section 37 of chapter 342 of the acts of 2024, is hereby amended by adding the following sections:-

Section 5. (a) A person, business or other entity shall not establish or operate as a pharmacy services administrative organization without obtaining a license from the division pursuant to this section. The division shall issue a pharmacy services administrative organization license to a person, business or other entity that demonstrates to the division that it has the necessary organization, background expertise and financial integrity to maintain such a license. A pharmacy services administrative organization license shall be valid for a period of 3 years and shall be renewable for additional 3-year periods. Initial application and renewal fees for the license shall be established pursuant to section 3B of chapter 7.

(b) A license granted pursuant to this section and any rights or interests therein shall not be transferable.

(c) A person, business or other entity licensed as a pharmacy services administrative organization shall submit data and reporting information to the center according to the standards and methods specified by the center pursuant to section 10A of chapter 12C.

(d) The division may issue or renew a license pursuant to this section, subject to restrictions in order to protect the interests of consumers. Such restrictions may include: (1) limiting the type of services that a license holder may provide; (2) limiting the activities in which the license holder may be engaged; or (3) addressing conflicts of interest between pharmacy services administrative organization and pharmacy benefit managers.

(e) The division shall develop an application for licensure of pharmacy services administrative organization that shall include, but not be limited to: (1) the name of the applicant or pharmacy services administrative organization; (2) the address and contact telephone number for the applicant or pharmacy services administrative organization; (3) the name and address of the agent of the applicant or pharmacy services administrative organization for service of process in the commonwealth; (4) the name and address of any person with management or control over the applicant or pharmacy services administrative organization; (5) the name and address of any person beneficially interested in the applicant or pharmacy services administrative organization; and (6) any audited financial statements specific to the applicant or pharmacy services administrative organization. An applicant or pharmacy services administrative organization shall report to the division any material change to the information contained in its application, certified by an officer of the pharmacy benefit manager, within 30 days of such a change.

(f) The division may suspend, revoke, refuse to issue or renew or place on probation a pharmacy services administrative organization license for cause, which shall include, but not be

limited to: (1) the applicant or pharmacy services administrative organization engaging in fraudulent activity that is found by a court of law to be a violation of state or federal law; (2) the division receiving consumer complaints that justify an action under this chapter to protect the health, safety and interests of consumers; (3) the applicant or pharmacy services administrative organization failing to pay an application or renewal fee for a license; (4) the applicant or pharmacy services administrative organization failing to comply with reporting requirements of the center under section 10A of chapter 12C; or (5) the applicant or pharmacy services administrative organization failing to comply with a requirement of this chapter.

The division shall provide written notice to the applicant or pharmacy services administrative organization and advise in writing of the reason for any suspension, revocation, refusal to issue or renew or placement on probation of a pharmacy services administrative organization license under this chapter. A copy of the notice shall be forwarded to the center. The applicant or pharmacy services administrative organization may make written demand upon the division within 30 days of receipt of such notification for a hearing before the division to determine the reasonableness of the division's action. The hearing shall be held pursuant to chapter 30A.

The division shall not suspend or cancel a license unless the division has first afforded the pharmacy services administrative organization an opportunity for a hearing pursuant to said chapter 30A.

(g) If a person, business or other entity performs the functions of a pharmacy services administrative organization in violation of this chapter, the person, business or other entity shall be subject to a fine of $5,000 per day for each day that the person, business or other entity is

found to be in violation; provided, however, that this subsection shall not apply to pharmacies. Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2EEEEEE of chapter 29.

(h) A pharmacy services administrative organization licensed under this section shall notify a pharmacy client in writing of any activity, policy, practice contract or arrangement of the pharmacy services administrative organization that directly or indirectly presents any conflict of interest with the pharmacy services administrative organization's relationship with or obligation to the pharmacy client.

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

Section 6. A pharmacy benefit manager shall not, by contract, written policy or written procedure, require that a pharmacy designated by the pharmacy benefit manager dispense a medication directly to a patient with the expectation or intention that the patient will transport the medication to a physician's office, hospital or clinic for administration.

Section 7. (a) The pharmacy benefit manager shall have a duty and obligation to perform pharmacy benefit services with care, skill, prudence, diligence and professionalism.

(b) A pharmacy benefit manager interacting with a covered individual shall have the same duty to a covered individual as the health benefit plan sponsor for whom it is performing pharmacy benefit services.

(c) A pharmacy benefit manager shall have a duty of good faith and fair dealing with all parties, including but not limited to covered individuals and pharmacies, with whom it interacts in the performance of pharmacy benefit services.

Section 8. (a) A pharmacy benefit manager shall establish a reasonably adequate and accessible pharmacy network that provides convenient access to network pharmacies within a reasonable distance from a covered individual's primary residence.

(b) A pharmacy benefit manager may not deny a pharmacy that is licensed by the board of registration in pharmacy and complies with all standards established by the board the opportunity to participate in a pharmacy network.

(c) The commissioner shall determine pharmacy network adequacy for a pharmacy benefit manager based on the availability of sufficient network pharmacies in the pharmacy network; provided, however, that a mail-order pharmacy shall not be included in the calculations for determining pharmacy network adequacy. The commissioner may take into consideration factors such as the location of network pharmacies and a covered individual's primary residence.

(d) A pharmacy benefit manager shall not prohibit a network pharmacy from offering and providing mail delivery services to a covered individual; provided, however, that the network pharmacy agrees to the reimbursement terms and conditions and discloses to the covered individual any delivery service fee associated with the delivery service.

(e) A pharmacy benefit manager shall not reimburse a network pharmacy an amount less than the amount that the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate pharmacy for providing the same pharmacy services.

Section 9. (a) After adjudication of a clean claim for payment made by a pharmacy, a pharmacy benefit manager shall not retroactively reduce payment on the claim, either directly or indirectly, through an aggregated effective rate, direct or indirect remuneration, quality assurance program or otherwise, except if the claim: (i) is found not to be a clean claim during the course of a routine audit performed pursuant to an agreement between the pharmacy benefit manager and the pharmacy; or (ii) was submitted as a result of fraud, waste, abuse or other intentional misconduct.

(b) When a pharmacy adjudicates a claim, the reimbursement amount provided to the pharmacy by the pharmacy benefit manager shall constitute a final reimbursement amount; provided, however, that nothing in this section shall be construed to prohibit any retroactive increase in payment to a pharmacy pursuant to a contract between the pharmacy benefit manager or a pharmacy.

(c) No pharmacy benefit manager shall charge or collect from a covered individual any cost-sharing amount that exceeds the total contracted amount by the pharmacy for which the pharmacy is paid. If a covered individual pays a copayment, the pharmacy shall retain the adjudicated costs and the pharmacy benefit manager shall not reduce or recoup the adjudicated cost.

Section 10. (a) A drug shall not be placed on a maximum allowable cost list unless: (i) the drug is a generic equivalent; (ii) the drug is in stock and available for purchase by each pharmacy in the pharmacy benefit manager’s network from wholesale drug distributors licensed under section 36B of chapter 112; and (iii) the drug is not obsolete.

(b) A pharmacy benefit manager shall: (i) provide access to its maximum allowable cost list to each pharmacy in the pharmacy benefit manager's network that is subject to the maximum allowable cost list; (ii) update its maximum allowable cost list on a timely basis, but not less than once every 7 calendar days; (iii) provide a process for each pharmacy subject to the maximum allowable cost list to receive prompt notification of an update to the maximum allowable cost list; and (iv) provide a reasonable internal grievance process consistent with subsection (c) to allow pharmacies to challenge a maximum allowable cost list as not compliant with this section, and to challenge reimbursements made under a maximum allowable cost list for a specific drug or drugs that are below the pharmacy acquisition cost.

(c)(1) A pharmacy benefit manager shall maintain a formal internal grievance process for pharmacies, in a form approved by the commissioner, and such formal internal grievance process shall provide for adequate consideration and timely resolution of grievances. A pharmacy benefit manager's internal grievance process shall include the following: (i) a dedicated telephone number, email address and website for the purpose of submitting a grievance; (ii) the ability to submit a grievance directly to the pharmacy benefit manager regarding the pharmacy benefits plan or program; and (iii) the ability to file a grievance within not less than 30 business days of the qualifying event.

(2) The pharmacy benefit manager shall respond to a grievance within 30 business days of receipt of the grievance. If the pharmacy benefit manager determines as a result of the internal grievance process that the pharmacy benefit manager's challenged conduct was not compliant with this section, the pharmacy benefit manager shall: (i) provide the pharmacy with the National Drug Code upon which the maximum allowable cost was based; (ii) reprocess the claim; (iii) reimburse the pharmacy in an amount that is not less than the pharmacy acquisition cost; and (iv)

to the extent practicable, reprocess claims submitted by similarly situated pharmacies and reimburse said pharmacies an amount that is not less than the pharmacy acquisition cost.

(3) If the pharmacy benefit manager determines as a result of the internal grievance process that the pharmacy benefit manager's challenged conduct was compliant with this section, the pharmacy benefit manager shall: (i) provide the pharmacy with the National Drug Code upon which the maximum allowable cost was based and the name of any wholesale drug distributors licensed under section 36B of chapter 112 that have the drug currently in stock at a price below the maximum allowable cost; or (ii) if the National Drug Code provided by the pharmacy benefit manager is not available at a price below the pharmacy acquisition cost from the wholesale drug distributor from whom the pharmacy purchases the majority of its prescription drugs for resale, then the pharmacy benefit manager shall adjust the maximum allowable cost as listed on the maximum allowable cost list above the challenging pharmacy's pharmacy acquisition cost, and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the challenged maximum allowable cost.

(d) A violation of this section shall constitute an unfair or deceptive act or practice under chapter 93A.

Section 11. (a) A pharmacy benefit manager shall, to the extent permissible under applicable law, report annually to the commissioner for each carrier the following information: (i) the aggregate amount a pharmacy benefit manager charged carriers for pharmacy services; and (ii) the aggregate amount a pharmacy benefit manager paid to pharmacies.

(b) The commissioner, in consultation with the health policy commission and the center for health information and analysis, shall report annually on the amounts reported under subsection (a), which shall be public record.

Section 12. (a) A pharmacy benefit manager shall pass 100 per cent of rebates to a health benefit plan or carrier.

(b) A pharmacy benefit manager shall, to the extent permissible under applicable law, report annually to the commissioner for each carrier the following information: (i) the total dollar amount in rebates received by the pharmacy benefit manager; and (ii) the total dollar amount in rebates distributed to a health benefit plan or carrier.

(c) A carrier shall, to the extent permissible under applicable law, use 100 per cent of rebates to reduce premiums or cost-sharing for covered individuals.

(d) A carrier shall, to the extent permissible under applicable law, report annually to the commissioner the following information: (i) the total dollar amount in rebates received from a pharmacy benefit manager; and (ii) the total dollar amount in rebates used to reduce premiums or cost-sharing for covered individuals.

Section 13. (a) A carrier or pharmacy benefit manager shall apply any payment for a prescription drug made by a covered individual or on behalf of a covered individual to the covered individual’s deductible, if any, and to the out-of-pocket maximum in the same manner as if the covered individual had purchased the prescription drug by paying the cost-sharing amount; provided, however, that the prescription drug: (i) does not have a generic equivalent, or, for a prescription drug that is a biological product, the prescription drug does not have a biosimilar drug, as defined in 42 U.S.C. sec.262 (i)(3); or (ii) has a generic equivalent, a biosimilar drug, or

an interchangeable biological product, and the covered individual has: (A) obtained prior authorization from the carrier or pharmacy benefit manager; (B) complied with step-therapy protocol required by the carrier or pharmacy benefit manager; or (C) received approval from the carrier or pharmacy benefit manager through the carrier‘s or pharmacy benefit manager’s exceptions, appeal, or review process. If under federal law, application of this requirement would result in health savings account ineligibility under section 223 of the federal Internal Revenue Code, this requirement shall apply for health savings account-qualified high deductible health plans with respect to the deductible of such a plan after the covered individual has satisfied the minimum deductible under section 223 of the federal Internal Revenue Code, except for with respect to items or services that are preventive care pursuant to section 223(c)(2)(C) of the federal Internal Revenue Code, in which case the requirements of this paragraph shall apply regardless of whether the minimum deductible under section 223 has been satisfied.

(b) A carrier, pharmacy benefit manager or third-party administrator shall not directly or indirectly set, alter, implement or condition the terms of health benefit plan coverage, including the benefit design, based in part or entirely on information about the availability or amount of financial or product assistance available for a prescription drug.

(c) The division may promulgate such rules and regulations as it may deem necessary to implement this section.

Section 14. (a)(1) A pharmacy benefit manager shall conduct an audit of the records of a pharmacy with which it contracts.

(2) The contract between a pharmacy and a pharmacy benefit manager shall identify and describe the audit procedures in detail.

(3) With the exception of an investigative fraud audit, the auditor shall give the pharmacy written notice not less than 2 weeks prior to conducting the initial on-site audit for each audit cycle.

(4) A pharmacy benefit manager shall not audit claims beyond 2 years prior to the date of audit.

(5) The auditor shall not interfere with the delivery of pharmacist services to a patient and shall make a reasonable effort to minimize the inconvenience and disruption to the pharmacy operations during the audit process.

(6) Any audit that involves clinical or professional judgment shall be conducted by, or in consultation with, a licensed pharmacist from any state.

(7) A finding of an overpayment or underpayment shall be based on the actual overpayment or underpayment. A statistically sound calculation for overpayment or underpayment may be used to determine recoupment as part of a settlement as agreed to by the pharmacy.

(8) The auditor shall audit each pharmacy under the same standards and parameters with which they audit other similarly situated pharmacies.

(9) An audit shall not be initiated or scheduled during the first 5 calendar days of any month for any pharmacy that averages more than 600 prescriptions per week without the pharmacy’s consent.

(10) A preliminary audit report shall be delivered to the pharmacy not later than 30 days after the conclusion of the audit.

(11) The preliminary audit report shall be signed and shall include the signature of any pharmacist participating in the audit.

(12) A pharmacy benefit manager shall not withhold payment to a pharmacy for reimbursement claims as a means to recoup money until after the final internal disposition of an audit, including the appeals process, as provided in subsection (b), unless fraud or misrepresentation is reasonably suspected or the discrepant amount exceeds $15,000.

(13) The auditor shall provide a copy of the final audit report to the pharmacy and plan sponsor within 30 days following the pharmacy's receipt of the signed preliminary audit report or the completion of the appeals process, as provided in subsection (b), whichever is later.

(14) No auditing company or agent shall receive payment based upon a percentage of the amount recovered or other financial incentive tied to the findings of the audit.

(b)(1) Each auditor shall establish an appeal process under which a pharmacy may appeal findings in a preliminary audit.

(2) To appeal a finding, a pharmacy may use the records of a hospital, physician or other authorized prescriber to validate the record with respect to orders or refills of prescription drugs or devices.

(3) A pharmacy shall have 30 days to appeal any discrepancy found during the preliminary audit.

(4) The National Council for Prescription Drug Programs or any other recognized national industry standard shall be used to evaluate claims submission and product size disputes.

(5) If an audit results in the identification of any clerical or record-keeping errors in a required document or record, the pharmacy shall not be subject to recoupment of funds by the pharmacy benefit manager; provided, that the pharmacy may provide proof that the patient received the medication billed to the plan via patient signature logs or other acceptable methods, unless there is financial harm to the plan or errors that exceed the normal course of business.

(c) This section shall not apply to any audit or investigation of a pharmacy that involves potential fraud, willful misrepresentation or abuse, including, but not limited to, investigative audits or any other statutory or regulatory provision which authorizes investigations relating to insurance fraud.

(d) This section shall not apply to a public health care payer, as defined in section 1 of chapter 12C.

(e) The commissioner shall promulgate regulations to enforce this section.

Section 15. A pharmacy benefit manager shall annually report to the commissioner: (i) any state or federal enforcement action taken against the pharmacy benefit manager, and (ii) any civil or criminal process or investigation involving the pharmacy benefit manager within the previous calendar year. The examination shall be conducted in accordance with subsection (6) of section 4 of chapter 175.

Section 16. A pharmacy benefit manager shall submit to periodic audits by a licensed carrier if the pharmacy benefit manager has entered into a contract with the carrier to provide pharmacy benefits to the carrier or its members. The commissioner shall direct or provide specifications for such audits.

Section 17. (a) A contract between a pharmacy benefit manager and a participating pharmacy or pharmacist or contracting agent shall not include any provision that prohibits, restricts, or limits a pharmacist or contracting agent or pharmacy's right to provide a covered individual with information on the amount of the covered individual's cost share for such covered individual's prescription drug and the clinical efficacy of a more affordable alternative drug if one is available. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefit manager for disclosing such information to a covered individual or for selling to a covered individual a more affordable alternative if one is available.

(b) A pharmacy benefit manager shall not charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including, without limitation, a fee for: (i) the receipt and processing of a pharmacy claim; (ii) the development or management of claims processing services in a pharmacy benefit manager network; or (iii) participation in a pharmacy benefit manager network, unless such fee is set out in a contract between the pharmacy benefit manager and the pharmacist or contracting agent or pharmacy.

(c) A contract between a pharmacy benefit manager and a participating pharmacy or pharmacist or contracting agent shall not include any provision that prohibits, restricts, or limits disclosure of information to the division deemed necessary by the division to ensure a pharmacy benefit manager's compliance with the requirements under this section or section 21C of chapter 94C.

SECTION 140. (a) Notwithstanding any general or special law to the contrary, the commonwealth health insurance connector authority, in consultation with the division of insurance, shall report on the impact of pharmaceutical pricing on health care costs and outcomes

for ConnectorCare and non-group and small group plans offered through the connector and its members.

The report shall include, but not be limited to: (i) information on the differential between drug list price and price net of rebates for plans offered and the impact of those differentials on member premiums; (ii) the relationship between drug list price and member cost-sharing requirements; (iii) the impact of drug price changes over time on premium and out-of-pocket costs in plans authorized under section 3 of chapter 176J of the General Laws offered through the commonwealth health insurance connector authority; (iv) trends in changes in drug list price and price net of rebates by health plan; (v) an analysis of the impact of member out-of-pocket costs on drug utilization and member experience; and (vi) an analysis of the impact of drug list price and price net of rebates on member formulary access to drug. Data collected under this subsection shall be protected as confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 of the General Laws or under chapter 66 of the General Laws.

The report shall be submitted to the joint committee on health care financing and the house and senate committees on ways and means not later than July 1, 2027; provided, however, that the report shall be published on the website of the commonwealth health insurance connector authority not later than July 1, 2027.

(b) In fiscal year 2026, the amount required to be paid pursuant to the last paragraph of section 6 of chapter 6D of the General Laws shall be increased by $500,000; provided, however, that said $500,000 shall be provided to the commonwealth health insurance connector authority

not later than March 14, 2026 for data collection and analysis costs associated with the report required by this section.

SECTION 141. The health policy commission shall consult with relevant stakeholders, including, but not limited to, consumers, consumer advocacy organizations, organizations representing people with disabilities and chronic health conditions, providers, provider organizations, payers, pharmaceutical manufacturers, pharmacy benefit managers and health care economists and other academics, to assist in the development and periodic review of regulations to implement section 24 of chapter 6D of the General Laws, including, but not limited to: (i) establishing the criteria and processes for identifying the proposed value of an eligible drug as defined in said section 24 of said chapter 6D; and (ii) determining the appropriate price increase for a public health essential drug as described within the definition of eligible drug in said section 24 of said chapter 6D.

The commission shall hold its first public outreach not more than 45 days after the effective date of this act and shall, to the extent possible, ensure fair representation and input from a diverse array of stakeholders.

SECTION 142. Notwithstanding subsection (b) of section 15A of chapter 6D of the General Laws, for the purposes of providing early notice under said section 15A of said chapter 6D, the health policy commission shall determine a significant price increase for a generic drug to be defined as a generic drug priced at $100 or more per wholesale acquisition cost unit that increases in cost by 100 per cent or more during any 12-month period.

SECTION 143. (a) Notwithstanding any general or special law to the contrary, for the purposes of monitoring and enforcing the health care cost growth benchmark for calendar years

2022 to 2026, inclusive, the center for health information and analysis shall apply sections 8, 9, 10, 16 and 18 of chapter 12C of the General Laws as those sections are in effect on December 1, 2025.

(b) Notwithstanding any general or special law to the contrary, for the purposes of monitoring and enforcing the health care cost growth benchmark for calendar years 2022 to 2026, inclusive, the health policy commission shall apply sections 9 and 10 of chapter 6D of the General Laws as those sections are in effect on December 1, 2025.

(c) Notwithstanding any general or special law to the contrary, the first benchmark cycle shall consist of the years 2026 and 2027. The health care cost growth benchmark for that benchmark cycle shall be the average of the 2026 health care cost growth benchmark that the health policy commission governing board established in 2025 and the growth rate of potential gross state product for 2027 established under section 7H½ of chapter 29 of the General Laws.

(d) Notwithstanding any general or special law to the contrary, not later than April 15, 2026, the board shall establish the health care cost growth benchmark pursuant to section 9 of chapter 6D of the general laws for: (i) the benchmark cycle consisting of the years 2026 and 2027; and (ii) the benchmark cycle consisting of the years 2027 and 2028.

(e) Notwithstanding any general or special law to the contrary, on or before January 15, 2026, the secretary and house and senate committees on ways and means shall jointly develop growth rates of potential gross state product pursuant to section 7H½ of chapter 29 of the General Laws for each of the calendar years of 2027 and 2028.

SECTION 144. Notwithstanding any general or special law, rule or regulation to the contrary, section 13 of chapter 6D of the General Laws, as amended by this act, shall apply only

to material change notices submitted after the effective date of this act; provided, however, that said section 13 of said chapter 6D shall apply to material changes that meet all of the following criteria: (i) the health policy commission received a completed material change notice regarding the material change on or after March 1, 2024; (ii) the health policy commission has not yet determined whether to conduct a cost and market impact review in regard to the material change; and (iii) the health policy commission classifies the material change as involving a provider or provider organization's merger or affiliation resulting in an increase in net patient service revenue of $10,000,000 or more. For such material change notices, the health policy commission shall be permitted to require submission of a new or revised material change form, request additional documentation and information and take an additional 30 days to conduct its preliminary review.

SECTION 145. Notwithstanding any general or special law to the contrary, section 26 of chapter 6D shall only apply to private equity companies that directly or indirectly own or controls a provider or provider organization and to financial actions taken by registered provider organizations with private equity investment after the effective date of this act.

SECTION 146. Notwithstanding any general or special law, rule or regulation to the contrary, section 4B of chapter 112 of the General Laws shall apply only to contracts or agreements between health care practices and management services organizations entered into after January 1, 2027.

SECTION 147. All health care practices required to register pursuant to section 4A of chapter 112 of the General Laws shall register with the board of registration in medicine not later than January 1, 2027.

SECTION 148. The commissioner of occupational licensure and the commissioner of public health shall adopt the regulations required under section 73 not later than 6 months after the effective date of this act.

SECTION 149. Section 142 is hereby repealed.

SECTION 150. The health policy commission, in consultation with the department of public health, the office of Medicaid, the group insurance commission and the division of insurance, shall study and analyze health insurance payer, including public and private payer, specialty pharmacy networks in the commonwealth. The study shall include: (i) a description of the type of specialty drugs most often provided by specialty pharmacies; (ii) the impact of existing health insurance payers' specialty pharmacy networks on patient access, availability of clinical support, continuity of care, safety, quality, cost sharing and health care costs; and (iii) any recommendations for increasing patient access to and choice of specialty drugs, maintaining high-quality specialty pharmacy standards and meeting the commonwealth's health care cost containment goals.

The commission shall submit a report of its findings and recommendations to the clerks of the senate and house of representatives, the senate and house committees on ways and means, the joint committee on health care financing and the joint committee on public health not later than July 1, 2025.

SECTION 151. The board of registration in pharmacy shall promulgate regulations required by subsection (f) of section 47DDD of chapter 175 of the General Laws not later than 3 months after the effective date of this act.

SECTION 152. Section 17Z of chapter 32A, section 10Z of chapter 118E, section 47CCC of chapter 175, section 8DDD of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G shall take effect on July 1, 2026.

SECTION 153. The commissioner of insurance shall promulgate regulations to implement sections 5 through 17, inclusive, of chapter 176Y of the General Laws not later than October 1, 2026.

SECTION 154. Sections 130 through 139, inclusive, shall take effect on March 30, 2026.

SECTION 155. Section 149 shall take effect on January 1, 2027.