SENATE DOCKET, NO. 1799 FILED ON: 1/18/2019

SENATE . . . . . No. 706

The Commonwealth of Massachusetts

PRESENTED BY:

Jason M. Lewis

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:	
Jason M. Lewis	*Fifth Middlesex*	
Lori A. Ehrlich	*8th Essex*	*1/24/2019*
Joanne M. Comerford	*Hampshire, Franklin and Worcester*	*1/25/2019*
Mike Connolly	*26th Middlesex*	*1/28/2019*
Jack Patrick Lewis	*7th Middlesex*	*1/29/2019*
Rebecca L. Rausch	*Norfolk, Bristol and Middlesex*	*1/30/2019*
Kay Khan	*11th Middlesex*	*1/30/2019*
Michelle M. DuBois	*10th Plymouth*	*1/31/2019*
Cindy F. Friedman	*Fourth Middlesex*	*1/31/2019*
Michael O. Moore	*Second Worcester*	*1/31/2019*
Michael D. Brady	*Second Plymouth and Bristol*	*1/31/2019*
Mary S. Keefe	*15th Worcester*	*1/31/2019*
Patricia D. Jehlen	*Second Middlesex*	*2/1/2019*
Thomas M. Stanley	*9th Middlesex*	*2/1/2019*
Mathew J. Muratore	*1st Plymouth*	*2/1/2019*
James K. Hawkins	*2nd Bristol*	*2/7/2019*
James B. Eldridge	*Middlesex and Worcester*	*2/11/2019*
Harriette L. Chandler	*First Worcester*	*4/30/2019*

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SENATE . . . . . No. 706

By Mr. Lewis, a petition (accompanied by bill, Senate, No. 706) of Jason M. Lewis, Lori A. Ehrlich, Joanne M. Comerford, Mike Connolly and other members of the General Court for legislation to ensure prescription drug cost transparency and affordability. Health Care Financing.

The Commonwealth of Massachusetts

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

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 2016 Official Edition, is hereby amended by inserting after the definition of "Alternative payment methodologies or methods" the following two 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 produced or distributed pursuant to: (1) 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; or (2) a biologics license application, approved under 42 U.S.C. § 262(a)(C).

SECTION 2. Said Section 1 of chapter 6D of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Fiscal year" the following definition:

"Generic drug", a retail drug that is marketed or distributed pursuant to: (1) an abbreviated new drug application, approved under 21 U.S.C. § 355(j); or (2) an authorized generic as defined by 42 C.F.R. § 447.502; or (3) a drug that entered the market before 1962 that was not originally marketed under a new drug application.

SECTION 3. Said Section 1 of chapter 6D of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Performance penalty" the following two definitions:

"Pharmacy benefit manager", a third-party administrator under contract to a health insurance sponsor for management of prescription drug benefits including claims processing and payment, pharmacy contracting, and drug manufacturer price concession negotiation. "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 center.

"Pharmaceutical manufacturing company", an entity engaged in producing, preparing, marketing, compounding, processing, packaging, repackaging, or labeling a brand-name or generic drug, and who sets or changes the wholesale acquisition cost of the prescription drug it manufactures or markets, but does not include an entity that is engaged in the preparation and dispensing of a brand-name or generic drug pursuant to a prescription.

SECTION 4. Said Section 1 of chapter 6D of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of “Third party administration” the following definition:

“Thirty-day supply”, the amount of a drug that is (1) a drug supply lasting a patient for a period consisting of 30 consecutive days based on the recommended dosage in the FDA-approved labeling; or (2) a drug supply lasting fewer than thirty days if such dosage is recommended in the FDA-approved labeling for such drug; or (3) one unit of the drug if there is no finite dosage in the FDA-approved labeling.

SECTION 5. Section 8 of chapter 6D of the General Laws, as so appearing, is hereby amended by striking out, in line 32, the words “and (xi) ” and inserting in place thereof the following words:- (xi) not less than 3 representatives of the pharmaceutical industry; (xii) at least 1 pharmacy benefit manager; (xiii) a representative of a health care consumer organization and (xiv).

SECTION 6. Said section 8 of said chapter 6D, as so appearing, is hereby 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 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. Pharmacy benefit managers and pharmaceutical manufacturing companies shall

not be required to disclose nonpublic clinical, financial, strategic or operational documents or information except pursuant to section 2A.

SECTION 7. 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 providers, provider organizations, insurers, 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 8. Chapter 6D of the General Laws is hereby amended by inserting after Section 10 the following section:-

Section 10A. (a) Upon the receipt of information from the center pursuant to section 10A of chapter 12C that identifies that (i) a prescription drug’s cost or proposed or implemented increase in its cost appears to be unreasonable or excessive based on a cost that (1) could lead to an entity increasing health care expenditures above the health care cost growth benchmark established pursuant to section 9 of chapter 6D; or (2) could create significant challenges to the affordability of health care in the commonwealth, including affordability for consumers; or (ii) a prescription drug’s cost falls under one of the following categories: (1) brand name drugs and biologics, not including biosimilars, that have a launch wholesale acquisition cost of $30,000 or more for a year or course of treatment, or a whole sale acquisition cost of $3,000 or more in any twelve-month period, or course of treatment if less than twelve months; (2) biosimilar drugs that

have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic at the time the biosimilar is launched; or (3) generic drugs with a price increase that results in an increase in the wholesale acquisition cost of the drug that is equal to 200 percent or more during the preceding twelve-month period, and the wholesale acquisition cost of the drug is equal to or greater than $100, as updated annually in accordance with the consumer price index for all urban consumers, for a thirty-day supply, with the increase defined as the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the previous twelve months; the commission shall determine if a prescription drug shall be reviewed pursuant to this section. The commission may permit an opportunity for interested parties and members of the public to provide comments prior to a determination to undertake a review. All comments received shall be public records.

(b) The commission's review of the drug shall determine if, based on the findings of the center and the review factors listed in subsection (c) the commission shall establish, in consultation with the center, an upper payment limit that applies to all purchasers and payor reimbursements of the prescription drug product in the commonwealth, including uninsured consumers or consumers in a deductible period for the drug in the commonwealth. Failure of the manufacturing company to provide the requested information to the center pursuant to section 10A of chapter 12C shall not impede the commission from establishing an upper payment limit under this paragraph.

(c) The factors to be considered in the review by the commission may include: (1) the price at which the prescription drug has been or will be sold in the commonwealth; (2) the average monetary price concession, discount or rebate the manufacturer provides or is expected to provide to payors as reported by manufacturers and health plans expressed as a percent of the

wholesale acquisition cost for the drug; (3) the price at which therapeutic alternates have been or will be sold; (4) the average monetary price concession, discount, or rebate the manufacturer provides or is expected to provide to payors for therapeutic alternates; (5) the relative clinical merits of the product under review compared to therapeutic alternates; (6) the cost to payors based on patient access consistent with FDA labeled indication or indications or standard medical practice; (7) the impact on patient access resulting from the cost of the product relative to insurance benefit design, including the average cost-sharing for the prescription drug; (8) the relative financial impacts to health, medical and other social services costs, as can be quantified and compared to baseline effects of existing therapeutic alternatives; (9) manufacturer research and development costs as shown on the company's federal tax filing for the most recent tax year, multiplied by the proportion of manufacturer's sales in the commonwealth to U.S. sales; (10) that portion of direct to consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year, which are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer sales in the commonwealth to total manufacturer U.S. sales for the product under review; (11) gross and net manufacturer revenues for the most recent tax year; and (12) any additional factors specified in regulations or that the commission considers relevant to the circumstances.

(d) Following the review, the commission may, by a majority vote of the board members voting, establish an upper payment limit that applies to all purchasers and payor reimbursements of the prescription drug product in the commonwealth, including uninsured consumers or consumers in a deductible period for the drug in the commonwealth. Payors shall use the established upper payment limit for the prescription drug in developing the benefit design for such drug, including, if applicable, any cost-sharing amounts.

(e) This section shall be enforced by the attorney general. Payment transactions that do not comply with the maximum level of reimbursement established under this section shall constitute a violation of chapter 93A. The attorney general shall provide guidance concerning activities that could be considered non-compliant, in addition to payment transactions where drug costs exceed the limit established under this section.

(f) Nothing in this section shall be construed to affect: (i) an entity's eligibility for the federal 340B Drug Pricing Program; or (ii) the discounts that are available to an entity that is eligible for the federal 340B Drug Pricing Program.

SECTION 9. Said chapter 6D is hereby further amended by inserting after section 15A the following section:-

Section 15A. (a) The commission shall develop, implement and promote an evidence-based outreach and education program to support the therapeutic and cost-effective utilization of prescription drugs for physicians, podiatrists, pharmacists and other health care professionals authorized to prescribe and dispense prescription drugs. In developing the program, the commission shall consult with physicians, podiatrists, pharmacists, nurses, private insurers, hospitals, pharmacy benefit managers, the MassHealth drug utilization review board, the University of Massachusetts medical school and researchers and organizations that are engaged in the development, training and deployment of health practitioner education outreach programs.

(b) The program shall arrange for physicians, podiatrists, pharmacists and nurses to conduct face-to-face visits with prescribers, utilizing evidence-based materials and borrowing methods from behavioral science, educational theory and, where appropriate, pharmaceutical industry data and outreach techniques; provided, however, that, to the extent possible, the

program shall inform prescribers about drug marketing that is intended to circumvent competition from generic or other therapeutically-equivalent pharmaceutical alternatives or other evidence-based treatment options. The program shall be designed to provide outreach to: physicians, podiatrists and other health care practitioners who participate in MassHealth, the subsidized catastrophic prescription drug insurance program established in section 39 of chapter 19A, other publicly-funded, contracted or subsidized health care programs, academic medical centers and other prescribers. The commission shall, to the extent possible, utilize or incorporate into its program other independent educational resources or models proven effective in promoting high quality, evidenced-based, cost-effective information regarding the effectiveness and safety of prescription drugs including, but not limited to: (i) the Pennsylvania Pharmaceutical Assistance Contract for the Elderly Independent Drug Information Service affiliated with Harvard University; (ii) the Academic Detailing Program through the University of Vermont Larner College of Medicine's Office of Primary Care and Area Health Education Centers Program; (iii) the Drug Effectiveness Review Project coordinated by the Center for Evidence-based Policy at Oregon Health and Science University; and (iv) the North Carolina evidence-based peer-to-peer education program outreach program.

(c) The commission shall make an annual report, not later than April 1, on the operation of the program. The report shall be made publicly available on the commission's website and include information on the outreach and education components of the program, revenues, expenditures and balances and savings attributable to the program in health care programs funded by the commonwealth.

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

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

SECTION 10. 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.

(b) The attorney general may investigate any provider organization referred to the attorney general by the health policy commission under section 13 of chapter 6D to determine whether the provider organization engaged in unfair methods of competition or anticompetitive behavior in violation of chapter 93A or any other law and, if appropriate, take action under said chapter 93A or any other law to protect consumers in the health care market.

(c) The attorney general may investigate a pharmaceutical manufacturing company or pharmacy benefit manager referred to the attorney general by the center for health information and analysis under section 11 of chapter 12C to determine whether the pharmaceutical manufacturing company or pharmacy benefit manager engaged in unfair methods of competition or anticompetitive behavior in violation of chapter 93A or any other law and, if appropriate, take action under said chapter 93A or any other law to protect consumers in the health care market.

(d) The attorney general may intervene or otherwise participate in efforts by the commonwealth to obtain exemptions or waivers from certain federal laws regarding provider market conduct, including, from the federal Office of the Inspector General, a waiver or expansion of the safe harbors' provided for under 42 U.S.C. § 1320a-7b and obtaining from the federal Office of the Inspector General a waiver of or exemption from 42 U.S.C. § 1395nn subsections (a) to (e), inclusive.

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

SECTION 11. Section 1 of chapter 12C of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Acute hospital" the following definition:

"Aggregate retained rebate percentage", the percentage of all rebates received from a manufacturer or other entity to a pharmacy benefit manager for prescription drug utilization which is not passed on to pharmacy benefit mangers' carrier clients. The percentage shall be calculated for each carrier for rebates in the prior calendar years as follows: (i) the sum total dollar amount of rebates received from all pharmaceutical manufacturers for all utilization of covered persons of a health carrier that was not passed through to the carrier; and (ii) divided by the sum total dollar amount of all rebates received from all pharmaceutical manufacturers for members of a health carrier.

SECTION 12. Said section 1 of chapter 12C of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Ambulatory surgical center services" the following two 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 produced or distributed pursuant to: (1) 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; or (2) a biologics license application, approved under 42 U.S.C. § 262(a)(C).

SECTION 13. Said section 1 of chapter 12C of the General Laws, as appearing in the 2016 Official Edition, is hereby 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 marketed or distributed pursuant to: (1) an abbreviated new drug application, approved under 21 U.S.C. § 355(j); or (2) an authorized generic as defined by 42 C.F.R. § 447.502; or (3) a drug that entered the market before 1962 that was not originally marketed under a new drug application.

SECTION 14. Said section 1 of chapter 12C of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Patient-centered medical home" the following 3 definitions:

"Pharmacy benefit manager", a third-party administrator under contract to a health insurance sponsor for management of prescription drug benefits including claims processing and payment, pharmacy contracting, and drug manufacturer price concession negotiation. "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 center.

"Pharmaceutical manufacturing company", an entity engaged in producing, preparing, marketing, compounding, processing, packaging, repackaging, or labeling a brand-name or generic drug, and who sets or changes the wholesale acquisition cost of the prescription drug it manufactures or markets, but does not include an entity that is engaged in the preparation and dispensing of a brand-name or generic drug pursuant to a prescription.

"Pipeline drugs", a prescription drug for which an FDA regulated entity has submitted a new drug application or biologics license application and received an action date from the federal Food and Drug Administration.

SECTION 15. Said section 1 of chapter 12C of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Quality measures" the following definition:

"Rebates or fees", all fees or price concessions paid by a manufacturer to a pharmacy benefit manager or carrier, including rebates, discounts, and other price concessions that are based on actual or estimated utilization of a prescription drug. Rebates also include price concessions based on the effectiveness a drug as in a value-based or performance-based contract.

SECTION 16. Said section 1 of chapter 12C of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after the definition of "Third party payer" the following definition:

"Thirty-day supply", the amount of a drug that is (1) a drug supply lasting a patient for a period consisting of 30 consecutive days based on the recommended dosage in the FDA-approved labeling; or (2) a drug supply lasting fewer than thirty days if such dosage is recommended in the FDA-approved labeling for such drug; or (3) one unit of the drug if there is no finite dosage in the FDA-approved labeling.

SECTION 17. Section 5 of said chapter 12C, as so appearing, is hereby amended by inserting after the word "payers", in line 11, the following words:- , pharmaceutical manufacturing companies, pharmacy benefit managers.

SECTION 18. Said section 5 of said chapter 12C, as so appearing, is hereby further amended by inserting after the word “organizations”, in line 15, the following words:- , affected pharmaceutical manufacturing companies, affected pharmacy benefit managers.

SECTION 19. Section 7 of said chapter 12C, as so appearing, is hereby amended by adding the following paragraph:-

To the extent that the analysis of pharmaceutical manufacturing companies and pharmacy benefit managers pursuant to section 10A increases the expenses of the center, the estimated increase in the center’s expenses shall be fully assessed to pharmaceutical manufacturing companies and pharmacy benefit managers in the same manner as the assessment under section 68 of chapter 118E. For pharmaceutical manufacturing companies, such assessments shall be determined based upon each manufacturer’s relative share of drug gross revenue in the state. A pharmacy benefit manager that is a surcharge payor subject to the preceding paragraph and administers either its own: (i) prescription drug, prescription device or pharmacist services; or (ii) prescription drug and device and pharmacist services portion shall not be subject to additional assessment under this paragraph.

SECTION 20. Said chapter 12C is hereby further amended by inserting after section 10 the following section[s]:-

Section 10A. (a) The center shall study of the impact of pharmaceutical manufacturing company pricing factors and methodologies and the pharmacy benefit manager business model on drug costs, including patented drugs, pipeline drugs, generic drugs and biosimilar drug products. The center shall develop a list of critical prescription drugs for which there is a substantial public interest in understanding the development of the drug’s pricing. In developing

the list, the commission shall include the top twenty selling drugs in the commonwealth, and other drugs based on the following factors: (i) the cost of the drug to public health care programs, including the office of Medicaid and the group insurance commission; (ii) the current cost of the drug in the commonwealth; (iii) the extent of utilization of the drug within the commonwealth; (iv) the seriousness and prevalence of the disease or condition that is treated by the drug; (v) identification of the drug as low comparative value by an independent non-profit organization; and (vi) the potential impact of the cost of the drug on the commonwealth's achievement of the statewide health care cost growth benchmark, as established by section 9. For each prescription drug that the center identifies, the center shall require the manufacturer of said prescription drug to report to the center the information pursuant to paragraph (b). Study findings shall be issued at least annually; provided, however, that the center may issue interim studies if it deems it necessary. The center may contract with a state or third-party entity that can access data available from public or proprietary sources, or collected or compiled by other states that satisfy the requirements of this section. The center shall post a summary of the study findings and the information received pursuant to this section on the center's website at least annually on or before October 1 of each year.

(b) The center shall require the submission of available data and other information from pharmaceutical manufacturing companies and pharmacy benefit managers; provided, however, that the center shall make its data requests compatible with the prescription drug transparency systems of other states. The center may obtain the data from information submitted to other states and may modify the specific data requested to take into account information available from public and proprietary data sources and prescription drug transparency information requests of other states. The data and information requested from pharmaceutical manufacturing companies

may include, but not be limited to: (i) changes in wholesale acquisition costs for prescription drug products as identified by the center; (ii) aggregate, company-level and product-specific research and development costs to the extent attributable to a specific product or products 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, provided that reasonable estimates may be provided if more precise costs are not available; (iii) the amount paid by the manufacturer to acquire the prescription drug product if not developed by the manufacturer; (iv) the 5-year history of any increases in the wholesale acquisition costs; (v) annual marketing and advertising expenditures apportioned by activities directed to consumers and prescribers for prescription drug products as identified by the center; (vi) the average cost-sharing for each prescription drug; and (vii) a description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition costs for prescription drug products as identified by the center; and (vii) any other information necessary to identify drugs that may be subject to reporting under paragraph (j). The center shall further require pharmacy benefit managers to submit data and information regarding: (i) the aggregate amount of all rebates or fees that the pharmacy benefit manager received from all pharmaceutical manufacturers for all health carrier clients and for each health carrier client; (ii) the aggregate administrative fees that the pharmacy benefit manager received from all manufacturers for all health carrier clients and for each health carrier client; (iii) the aggregate retained rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers and did not pass through to health benefit plans; (iv) the aggregate retained rebate percentage; and (v) the highest, lowest, and mean aggregate retained rebate percentage for all health benefit plan clients and for each health carrier client.

(c) The study shall include, to the extent supported by available information, the following: (i) annual changes in wholesale acquisition costs and net expenditures for products identified by the center, including manufacturing and distribution costs; (ii) annual marketing and advertising costs, identifying costs for consumer-directed advertising; (iii) gross revenue, volume and profits derived from sales in the commonwealth during the previous five years; (iv) research and development costs as a percentage of revenue, including research costs received from public sources, including costs paid by grants from the federal Department of Health and Human Services and Department of Defense, tax credits received in connection with research and development or marketing, and costs paid by third parties, to the extent such costs are attributable to a specific product or set of products; (viii) estimated aggregate drug rebates and other price reductions paid by a pharmaceutical manufacturing company in connection with purchase of drugs produced by the pharmaceutical manufacturing company; (ix) information regarding trends of estimated aggregate rebates or fees and other price reductions paid by a pharmacy benefit manager in connection with utilization of all drugs offered through the pharmacy benefit manager; (x) information regarding pharmacy benefit manager practices in passing drug rebates or other price reductions received by the pharmacy benefit manager to a private or public health care payer or to the consumer; (xi) information regarding discount or free product coupons that a pharmacy provides to a consumer in connection with a pharmacy service, item or prescription transfer offer or to any discount, rebate, product voucher or other reduction in an individual's out-of-pocket expenses, including co-payments and deductibles under section 3 of chapter 175H; (xii) disparities between costs for purchasers in the commonwealth and purchasers outside of the United States and (xiii) any other information deemed necessary by the center.

(d) A pharmaceutical manufacturing company shall provide early notice to the center for: (i) a pipeline drug; (ii) an abbreviated new drug application for generic drugs, upon submission to the federal Food and Drug Administration; or (iii) a biosimilar biologics license application upon the receipt of an action date from the federal Food and Drug Administration. The center may arrange to receive notices required by this subsection from publicly available information or subscription data sources. The center shall make early notice information available to the office of Medicaid or another agency and to acute hospitals, ambulatory surgical centers and surcharge payors, as deemed appropriate. Early notice shall be submitted to the center not later than 60 days after receipt of the federal Food and Drug Administration action date or after the submission of an abbreviated new drug application to the federal Food and Drug Administration action. For each prescription drug product, early notice shall include a brief description of the: (i) primary disease, health condition or therapeutic area being studied and the indication; (ii) route of administration being studied; (iii) clinical trial comparators; and (iv) estimated year of market entry. To the extent possible, information shall be collected using data fields consistent with those used by the federal National Institutes of Health for clinical trials. For each pipeline drug, early notice shall include whether the drug has been designated by the federal Food and Drug Administration: (i) orphan drug; (ii) fast track; (iii) breakthrough therapy; (iv) for accelerated approval; or (v) priority review for a new molecular entity. Notwithstanding the foregoing, submissions for drugs in development that receive such a designation by the federal Food and Drug Administration for new molecular entities shall be provided as soon as practical upon receipt of the relevant designation.

(e) A pharmaceutical manufacturing company shall provide notice to the center for any drug purchased or reimbursed by a health insurance plan or a pharmacy benefit manager in the

commonwealth with a wholesale acquisition cost over forty dollars for a course of therapy if the wholesale acquisition cost will increase by more than 10 percent, including any increases in the previous two calendar years. The notice shall specify the amount of the proposed increase, the cumulative increase in the past 24-month period, the date that the increase will take effect, and the current wholesale acquisition cost of the drug. The notice required by this subsection shall be provided at least sixty days before the planned increase. The notice provided under this subsection shall be accompanied by a statement providing the specific financial and non-financial factors used to make the decision to increase the wholesale acquisition cost of the drug, including pricing of competitive drugs, policy changes, changes in treatment, any improved clinical efficacy and any other information as required by the center. The center shall publish the information it receives pursuant to this subsection on its public internet site in a format that allows members of the public to be informed when new notices are published on the site.

(f) The center shall report on the operation of the United States generic market, including a review of physician-administered drugs. Such report shall consider: (1) the prices of generic drugs on a year over year basis; (2) the degree to which generic drug prices affect yearly insurance premium changes; (3) annual changes in insurance cost-sharing for generic drugs; (4) the potential for and history of drug shortages; (5) the degree to which generic drug prices affect yearly state Medicaid spending; and (6) any other relevant study questions.

(g) The center shall promulgate regulations necessary to ensure the uniform analysis of information regarding pharmaceutical manufacturing companies and pharmacy benefit managers and that enable the center to receive the required information necessary to perform the analysis and reporting required by this section. The center may obtain data from information submitted to other states and may modify the specific data requested to take into account information

available from public and proprietary data sources and prescription drug transparency information requests of other states.

(h) The center shall notify pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable reporting deadlines under this section. The center shall notify, in writing, a pharmacy benefit manager or pharmaceutical manufacturing company that it has failed to meet a reporting deadline and that failure to respond within two weeks of the receipt of the notice shall result in penalties. The center shall assess a penalty against a pharmacy benefit manager or pharmaceutical manufacturing company that fails, without just cause, to provide the requested information within two weeks following receipt of the written notice required under this paragraph of up to $10,000 per day for each week of delay after the two-week period following receipt of the written notice; provided, however, that the maximum annual penalty against a pharmacy benefit manager or pharmaceutical manufacturing company under this section shall be $1,000,000. 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. The center may additionally identify any such pharmaceutical manufacturing company that fails, without just cause, to provide the requested information within two weeks following receipt of the written notice required under this paragraph and may recommend any drug manufactured by such manufacturing company for automatic review by the commission pursuant to paragraph (j). The center shall notify the attorney general of any pharmaceutical manufacturing company or pharmacy benefit manager that fails to comply with this section for further action pursuant to section 11N of chapter 12 or any other law. For the purposes of this section, the center may promulgate regulations to define “just cause”.

(i) The center shall keep confidential all nonpublic clinical, financial, strategic or operational documents or information provided or reported in connection with this section and shall not disclose the information or documents to any person without the consent of the entity providing or reporting the information or documents, except in summary form in evaluative reports of such activities or when the center 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.

(j) The center shall identify and regularly report to the commission, based on the information gathered and analyzed in this section, the following: (i) any drug or group of drugs whose cost or proposed or implemented cost increase appears to be unreasonable or excessive based on a cost that (1) could lead to an entity increasing health care expenditures above the health care cost growth benchmark established pursuant to section 9 of chapter 6D; or (2) could create significant challenges to the affordability of health care in the commonwealth, including affordability for consumers based on the information received by the center; or (ii) any drug or group of drugs that falls under one of the following categories: (1) brand name drugs and biologics, not including biosimilars, that have a launch wholesale acquisition cost of $30,000 or more for a year or course of treatment, or a wholesale acquisition cost of $3,000 or more in any twelve-month period, or course of treatment if less than twelve months; (2) biosimilar drugs that have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic at the time the biosimilar is launched; or (3) generic drugs with a price increase that results in an increase in the wholesale acquisition cost of the drug that is equal to 200 percent or

more during the preceding twelve-month period, and the wholesale acquisition cost of the drug is equal to or greater than $100, as updated annually in accordance with the consumer price index for all urban consumers, for a thirty-day supply, with the increase defined as the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the previous twelve months.

SECTION 21. 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 22. 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)(1) A health benefit plan shall (i) 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 (ii) 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. (2) 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; or (iv) the amount the pharmacy will be reimbursed for the drug from pharmacy benefit manager or health benefit plan. (3) A pharmacy shall post a notice informing consumers that a consumer may request, at the point of sale, the current pharmacy retail price for each prescription medication the consumer intends to purchase. 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. (4) 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. (5) A pharmacy benefit manager shall not require pharmacy or other provider accreditation standards or certification requirements

inconsistent with, more stringent than, or in addition to requirements of the board of registration of pharmacy or other state or federal entity. (6) 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. (7) A violation of this section shall be an unfair or deceptive act or practice under chapter 93A.

SECTION 23. Chapter 118E of the General Laws is hereby amended by inserting after section 12 the following section:-

Section 12A. (a) As used in this section, the following words shall have the following meanings unless the context clearly indicates otherwise:

"Board", the MassHealth drug utilization review board established in accordance with 42 U.S.C. 1396r-8.

"Manufacturer", an entity that manufacturers a pharmaceutical drug covered by MassHealth.

"Pharmaceutical spending target", the reduction in the projected increase in the commonwealth's net share of pharmaceutical spending for the next fiscal year for the MassHealth program as compared to the current fiscal year.

"Secretary", the secretary of health and human services.

(b) The secretary, in consultation with the board, shall establish a pharmaceutical spending target pursuant to the supplemental rebate cost containment efforts set forth in this section. When establishing the pharmaceutical spending target, the board shall annually hold at least 1 public hearing and solicit input from interested stakeholders not later than December 15. The secretary shall provide notice of the pharmaceutical spending target for the next fiscal year not later than January 1 to the clerks of the senate and house of representatives and the chairs of the senate and house committees on ways and means.

(c) Notwithstanding any general or special law to the contrary, including 801 CMR 21.00 or any successor regulation, and subject to required federal approvals, the secretary may directly negotiate supplemental rebate agreements with manufacturers including, but not limited to, agreements utilizing guaranteed net prices that are (i) reasonable, affordable and sustainable for the commonwealth; and (ii) reflects the public health value of such drugs as determined by an independent third party designated by the secretary or other appropriate measure of value. In requesting a supplemental rebate, the secretary shall consider any data received or analysis performed by the center for health information and analysis pursuant to section 10A of chapter 12C and of determinations, including any upper payment limit imposed, of the health policy commission pursuant to section 10A of chapter 6D. A manufacturer may request to enter into negotiations for a supplemental rebate agreement for a prescription drug; provided, however, that the secretary may prioritize other negotiations or refuse to enter into such negotiations. Nothing in this paragraph shall preclude the secretary from entering into a supplemental rebate agreement negotiation with a manufacturer at a later date.

(d) If a manufacturer and the secretary are unable to establish a supplemental rebate agreement under subsection (c), the secretary may require the manufacturer to disclose within a

reasonable time any records that describe or relate to the manufacturer's pricing of any such drugs that are the subject of a supplemental rebate agreement negotiation. Records disclosed by a manufacturer shall not be public records under section 7 of chapter 4 and under chapter 66 and shall remain confidential; provided, however, that the secretary may produce reports summarizing any findings related to records received under this section to the extent allowable under applicable state and federal laws. The secretary, in conjunction with the board, may hold a public hearing at which the manufacturer shall be required to appear and testify to provide further information related to any prescription drug that is the subject of a negotiation for a supplemental rebate agreement.

(e) If a manufacturer does not comply with subsection (d), the secretary may impose a reasonable penalty on the manufacturer which shall not exceed the difference between the gross cost of the pharmaceutical drug subject to the supplemental rebate negotiation in the previous fiscal year and the fiscal year preceding the previous fiscal year; provided, however, that if there is no information available for the preceding 2 fiscal years for the pharmaceutical drug subject to the supplemental rebate, then the maximum penalty shall be the amount of the supplemental rebate first requested by the secretary during a negotiation under subsection (c).

(f) If, after review of any records furnished to the executive office under subsection (d), no supplemental rebate agreement is completed and the secretary determines that the manufacturer's pricing of the drug is excessive, the secretary may impose a reasonable penalty against the manufacturer which shall not exceed the difference between the gross cost of the pharmaceutical drug subject to the supplemental rebate negotiation in the previous fiscal year and the fiscal year preceding the previous fiscal year; provided, however, that if there is no information available for the preceding 2 fiscal years for the pharmaceutical drug subject to the

supplemental rebate negotiation, then the maximum penalty shall be the amount of the supplemental rebate first requested by the secretary during a negotiation under subsection (c).

(g) A penalty assessed under subsection (e) or (f) shall be accompanied by a written determination by the secretary that shall include: (i) the reason for the penalty; (ii) the amount of the penalty; and (iii) a notice outlining the appeals process for the penalty.

(h) The secretary may, pursuant to an interagency agreement, share information received under this section with the health policy commission, established under chapter 6D; provided, however, that any shared information shall be held confidential and shall not be a public record under section 7 of chapter 4 and under chapter 66. The health policy commission may use the information received under this subsection in relevant reporting in a de-identified, aggregate format. The secretary may, pursuant to an interagency agreement, share information received under this section with the state office of pharmacy services in the department of public health; provided, however, that any shared information shall be held confidential and shall not be a public record under section 7 of chapter 4 and under chapter 66.

(i) Annually, not later than October 15, the secretary shall report to the clerks of the senate and house of representatives, the joint committee on healthcare financing and the house and senate committees on ways and means on activities conducted pursuant to this section which shall include, but not limited to, the following information: (i) whether the pharmaceutical spending target was achieved; (ii) the amount of supplemental rebates received under this section; (iii) the number of pharmaceutical drugs receiving a supplemental rebate under this section, broken down by manufacturer; (iv) a breakdown of the duration of the supplemental

rebates received; and (v) a breakdown of the percentage of each supplemental rebate's contribution to meeting the pharmaceutical spending target.

(j) The executive office shall adopt regulations necessary to implement this section.

SECTION 24. Section 6 of chapter 176J of the General Laws, as so appearing, is hereby amended by striking subsection (c) and inserting in place thereof the following subsection:-

(c) Notwithstanding any general or special law to the contrary, carriers offering small group health insurance plans, including carriers licensed under chapters 175, 176A, 176B or 176G, shall file small group product base rates and any changes to small group rating factors that are to be effective on January 1 of each year, on or before July 1 of the preceding year. The commissioner shall disapprove any proposed changes to base rates that are excessive, inadequate or unreasonable in relation to the benefits charged. The commissioner shall further disapprove any proposed changes to base rates that do not take into account the upper payment limit established for any prescription drug pursuant to section 10A of chapter 6D. The commissioner shall disapprove any change to small group rating factors that is discriminatory or not actuarially sound. Rates of reimbursement or rating factors included in the rate filing materials submitted for review by the division shall be deemed confidential and exempt from the definition of public records in clause Twenty-sixth of section 7 of chapter 4. The commissioner shall adopt regulations to carry out this section.

SECTION 25. The General Laws are hereby amended by inserting after Chapter 176V the following chapter:-

Chapter 176W

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 and health insurance under chapter 175; a nonprofit hospital service corporation organized under chapter 176A; a non-profit medical service corporation organized under chapter 176B; or a health maintenance organization organized under chapter 176G.

"Commissioner", the commissioner of the division of insurance.

"Division", the division of insurance.

"Health benefit plan", any individual, general, blanket or group policy of health, accident and sickness insurance issued by an insurer licensed under chapter 175; an individual or group hospital service plan issued by a non-profit hospital service corporation under chapter 176A; an individual or group medical service plan issued by a nonprofit medical service corporation under chapter 176B; and an individual or group health maintenance contract issued by a health maintenance organization under chapter 176G. Health benefit plans shall not include: accident only, credit only, limited scope vision or dental benefits if offered separately; hospital indemnity insurance policies that provide a benefit to be paid to an insured or a dependent, including the spouse of an insured, on the basis of a hospitalization of the insured or a dependent, that are sold as a supplement and not as a substitute for a health benefit plan and that meet any requirements set by the commissioner by regulation; disability income insurance; coverage issued as a supplement to liability insurance; specified disease insurance that is purchased as a supplement and not as a substitute for a health plan and meets any requirements the commissioner by regulation may set; insurance arising out of a workers' compensation law or similar law;

automobile medical payment insurance; insurance under which benefits are payable with or without regard to fault and which is statutorily required to be contained in a liability insurance policy or equivalent self insurance; long-term care if offered separately; coverage supplemental to the coverage provided under 10 U.S.C. 55 if offered as a separate insurance policy; travel insurance; or any policy subject to chapter 176K or any similar policies issued on a group basis, Medicare Advantage plans or Medicare Prescription drug plans. A health plan issued, renewed or delivered within or without the commonwealth to an individual who is enrolled in a qualifying student health insurance program under section 18 of chapter 15A shall not be considered a health plan for the purposes of this chapter and shall be governed by said chapter 15A. The commissioner may by regulation define other health coverage as a health benefit plan for the purposes of this chapter.

"Insured", an enrollee, covered person, insured, member, policyholder or subscriber of a carrier, including an individual whose eligibility as an insured of a carrier is in dispute or under review, or any other individual whose care may be subject to review by a utilization review program or entity as described under other provisions of this chapter.

"Mail Order Pharmacy", a pharmacy whose primary business is to receive prescriptions by mail, telefax or through electronic submissions and to dispense medication to insureds through the use of the United States mail or other common or contract carrier services and that provides any consultation with patients electronically rather than face to face.

"Network Pharmacy", a retail or other licensed pharmacy provider that contracts with a pharmacy benefit manager.

"Pharmacy", a facility, either physical or electronic, under the direction or supervision of a registered pharmacist which 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 that, pursuant to a contract or under an employment relationship with a carrier, a self-insurance plan, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, self-insurance plan, or other third-party payer including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

"Rebates or fees", all fees or price concessions paid by a manufacturer to a pharmacy benefit manager or carrier, including rebates, discounts, and other price concessions that are based on actual or estimated utilization of a prescription drug. Rebates also include price concessions based on the effectiveness a drug as in a value-based or performance-based contract.

"Retail Pharmacy", a chain pharmacy, a supermarket pharmacy, a mass merchandiser pharmacy, an independent pharmacy, or a network of independent pharmacies that is licensed as a pharmacy by the commonwealth and that dispenses medications to the public.

Section 2. (a) Any pharmacy benefit manager contracting with a pharmacy that operates in the commonwealth shall comply with the provisions of this chapter.

(b) A pharmacy benefit manager shall receive a license from the division before conducting business in the commonwealth. A license granted pursuant to this section is not transferable.

(c) A license may be granted only when the division is satisfied that the entity possesses the necessary organization, background expertise, and financial integrity to supply the services sought to be offered.

(d) The division may issue a license subject to restrictions or limitations upon the authorization, including the type of services that may be supplied or the activities in which the entity may be engaged.

(e) A license shall be valid for a period of three years.

(f) The division shall develop an application for licensure that includes at least the following information: (i) the name of the pharmacy benefit manager; (ii) the address and contact telephone number for the pharmacy benefit manager; (iii) the name and address of the pharmacy benefit manager's agent for service of process in the commonwealth; (iv) the name and address of each person beneficially interested in the pharmacy benefit manager; and (v) the name and address of each person with management or control over the pharmacy benefit manager.

(g) The division may suspend, revoke, or place on probation a pharmacy benefit manager license under any of the following circumstances: (i) the pharmacy benefit manager has engaged in fraudulent activity that constitutes a violation of state or federal law; (ii) the division received consumer complaints that justify an action under this chapter to protect the safety and interests of consumers; (iii) the pharmacy benefit manager fails to pay an application fee for the license; or (iv) the pharmacy benefit manager fails to comply with a requirement set forth in this chapter.

(h) If an entity performs the functions of pharmacy benefit manager acts without registering, it will be subject to a fine of $5,000 per day for the period they are found to be in violation.

Section 3. (a) A pharmacy benefit manager has a fiduciary duty to a health benefit plan client and shall discharge that duty in accordance with the provisions of state and federal law.

(b) A pharmacy benefit manager shall perform its duties with care, skill, prudence, diligence, and professionalism.

(c) A pharmacy benefit manager shall notify a carrier client in writing of any activity, policy or practice of the pharmacy benefit manager that directly or indirectly presents any conflict of interest with the duties imposed in this section.