HOUSE DOCKET, NO. 2503 FILED ON: 1/19/2023

HOUSE . . . . . No. 945

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*	*1/19/2023*
Jon Santiago	*9th Suffolk*	*1/19/2023*
Lindsay N. Sabadosa	*1st Hampshire*	*1/19/2023*
Mindy Domb	*3rd Hampshire*	*1/19/2023*
Carmine Lawrence Gentile	*13th Middlesex*	*1/25/2023*
David Paul Linsky	*5th Middlesex*	*1/26/2023*
Lenny Mirra	*2nd Essex*	*1/26/2023*
Peter Capano	*11th Essex*	*1/27/2023*
Susannah M. Whipps	*2nd Franklin*	*1/27/2023*
Brian W. Murray	*10th Worcester*	*1/29/2023*
Jack Patrick Lewis	*7th Middlesex*	*2/1/2023*
Vanna Howard	*17th Middlesex*	*2/1/2023*
Patricia A. Duffy	*5th Hampden*	*2/2/2023*
Kevin G. Honan	*17th Suffolk*	*2/3/2023*
Jennifer Balinsky Armini	*8th Essex*	*2/4/2023*
David Henry Argosky LeBoeuf	*17th Worcester*	*2/6/2023*
Jason M. Lewis	*Fifth Middlesex*	*2/7/2023*
Patrick M. O'Connor	*First Plymouth and Norfolk*	*2/8/2023*

Colleen M. Garry	*36th Middlesex*	*2/13/2023*
James C. Arena-DeRosa	*8th Middlesex*	*2/13/2023*
James B. Eldridge	*Middlesex and Worcester*	*2/16/2023*
Kate Lipper-Garabedian	*32nd Middlesex*	*2/22/2023*
Natalie M. Higgins	*4th Worcester*	*2/23/2023*
Tram T. Nguyen	*18th Essex*	*2/27/2023*
Tommy Vitolo	*15th Norfolk*	*3/15/2023*
Samantha Montaño	*15th Suffolk*	*3/25/2023*
William J. Driscoll, Jr.	*7th Norfolk*	*4/25/2023*
Mike Connolly	*26th Middlesex*	*4/28/2023*
Jessica Ann Giannino	*16th Suffolk*	*6/28/2023*
Rebecca L. Rausch	*Norfolk, Worcester and Middlesex*	*7/7/2023*

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HOUSE . . . . . No. 945

By Representatives Barber of Somerville and Santiago of Boston, a petition (accompanied by bill, House, No. 945) of Christine P. Barber, Jon Santiago and others for legislation to ensure prescription drug cost transparency and affordability. Financial Services.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court
(2023-2024)

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 so appearing, 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 authorized under sections 7, 10, 14, 15 or 20 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, or 20 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 and 20. 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, as so appearing, is hereby further amended by adding the following section:

Section 20. (a) For the purposes of this section, "Manufacturer" shall mean an entity that manufactures a pharmaceutical drug.

(b) 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 that 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 5 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 5 calendar years; and

(4) Any other information that the manufacturer wishes to provide to the commission.

Based on the records furnished, the commission may identify a proposed value for a prescribed drug specified in subsection (c). The Commission may request additional relevant information that it deems necessary.

(c) A manufacturer of a drug for which the commission has received a referral from the center under subsection (b) of section 25 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) 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 section 7 of chapter 4 or chapter 66; and (iii) 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.

(e) If, after review of any records furnished to the commission under subsection (b), the commission determines that the manufacturer's pricing of the drug is potentially unreasonable or excessive in relation to the commission's proposed value under subsection (b), the commission shall require that the manufacturer provide within 30 days 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 may identify other relevant parties including but not limited to patients, providers, provider organizations and payers who may provide information to the commission.

(f) The commission shall provide to the manufacturer for review and input any information, analyses or reports regarding a particular drug reviewed or relied on by the commission in assessing the proposed value of the drug shall be provided to the manufacturer. The commission shall consider any clarifications or data provided by the manufacturer with respect to its drug. The commission may not rely solely on the analysis or research of an outside third party in reaching its determination regarding the proposed value or the reasonableness of the drug pricing.

(g) If the commission relies upon a third party to provide cost-effectiveness analysis or research related to the proposed value, such analysis or research shall also provide, without limitation (i) a description of the methodologies and models used by the third party 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.

(h) Not later than 60 days after receiving information from the manufacturer, as required under subsections (b) or (e), the commission shall 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. Following the determination, the commission shall issue recommendations on measures to reduce the cost of the drug and to improve the affordability of the drug for patients. Recommendations may include, but not be limited to: (i) an alternative purchasing plan or value-based payment methodology; (ii) a bulk purchasing program; (iii) changes to co-pay, deductibles, coinsurance or other cost-sharing requirements; or (iv) a reinsurance program to subsidize the cost of the eligible drug. The commission shall make its determination and recommendations public and shall post them on its website and shall provide them to private and public health care payers.

(i) 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 (h), including, but not limited to, providing incomplete, false or misleading information, the commission may assess a civil penalty to a manufacturer of not more than $500,000. A civil penalty assessed under this subsection shall be deposited into the Payment Reform Fund established pursuant to section 100 of chapter 194 of the acts of 2011. The commission shall seek to promote compliance with this section and shall only impose a civil penalty on the manufacturer as a last resort.

(j) 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,

(k) The commission shall adopt any written policies, procedures or regulations that the commission determines 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 so appearing, 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. Subsection (b) of section 10 of chapter 12C of the General Laws, as so appearing, is hereby amended by striking out, in line 55, the word “and”.

SECTION 30. Said subsection (b) of said section 10 of said chapter 12C is hereby further amended by adding the following words:- ; (12) information about prescription drug utilization and spending for all covered drugs, including for generic drugs, brand-name drugs, and specialty drugs provided in an outpatient setting or sold in a retail setting, including but not limited to information sufficient to show (i) highest utilization drugs, (ii) drugs with the greatest increases in utilization, (iii) drugs that are most impactful on plan spending, net of rebates, and (iv) drugs with the highest year-over-year price increases, net of rebates; and (13) information on claims and non-claims based payments to providers for the provision of primary care and behavioral health, including mental health and substance use disorder, services, as defined by the center.

SECTION 31. Subsection (c) of said section 10 of said chapter 12C, as so appearing, is hereby amended by striking out, in line 91, the words "()" and inserting in place thereof the following words:- (10).

SECTION 32. Said subsection (c) of said section 10 of said chapter 12C, as so appearing, is hereby further amended by striking out, in line 99, the word "and".

SECTION 33. Said subsection (c) of said section 10 of said chapter 12C, as so appearing, is hereby further amended by adding the following words:- ; (12) information, to the extent permissible under 42 U.S.C. 1396r-8(b)(3)(D), about prescription drug utilization and spending for all covered drugs, including for generic drugs, brand-name drugs, and specialty drugs provided in an outpatient setting or sold in a retail setting, including but not limited to information sufficient to show (i) highest utilization drugs, (ii) drugs with the greatest increases in utilization, (iii) drugs that are most impactful on plan spending, net of rebates, and (iv) drugs with the highest year-over-year price increases, net of rebates; and (13) information on claims and non-claims based payments to providers for the provision of primary care and behavioral health, including mental health and substance use disorder services, as defined by the center.

SECTION 34. Said chapter 12C is hereby further amended by inserting after section 10 the following section:-

Section 10A. (a) The center shall promulgate regulations necessary to ensure the uniform annual reporting of information from pharmacy benefit managers certified under chapter 175N, including but not limited to information on: (1) prices charged to payers on average by pharmacy benefits managers for select prescription drug products, net of any rebate, discounts, fees or other payments from the manufacturer to the pharmacy benefits manager and from the pharmacy

benefits manager to the manufacturer; (2) payments received by pharmacy benefit managers by payers related to drugs provided to Massachusetts residents; (3) payments made by pharmacy benefit managers to pharmacies related to drugs provided to Massachusetts residents; (4) rebates received by pharmacy benefit managers from drug manufacturers related to drugs provided to Massachusetts residents; (5) rebates paid by pharmacy benefit managers to payers related to drugs provided to Massachusetts residents; (6) other payments made or received by pharmacy benefit managers by payers or pharmacies, including but not limited to administrative or performance-based payments, related to doing business in Massachusetts; (7) other rebates paid to or received by pharmacy benefit managers by drug manufacturers or payers related to doing business in Massachusetts; (8) information about prescription drug utilization and spending for all covered drugs, including for generic drugs, brand-name drugs, and specialty drugs provided in an outpatient setting or sold in a retail setting, including but not limited to information sufficient to show: (i) highest utilization drugs; (ii) drugs with the greatest increases in utilization; (iii) drugs that are most impactful on plan spending, net of rebates; and (iv) drugs with the highest year-over-year price increases, net of rebates; (9) the Medicare Maximum Fair Price (42USC Sec 1191(c)) for a prescription drug; and (10) any other information deemed necessary by the center.

(b) The center shall analyze the information and data collected under subsection (a) and shall publish an annual report summarizing, at minimum, the information collected under subsection (a) and comparing the information as it relates to each pharmacy benefit manager certified under chapter 175N with respect to drugs provided to Massachusetts residents. The center may also consult with other states collecting similar data to inform their analysis and annual report.

(c) Except as provided otherwise by the center or under this chapter, pharmacy benefit manager data collected by the center under this section shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 or under chapter 66. The center may confidentially provide pharmacy benefit manager data collected by the center under this section to the health policy commission.

SECTION 35. Said chapter 12C is hereby further amended by striking out section 11, as so appearing, 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 36. 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 37. 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 38. 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 39. Said chapter 12C is hereby further amended by adding the following section:-

Section 25. (a) The center shall analyze data on Massachusetts drug utilization and spending, including but not limited to data reported under Sections 10 and 10A. Annually, the center shall refer drugs to the health policy commission for review under section 8B of chapter 6D that meet any of the following criteria: (i) a current average annual gross cost per utilizer for public and private health care payers in Massachusetts of greater than $50,000; (ii) a biosimilar drug that has a launch wholesale acquisition cost that is not at least 15 per cent lower than the referenced brand biologic at the time the biosimilar is launched; or (iii) among the 25 drugs determined by the center to have the most impact on health care spending in the most recent year of available data, based upon utilization, price, utilization and price growth, patient cost sharing amounts, net spending and other factors as determined by the center. The center shall provide notice of the referral to the manufacturer of the drug.

(b) Not later than May 1, the center shall publish an annual report detailing, at minimum, each drug referred to the health policy commission under subsection (a).

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

SECTION 40. 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 41. 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 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.