HOUSE DOCKET, NO. 2948 FILED ON: 2/18/2021

HOUSE . . . . . No. 729

The Commonwealth of Massachusetts

PRESENTED BY:

Christine P. Barber and Jon Santiago

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

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

An Act to ensure prescription drug cost transparency and affordability.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Christine P. Barber	*34th Middlesex*	*2/18/2021*
Jon Santiago	*9th Suffolk*	*2/18/2021*
Mindy Domb	*3rd Hampshire*	*2/21/2021*
Elizabeth A. Malia	*11th Suffolk*	*2/24/2021*
James J. O'Day	*14th Worcester*	*2/25/2021*
Lindsay N. Sabadosa	*1st Hampshire*	*2/25/2021*
David M. Rogers	*24th Middlesex*	*2/26/2021*
Kate Lipper-Garabedian	*32nd Middlesex*	*2/26/2021*
Tommy Vitolo	*15th Norfolk*	*2/26/2021*
Jack Patrick Lewis	*7th Middlesex*	*2/26/2021*
James K. Hawkins	*2nd Bristol*	*2/26/2021*
Michael J. Moran	*18th Suffolk*	*2/26/2021*
William J. Driscoll, Jr.	*7th Norfolk*	*2/26/2021*
Michelle L. Ciccolo	*15th Middlesex*	*2/26/2021*
Joanne M. Comerford	*Hampshire, Franklin and Worcester*	*3/4/2021*
Peter Capano	*11th Essex*	*3/4/2021*
Ruth B. Balser	*12th Middlesex*	*3/4/2021*
Adrian C. Madaro	*1st Suffolk*	*3/16/2021*

Patrick M. O'Connor	*Plymouth and Norfolk*	*3/16/2021*
Tami L. Gouveia	*14th Middlesex*	*3/16/2021*
Tram T. Nguyen	*18th Essex*	*3/16/2021*
Walter F. Timilty	*Norfolk, Bristol and Plymouth*	*3/18/2021*
Jessica Ann Giannino	*16th Suffolk*	*3/25/2021*
Steven Ultrino	*33rd Middlesex*	*4/1/2021*
Natalie M. Higgins	*4th Worcester*	*4/1/2021*
Mary S. Keefe	*15th Worcester*	*4/2/2021*

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HOUSE . . . . . No. 729

By Representatives Barber of Somerville and Santiago of Boston, a petition (accompanied by bill, House, No. 729) of Christine P. Barber, Jon Santiago and others relative to prescription drug cost transparency and affordability. Elder Affairs.

The Commonwealth of Massachusetts

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

An Act to ensure prescription drug cost transparency and affordability.

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 "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 3. 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 4. 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 5. 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 6. 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, or affordability improvement plan activities authorized under sections 7, 10, 14, 15, 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, 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 7. 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 8. 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 9. 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, 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 10. 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 11. 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 12. 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) at least 3 representatives of the pharmaceutical industry; (xii) at least 1 pharmacy benefit manager; and (xiii).

SECTION 13. 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 14. 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 15. 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 16. 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:

"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 develop criteria to identify eligible drugs for the purposes of this section based on the following categories and considerations:

(1) brand name drugs or biologics that have a launch wholesale acquisition cost exceeding a specified amount, as determined by the commission, for a 1-year supply or full course of treatment;

(2) biosimilar drug that has a launch wholesale acquisition cost that exceeds a specified amount, as determined by the commission; or

(3) 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, or with a wholesale acquisition cost exceeding a specified amount for a 1-year supply or full course of treatment, as determined by the commission.

The criteria for identifying eligible drugs shall be in effect for a term of 5 years. The commission shall conduct a review of the established criteria in the fourth year of the criteria's application. Based on the review, the commission may amend the criteria to be effective for the next 5-year term.

(c) A manufacturer of an eligible drug for which the commission has received a referral from the center under subsection (b) of section 24 of chapter 12C shall comply with the requirements set forth in this section, provided that the commission may select or prioritize a subset of the referred drugs for the commission's review.

(d) The commission may require a manufacturer specified in subsection (c) to disclose to the commission within a reasonable time information relating to the manufacturer's pricing of an

eligible drug, on a standard reporting form developed by the commission with the input of the manufacturers, which includes but shall not be limited to, the following: (1) A schedule of the drug's wholesale acquisition cost increases over the previous five calendar years; (2) The manufacturer's aggregate, company-level research and development and other relevant capital expenditures, including facility construction, for the most recent year for which final audited data are available; (3) A written, narrative description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition cost during the previous five calendar years; and (4) Any other information that the manufacturer wishes to provide to the commission.

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

(e) Records disclosed by a manufacturer under this section shall: (1) be accompanied by an attestation that all information provided is true and correct; (2) not be public records under section 7 of chapter 4 or chapter 66; and (3) remain confidential; provided, however, that the commission may produce reports summarizing any findings; provided that any such report shall not be in a form that identifies specific prices charged for or rebate amounts associated with drugs by a manufacturer, or in a manner that is likely to compromise the financial, competitive or proprietary nature of the information.

(f) If, after review of any records furnished to the commission under subsection (c), the commission determines that the manufacturer's pricing of the eligible drug is potentially unreasonable or excessive in relation to the commission's proposed value under subsection (c),

the commission shall, with 30 days' advance notice to the manufacturer, request that the manufacturer provide further information related to the pricing of the prescribed drug and the manufacturer's justification for the pricing. In addition to the manufacturer, the commission shall identify whether other relevant parties, including but not limited to patients, providers, provider organizations, organizations representing impacted communities, and payers, would be impacted by a change in the cost or availability of the eligible drug. If the commission determines that these entities would be impacted, it shall then convene opportunities for verbal and written testimony related to the value of the eligible drug and shall incorporate this information into its determination. The assessment methodology used by the commission shall allow for public input to meaningfully impact the commission's final proposed value.

(g) Any information, analyses or reports regarding a particular drug reviewed or used in assessing the proposed value of the eligible drug shall be provided to the manufacturer for review and input. The commission shall consider any clarifications or data provided by the manufacturer with respect to its drug. The commission may not base its determination on the proposed value or the reasonableness of the drug pricing solely on the analysis or research of an outside third party, and may not assign a lower proposed value to an eligible drug based upon the race, ethnicity, gender, age, or disability status of the patients who would likely use it.

(h) In determining a proposed value, the commission shall not consider any analysis, whether by itself or a third party, which contravenes any state or federal civil rights statute, or which discriminates based on the race, ethnicity, gender, age, or disability of those prospective users.

(i) When the commission relies upon research or analysis in support of the proposed value, whether conducted by the commission or by a third party, such analysis or research shall also provide, but not be limited in scope 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 minority racial or ethnic groups, and on individuals with specific disabilities or health conditions who regularly utilize the eligible drug.

(j) Not later than 60 days after receiving information from the manufacturer, as required under subsection (d) or (f), 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 affordability improvement plan under section 21.

(k) If the commission determines that the manufacturer's pricing of a drug is not unreasonable or excessive in relation to the commission's proposed value of the drug but the commission identifies patient access and affordability barriers, the commission shall confidentially notify the manufacturer, in writing, of its determination and request the manufacturer to enter into an affordability improvement plan under section 21.

(l) 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.

(m) Any proposed value of an eligible drug as determined by the commission is solely intended to enhance the ability of the commonwealth to work with manufacturers and pharmacy benefit managers to increase the affordability of prescription drugs. Neither the proposed value, nor the analysis produced via the process to determine a proposed value, is intended to be used by MassHealth, health insurance carriers, managed care organizations, accountable care organizations, hospitals or pharmacies to determine whether a treatment should be approved for an individual patient, whether any individual patient should be subjected to step therapy or other utilization management methodology, or whether a drug should be included in a formulary.

(n) 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 affordability improvement plan.

Upon providing written notice provided under subsections (i) or (j) 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 affordability improvement plan with the commission. Not later than 45 days after receipt of a notice under subsections (i) or (j)

of section 20, a manufacturer shall: (1) file an affordability improvement plan; or (2) provide written notice declining the commission's request.

(b) An affordability improvement plan shall: (1) be generated by the manufacturer; (2) identify the reasons for the manufacturer's drug price; and (3) 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 affordability and access to the eligible drug. The proposed affordability improvement plan shall include specific identifiable and measurable expected outcomes and a timetable for implementation. The timetable for an affordability improvement plan shall not exceed 18 months.

(c) The commission shall approve any affordability improvement plan that it determines: (1) is reasonably likely to address the cost of an eligible drug in order to substantially improve patient affordability and access to the eligible drug; and (2) has a reasonable expectation for successful implementation.

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

(e) Upon approval of the proposed affordability improvement plan, the commission shall notify the manufacturer to begin immediate implementation of the affordability improvement plan. Public notice shall be provided by the commission on its website, identifying that the manufacturer is implementing an affordability improvement plan and for which eligible drug. All

manufacturers implementing an approved affordability 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 affordability improvement plan.

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

(g) At the conclusion of the timetable established in the affordability improvement plan, the manufacturer shall report to the commission regarding the outcome of the affordability improvement plan. If the commission determines that the affordability improvement plan was unsuccessful, the commission shall: (1) extend the implementation timetable of the existing affordability improvement plan; (2) approve amendments to the affordability improvement plan as proposed by the manufacturer; (3) require the manufacturer to submit a new affordability improvement plan; or (4) waive or delay the requirement to file any additional affordability improvement plans.

(h) Upon the successful completion of the affordability improvement plan, the identity of the health manufacturer shall be removed from the commission's website.

(i) The commission shall provide opportunities for patients who utilize the eligible drug and other members of the public, as well as providers who prescribe the eligible drug, to comment on whether they have been successfully able to access the eligible drug at a lower cost following implementation of an affordability improvement plan. The commission shall compile

an annual report summarizing the outcomes of any affordability improvement plans that were implemented during the prior year and any impact on improving patient access to eligible drugs. The report 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.

(j) 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 affordability improvement plans or otherwise ensure compliance with this section.

(k) 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: (1) willfully neglected to file an affordability improvement plan with the commission under subsection (a); (2) failed to file an acceptable affordability improvement plan in good faith with the commission; (3) failed to implement the affordability improvement plan in good faith; or (4) 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.

(l) If a manufacturer (1) declines to enter into an affordability improvement plan under this section, or (2) is deemed to not be acting in good faith to develop or implement an acceptable affordability improvement plan, the commission shall publically issue a determination on whether the manufacturer's pricing of a drug is unreasonable or excessive in relation to the commission's proposed value of the drug and shall publicly post the proposed value of the

eligible drug. The commission shall further 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 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 calendars days from the date that the commission issued its request that the manufacturer enter into the affordability improvement plan.

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

SECTION 17. Section 11N of chapter 12 of the General Laws, as so appearing, is hereby amended by striking out subsection (a) and inserting in place thereof the following subsection:-

(a) The attorney general shall monitor trends in the health care market including, but not limited to, trends in provider organization size and composition, consolidation in the provider market, payer contracting trends, patient access and quality issues in the health care market and prescription drug cost trends. The attorney general may obtain the following information from a

private health care payer, public health care payer, pharmaceutical manufacturing company, pharmacy benefit manager, provider or provider organization as any of those terms may be defined in section 1 of chapter 6D: (i) any information that is required to be submitted under sections 8, 9 10 and 10A of chapter 12C; (ii) filings, applications and supporting documentation related to any cost and market impact review under section 13 of said chapter 6D; (iii) filings, applications and supporting documentation related to a determination of need application filed under section 25C of chapter 111; and (iv) filings, applications and supporting documentation submitted to the federal Centers for Medicare and Medicaid Services or the Office of the Inspector General for any demonstration project. Under section 17 of said chapter 12C and section 8 of said chapter 6D and subject to the limitations stated in those sections, the attorney general may require that any provider, provider organization, pharmaceutical manufacturing company, pharmacy benefit manager, private health care payer or public health care payer produce documents, answer interrogatories and provide testimony under oath related to health care costs and cost trends, pharmaceutical costs, pharmaceutical cost trends, the factors that contribute to cost growth within the commonwealth's health care system and the relationship between provider costs and payer premium rates and the relationship between pharmaceutical drug costs and payer premium rates.

SECTION 18. 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 19. 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 20. 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 21. 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 22. 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 23. 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 24. 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 25. 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 26. 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 27. 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 28. 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. 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; (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) cost 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) 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; (iii) annual marketing and advertising expenditures; and (iv) 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 $2,000 per week for each week of delay after the 2-week period following receipt of the written notice. Amounts collected under this section shall be deposited in the Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

SECTION 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. Said chapter 12C is hereby further amended by striking out section 17, as so appearing, and inserting in place thereof the following section:-

Section 17. The attorney general may review and analyze any information submitted to the center under sections 8, 9, 10 and 10A and the health policy commission under section 8 of chapter 6D. The attorney general may require that any provider, provider organization, pharmaceutical manufacturing company, pharmacy benefit manager or payer produce documents, answer interrogatories and provide testimony under oath related to health care costs and cost trends, pharmaceutical cost trends, factors that contribute to cost growth within the commonwealth's health care system and the relationship between provider costs and payer premium rates. The attorney general shall keep confidential all nonpublic information and documents obtained under this section and shall not disclose the information or documents to any person without the consent of the provider, pharmaceutical manufacturing company, pharmacy

benefit manager or payer that produced the information or documents except in a public hearing under said section 8 of said chapter 6D, a rate hearing before the division of insurance or in a case brought by the attorney general, if the attorney general believes that such disclosure will promote the health care cost containment goals of the commonwealth and that the disclosure shall 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 34. Said chapter 12C is hereby further amended by adding the following section:-

Section 24. (a) The center shall identify any prescription drugs that meet the criteria established by the health policy commission for an eligible drug under section 20 of chapter 6D.

(b) The center shall confidentially refer each eligible drug identified under subsection (a) to the health policy commission such that the commission may pursue further action under section 20 of chapter 6D. The center shall additionally provide notice of the referral to the manufacturer of the drug.

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

SECTION 35. 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 federal Food and Drug Administration that: (i) appears in any formulation of the medicines included 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 also notify and forward a copy of the list to the health policy commission established under chapter 6D.

SECTION 36. Chapter 29 of the General Laws, as appearing in the 2018 Official Edition, is hereby amending by inserting after section 2CCCCC the following section:-

2DDDDD. (a) There shall be a Prescription Drug Cost Assistance Trust Fund. The secretary of health and human services, as trustee, shall administer the fund and shall make expenditures from the fund, without further appropriation, to provide financial assistance to state residents for the cost of prescription drugs through the prescription drug cost assistance program established under section 238 of chapter 111.

The fund shall consist of: (1) revenue generated from the assessment established under chapter 63D; (2) revenue from appropriations or other money authorized by the general court and specifically designated to be credited to the fund; and (3) 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. An amount equal to the total receipts from the assessments established under chapter 63D shall be transferred from the General Fund to the Prescription Drug Cost Assistance Trust Fund before the end of each fiscal year. 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.

SECTION 37. The General Laws, as appearing in the 2018 Official Edition, are hereby amended by inserting after chapter 63C the following chapter:-

Chapter 63D. ASSESSMENT ON THE MANUFACTURE AND SALE OF CERTAIN PHARMACEUTICALS DISTRIBUTED IN THE COMMONWEALTH.

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

“Commissioner”, the commissioner of revenue.

“Person”, any natural person or legal entity.

“Secretary”, the secretary of health and human services.

Section 2. (a) Any person who manufactures and sells prescription drugs, as defined in section 1 of chapter 94C, directly or through another person, for distribution in the commonwealth, shall pay an assessment, which shall be proportionate to the person’s percent of

total prescription drug sales generated by all persons for prescription drugs distributed in the commonwealth during the previous calendar year. The amount of the assessment that each person is required to pay shall be determined by the secretary, in collaboration with the commissioner; provided, that the total amount assessed across all persons shall not exceed $200,000,000 in any calendar year.

(b) A person who manufactures and sells prescription drugs, directly or through another person, for distribution in the commonwealth shall file a return, as provided in section 4, declaring total sales of all prescription drugs, directly or through another person, for distribution in the commonwealth during the previous calendar year.

Section 3. The assessment under section 2 shall apply for any calendar year only to a person whose total sales of all prescription drugs, directly or through another person, for distribution in the commonwealth were more than $250,000 in the calendar year for which the assessment is imposed.

Section 4. Any person subject to the assessment under section 2 shall file a return with the commissioner and shall pay the assessment for the previous calendar year annually, by March 1, subject to such reasonable extensions of time for filing as the commissioner may allow. The return shall set out the person's total sales of all prescription drugs, directly or through another person, for distribution in the commonwealth in the immediately preceding calendar year and shall provide such other information as the commissioner may require.

Section 5. The commissioner may disclose information contained in returns filed under this chapter to the secretary for purposes of verifying that a filer's sales are properly declared and

that all reporting is otherwise correct. Return information so disclosed shall remain confidential and shall not be public record.

Section 6. The commissioner shall annually submit a report to the clerks of the senate and house of representatives, the chairs of the joint committee on ways and means and the chairs of the joint committee on health care financing, which shall include: (1) the total amount assessed across all persons and deposited in the Prescription Drug Cost Assistance Trust Fund established under section 2DDDDD of chapter 29 in the previous calendar year; and (2) the assessment amount that each person was required to pay in the previous calendar year.

Section 7. The commissioner, in consultation with the secretary, shall promulgate regulations or issue other guidance for the implementation and enforcement of this chapter.

SECTION 38. 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, unless the context clearly requires otherwise, have the following meanings:-

"Cost-sharing", the amount owed by an insured under the terms of the insured's health benefit plan or as required by a pharmacy benefit manager, including any copayment, coinsurance or deductible.

"Pharmacy retail price", the amount a pharmacy bills for a prescription medication regardless of whether the individual purchases that prescription medication at that pharmacy using a health benefit plan or any other prescription medication benefit or discount.

"Registered pharmacist", a pharmacist who holds a valid certificate of registration issued by the board of registration in pharmacy pursuant to section 24 of chapter 112.

(b) A health benefit plan shall (1) not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an insured in the plan from informing, or penalize such pharmacy for informing, an insured of any differential between the insured's cost-sharing amount under the plan with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and (2) ensure that any pharmacy benefit manager under a contract with any such health benefit plan does not, with respect to such plan, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing, or penalize such pharmacy for informing, an insured of any differential between the insured's cost-sharing amount under the plan with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

(c) A health benefit plan or a pharmacy benefit manager may not require an insured to make a payment at the point of sale for a covered prescription medication in an amount greater than the lesser of: (i) the applicable copayment for the prescription medication; (ii) the allowable claim amount for the prescription medication; (iii) the amount an insured would pay for the prescription medication if the insured purchased the prescription medication without using a health benefit plan or any other source of prescription medication benefits or discounts, to the extent this information is available to the health benefit plan; or (iv) the amount the pharmacy will be reimbursed for the drug from pharmacy benefit manager or health benefit plan.

(d) A pharmacy shall affirmatively inform 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. The pharmacy shall provide the information through verbal indication, posting of a notice, or other methods. If the consumer's cost-sharing amount for a prescription medication exceeds the current pharmacy retail price, the pharmacist, or an authorized individual at the direction of a pharmacist, shall notify the consumer that the pharmacy retail price is less than the patient's cost-sharing amount. The pharmacist shall charge the consumer the applicable cost-sharing amount or the current pharmacy retail price for that prescription medication, as directed by the consumer.

(e) A contractual obligation shall not prohibit a pharmacist from complying with this section; provided, however, that a pharmacist shall submit a claim to the insured's health benefit plan or its pharmacy benefit manager if the pharmacist has knowledge that the prescription medication is covered under the insured's health benefit plan.

(f) A health benefit plan or pharmacy benefit manager shall not penalize, require, or provide financial incentives, including variations in premiums, deductibles, copayments, or coinsurance, to insureds as incentives to use specific retail, mail order pharmacy, or other network pharmacy provider in which a pharmacy benefit manager has an ownership interest or that has an ownership interest in a pharmacy benefit manager.

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

SECTION 39. Chapter 111 of the General Laws shall hereby be amended by adding the following section:-

Section 238. (a) The department shall establish and administer a prescription drug cost assistance program, which shall be funded by the Prescription Drug Cost Assistance Trust Fund established in section 2DDDDD of chapter 29. The program shall provide financial assistance for prescription drugs used to treat: (1) chronic respiratory conditions, including, but not limited to, chronic obstructive pulmonary disease and asthma; (2) chronic heart conditions, including, but not limited to, heart failure, coronary artery disease, hypertension and high blood pressure; (3) diabetes; and (4) any other chronic condition identified by the department that disproportionally impacts people of color or is a risk factor for increased COVID-19 complications; provided, that for paragraphs (1) and (3), "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. Such financial assistance shall cover the full cost of any co-payment, co-insurance or deductible for the prescription drug for an individual who is eligible for the program.

(b) An individual shall be eligible for the program if the individual: (1) is a resident of Massachusetts; (2) has a current prescription from a health care provider for a drug that is used to treat a chronic condition listed in subsection (a); (3) has a family income equal to or less than 500 per cent of the federal poverty level; and (4) is not enrolled in MassHealth.

(c) The department shall create an application process, which shall be available to the public electronically and in hard copy form, to determine whether an individual meets the program eligibility requirements under subsection (b). Upon receipt of such application, the department shall determine an applicant's eligibility and notify the applicant of the department's determination within 10 business days. If necessary for its determination, the department may request additional information from the applicant; provided, that the department shall notify the

applicant within 5 business days of receipt of the original application as to what specific additional information is being requested. If additional information is being requested, the department shall, within 3 business days of receipt of the additional information, determine whether the applicant is eligible for the program and notify the applicant of the department's determination.

If the department determines that an applicant is not eligible for the program, the department shall notify the applicant and shall include in the department's notification the specific reasons why the applicant is not eligible. The applicant may appeal this determination to the department within 30 days of receiving such notification.

If the department determines that an applicant is eligible for the program, the department shall provide the applicant with a prescription drug cost assistance program identification card, which shall clearly indicate that the department has determined that the applicant is eligible for the program; provided, that the program identification card shall include, at a minimum: (1) the applicant's full name; and (2) the full name of the prescription drug that the applicant is eligible to receive under the program without having to pay a co-payment, co-insurance or deductible. An applicant's program identification card shall be valid for 12 months, and shall be renewable upon a redetermination of program eligibility.

(d) An individual with a valid program identification card issued under subsection (c) may present such card at any pharmacy in the commonwealth and, upon presentation of such card, the pharmacy shall fill the individual's prescription and provide the prescribed drug to the individual without requiring the individual to pay a co-payment, co-insurance or deductible; provided, that the pharmacy shall be reimbursed for its costs by the Prescription Drug Cost

Assistance Trust Fund established in section 2DDDDD of chapter 29, in a manner determined by the department, in an amount equal to what the pharmacy would have received had the individual been required to pay a co-payment, co-insurance or deductible.

(e) The department, in collaboration with the division of insurance and board of registration in pharmacy, shall develop and implement a plan to educate consumers, pharmacists, providers, hospitals and insurers regarding eligibility for and enrollment in the program under this section. The plan shall include, but not be limited to, appropriate staff training, notices provided to consumers at the pharmacy, and a designated website with information for consumers, pharmacists and other health care entities. The plan shall be developed in consultation with groups representing consumers, pharmacists, providers, hospitals and insurers.

(f) The department shall compile a report detailing information about the program from the previous calendar year. The report shall include: (1) the number of applications received, approved, denied and appealed; (2) the total number of applicants approved, and the number of applicants approved broken down by race, gender, age range and income level; (3) a list of all prescription drugs that qualify for the program under subsection (b) and a list of prescription drugs that applicants actually received financial assistance for; and (4) the total cost savings received by all approved applicants, and the cost savings broken down by race, gender, age range and income level. The report shall be submitted annually, by March 1, to the clerks of the senate and house of representatives, the chairs of the joint committee on ways and means and the chairs of the joint committee on health care financing.

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

SECTION 40. 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 41. Subsection (b) of section 6 of chapter 176J of the General Laws, as appearing in the 2018 Official Edition, is hereby amended by striking out clauses (vi) through (x), inclusive, in lines 35 to 41, inclusive, and inserting in place thereof the following clauses:-

(vi) information demonstrating how the carrier took into consideration any cost reductions of eligible drugs under section 21 of chapter 6D, including any changes to a benefit

design related to an eligible drug or any reductions in premiums as a result of cost reductions of eligible drugs;

(vii) charitable expenses, including, but not limited to, contributions to tax-exempt foundations and community benefits;

(viii) state premium taxes;

(ix) board, bureau and association fees;

(x) depreciation; and

(xi) miscellaneous expenses described in detail by expense, including any expense not included in clauses (i) to (x), inclusive.

SECTION 42. 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 43. 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 44. 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: (1) the name of the pharmacy benefit manager; (2) the address and contact telephone number for the pharmacy benefit manager; (3) the name and address of the pharmacy benefit manager's agent for service of process in the commonwealth; (4) the name and address of each person with management or control over the pharmacy benefit manager; and (5) 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: (1) the

pharmacy benefit manager engaging in fraudulent activity that constitutes a violation of state or federal law; (2) the division receiving consumer complaints that justify an action under this chapter to protect the health, safety and interests of consumers; (3) the pharmacy benefit manager failing to pay an application or renewal fee for a license; (4) the pharmacy benefit manager failing to comply with reporting requirements of the center under section 10A of chapter 12C; or (5) the pharmacy benefit manager failing to comply with a requirement of this chapter.

The division shall provide written notice to 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.

(i) 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.

SECTION 45. (a) Notwithstanding any general or special law to the contrary, there shall be a program to make insulin available to eligible individuals who are in urgent need of insulin. By July 1, 2022, each manufacturer of insulin must establish procedures to make insulin available in accordance with this section.

(b) To be eligible to receive an urgent-need supply of insulin under this section, an individual must attest to: (1) being a resident of Massachusetts; (2) not being enrolled in MassHealth; (3) not being enrolled in prescription drug coverage that limits the total amount of cost-sharing that the enrollee is required to pay for a 30-day supply of insulin, including co-payments, deductibles, or coinsurance, to $25 or less, regardless of the type or amount of insulin prescribed; (4) not having received an urgent-need supply of insulin through this program within the previous 12 months; and (5) being in urgent need of insulin. For purposes of this section, "urgent need of insulin" means having readily available for use less than a 7-day supply of insulin and in need of insulin in order to avoid the likelihood of suffering significant health consequences.

(c) The executive office of health and human services shall develop an application form to be used by an individual who is in urgent need of insulin. The application must ask the

individual to attest to the eligibility requirements described in subsection (c). The form shall be accessible through a designated website, and shall be available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics, and community health clinics. By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information contained in the application is correct.

(d) If the individual is in urgent need of insulin, the individual may present a completed, signed, and dated application form to a pharmacy. The individual must also: (1) have a valid insulin prescription; and (2) present the pharmacist with identification indicating Massachusetts residency. If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian must provide the pharmacist with proof of residency.

(e) Upon receipt of a completed and signed application, the pharmacist shall dispense the prescribed insulin in an amount that will provide the individual with a 30-day supply. The pharmacy must notify the health care practitioner who issued the prescription order no later than 72 hours after the insulin is dispensed.

(f) The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment that is in accordance with the National Council for Prescription Drug Program standards for electronic claims processing, unless the manufacturer agrees to send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed. If the pharmacy submits an electronic claim to the manufacturer or the manufacturer's vendor, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost.

(g) The pharmacy may collect an insulin co-payment from the individual to cover the pharmacy's costs of processing and dispensing in an amount not to exceed $25 for the 30-day supply of insulin dispensed.

(h) The pharmacist shall retain a copy of the application form submitted by the individual to the pharmacy for reporting and auditing purposes.

SECTION 46. Notwithstanding any general or special law to the contrary, the definition of eligible drug under chapter 6D of the General Laws shall be the following:

(i) brand name drug or biologic, not including a biosimilar, that (1) is included in top fifty drugs by spending in the commonwealth using data on the highest cost and most widely prescribed drugs according to commercial health insurance claims from the Center for Health Information and Analysis and (2) has a launch wholesale acquisition cost of $30,000 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) drug that has had a 20 percent increase in its wholesale acquisition cost in a single year or a 40 percent increase over a three-year period.

SECTION 47. 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 48. Section 46 is hereby repealed.

SECTION 49. Section 48 shall take effect on January 1, 2023.