# SENATE . . . . . No. 2397

## The Commonwealth of Massachusetts

**In the One Hundred and Ninety-First General Court**
**(2019-2020)**

SENATE, November 7, 2019

The committee on Ways and Means to whom was referred the Senate Bill relative to consumer protection for prescription drug purchases (Senate, No. 733),-- reports, recommending that the same ought to pass with an amendment substituting a new draft entitled "An Act relative to pharmaceutical access, costs and transparency" (Senate, No. 2397).

For the committee,
Michael J. Rodrigues

# SENATE . . . . . No. 2397

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**In the One Hundred and Ninety-First General Court**
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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 2018 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 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 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 15B.

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 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 of "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, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to prescription drug coverage contracts, formulary administration, drug benefit design, mail and specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for pharmacy services and 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 drugs", prescription drug products 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 federal 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, academic detailing, early notification or access improvement plan activities authorized under sections 7, 10, 14, 15, 15A, 15B, 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, 15B, 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 adding the following paragraph:-

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, 15B, 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 11. 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 12. 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 13. 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 pharmacy benefit manager; and (xiii).

SECTION 14. 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 15. 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 16. 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 sentence:- 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.

SECTION 17. 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 18. Said chapter 6D is hereby further amended by inserting after section 15 the following 2 sections:-

Section 15A. (a) The commission shall develop, implement and promote an evidence-based outreach and education program to support the therapeutic and cost-effective utilization of prescription drugs for health care practitioners authorized to prescribe and dispense prescription drugs including, but not limited to, physicians, podiatrists and pharmacists.

The commission shall develop the program in consultation with health care practitioners authorized to prescribe and dispense prescription drugs including, but not limited to, physicians, podiatrists, pharmacists, nurses, private insurers, hospitals, pharmacy benefit managers, consumers, the MassHealth drug utilization review board, the University of Massachusetts medical school and researchers and organizations engaged in the development, training and deployment of health practitioner education outreach programs.

(b) The program shall provide outreach to: (i) health care practitioners who participate in: (A) MassHealth; (B) the subsidized catastrophic prescription drug insurance program established in section 39 of chapter 19A; and (C) other publicly-funded, contracted or subsidized health care programs; (ii) academic medical centers; and (iii) other health care practitioners authorized to prescribe and dispense prescription drugs.

The program shall include in-person visits to prescribers by physicians, podiatrists, pharmacists and nurses that utilize evidence-based materials and borrowing methods from behavioral science, educational theory and, where appropriate, pharmaceutical industry data and outreach techniques; provided, however, that the program shall inform prescribers about drug marketing intended to circumvent competition from generic or other therapeutically-equivalent pharmaceutical alternatives or other evidence-based treatment options, if applicable.

The commission shall, to the extent possible, utilize or incorporate into its program other independent educational resources or models proven effective in promoting high quality, evidenced-based, cost-effective information regarding the effectiveness and safety of prescription drugs.

(c) Annually, not later than April 1, the commission shall report on the operation of the program including, but not limited to, information on the outreach and education components of

the program, revenues, expenditures and balances, including an accounting of the estimated expenses of the program for the following year, and savings attributable to the program in health care programs funded by the commonwealth. The report shall be made publicly available on the commission's website.

(d) The commission shall undertake a public education initiative to inform residents of the commonwealth about clinical trials and drug safety information.

(e) The commission may establish and collect fees for subscriptions and contracts with private health care payers related to this section. The commission may seek funding from nongovernmental health access foundations and undesignated drug litigation settlement funds associated with pharmaceutical marketing and pricing practices.

Section 15B. (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 make non-confidential early notice information available to the office of Medicaid or another agency, as the commission deems appropriate.

Early notice for a pipeline drug or biosimilar drug under this subsection shall be submitted to the commission in writing not later than 60 days after receipt of the federal Food and Drug Administration action date. Early notice for a generic drug under this subsection shall be submitted to the commission in writing not later than 60 days before the generic drug's effective date of distribution.

For each prescription drug product, 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 year 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 federal Food and Drug Administration: (i) as an orphan drug; (ii) 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 federal Food and Drug Administration shall be provided as soon as practical upon receipt of the relevant designations.

(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 20 per cent per wholesale acquisition cost unit during any 12-month period; or (ii) generic drug priced at $100 or more per wholesale acquisition cost unit by 200 per cent or more during any 12-month period. The commission shall make non-confidential early notice information available to the office of Medicaid or another agency, as the commission deems appropriate.

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) drug

acquisition information, if applicable; (v) revenue from the sale of the drug; and (vi) 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.

SECTION 19. 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", a (i) 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) biosimilar drug that has a launch wholesale acquisition cost that is not at least 15 per cent lower than the referenced brand biologic at the time the biosimilar is launched; or (iii) public health essential drug, as defined in section 239 of chapter 111, 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.

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

"Public health essential drug", shall have the same meaning as defined in section 239 of chapter 111.

(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 written, narrative description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition cost during the previous 5 calendar years; and

(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.

(d) If, after review of an eligible drug and after receiving information from the manufacturer under subsections (b) or (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, 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 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 subsections (b) or (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 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) If the manufacturer fails to timely comply with the commission's request for records under subsections (b) or (e), or otherwise knowingly obstructs the commission's ability to issue its determination under subsection (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.

(i) 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 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 improvement plan with the commission. Not later than 45 days after receipt of a notice under subsection (g) of section 20, a manufacturer shall: (i) file an access improvement plan; or (ii) provide written notice declining the commission's request.

(b) An access 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 patient access to the eligible drug. The proposed access improvement plan shall include specific identifiable and measurable expected outcomes and a timetable for implementation. The timetable for an access improvement plan shall not exceed 18 months.

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

(d) If the commission determines that the access 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 improvement plan shall be proposed by the manufacturer and the commission shall not require specific elements for approval.

(e) Upon approval of the proposed access improvement plan, the commission shall notify the manufacturer to begin immediate implementation of the access improvement plan. 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 improvement plan.

(f) All manufacturers shall work in good faith to implement the access improvement plan. At any point during the implementation of the access 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 improvement plan, the manufacturer shall report to the commission regarding the outcome of the access improvement plan. If the commission determines that the access improvement plan was unsuccessful, the commission shall: (i) extend the implementation timetable of the existing access improvement plan; (ii) approve amendments to the access improvement plan as proposed by the manufacturer;

(iii) require the manufacturer to submit a new access improvement plan; or (iv) waive or delay the requirement to file any additional access 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 improvement plans or otherwise ensure compliance with this section.

(i) An access 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 improvement plan with the commission under subsection (a); (ii) failed to file an acceptable access improvement plan in good faith with the commission; (iii) failed to implement the access 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.

(k) If a manufacturer declines to enter into an access 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 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.

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

SECTION 20. Section 1 of chapter 12C of the General Laws, as appearing in the 2018 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 wholesaler for drugs distributed to pharmacies and by a 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 21. 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 22. 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, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to prescription drug coverage contracts, formulary administration, drug benefit design, mail and specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for pharmacy services and 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 23. 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 24. 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 25. 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 26. 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 27. 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 28. Section 7 of said chapter 12C, as so appearing, is hereby amended by adding the following paragraph:-

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. 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 29. 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 that enables 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; and (vi) 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) changes in wholesale acquisition costs and average manufacturer prices for prescription drug products as identified by the center; (ii) 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 are available for prescription drug products as identified by the center; and (iii) a description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition costs 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 that enables 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 the drugs offered through the pharmacy benefit manager and a measure of lives covered by each health carrier client or health plan sponsor; (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 to the consumer or passed through from a pharmacy benefit manager to a health carrier client or to the consumer; 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) 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 individually; (ii) the administrative fees that the pharmacy benefit manager received from all health carrier clients in the aggregate and for each health carrier client individually; (iii) the aggregate amount of all retained rebates that the pharmacy benefit manager received from all pharmaceutical manufacturing companies and did not pass through to the pharmacy benefit manager's health carrier clients; (iv) the aggregate amount of rebates a pharmacy benefit manager: (A) retains based on its contractual arrangement with its client; and (B) passes through to its clients; and (v) 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.

(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 30. Said chapter 12C is hereby further amended by striking out section 11, as appearing in the 2018 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 payers, providers, provider organizations, pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable reporting deadlines. The center shall notify, in writing, a private health care payer, provider,

provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that it has failed to meet a reporting deadline and that failure to respond within 2 weeks of the receipt of the notice may result in penalties. The center may assess a penalty against a private health care payer, provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that fails, without just cause, to provide the requested information within 2 weeks following receipt of the written notice required under this section of not more than $1,000 per week for each week of delay after the 2-week period following receipt of the written notice. Amounts collected under this section shall be deposited in the Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

SECTION 31. 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 32. 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 33. Chapter 94C of the General Laws is hereby amended by inserting after section 21B the following section:-

Section 21C. (a) For the purposes of this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Cost-sharing", amounts owed by a consumer under the terms of the consumer's health benefit plan as defined in section 1 of chapter 176O or as required by a pharmacy benefit manager as defined in section 1 of chapter 6D.

"Pharmacy retail price", the amount an individual would pay for a prescription medication at a pharmacy if the individual purchased that prescription medication at that pharmacy without using a health benefit plan as defined in section 1 of chapter 176O or any other prescription medication benefit or discount.

(b) A pharmacy shall provide the consumer, at the point of sale, the current pharmacy retail price and the applicable cost-sharing amount for each prescription medication the consumer is purchasing; provided, however, that the lower cost prescription medication is clearly indicated. The consumer shall affirm by signature in writing that the pharmacy has provided this price information and an opportunity for counseling. The pharmacy shall charge the consumer the applicable cost-sharing amount or the current pharmacy retail price for that prescription medication, as directed by the consumer.

A pharmacy shall post a notice informing consumers that a consumer may request, at the point of sale, the current pharmacy retail price for each prescription medication the consumer intends to purchase.

(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; provided, however, that a pharmacist shall submit a claim to the consumer's health benefit plan or its pharmacy benefit manager if the pharmacist has knowledge that the prescription medication is covered under the consumer's health benefit plan.

SECTION 34. Chapter 111 of the General Laws is hereby amended by adding the following section:-

Section 239. (a) As used in this section, 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 federal 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 commissioner 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.

(b) The department 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 department may provide an interim listing of a public health essential drug prior to an annual update. The department shall also notify and forward a copy of the list to the health policy commission established under chapter 6D.

SECTION 35. Section 226 of chapter 175 of the General Laws, as appearing in the 2018 Official Edition, 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, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to prescription drug coverage contracts, formulary administration, drug benefit design, mail and specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for pharmacy services and 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 36. Section 2 of Chapter 176O of the General Laws, as so appearing, is hereby amended by adding the following subsection:-

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

SECTION 37. Said chapter 176O of the General Laws is hereby further amended by inserting after section 22 the following section:-

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

SECTION 38. 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 noted 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, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, pharmacy contracting, the adjudication of appeals or grievances related to prescription drug coverage contracts, formulary administration, drug benefit design, mail and specialty drug pharmacy services, cost containment, clinical, safety and adherence programs for pharmacy services and managing the cost of covered prescription drugs; provided further, that “pharmacy benefit manager” shall not include a health benefit plan 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 in the commonwealth 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 subject to restrictions in order to protect the interests of consumers. Such restrictions may include limiting the type of services that a license holder may provide, limiting the activities in which the license holder may be engaged or addressing conflicts of interest between pharmacy benefit managers and health plan sponsors.

(e) The division shall develop an application for licensure that shall include, but not be limited to: (i) the name of the pharmacy benefit manager; (ii) the address and contact telephone number for the pharmacy benefit manager; (iii) the name and address of the pharmacy benefit manager's agent for service of process in the commonwealth; (iv) the name and address of each person with management or control over the pharmacy benefit manager; and (v) any audited financial statements specific to the pharmacy benefit manager. A 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 pharmacy benefit manager engaging in fraudulent activity that constitutes 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 pharmacy benefit manager failing to pay an application or renewal fee for a license; (iv) the pharmacy benefit manager failing to comply with reporting requirements of the center under section 10A of

chapter 12C; or (v) the pharmacy benefit manager failing to comply with a requirement of this chapter.

The division shall notify the 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.

(h) A pharmacy benefit manager shall be required to submit to periodic audits by a carrier licensed under chapters 175, 176A, 176B or 176G if the pharmacy benefit manager has entered into a contract with the carrier to provide pharmacy benefit services to the carrier or its members. The division may direct or provide specifications for such audits.

SECTION 39. Notwithstanding any general or special law to the contrary, there shall be a 4-year program to assess the public health utilization and cost impacts of capping co-pays and eliminating deductible and co-insurance requirements for insulin for individuals with diabetes. To implement the program any policy, contract or certificate of health insurance subject to chapters 32A, 118E, 175, 176A, 176B, 176G or 176Q of the General Laws that is delivered,

issued or renewed from January 1, 2020 to December 31, 2023, inclusive, shall provide coverage for insulin for the treatment of diabetes. Such coverage shall not be subject to any deductible or co-insurance and any co-pay shall not exceed $25 per month per insulin prescription.

The center for health information and analysis shall collect, analyze and evaluate data at the start of the program and annually thereafter, including, but not limited to: (i) rates of insulin utilization; (ii) average monthly out-of-pocket insulin costs; (iii) annual plan costs and member premiums; (iv) the average price of insulin, net of rebates or discounts received by or accrued directly or indirectly by health insurance carriers; and (v) average and total out-of-pocket expenditures on insulin delivery devices that are not included as part of an insulin prescription. The center shall file an interim 2-year report and a final 4-year report assessing the program's impact on insulin utilization, member premiums and insulin costs and providing data on expenditures on insulin delivery devices separate from insulin prescriptions. The reports 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 March 1, 2022 and March 1, 2024, respectively.

SECTION 40. (a) Notwithstanding any general or special laws to the contrary, the commonwealth health insurance connector authority, in consultation with the division of insurance, shall report to the joint committee on health care financing and the house and senate committees on ways and means not later than January 15, 2021 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 health outcomes; 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 of the General Laws or under chapter 66 of the General Laws.

(b) In fiscal year 2021, 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, 2020 for data collection and analysis costs associated with the report required by this section.

SECTION 41. (a) As used in this section, the following words shall have the following meanings unless 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; and (x) 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.

(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 either 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 to the task force, each appointee shall represent a distinct practice setting and if more than 1 chain pharmacist is appointed to the task force, 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, 2020.

SECTION 42. The health policy commission shall consult with relevant stakeholders, including, but not limited to, consumers, consumer advocacy organizations, 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 43. Sections 19 and 34 shall take effect on July 1, 2021.