SENATE . . . . . No. 2651

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

SENATE, February 3, 2022.

The committee on Senate Ways and Means to whom was referred the Senate Bill relative to pharmaceutical access, costs and transparency (Senate, No. 771), - reports, recommending that the same ought to pass with an amendment substituting a new draft with the same title (Senate, No. 2651).

For the committee,
Michael J. Rodrigues

FILED ON: 2/3/2022

SENATE . . . . . No. 2651

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In the One Hundred and Ninety-Second General Court
(2021-2022)

An Act relative to pharmaceutical access, costs and transparency.

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

SECTION 1. Section 1 of chapter 6D of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by inserting after the definition of "Alternative payment methodologies or methods" the following 2 definitions:-

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

"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 health benefit plan 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 development 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 inserting after the definition of "Fiscal year" 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 and was not originally marketed under a new drug application; or (iv) identified by the health benefit plan as a generic drug based on available data resources such as Medi-Span.

SECTION 4. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by striking out, in line 189, the words "not include excludes ERISA plans" and inserting in place thereof the following words:- include self-insured plans to the extent allowed under the federal Employee Retirement Income Security Act of 1974.

SECTION 5. Said section 1 of said chapter 6D, as so appearing, is hereby further amended by inserting after the definition of "Performance penalty" the following 2 definitions:-

"Pharmaceutical manufacturing company", an entity engaged in the: (i) production, preparation, propagation, compounding, conversion or processing of prescription drugs, directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that "pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

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

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

"Wholesale acquisition cost", shall have the same meaning as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

SECTION 8. Said chapter 6D 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, 20 or 21 of this chapter or under section 2GGGG of chapter 29 and shall not disclose the information or documents to any person without the consent of the payer, provider or pharmaceutical manufacturing company providing or reporting the information or documents under said sections 7, 10, 14, 15, 15A, 20 or 21 of this chapter or under said section 2GGGG of said chapter 29, except in summary form in evaluative reports of such activities or when the commission believes that such disclosure should be made in the public interest after taking into account any privacy, trade secret or anticompetitive considerations. The confidential

information and documents shall not be public records and shall be exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66.

SECTION 9. Section 4 of said chapter 6D, as so appearing, is hereby amended by striking out, in lines 6 and 7, the word “manufacturers” and inserting in place thereof the following words:- manufacturing companies, pharmacy benefit managers.

SECTION 10. Section 6 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “center”, in line 1, the following words:- , pharmaceutical and biopharmaceutical manufacturing company, pharmacy benefit manager.

SECTION 11. Said section 6 of said chapter 6D, as so appearing, is hereby further amended by striking out, in lines 5 and 36, the figure “33” and inserting in place thereof, in each instance, the following figure:- 25.

SECTION 12. Said section 6 of said chapter 6D, as so appearing, is hereby further amended by adding the following paragraph:-

The assessed amount for pharmaceutical and biopharmaceutical manufacturing companies and pharmacy benefit managers shall be not less than 25 per cent of the amount appropriated by the general court for the expenses of the commission minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the commission's publication or dissemination of reports and information; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies. Pharmaceutical and biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner and distribution determined by the commission, pay to the commonwealth an amount of the estimated expenses of the commission attributable to the commission’s activities under sections

8, 9, 15A, 20 and 21. A pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and manages its own prescription drug benefits shall not be subject to additional assessment under this paragraph

SECTION 13. Section 8 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 14. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “organizations”, in line 14, the following words:- , pharmacy benefit managers, pharmaceutical manufacturing companies.

SECTION 15. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in line 32, the words “and (xi)” and inserting in place thereof the following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least 1 representative of the pharmacy benefit management industry; and (xiii).

SECTION 16. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in line 48, the first time it appears, the word “and”.

SECTION 17. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “commission”, in line 59, the first time it appears, the following words:- ; and (iii) in the case of pharmacy benefit managers and pharmaceutical manufacturing companies, testimony concerning factors underlying prescription drug costs and price increases including, but not limited to, the initial prices of drugs coming to market and subsequent price increases, changes in industry profit levels, marketing expenses, reverse payment patent settlements, the impact of manufacturer rebates, discounts and other price

concessions on net pricing, the availability of alternative drugs or treatments and any other matters as determined by the commission.

SECTION 18. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the second sentence and inserting in place thereof the following 2 sentences:-

The report shall be based on the commission's analysis of information provided at the hearings by witnesses, providers, provider organizations, payers, pharmaceutical manufacturing companies and pharmacy benefit managers, registration data collected under section 11, data collected or analyzed by the center under sections 8, 9, 10 and 10A of chapter 12C and any other available information that the commission considers necessary to fulfill its duties under this section as defined in regulations promulgated by the commission. To the extent practicable, the report shall not contain any data that is likely to compromise the financial, competitive or proprietary nature of the information.

SECTION 19. Section 9 of said chapter 6D, as so appearing, is hereby amended by inserting after the word "organization", in line 72, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 20. Said chapter 6D is hereby further amended by inserting after section 15 the following section:-

Section 15A. (a) A pharmaceutical manufacturing company shall provide early notice to the commission in a manner described in this section for a: (i) pipeline drug; (ii) generic drug; or (iii) biosimilar drug. The commission shall provide 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 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 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) Notwithstanding any general or special law to the contrary, information provided under this section shall be protected as confidential and shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 or under chapter 66.

(e) 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 2RRRRR of chapter 29.

SECTION 21. Said chapter 6D is hereby further amended by adding the following 2 sections:-

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

"Eligible drug", (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; or (iv) other prescription drug products that may have a direct and significant impact and create affordability challenges for the state's health care system and patients, as determined by the commission; provided, however, that the commission shall promulgate regulations to establish the type of prescription drug products classified under clause (iv) prior to classification of any such prescription drug product under said clause (iv).

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

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

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

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

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

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

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

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

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

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

(d) If, after review of an eligible drug and after receiving information from the manufacturer under subsection (b) or subsection (e), the commission determines that the manufacturer’s pricing of the eligible drug does not substantially exceed the proposed value of the drug, the commission shall notify the manufacturer, in writing, of its determination and shall evaluate other ways to mitigate the eligible drug’s cost in order to improve patient access to the

eligible drug. The commission may engage with the manufacturer and other relevant stakeholders, including, but not limited to, patients, patient advocacy organizations, consumer advocacy organizations, providers, provider organizations and payers, to explore options for mitigating the cost of the eligible drug. Upon the conclusion of a stakeholder engagement process under this subsection, the commission shall issue recommendations on ways to reduce the cost of the eligible drug for the purpose of improving patient access to the eligible drug. Recommendations may include, but shall not be limited to: (i) an alternative payment plan or methodology; (ii) a bulk purchasing program; (iii) co-pay, deductible, coinsurance or other cost-sharing restrictions; and (iv) a reinsurance program to subsidize the cost of the eligible drug. The recommendations shall be publicly posted on the commission's website and provided to the clerks of the house of representatives and senate, the joint committee on health care financing and the house and senate committees on ways and means.

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

(f) Not later than 60 days after receiving information from the manufacturer under subsection (b) or subsection (e), the commission shall confidentially issue a determination on whether the manufacturer's pricing of an eligible drug substantially exceeds the commission's proposed value of the drug. If the commission determines that the manufacturer's pricing of an eligible drug substantially exceeds the proposed value of the drug, the commission shall

confidentially notify the manufacturer, in writing, of its determination and request the manufacturer to enter into an access and affordability improvement plan under section 21.

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

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

(h) The proposed value of an eligible drug as determined by the commission and the commission's underlying analysis of the eligible drug shall not be used as the sole source of information by the office of Medicaid, health insurance carriers, managed care organizations, accountable care organizations, hospitals or pharmacies to determine whether to implement step therapy or utilization management or whether a drug should be included in a formulary.

(i) If the manufacturer fails to timely comply with the commission's request for records under subsection (b) or subsection (e), or otherwise knowingly obstructs the commission's ability to issue its determination under subsection (f), including, but not limited to, by providing incomplete, false or misleading information, the commission may impose appropriate sanctions

against the manufacturer, including reasonable monetary penalties not to exceed $500,000, in each instance. The commission shall seek to promote compliance with this section and shall only impose a civil penalty on the manufacturer as a last resort. Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2RRRRR of chapter 29.

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

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

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

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

outcomes and a timetable for implementation. The timetable for an access and affordability improvement plan shall not exceed 18 months.

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

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

(e) Upon approval of the proposed access and affordability improvement plan, the commission shall notify the manufacturer to begin immediate implementation of the access and affordability improvement plan. Public notice shall be provided by the commission on its website, identifying that the manufacturer is implementing an access and affordability improvement plan; provided, however, that upon the successful completion of the access and affordability improvement plan, the identity of the manufacturer shall be removed from the commission's website. All manufacturers implementing an approved access improvement plan shall be subject to additional reporting requirements and compliance monitoring as determined by the commission. The commission shall provide assistance to the manufacturer in the successful implementation of the access and affordability improvement plan.

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

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

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

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

(j) The commission may assess a civil penalty to a manufacturer of not more than $500,000, in each instance, if the commission determines that the manufacturer: (i) willfully neglected to file an access and affordability improvement plan with the commission under subsection (a); (ii) failed to file an acceptable access and affordability improvement plan in good

faith with the commission; (iii) failed to implement the access and affordability improvement plan in good faith; or (iv) knowingly failed to provide information required by this section to the commission or knowingly falsified the information. The commission shall seek to promote compliance with this section and shall only impose a civil penalty as a last resort. Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2RRRRR of chapter 29.

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

If a manufacturer is deemed to not be acting in good faith to develop an acceptable or complete access and affordability improvement plan, the commission may publicly post the proposed value of the eligible drug, hold a public hearing on the proposed value of the eligible drug and solicit public comment. The manufacturer shall appear and testify at any hearing held on the eligible drug's proposed value. Upon the conclusion of a public hearing under this subsection, the commission shall issue recommendations on ways to reduce the cost of an eligible drug for the purpose of improving patient access to the eligible drug. The

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

Before making a determination that the manufacturer is not acting in good faith, the commission shall send a written notice to the manufacturer that the commission shall deem the manufacturer to not be acting in good faith if the manufacturer does not submit an acceptable access and affordability improvement plan within 30 days of receipt of notice; provided, however, that the commission shall not send a notice under this paragraph within 120 calendar days from the date that the commission issued its request that the manufacturer enter into the access and affordability improvement plan.

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

SECTION 22. Section 1 of chapter 12C of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by inserting after the definition of "Ambulatory surgical center services" the following 3 definitions:-

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

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

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for an authorized generic 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 health benefit plan as a brand name drug based on available data resources such as Medi-Span.

SECTION 23. 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 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 health benefit plan as a generic drug based on available data resources such as Medi-Span.

SECTION 24. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by inserting after the definition of "Patient-centered medical home" the following 2 definitions:-

"Pharmaceutical manufacturing company", an entity engaged in the: (i) production, preparation, propagation, compounding, conversion or processing of prescription drugs, directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (ii) packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that "pharmaceutical manufacturing company" shall not include a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

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

SECTION 25. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by adding the following definition:-

“Wholesale acquisition cost”, shall have the same meaning as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

SECTION 26. Section 3 of said chapter 12C, as so appearing, is hereby amended by inserting after the word “organizations”, in lines 13 and 14, the following words:- , pharmaceutical manufacturing companies, pharmacy benefit managers.

SECTION 27. Said section 3 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 24, the words “and payer” and inserting in place thereof the

following words:- , payer, pharmaceutical manufacturing company and pharmacy benefit manager.

SECTION 28. Section 5 of said chapter 12C, as so appearing, is hereby amended by striking out, in lines 11 and 12, the words “and public health care payers” and inserting in place thereof the following words:- , public health care payers, pharmaceutical manufacturing companies and pharmacy benefit managers.

SECTION 29. Said section 5 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 15, the words “and affected payers” and inserting in place thereof the following words:- affected payers, affected pharmaceutical manufacturing companies and affected pharmacy benefit managers.

SECTION 30. The first paragraph of section 7 of said chapter 12C, as so appearing, is hereby amended by adding the following sentence:- Each pharmaceutical and biopharmaceutical manufacturing company and pharmacy benefit manager shall pay to the commonwealth an amount for the estimated expenses of the center and for the other purposes described in this chapter.

SECTION 31. Said section 7 of said chapter 12C, as so appearing, is hereby further amended by striking out, in lines 8 and 42, the figure “33” and inserting in place thereof, in each instance, the following figure:- 25.

SECTION 32. Said section 7 of said chapter 12C, as so appearing, is hereby further amended by adding the following paragraph:-

The assessed amount for pharmaceutical and biopharmaceutical manufacturing companies and pharmacy benefit managers shall be not less than 25 per cent of 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 commission's publication or dissemination of reports and information; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies. Pharmaceutical and biopharmaceutical manufacturing companies and pharmacy benefit managers shall, in a manner and distribution determined by the center, pay to the commonwealth an amount of the estimated expenses of the center attributable to the center’s activities under sections 3, 10A, 12 and 16. The assessed amount shall be based on business conducted in the commonwealth by the pharmaceutical and biopharmaceutical manufacturing company and pharmacy benefit manager. A pharmacy benefit manager that is also a surcharge payor subject to the preceding paragraph and manages its own prescription drug benefits shall not be subject to additional assessment under this paragraph.

SECTION 33. Said chapter 12C is hereby further amended by inserting after section 10 the following section:-

Section 10A. (a) The center shall promulgate the 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 expenditures; and (v) a description, absent proprietary information and written in plain language, of factors that contributed to reported changes in wholesale acquisition

costs, net prices and average manufacturer prices for prescription drug products as identified by the center.

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

The center shall require the submission of available data and other information from pharmacy benefit managers including, but not limited to: (i) true net typical prices charged by pharmacy benefits managers for prescription drug products identified by the center, net of any rebate or other payments from the manufacturer to the pharmacy benefits manager and from the pharmacy benefits manager to the manufacturer; (ii) the amount of all rebates that the pharmacy benefit manager received from all pharmaceutical manufacturing companies for all health carrier clients in the aggregate and for each health carrier client or health plan sponsor individually, attributable to patient utilization in the commonwealth; (iii) the administrative fees that the pharmacy benefit manager received from all health carrier clients or health plan sponsors in the

aggregate and for each health carrier client or health plans sponsors individually; (iv) the aggregate amount of all retained rebates that the pharmacy benefit manager received from all pharmaceutical manufacturing companies and did not pass through to each pharmacy benefit manager's health carrier client or health plan sponsor individually; (v) the aggregate amount of rebates a pharmacy benefit manager: (A) retains based on its contractual arrangement with each health plan client or health plan sponsor individually; and (B) passes through to each health care client individually; (vi) the percentage of contracts that a pharmacy benefit manager holds where the pharmacy benefit manager: (A) retains all rebates; (B) passes all rebates through to the client; and (C) shares rebates with the client; and (vii) other information as determined by the center, including, but not limited to, pharmacy benefit manager practices related to spread pricing, administrative fees, claw backs and formulary placement.

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

SECTION 34. Said chapter 12C is hereby further amended by striking out section 11, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 11. The center shall ensure the timely reporting of information required under sections 8, 9, 10 and 10A. The center shall notify private health care payers, providers, provider organizations, pharmacy benefit managers, pharmaceutical manufacturing companies and their parent organization and other affiliates of any applicable reporting deadlines. The center shall notify, in writing, a private health care payer, provider, provider organization, pharmacy benefit

manager or pharmaceutical manufacturing company, and their parent organization and other affiliates, that has failed to meet a reporting deadline of such failure and that failure to respond within 2 weeks of the receipt of the notice may result in penalties. The center may assess a penalty against a private health care payer, provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing company, and their parent organization and other affiliates, that fails, without just cause, to provide the requested information, including subsets of the requested information, within 2 weeks following receipt of the written notice required under this section, of not more than $2,000 per week for each week of delay after the 2-week period following receipt of the notice. Amounts collected under this section shall be deposited in the Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

SECTION 35. Section 12 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 2, the words “and 10” and inserting in place thereof the following words:- , 10 and 10A.

SECTION 36. Subsection (a) of section 16 of said chapter 12C, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:- The center shall publish an annual report based on the information submitted under: (i) sections 8, 9, 10 and 10A concerning health care provider, provider organization, private and public health care payer, pharmaceutical manufacturing company and pharmacy benefit manager costs and cost and price trends; (ii) section 13 of chapter 6D relative to market power reviews; and (iii) section 15 of said chapter 6D relative to quality data.

SECTION 37. Said section 16 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 18, the words “in the aggregate”.

SECTION 38. Said section 16 of said chapter 12C, as so appearing , is hereby 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 (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.

SECTION 39. Section 13 of chapter 17 of the General Laws, as so appearing, is hereby amended by adding the following subsection:-

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

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

The commission shall identify and publish a list of public health essential prescription drugs. The list shall be updated not less than annually and be made publicly available on the department's website; provided, however, that the 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 40. Chapter 29 of the General Laws is hereby amending by inserting after section 2QQQQQ the following section:-

2RRRRR. (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 state residents to lower the cost of prescription drugs. Money in the fund shall be spent to 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, heart failure, coronary artery disease, hypertension and high blood pressure; (iii) diabetes; and (iv) any other chronic condition identified by the department that disproportionally impacts marginalized communities. 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 activities detailing the funds 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 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.

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

SECTION 41. Section 17G of chapter 32A of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by adding the following sentence:-

Coverage for insulin under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured’s prescription; provided, however, that nothing in this section shall prevent the commission and its contracted health benefit plans from reducing the co-payment for insulin for a 30-day supply below the amount specified in this section.

SECTION 42. Chapter 112 of the General Laws is hereby amended by inserting after section 39J the following section:-

Section 39K. (a) For the purposes of this section, a “specialty pharmacy” may include any pharmacy in the commonwealth engaged in the dispensing of specialty medications as

644 defined in section 3B of chapter 176D; provided further, that “specialty pharmacy” shall not
645 include a mail service pharmacy.

646 The board shall establish a procedure to license specialty pharmacies, which prescribe,
647 ship, mail, sell or dispense specialty medications in the commonwealth. The board shall take
648 steps to ensure that all shipments of pharmaceutical drugs from in-state pharmacies to out-of-
649 state destinations are in compliance with the licensing procedures applicable to pharmacies in the
650 commonwealth.

651 (b) (1) A specialty pharmacy shall designate a pharmacist in charge who shall register
652 with the board and shall be responsible for the pharmacy’s compliance with this chapter. Such
653 pharmacist in charge shall be licensed and in good standing with the competent board of
654 registration in pharmacy in the jurisdiction where the pharmacy is located.

655 (2) The designated pharmacist in charge shall disclose to the board the location, name
656 and title of all principal managers and the name and applicable in-state board of registration
657 license number of the designated pharmacist in charge, if applicable, and a letter from the board
658 of registration of pharmacy certifying that the pharmacist in charge is in good standing with the
659 applicable in-state board of registration. The designated pharmacist in charge shall submit a
660 report containing this information and a copy of the certifying letter of good standing annually
661 and within 30 days after any change of office, corporate office or manager of record.

662 (3) The designated pharmacist in charge shall certify to the board that the pharmacy
663 maintains, at all times, a current unrestricted license, permit or registration to conduct the
664 pharmacy in compliance with the laws and regulations of the jurisdiction in which the designated
665 pharmacist in charge is licensed to practice. The pharmacy shall certify its compliance with

reasonable informational requests made by the board and shall notify the board of any enforcement or disciplinary action taken against the pharmacy regardless of the state in which the enforcement action is taken.

(4) Annually, the designated pharmacist in charge shall certify to the board that the pharmacy maintains records of all drugs dispensed to patients in the commonwealth, and that these records are readily available, upon the request of the board. Annually, the designated pharmacist in charge shall send to the board a list of drugs dispensed in the commonwealth.

(c) No pharmacy or pharmacist operating outside of the state shall prescribe, ship, mail, sell, transfer or dispense drug preparations in the commonwealth unless that pharmacy has been granted a specialty license pursuant to this section.

(d) The division of insurance may adopt any written policies or procedures or promulgate regulations that the division determines are necessary to implement this section.

SECTION 43. Section 10C of chapter 118E of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by adding the following sentence:-

Coverage for insulin under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured’s prescription; provided, however, that nothing in this section shall prevent the division and its contracted health insurers, health plans, health maintenance organizations, behavioral health management firms and third-party administrators under contract with the division, a Medicaid managed care organization or a primary care clinician plan, from reducing the co-payments for insulin for a 30-day supply below the amount specified in this section.

SECTION 44. Section 47N of chapter 175 of the General Laws, as so appearing, is hereby amended by adding the following paragraph:-

Coverage for insulin under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's insulin prescription; provided, however, that nothing in this section shall prevent an individual policy of accident and sickness insurance issued under section 108 that provides hospital expense and surgical expense insurance or a group blanket or general policy of accident and sickness insurance issued under section 110 that provides hospital expense and surgical expense insurance that is issued or renewed within or without the commonwealth, from reducing the co-payment for insulin for a 30-day supply below the amount specified in this section.

SECTION 45. Section 226 of said chapter 175, as so appearing, is hereby amended by striking out subsection (a) and inserting in place thereof the following subsection:-

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

(viii) mail and specialty drug pharmacy services; (ix) cost containment; (x) clinical, safety and adherence programs for pharmacy services; and (xi) managing the cost of covered prescription drugs; provided further, that "pharmacy benefit manager" shall include a health benefit plan that does not contract with a pharmacy benefit manager and manages its own prescription drug benefits unless specifically exempted.

SECTION 46. Section 8P of chapter 176A of the General Laws, as so appearing, is hereby amended by adding the following paragraph:-

Coverage for insulin under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's insulin prescription; provided, however, that nothing in this section shall prevent a contract between a subscriber and the corporation under an individual or group hospital service plan that is delivered, issued or renewed within or without the commonwealth, from reducing the co-payment for insulin for a 30-day supply below the amount specified in this section.

SECTION 47. Section 4S of Chapter 176B of the General Laws, as so appearing, is hereby amended by adding the following sentence:-

Coverage for insulin under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's insulin prescription; provided, however, that nothing in this section shall prevents a subscription certificate under an individual or group medical service agreement that is issued or renewed within or without the commonwealth, from reducing the co-payment for insulin for a 30-day supply below the amount specified in this section.

SECTION 48. The fourth paragraph of section 3B of chapter 176D of the General Laws, as so appearing, is hereby amended by inserting after the second sentence the following sentences:- A carrier shall not prohibit the dispensing of specialty drugs as defined by this section that are included in its pharmaceutical drug benefits to insureds by any licensed pharmacy; provided, however, that the pharmacy is able to comply with the special handling, administration and monitoring requirements of the specialty drug. A carrier shall allow any network pharmacy to provide specialty drugs if the pharmacy agrees to the same reimbursement terms and conditions.

SECTION 49. Said section 3B of said Chapter 176D, as so appearing, is hereby further amended by striking out the fifth paragraph and inserting in place thereof the following paragraph:-

A carrier shall allow any network pharmacy to provide mail order prescriptions if the pharmacy agrees to the same reimbursement terms and conditions. A carrier shall not impose: (i) any agreement, terms or conditions on the network pharmacy that are more restrictive than those imposed on the participating mail order pharmacy; (ii) any terms or restrictions on network pharmacies that are designed to exclude them from providing mail order prescriptions; and (iii) impose a co-payment fee or other cost-sharing condition on any insured who elects to purchase mail order prescription drugs from a network pharmacy that is not also imposed on the insured's mail order pharmacy.

SECTION 50. The eighth paragraph of said section 3B of said chapter 176D, as so appearing, is hereby amended by adding the following sentence:- The term "specialty drugs"

shall mean a prescription medication that requires special handling, administration or monitoring.

SECTION 51. Section 4H of Chapter 176G of the General Laws, as so appearing, is hereby amended by adding the following paragraph:-

Coverage for insulin under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's insulin prescription; provided, however, that nothing in this section shall prevent any individual or group health maintenance contract that is issued or renewed within or without the commonwealth, from reducing the co-payment for insulin for a 30-day supply below the amount specified in this section.

SECTION 52. Section 2 of Chapter 176O of the General Laws, as so appearing, is hereby amended by adding the following subsection:-

(i) Every 3 years, a carrier that contracts with a pharmacy benefit manager shall coordinate an audit of the operations of the pharmacy benefit manager to ensure compliance with this chapter and to examine the pricing and rebates applicable to prescription drugs that are provided to the carrier's covered persons.

SECTION 53. Said chapter 176O 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 176X as a condition of contracting with that carrier.

SECTION 54. Said chapter 176O is hereby further amended by adding the following section:-

Section 30. (a) For the purposes of this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Cost-sharing", an amount owed by a consumer under the terms of the consumer's health benefit plan .

"Negotiated price", the amount that the health benefit plan or a pharmacy benefit manager, as defined in section 1 of chapter 6D, would pay for a prescription medication at a pharmacy under an agreement between the health benefit plan and the pharmacy.

"Usual and customary charge", the lowest price that a provider charges or accepts from any payer for the same quantity of a drug on the same date of service in the commonwealth, including, but not limited to, the shelf price, sale price or advertised price for any drug including an over-the-counter drug; provided, however, that if an insurer and the provider have a contract that specified that the insurer will pay an average or similarly computed fixed amount for multiple therapeutic categories of drugs with different acquisition costs, the fixed amount will not be the provider's usual and customary charge.

(b) A carrier, or an entity that manages or administrators benefits for a carrier, shall not impose cost sharing, including co-pays, deductibles and coinsurance, on a member for a covered prescription drug that exceeds the negotiated price or usual and customary charge, whichever is lower.

(c) A contract shall not: (i) prohibit a pharmacist from complying with this section; or (ii) impose a penalty on the pharmacist or pharmacy for complying with this section.

SECTION 55. The General Laws are hereby amended by inserting after chapter 176W the following chapter:-

Chapter 176X.

LICENSING AND REGULATION OF PHARMACY BENEFIT MANAGERS.

Section 1. As used in this chapter, the following words shall have the following meanings unless the context clearly requires otherwise:

"Carrier", an insurer licensed or otherwise authorized to transact accident or health insurance under chapter 175, a nonprofit hospital service corporation organized under chapter 176A, a non-profit medical service corporation organized under chapter 176B, a health maintenance organization organized under chapter 176G and an organization entering into a preferred provider arrangement under chapter 176I; provided, however, that the term "carrier" shall not include an employer purchasing coverage or acting on behalf of its employees or the employees of any subsidiary or affiliated corporation of the employer; provided further, that unless otherwise provided, the term "carrier" shall not include any entity to the extent it offers a policy, certificate or contract that provides coverage solely for dental care services or vision care services.

"Center", the center for health information and analysis established in chapter 12C.

"Commissioner", the commissioner of insurance.

"Division", the division of insurance.

"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.

"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.

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

Section 2. (a) A person, business or other entity shall not establish or operate as a pharmacy benefit manager without obtaining a license from the division pursuant to this section.

The division shall issue a pharmacy benefit manager 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 benefit manager 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 benefit manager 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: (i) limiting the type of services that a license holder may provide; (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.

(e) The division shall develop an application for licensure of pharmacy benefit managers that shall include, but not be limited to: (i) the name of the applicant or pharmacy benefit manager; (ii) the address and contact telephone number for the applicant or pharmacy benefit manager; (iii) the name and address of the agent of the applicant or pharmacy benefit manager for service of process in the commonwealth; (iv) the name and address of any person with management or control over the applicant or pharmacy benefit manager; and (v) any audited financial statements specific to the applicant or pharmacy benefit manager. An applicant or

pharmacy benefit manager 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 benefit manager license for cause, which shall include, but not be limited to: (i) the applicant or pharmacy benefit manager engaging in fraudulent activity that is found by a court of law to be a violation of state or federal law; (ii) the division receiving consumer complaints that justify an action under this chapter to protect the health, safety and interests of consumers; (iii) the applicant or pharmacy benefit manager failing to pay an application or renewal fee for a license; (iv) the applicant or pharmacy benefit manager failing to comply with reporting requirements of the center under section 10A of chapter 12C; or (v) the applicant pharmacy benefit manager's failing to comply with a requirement of this chapter.

The division shall provide written notice to the applicant or pharmacy benefit manager and advise in writing of the reason for any suspension, revocation, refusal to issue or renew or placement on probation of a pharmacy benefit manager license under this chapter. A copy of the notice shall be forwarded to the center. The applicant or pharmacy benefit manager 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 benefit manager an opportunity for a hearing pursuant to said chapter 30A.

(g) If a person, business or other entity performs the functions of a pharmacy benefit manager 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. Penalties collected under this subsection shall be deposited into the Prescription Drug Cost Assistance Trust Fund established in section 2RRRRR of chapter 29.

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

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

Section 3. (a) The commissioner may make an examination of the affairs of a pharmacy benefit manager when the commissioner deems prudent but not less frequently than once every 3 years. The focus of the examination shall be to ensure that a pharmacy benefit manager is able to meet its responsibilities under contracts with carriers licensed under chapters 175, 176A, 176B, or 176G. The examination shall be conducted according to the procedures set forth in subsection (6) of section 4 of chapter 175.

(b) The commissioner, a deputy or an examiner may conduct an on-site examination of each pharmacy benefit manager in the commonwealth to thoroughly inspect and examine its affairs.

(c) The charge for each such examination shall be determined annually according to the procedures set forth in subsection (6) of section 4 of chapter 175.

(d) Not later than 60 days following completion of the examination, the examiner in charge shall file with the commissioner a verified written report of examination under oath. Upon receipt of the verified report, the commissioner shall transmit the report to the pharmacy benefit manager examined with a notice that shall afford the pharmacy benefit manager examined a reasonable opportunity of not more than 30 days to make a written submission or rebuttal with respect to any matters contained in the examination report. Within 30 days of the end of the period allowed for the receipt of written submissions or rebuttals, the commissioner shall consider and review the reports together with any written submissions or rebuttals and any relevant portions of the examiner's work papers and enter an order:

(i) adopting the examination report as filed with modifications or corrections and, if the examination report reveals that the pharmacy benefit manager is operating in violation of this section or any regulation or prior order of the commissioner, the commissioner may order the pharmacy benefit manager to take any action the commissioner considered necessary and appropriate to cure such violation;

(ii) rejecting the examination report with directions to examiners to reopen the examination for the purposes of obtaining additional data, documentation or information and re-filing pursuant to the above provisions; or

(iii) calling for an investigatory hearing with not less than 20 days' notice to the pharmacy benefit manager for purposes of obtaining additional documentation, data, information and testimony.

(e) Notwithstanding any general or special law to the contrary, including clause Twenty sixth of section 7 of chapter 4 and chapter 66, the records of any such audit, examination or other

inspection and the information contained in the records, reports or books of any pharmacy benefit manager examined pursuant to this section shall be confidential and open only to the inspection of the commissioner, or the examiners and assistants. Access to such confidential material may be granted by the commissioner to law enforcement officials of the commonwealth or any other state or agency of the federal government at any time if the agency or office receiving the information agrees in writing to keep such material confidential. Nothing in this subsection shall be construed to prohibit the required production of such records, and information contained in the reports of such company or organization before any court of the commonwealth or any master or auditor appointed by any such court, in any criminal or civil proceeding, affecting such pharmacy benefit manager, its officers, partners, directors or employees. The final report of any such audit, examination or any other inspection by or on behalf of the division of insurance shall be a public record.

SECTION 56. Notwithstanding any general or special law to the contrary, the health policy commission, in consultation with the center for health information and analysis, the executive office of health and human services and the division of insurance, shall produce interim and final reports on the use of insulin in the commonwealth and the effects of capping copayments and eliminating deductible and co-insurance requirements for insulin for individuals with diabetes on health care access and system cost.

The interim and final report shall include, but not be limited to: (i) rates of insulin utilization; (ii) an analysis of the use of insulin, broken down by patient demographics, geographic region and insulin delivery device; (iii) annual plan costs and member premiums; (iv) the average price of insulin; (v) the average insulin price net of rebates or discounts received by or accrued directly or indirectly by health insurance carriers; (vi) average and total out-of-pocket

expenditures on insulin delivery devices and glucose monitoring tests that are not included as part of an insulin prescription; (vii) an analysis of the impact of capping co-payments and eliminating deductible and co-insurance requirements for insulin on patient access to and cost of care by patient demographics and geographic region; (viii) additional funding sources for the Prescription Drug Cost Assistance Trust Fund established in section 2RRRRR of chapter 29 of the General Laws; and (ix) any barriers to accessing insulin for individuals with diabetes and policy recommendations for resolving such barriers. The interim report, including any recommendations for expanding access to insulin for individuals with diabetes, shall be filed with the clerks of the house of representatives and senate, the joint committee on public health, the joint committee on health care financing and the house and senate committees on ways and means not later than 18 months after the effective date of this act. The final report, including any recommendations for expanding access to insulin for individuals with diabetes, shall be filed with the clerks of the house of representatives and senate, the joint committee on public health, the joint committee on health care financing and the house and senate committees on ways and means not later than 3 years after the effective date of this act.

SECTION 57. (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 medication list price and price net of rebates for plans offered and the impact of those differentials on member premiums; (ii) the relationship between medication list price and

member cost-sharing requirements; (iii) the impact of medication 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 medication list price and price net of rebates by health plan; (v) an analysis of the impact of member out-of-pocket costs on medication utilization and member experience; and (vi) an analysis of the impact of medication list price and price net of rebates on member formulary access to medications. 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 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, 2024.

(b) In fiscal year 2023, 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 October 14, 2022 for data collection and analysis costs associated with the report required by this section.

SECTION 58. Notwithstanding any general or special law to the contrary, there shall be a special commission to examine the feasibility of: (i) establishing a system for the bulk purchasing and distribution of pharmaceutical products with a significant public health benefit and the potential for significant health care cost savings for consumers through overall increased purchase capacity; and (ii) making bulk purchase pricing information available to purchasers in other states.

The commission shall consist of: the commissioner of public health or a designee, who shall serve as chair; the executive director of the group insurance commission or a designee; the chief of pharmacy of the state office for pharmacy services; the MassHealth director of pharmacy; the secretary of technology services and security; and 8 members appointed by the commissioner of public health, 2 of whom shall be health care economists, 1 of whom shall be an expert in health law and policy innovation, 1 of whom shall be an academic with relevant expertise in the field, 1 of whom shall be the chief executive officer of a licensed hospital in the commonwealth, 1 of whom shall be a representative of the Massachusetts Association of Health Plans, Inc., 1 of whom shall be a representative of Blue Cross Blue Shield of Massachusetts, Inc. and 1 of whom shall be a member of the public with experience with health care and consumer protection.

The commission shall hold not less than 3 public hearings in different geographic areas of the commonwealth, accept input from the public and solicit expert testimony from individuals representing health insurance carriers, pharmaceutical companies, independent and chain pharmacies, hospitals, municipalities, health care practitioners, health care technology professionals, community health centers, substance abuse disorder providers, public health educational institutions and other experts identified by the commission.

The commission shall consider: (i) the process by which the commonwealth could make bulk purchases of pharmaceutical products with a significant public health benefit and the potential for significant health care cost savings to consumers; (ii) the process by which both governmental and nongovernmental entities may participate in a collaborative to purchase pharmaceutical products with a significant public health benefit and the potential for significant health care cost savings; (iii) the feasibility of developing an electronic information interchange

system to exchange bulk purchase price information with partnering states; (iv) potential sources of funding available to implement bulk purchases; (v) potential cost savings of bulk purchases to the commonwealth or other participating nongovernmental entities; (vi) the feasibility of partnering with the federal government and or other states in the New England region; and (vii) any other factors that the commission deems relevant.

The commission shall file a report of its analysis, along with any recommended legislation, if any, to the clerks of the senate and house of representatives, the house and senate committees on ways and means, the joint committee on health care financing, the joint committee on public health, the joint committee on elder affairs and the joint committee on mental health, substance abuse and recovery not later than September 1, 2023.

SECTION 59. (a) As used in this section, the following words shall have the following meanings, unless the context clearly requires otherwise:

"Chain pharmacist", a pharmacist employed by a retail drug organization operating not less than 10 retail drug stores within the commonwealth under section 39 of chapter 112 of the General Laws.

"Independent pharmacist", a pharmacist actively engaged in the business of retail pharmacy and employed in an organization of not more than 9 registered retail drugstores in the commonwealth under said section 39 of said chapter 112 that employs not more than a total of 20 full-time pharmacists.

(b) There shall be a task force to: (i) review the drug supply chain including, but not limited to: (A) plan and pharmacy benefit manager reimbursements to pharmacies; (B) wholesaler or pharmacy service administrative organization prices to pharmacies; and (C) drug

manufacturer prices to pharmacies; (ii) review ways to recognize the unique challenges of small and independent pharmacies; (iii) identify methods to increase pricing transparency throughout the supply chain; (iv) make recommendations on the use of multiple maximum allowable costs lists and their frequency of use for mail order products; (v) review the utilization of maximum allowable costs lists or similar reimbursement structures established by a pharmacy benefit manager or payer; (vi) review the availability of drugs to independent and chain pharmacies on the maximum allowable cost list or any similar reimbursement structures established by a pharmacy benefit manager or payer; (vii) review the pharmacy acquisition cost from national or regional wholesalers that serve pharmacies compared to the reimbursement amount provided through a maximum allowable cost list or any similar reimbursement structures established by a pharmacy benefit manager or payer and the conditions under which an adjustment to a reimbursement is appropriate; (viii) review the timing of pharmacy purchases of products and the relative risk of list price changes related to the timing of dispensing the products; (ix) assess ways to increase transparency for chain and independent pharmacists to understand the methodology used by a pharmacy benefit manager or payer to develop a maximum allowable cost list or any similar reimbursement structure established by the pharmacy benefit manager or payer; (x) assess the prevalence and appropriateness of pharmacy benefit managers requiring, or using financial incentives or penalties to incentivize, customer use of pharmacies with whom the pharmacy benefit manager has an ownership or financial interest; (xi) examine the impact of the merger or consolidation of pharmacy benefit managers and health carrier clients on drug costs; (xii) review current appeals processes for a chain or independent pharmacist to request an adjustment on a reimbursement subject to a maximum allowable cost list or any similar reimbursement structure established by a pharmacy benefit manager or payer; and (xiii) evaluate

the effect of differences between pharmacy benefit manager payments to pharmacies and charges made to health carrier clients on drug price.

(c) The task force shall consist of: the commissioner of insurance or a designee, who shall serve as chair; and 6 members to be appointed by the commissioner, 2 of whom shall be independent pharmacists employed in the independent pharmacy setting or representatives of independent pharmacies, 2 of whom shall be chain pharmacists employed in the chain pharmacy setting or representatives of chain pharmacies and 2 of whom shall be representatives of a pharmacy benefit managers or payers who manage their own pharmacy benefit services. If more than 1 independent pharmacist is appointed, each appointee shall represent a distinct practice setting. If more than 1 chain pharmacist is appointed, each appointee shall represent a distinct practice setting. A pharmacy benefit manager or payer appointed to the task force shall not be co-owned or have any ownership relationship with any other payer, pharmacy benefit manager or chain pharmacist also appointed to the task force.

(d) The commissioner shall file the task force's findings with the clerks of the house of representatives and the senate, the joint committee on health care financing and the house and senate committees on ways and means not later than December 1, 2023.

SECTION 60. 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 20 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 20 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 20 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 61. 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 62. Section 61 is hereby repealed.

SECTION 63. Sections 21 and 39 shall take effect on July 1, 2023.

SECTION 64. Sections 41, 43, 44, 46, 47 and 51 shall take effect January 1, 2023.

SECTION 65. Section 42 shall take effect on December 15, 2022.

SECTION 66. Section 53 shall take effect on July 1, 2023.

SECTION 67. Section 55 shall take effect on March 30, 2023.

SECTION 68. Section 62 shall take effect on January 1, 2024.