SENATE . . . . . No. 3012

The Commonwealth of Massachusetts

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

SENATE, December 27, 2024

Report of the committee of conference on the disagreeing votes of the two branches with reference to the House amendment to the Senate relative to pharmaceutical access, costs and transparency (Senate, No. 2520) (amended by the House all after the enacting clause and inserting in place thereof the text of House document numbered 4910; and by striking out the title and inserting in place thereof the following title: "An Act promoting access and affordability of prescription drugs."),-- reports, a "Bill relative to pharmaceutical access, costs and transparency" (Senate, No. 3012).

For the Committee:

Cindy F. Friedman	John J. Lawn, Jr.
John J. Cronin	Frank A. Moran

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An Act relative to pharmaceutical access, costs and transparency.

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

SECTION 1. Section 1 of chapter 6D of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by inserting after the definition of "Fiscal year" the following definition:-

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined by 42 C.F.R. 447.502; (iii) a drug that entered the market before January 1, 1962 and was not originally marketed under a new drug application; or (iv) identified by the carrier as a generic 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 "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 hospital licensed under section 51 of chapter 111, 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", as defined in section 1 of chapter 176Y.

SECTION 3. Said chapter 6D is hereby further amended by inserting after section 3 the following section:-

Section 3A. (a) There shall be within the commission an office for pharmaceutical policy and analysis. The office shall: (i) analyze pharmaceutical spending data and information collected by the commission and other agencies of the commonwealth pursuant to subsection (b); (ii) produce reports and analyses of trends related to the access, affordability of and spending on pharmaceutical drugs in the commonwealth pursuant to subsection (c); (iii) analyze records related to pharmaceutical pricing disclosed to the commission pursuant to section 8A and assist the commission in identifying proposed supplemental rebates for eligible drugs under said section 8A; and (iv) advise the general court and state agencies on matters related to pharmaceutical drug policy.

(b) The office shall analyze pharmaceutical spending data collected by the commission and other agencies of the commonwealth, including pharmaceutical spending data collected by the center under sections 8 to 10A, inclusive, of chapter 12C, and pharmaceutical spending data available through publicly available sources. As part of its analysis, the office shall conduct an annual survey of payers on pharmaceutical access and plan design, including tiering, cost-sharing

and other utilization management techniques employed by payers; provided, however, that any confidential data shall not be a public record and shall be exempt from disclosure pursuant to clause Twenty-sixth of section 7 of chapter 4 and section 10 of chapter 66.

(c)(1) The office shall produce an annual report on trends related to access, affordability and spending on pharmaceutical drugs in the commonwealth and other reports from time to time. The annual report shall address such trends and underlying factors for pharmaceutical drug spending, including an analysis of trends in: (i) prices and utilization; (ii) drugs or categories of drugs with the highest impact on spending; (iii) patient out-of-pocket spending; and (iv) access and affordability issues for patients with rare diseases and chronic diseases; provided, however, that any analysis pursuant to section 8A of a drug prescribed to treat a rare disease, or that is otherwise designated as a first-in-class drug, shall be conducted pursuant to paragraph (3). The report shall include any recommendations for strategies to mitigate pharmaceutical spending growth, promote affordability and enhance pharmaceutical access.

(2) The annual report shall be based on factors, including, but not limited to: (i) drug pricing; (ii) the impact of aggregate manufacturer rebates, discounts and other price concessions on net drug pricing; (iii) patient cost-sharing such as deductibles, coinsurance, copayments or similar charges paid by patients for drugs; (iv) the impact of aggregate rebates, discounts and other price concessions on such cost-sharing; and (v) the impact of utilization management techniques on pharmaceutical access employed by payers, including tiering, prior authorization and step therapy. The annual report shall be informed by: (A) the office's analysis of information provided at the annual cost trends hearing by providers, provider organizations and payers; (B) data collected by the center under sections 8 to 10A, inclusive, of chapter 12C; and (C) any other

information available to the commission that is necessary to fulfill its duties under this section, as further defined in regulations promulgated by the commission.

(3) The office shall consult with the rare disease advisory council established pursuant to section 241 of chapter 111 and other stakeholders as determined by the office for any analysis the office performs pursuant to section 8A of a drug that is prescribed to treat a rare disease or is otherwise designated as a first-in-class drug by the United States Food and Drug Administration's Center for Drug Evaluation and Research. Such analysis shall include:

(i) the disease treated by the drug;

(ii) the severity of disease treated by the drug;

(iii) the unmet medical need associated with the disease treated by the drug;

(iv) the impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management or other utilization management policies on access to the drug and on patients' adherence to the treatment regimen prescribed or otherwise recommended by their health care provider;

(v) an assessment of the benefits and risks of the drug for patients;

(vi) whether patients who need treatment from or a consultation with a rare disease specialist or a specialist in the disease being treated by the first-in-class drug have adequate access and, if not, what factors are causing the limited access; and

(vii) the demographic and the clinical description of patient populations.

(4) Annually, but in no event later than September 1, the report shall be submitted to the house and senate committees on ways and means and the joint committee on health care financing and shall be published and made available to the public.

(d) The office shall analyze records related to pharmaceutical pricing disclosed to the commission pursuant to section 8A and assist the commission in identifying proposed supplemental rebates for eligible drugs under said section 8A. The office's analysis of such records shall consider: (i) the effectiveness of the drug in treating the conditions for which it is prescribed; (ii) improvements to a patient's health, quality of life or overall health outcomes; and (iii) the likelihood that use of the drug will reduce the need for other medical care, including hospitalization.

(e) The office may consult with external experts or other third-party entities when the office lacks the specific scientific, medical or technical expertise necessary for the performance of its responsibilities under this section; provided, however, that the commission shall disclose when such external expert or third-party entity contributes to its analysis and reporting and the identity of such external expert or third-party entity.

SECTION 4. Section 4 of said chapter 6D, as appearing in the 2022 Official Edition, is hereby amended by striking out, in line 8, the word "manufacturers" and inserting in place thereof the following words:- manufacturing companies, pharmacy benefit managers.

SECTION 5. Said chapter 6D is hereby further amended by striking out section 6, most recently amended by section 5 of chapter 140 of the acts of 2024, and inserting in place thereof the following section:-

Section 6. (a) For the purposes of this section, “non-hospital provider organization” shall mean a provider organization required to register under section 11 that is: (i) a non-hospital-based physician practice with not less than $500,000,000 in annual gross patient service revenue; (ii) a clinical laboratory; (iii) an imaging facility; or (iv) a network of affiliated urgent care centers.

(b) Each acute hospital, ambulatory surgical center, non-hospital provider organization, pharmaceutical manufacturing company and pharmacy benefit manager shall pay to the commonwealth an amount for the estimated expenses of the commission.

(c) The assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations shall be not less than 30 per cent nor more than 40 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; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies; provided, however, that, to the maximum extent permissible under federal law, non-hospital provider organizations shall be assessed not less than 3 per cent nor more than 8 per cent of the total assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay such assessed amount multiplied by the ratio of the acute hospital’s, ambulatory surgical center’s or non-hospital provider organization’s gross patient service revenues to the total gross patient service revenues of all such hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall make a preliminary payment to the commission on October 1 of each year in an amount equal to 1/2 of the previous year’s total

assessment. Thereafter, each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay, within 30 days' notice from the commission, the balance of the total assessment for the current year based upon its most current projected gross patient service revenue. The commission shall subsequently adjust the assessment for any variation in actual and estimated expenses of the commission and for changes in acute hospital, ambulatory surgical center and non-hospital provider organization gross patient service revenue. Such estimated and actual expenses shall include an amount equal to the cost of fringe benefits and indirect expenses, as established by the comptroller under section 5D of chapter 29. In the event of late payment by any such acute hospital, ambulatory surgical center or non-hospital provider organization, the treasurer shall advance the amount of due and unpaid funds to the commission prior to the receipt of such monies in anticipation of such revenues up to the amount authorized in the then current budget attributable to such assessments and the commission shall reimburse the treasurer for such advances upon receipt of such revenues. This section shall not apply to any state institution or to any acute hospital which is operated by a city or town.

(d) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmaceutical manufacturing companies shall be not less than 5 per cent nor more than 10 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; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies. Each pharmaceutical manufacturing company shall pay such assessed amount multiplied by the ratio of MassHealth's net spending for the

manufacturer’s prescription drugs used in the MassHealth rebate program to MassHealth’s total pharmacy spending.

(e) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmacy benefit managers shall be not less than 5 per cent nor more than 10 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; and (iii) federal matching revenues received for these expenses or received retroactively for expenses of predecessor agencies. Each pharmacy benefit manager shall pay such assessed amount multiplied by the ratio of the claims paid by the pharmacy benefit manager attributed to residents of the commonwealth for whom it manages pharmaceutical benefits on behalf of carriers to the total of all such claims paid by all pharmacy benefit managers attributed to residents of the commonwealth for whom they manage pharmaceutical benefits on behalf of carriers.

(f) Each pharmaceutical manufacturing company and each pharmacy benefit manager shall make a preliminary payment to the commission annually on October 1 in an amount equal to 1/2 of the previous year's total assessment. Thereafter, each pharmaceutical manufacturing company and each pharmacy benefit manager shall pay, within 30 days of receiving notice from the commission, the balance of the total assessment for the current year as determined by the commission.

SECTION 6. Subsection (a) of 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 hearings shall examine the costs, prices and cost trends of health care providers, provider organizations, private and public health care payers, pharmaceutical manufacturing companies and pharmacy benefit managers and any relevant impact of significant equity investors, health care real estate investment trusts, management services organizations on such costs, prices and cost trends, with particular attention to factors that contribute to cost growth within the commonwealth's health care system and trends in annual primary care and behavioral health expenditures.

SECTION 7. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “payers” in line 16, the following words:- , significant equity investors, health care real estate investment trusts, management services organizations, pharmaceutical manufacturing companies, pharmacy benefit managers.

SECTION 8. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in lines 29 through 34, inclusive, the words “(x) at least 4 provider organizations, at least 2 of which shall be certified as accountable care organizations, 1 of which has been certified as a model ACO, which shall be from diverse geographic regions of the commonwealth; and (xi) any witness identified by the attorney general or the center” and inserting in place thereof the following words:- (x) at least 4 provider organizations which shall be from diverse geographic regions of the commonwealth, at least 2 of which shall be certified as accountable care organizations and 1 of which shall be certified as a model ACO; (xi) any significant equity investor, health care real estate investment trust or management services organization associated with a provider or provider organization; (xii) a representative from the division of insurance; (xiii) the executive director of the commonwealth health insurance connector authority; (xiv) the assistant secretary for MassHealth; (xv) not less than 2

representatives of the pharmacy benefit management industry; (xvi) not less than 3 representatives of pharmaceutical manufacturing companies, 1 of whom shall be a representative of a publicly traded company that manufactures specialty drugs, 1 of whom shall be a representative of a company that manufacturers generic drugs and 1 of whom shall be a representative of a company that has been in existence for fewer than 10 years; and (xvii) any witness identified by the attorney general or the center. The commission shall also request testimony from officials representing the federal Centers for Medicare and Medicaid Services.

SECTION 9. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in line 49, the first time it appears, the word “and”.

SECTION 10. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “commission”, in line 60, the first time it appears, the following words:- ; (iii) in the case of the assistant secretary for MassHealth, testimony concerning the structure, benefits, eligibility, caseload and financing of MassHealth and other Medicaid programs administered by the office of Medicaid or in partnership with other state and federal agencies and the agency’s activities to align or redesign those programs in order to encourage the development of more integrated and efficient health care delivery systems; (iv) in the case of pharmacy benefit managers and pharmaceutical manufacturing companies, testimony concerning factors underlying prescription drug costs and price increases, the impact of aggregate manufacturer rebates, discounts and other price concessions on net pricing; provided, however, that such testimony shall be suitable for public release and not likely to compromise the financial, competitive or proprietary nature of any information or data; and (v) in the case of significant equity investors, health care real estate investment trusts or management services organization associated with a provider or provider organization, testimony concerning health

outcomes, prices charged to insurers and patients, staffing levels, clinical workflow, financial stability and ownership structure of an associated provider or provider organization, dividends paid out to investors, compensation including, but not limited to, base salaries, incentives, bonuses, stock options, deferred compensations, benefits and contingent payments to officers, managers and directors of provider organizations in the commonwealth acquired, owned or managed, in whole or in part, by said significant equity investors, health care real estate investment trusts or management services organizations.

SECTION 11. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out subsection (g) and inserting in place thereof the following subsection:-

(g) The commission shall compile an annual report concerning spending trends, including primary care and behavioral health expenditures, and the underlying factors influencing said spending trends. The report shall be based on the commission's analysis of information provided at the hearings by witnesses, providers, provider organizations and payers, registration data collected pursuant to section 11, data collected or analyzed by the center pursuant to sections 8 to 10A, inclusive, 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. The report shall be submitted to the house and senate committees on ways and means and the joint committee on health care financing and shall be published and available to the public not later than December 31 of each year. The report shall include recommendations for strategies to increase the efficiency of the health care system and promote affordability for individuals and families, recommendations on the specific spending trends that impede the commonwealth's ability to meet the health care cost growth benchmark and draft legislation necessary to implement said recommendations.

SECTION 12. 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 13. Said section 9 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “organizations”, in line 82, the following words:- , pharmacy benefit managers, pharmaceutical manufacturing companies.

SECTION 14. Said chapter 6D is hereby further amended by inserting after section 22 the following section:-

Section 23. Every 2 years, the commission, in consultation with the center, the group insurance commission, the office of Medicaid and the division of insurance, shall evaluate the impact of section 17Z of chapter 32A, section 10Z of chapter 118E, section 47CCC of chapter 175, section 8DDD of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G on the effects of capping co-payments on health care costs, including premiums, pharmaceutical spending, aggregate rebates, cost-sharing, drug treatment utilization and adherence, incidence of related acute events and health equity. Biennially, not later than November 30, the commission shall file a report of its findings with the clerks of the house of representatives and senate, the chairs of the joint committee on public health, the chairs of the joint committee on health care financing and the chairs of house and senate committees on ways and means.

SECTION 15. Section 1 of chapter 12C of the General Laws, as appearing in the 2022 Official Edition, is hereby amended by inserting after the definition of “Patient-centered medical home” the following 3 definitions:-

"Payer", any entity, other than an individual, that pays providers for the provision of health care services; provided, however, that "payer" shall include both governmental and private entities; and provided further, that "payer" shall include self-insured plans to the extent allowed under the Employee Retirement Income Security Act of 1974.

"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 hospital licensed under section 51 of chapter 111, 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", as defined in section 1 of chapter 176Y.

SECTION 16. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by adding the following definition:-

"Wholesale acquisition cost", the cost of a prescription drug as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

SECTION 17. 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 18. 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 19. Section 5 of said chapter 12C, as so appearing, is hereby amended by inserting after the word “organizations”, in line 11, the following words:- , pharmacy benefit managers, pharmaceutical manufacturing companies.

SECTION 20. 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 21. Said chapter 12C is hereby further amended by striking out section 7, as amended by section 18 of chapter 140 of the acts of 2024, and inserting in place thereof the following section:-

Section 7. (a) For the purposes of this section, “non-hospital provider organization” shall mean a provider organization required to register under section 11 under chapter 6D that is: (i) a non-hospital-based physician practice with not less than $500,000,000 in annual gross patient service revenue; (ii) a clinical laboratory; (iii) an imaging facility; or (iv) a network of affiliated urgent care centers.

(b) Each acute hospital, ambulatory surgical center, non-hospital provider organization, pharmaceutical 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 which shall include any transfer made to the Community Hospital Reinvestment Trust Fund established in section 2TTTT of chapter 29.

(c) The assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations shall be not less than 30 per cent nor more than 40 per cent of the amount appropriated by the general court for the expenses of the center and for the other purposes described in this chapter which shall include any transfer made to the Community Hospital Reinvestment Trust Fund established in section 2TTTT of chapter 29 minus amounts collected from: (i) filing fees; (ii) fees and charges generated by the center'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; provided, however, that, to the maximum extent permissible under federal law, non-hospital provider organizations shall be assessed not less than 3 per cent nor more than 8 per cent of the total assessed amount for acute hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay such assessed amount multiplied by the ratio of the acute hospital's, ambulatory surgical center's or non-hospital provider organization's gross patient service revenues to the total gross patient services revenues of all such hospitals, ambulatory surgical centers and non-hospital provider organizations. Each acute hospital, ambulatory surgical center and non-hospital provider organization shall make a preliminary payment to the center on October 1 of each year in an amount equal to 1/2 of the previous year's total assessment. Thereafter, each acute hospital, ambulatory surgical center and non-hospital provider organization shall pay, within 30 days' notice from the center, the balance of the total assessment for the current year based upon its most current projected gross patient service revenue. The center shall subsequently adjust the

assessment for any variation in actual and estimated expenses of the center and for changes in acute hospital, ambulatory surgical center and non-hospital provider organization gross patient service revenue. Such estimated and actual expenses shall include an amount equal to the cost of fringe benefits and indirect expenses, as established by the comptroller under section 5D of chapter 29. In the event of late payment by any such acute hospital, ambulatory surgical center or non-hospital provider organization, the treasurer shall advance the amount of due and unpaid funds to the center prior to the receipt of such monies in anticipation of such revenues up to the amount authorized in the then current budget attributable to such assessments and the center shall reimburse the treasurer for such advances upon receipt of such revenues. This section shall not apply to any state institution or to any acute hospital which is operated by a city or town.

(d) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmaceutical manufacturing companies shall be not less than 5 per cent nor more than 10 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 center'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. Each pharmaceutical manufacturing company shall pay such assessed amount multiplied by the ratio of MassHealth's net spending for the manufacturer's prescription drugs used in the MassHealth rebate program to MassHealth's total pharmacy spending.

(e) To the maximum extent permissible under federal law, and provided that such assessment will not result in any reduction of federal financial participation in Medicaid, the assessed amount for pharmacy benefit managers shall be not less than 5 per cent nor more than

10 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 center'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. Each pharmacy benefit manager shall pay such assessed amount multiplied by the ratio of the claims paid by the pharmacy benefit manager attributed to residents of the commonwealth for whom it manages pharmaceutical benefits on behalf of carriers to the total of all such claims paid by all pharmacy benefit managers attributed to residents of the commonwealth for whom they manage pharmaceutical benefits on behalf of carriers.

(f) Each pharmaceutical manufacturing company and each pharmacy benefit manager shall make a preliminary payment to the center annually on October 1 in an amount equal to 1/2 of the previous year's total assessment. Thereafter, each pharmaceutical manufacturing company and each pharmacy benefit manager shall pay, within 30 days' notice from the center, the balance of the total assessment for the current year as determined by the center.

SECTION 22. 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 reporting of information from pharmacy benefit managers to enable the center to analyze: (i) year-over-year changes in wholesale acquisition cost; (ii) year-over-year trends in formulary, maximum allowable cost lists and cost-sharing design, including the establishment and management of specialty product lists; (iii) aggregate information regarding discounts, utilization limits, rebates, administrative fees charged to pharmaceutical manufacturing companies and

other financial incentives or concessions related to pharmaceutical products or formulary programs; (iv) trends in estimated aggregate drug rebates and other aggregate drug price reductions, if any, provided by a pharmacy benefit manager to a carrier client or health plan sponsor or passed through from a pharmacy benefit manager to a carrier client or health plan sponsor in connection with utilization of drugs in the commonwealth offered through the pharmacy benefit manager and a measure of lives covered by each carrier client or health plan sponsor in the commonwealth; and (v) any other information deemed reasonably necessary by the center by regulation.

(b) The center shall require the submission of available data and other information from pharmacy benefit managers including, but not limited to: (i) the aggregate amount of all rebates that the pharmacy benefit manager received from all pharmaceutical manufacturing companies and for all carrier clients or health plan sponsors; (ii) the administrative fees that the pharmacy benefit manager received from all carrier clients or health plan sponsors in the aggregate and for each carrier client or health plan sponsor individually; (iii) the aggregate amount of rebates a pharmacy benefit manager: (A) retains based on its contractual arrangement with each carrier client or health plan sponsor individually; and (B) passes through to each carrier client or health plan sponsor individually; (iv) the aggregate amount of all retained rebates that the pharmacy benefit manager received from all pharmaceutical manufacturing companies and did not pass through to each pharmacy benefit manager's carrier client or health plan sponsor individually; (v) the percentage of contracts that a pharmacy benefit manager holds where the pharmacy benefit manager: (A) retains all rebates; (B) passes all rebates through to the carrier client or health plan sponsor; and (C) shares rebates with the carrier client or health plan sponsor; and (vi)

information related to the pharmacy benefit manager practices of spread pricing, administrative fees, claw backs and formulary placement.

(c) Except as specifically provided otherwise under this chapter, data collected by the center pursuant to this section shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 and section 10 of chapter 66. No such data shall be disclosed in a manner that is likely to compromise the financial, competitive or proprietary nature of such data and other information, or that may identify specific prices charged for drugs, the value of any rebate amounts, individual drugs, or any pharmaceutical manufacturing company.

SECTION 23. Section 11 of said chapter 12C of the General Laws, as so appearing, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:- The center shall ensure the timely reporting of information required under sections 8 to 10A, inclusive.

SECTION 24. Section 12 of said chapter 12C, as appearing in the 2022 Official Edition, is hereby amended by striking out, in line 2, the words “8, 9 and 10” and inserting in place thereof the following words:- 8 to 10A, inclusive.

SECTION 25. 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 to 10A, inclusive, 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 cost and market impact reviews; and (iii) section 15 relative to quality data.

SECTION 26. Chapter 32A of the General Laws is hereby amended by inserting after section 17Y the following section:-

Section 17Z. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (A) any drug approved through an application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c); (B) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services under section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or (C) an authorized generic drug as defined in 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, including Medi-Span.

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined in 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.

(b) The commission shall identify 1 generic drug and 1 brand name drug used to treat each of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 2 most prevalent heart conditions among its members.

(c) The commission shall identify insulin as the drug used to treat diabetes. In determining the 1 generic drug and 1 brand name drug used to treat each chronic condition, the commission shall consider whether the drug is:

(i) of clear benefit and strongly supported by clinical evidence;

(ii) likely to: (A) reduce hospitalizations or emergency department visits; (B) reduce future exacerbations of illness progression; or (C) improve quality of life; (iii) cost effective for the commission and its members; (iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and (v) one of the most widely utilized as a treatment for the chronic condition.

(d) The commission shall provide coverage for the brand name drugs and generic drugs identified pursuant to subsection (b). Coverage for the identified generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible; provided, however, that cost-sharing shall be required if the applicable plan is governed by the Internal Revenue Code and would lose its tax-exempt status as a result of the prohibition on cost-sharing under this section. Coverage for the identified brand name drugs shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply. Coverage for 1 brand name insulin drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply.

(e) The commission shall implement a continuity of coverage policy to apply to members that are new to the commission and that provides coverage for a 30-day fill of a United States Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the member has already been prescribed and on which the member is stable, upon documentation by the member's prescriber; provided, however, that the commission shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs covered by the plan.

(f) The commission may make changes in its selection of drugs pursuant to this section not more than annually.

(g) The commission shall make public the drugs selected pursuant to subsection (b).

SECTION 27. Chapter 94C of the General Laws is hereby amended by inserting after section 21B the following section:-

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

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

"Health benefit plan", as defined in section 1 of chapter 176O.

"Pharmacy benefit manager", as defined in section 1 of chapter 176Y.

"Pharmacy retail price", the amount an individual would pay for a prescription drug at a pharmacy if the individual purchased that prescription drug at that pharmacy without using a health benefit plan or any other prescription medication benefit or discount.

(b) At the point of sale, a pharmacy shall charge an individual for a prescription drug the lesser of: (i) the applicable cost-sharing amount; or (ii) the pharmacy retail price.

(c) A health benefit plan or carrier shall not require an insured to make a cost-sharing payment for a prescription drug in an amount greater than that charged pursuant to subsection (b).

(d) No contractual obligation between a pharmacy benefit manager and a pharmacist shall prohibit a pharmacist from complying with this section.

SECTION 28. Chapter 118E of the General Laws is hereby amended by inserting after section 10Y the following section:-

Section 10Z. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (A) any drug approved through an application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c); (B) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services under section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or (C) an authorized generic drug as defined in 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, including Medi-Span.

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined in 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, including Medi-Span.

(b) The division shall identify 1 generic drug and 1 brand name drug used to treat each of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 2 most prevalent heart conditions among its enrollees.

(c) The division shall identify insulin as the drug used to treat diabetes. In determining the 1 generic drug and 1 brand name drug used to treat each chronic condition, the division shall consider whether the drug is:

(i) of clear benefit and strongly supported by clinical evidence;

(ii) likely to: (A) reduce hospitalizations or emergency department visits: (B) reduce future exacerbations of illness progression; or (C) improve quality of life;

(iii) cost effective for the division and its enrollees;

(iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and

(v) one of the most widely utilized as a treatment for the chronic condition.

(d) The division and its contracted health insurers, health plans, health maintenance organizations, behavioral health management firms and third-party administrators under contract to a Medicaid managed care organization or primary care clinician plan shall provide coverage for the brand name drugs and generic drugs identified pursuant to subsection (b). Coverage for the identified generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible. Coverage for identified brand name drugs shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply. Coverage for 1 brand name insulin drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply.

(e) This section shall not apply to health plans providing coverage in the senior care options program to MassHealth-only members who are age 65 or older.

(f) The division shall implement a continuity of coverage policy that apply to enrollees that are new to the Medicaid program and that provides coverage for a 30-day fill of a United States Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the enrollee has already been prescribed and on which the enrollee is stable, upon documentation by the enrollee’s prescriber; provided, however, that the division shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs covered by the plan.

(g) The division may make changes in its selection of drugs pursuant to this section not more than annually.

(h) The division shall make public the drugs selected pursuant to subsection (b).

SECTION 29. Section 64 of said chapter 118E is hereby amended by striking out the definition of "Center for health information and analysis revenue amount", inserted by section 120 of chapter 140 of the acts of 2024, and inserting in place thereof the following definition:-

"Center for health information and analysis revenue amount", an amount equal to the sum of the amount collected by the center for health information and analysis from acute hospitals, ambulatory surgical centers and non-hospital provider organizations pursuant to section 7 of chapter 12C.

SECTION 30. Said section 64 of said chapter 118E is hereby further amended by striking out the definition "Health policy commission revenue amount", inserted by section 121 of said chapter 140, and inserting in place thereof the following definition:-

"Health policy commission revenue amount", the amount collected by the health policy commission from acute hospitals, ambulatory surgical centers and non-hospital provider organizations pursuant to section 6 of chapter 6D.

SECTION 31. Chapter 175 of the General Laws is hereby amended by inserting after section 47BBB the following section:-

Section 47CCC. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (A) any drug approved through an application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that

is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c); (B) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services under section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or (C) an authorized generic drug as defined in 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, including Medi-Span.

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined in 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, including Medi-Span.

(b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth and which is considered creditable coverage under section 1 of chapter 111M shall identify 1 generic drug and 1 brand name drug used to treat each of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 2 most prevalent heart conditions among its enrollees.

(c) The carrier shall identify insulin as the drug used to treat diabetes. In determining the 1 generic drug and 1 brand name drug used to treat each chronic condition, the carrier shall consider whether the drug is:

(i) of clear benefit and strongly supported by clinical evidence;

(ii) likely to: (A) reduce hospitalizations or emergency department visits; (B) reduce future exacerbations of illness progression; or (C) improve quality of life;

(iii) cost effective for the carrier and its enrollees;

(iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and

(v) one of the most widely utilized as a treatment for the chronic condition.

(d) Any such policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth, which is considered creditable coverage under section 1 of chapter 111M, shall provide coverage for the brand name drugs and generic drugs identified pursuant to subsection (b). Coverage for the identified generic drugs shall not be subject to cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible; provided, however, that cost-sharing shall be required if the applicable plan is governed by the Internal Revenue Code and would lose its tax-exempt status as a result of the prohibition on cost-sharing under this section. Coverage for identified brand name drugs shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply. Coverage for 1 brand name insulin drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply.

(e) The carrier shall implement a continuity of coverage policy to apply to enrollees that are new to the carrier and that provides coverage for a 30-day fill of a United States Food and

Drug Administration-approved drug reimbursed through a pharmacy benefit that the enrollee has already been prescribed and on which the enrollee is stable, upon documentation by the enrollee's prescriber; provided, however, that a carrier shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs covered by the plan.

(f) The carrier may make changes in its selection of drugs pursuant to this section not more than annually.

(g) The carrier shall make public the drugs selected pursuant to subsection (b).

SECTION 32. Section 226 of said chapter 175, as appearing in the 2022 Official Edition, is hereby amended by striking out, in line 81, the word "may" and inserting in place thereof the following word:- shall.

SECTION 33. Chapter 176A of the General Laws is hereby amended by inserting after 8CCC the following section:-

Section 8DDD. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (A) any drug approved through an application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c); (B) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services

under section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or (C) an authorized generic drug as defined in 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, including Medi-Span.

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined in 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, including Medi-Span.

(b) Any contract between a subscriber and the corporation under an individual or group hospital service plan that is delivered, issued or renewed within the commonwealth shall identify 1 generic drug and 1 brand name drug used to treat each of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 2 most prevalent heart conditions among its enrollees.

(c) The carrier shall identify insulin as the drug used to treat diabetes. In determining the 1 generic drug and 1 brand name drug used to treat each chronic condition, the carrier shall consider whether the drug is:

(i) of clear benefit and strongly supported by clinical evidence;

(ii) likely to: (A) reduce hospitalizations or emergency department visits; (B) reduce future exacerbations of illness progression; or (C) improve quality of life;

(iii) cost effective for the carrier and its enrollees;

(iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and

(v) one of the most widely utilized as a treatment for the chronic condition.

(d) Any contract between a subscriber and the corporation under an individual or group hospital service plan that is delivered, issued or renewed within the commonwealth shall provide coverage for the brand name drugs and generic drugs identified pursuant to subsection (b). Coverage for the identified generic drugs shall not be subject to cost-sharing, including co-payments and co-insurance, and shall not be subject to any deductible; provided, however, that cost-sharing shall be required if the applicable plan is governed by the Internal Revenue Code and would lose its tax-exempt status as a result of the prohibition on cost-sharing under this section. Coverage for identified brand name drugs shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply. Coverage for 1 brand name insulin drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply.

(e) The carrier shall implement a continuity of coverage policy to apply to enrollees that are new to the plan and that provides coverage for a 30-day fill of a United States Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the enrollee has already been prescribed and on which the enrollee is stable, upon documentation by the enrollee’s prescriber; provided, however, that a carrier shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs covered by the plan.

(f) The carrier may make changes in its selection of drugs pursuant to this section not more than annually.

(g) The carrier shall make public the drugs selected pursuant to subsection (b).

SECTION 34. Chapter 176B of the General Laws is hereby amended by inserting after section 4CCC the following section:-

Section 4DDD. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (A) any drug approved through an application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c); (B) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services under section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or (C) an authorized generic drug as defined in 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, including Medi-Span.

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined in 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, including Medi-Span.

(b) A subscription certificate under an individual or group medical service agreement delivered, issued or renewed within the commonwealth shall identify 1 generic drug and 1 brand name drug used to treat each of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 2 most prevalent heart conditions among its enrollees.

(c) The carrier shall identify insulin as the drug used to treat diabetes. In determining the 1 generic drug and 1 brand name drug used to treat each chronic condition, the carrier shall consider whether the drug is:

(i) of clear benefit and strongly supported by clinical evidence;

(ii) likely to: (A) reduce hospitalizations or emergency department visits; (B) reduce future exacerbations of illness progression; or (C) improve quality of life;

(iii) cost effective for the carrier and its enrollees;

(iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and

(v) one of the most widely utilized as a treatment for the chronic condition.

(d) A subscription certificate under an individual or group medical service agreement delivered, issued or renewed within the commonwealth shall provide coverage for the brand name drugs and generic drugs identified pursuant to subsection (b). Coverage for the identified generic drugs shall not be subject to any cost-sharing, including co-payments and co-insurance and shall not be subject to any deductible; provided, however, that cost-sharing shall be required if the applicable plan is governed by the Internal Revenue Code and would lose its tax-exempt

status as a result of the prohibition on cost-sharing under this section. Coverage for identified brand name drugs shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply. Coverage for 1 brand name insulin drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply.

(e) The carrier shall implement a continuity of coverage policy to apply to enrollees that are new to the plan and that provides coverage for a 30-day fill of a United States Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the enrollee has already been prescribed and on which the enrollee is stable, upon documentation by the enrollee's prescriber; provided, however, that a carrier shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs covered by the plan.

(f) The carrier may make changes in its selection of drugs pursuant to this section not more than annually.

(g) The carrier shall make public the drugs selected pursuant to subsection (b).

SECTION 35. Chapter 176G of the General Laws is hereby amended by inserting after section 4UU the following section:-

Section 4VV. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Brand name drug", a drug that is: (i) produced or distributed pursuant to an original new drug application approved under 21 U.S.C. 355(c) except for: (A) any drug approved through an application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that is pharmaceutically equivalent, as that term is defined by the United States Food and Drug Administration, to a drug approved under 21 U.S.C. 355(c); (B) an abbreviated new drug application that was approved by the United States Secretary of Health and Human Services under section 505(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c), before the date of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585; or (C) an authorized generic drug as defined in 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, including Medi-Span.

"Generic drug", a retail drug that is: (i) marketed or distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j); (ii) an authorized generic drug as defined in 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, including Medi-Span.

(b) An individual group health maintenance contract that is issued or renewed within or without the commonwealth shall identify 1 generic drug and 1 brand name drug used to treat each of the following chronic conditions: (i) diabetes; (ii) asthma; and (iii) the 2 most prevalent heart conditions among its enrollees.

(c) The carrier shall identify insulin as the drug used to treat diabetes. In determining the 1 generic drug and 1 brand name drug used to treat each chronic condition, the carrier shall consider whether the drug is:

(i) of clear benefit and strongly supported by clinical evidence to be cost-effective;

(ii) likely to: (A) reduce hospitalizations or emergency department visits; (B) reduce future exacerbations of illness progression; or (C) improve quality of life;

(iii) cost effective for the carrier and its enrollees;

(iv) at low risk for overutilization, abuse, addiction, diversion or fraud; and

(v) one of the most widely utilized as a treatment for the chronic condition.

(d) An individual group health maintenance contract that is issued or renewed within or without the commonwealth shall provide coverage for the brand name drugs and generic drugs identified pursuant to subsection (b). Coverage for the identified generic drugs shall not be subject to cost-sharing, including co-payments and co-insurance and shall not be subject to any deductible; provided, however, that cost-sharing shall be required if the applicable plan is governed by the Internal Revenue Code and would lose its tax-exempt status as a result of the prohibition on cost-sharing under this section. Coverage for identified brand name drugs shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply. Coverage for 1 brand name insulin drug per dosage and type, including rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed under this section shall not be subject to any deductible or co-insurance and any co-payment shall not exceed $25 per 30-day supply.

(e) The carrier shall implement a continuity of coverage policy to apply to enrollees that are new to the plan and that provides coverage for a 30-day fill of a United States Food and Drug Administration-approved drug reimbursed through a pharmacy benefit that the enrollee has already been prescribed and on which the enrollee is stable, upon documentation by the enrollee's prescriber; provided, however, that a carrier shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other drugs covered by the plan.

(f) The carrier may make changes in its selection of drugs pursuant to this section not more than annually.

(g) The carrier shall make public the drugs selected pursuant to subsection (b).

SECTION 36. Chapter 176O of the General Laws is hereby amended by adding the following section:-

Section 30. (a) On an annual basis, each carrier shall report to the division the drugs selected to be provided with no or limited cost-sharing under section 47CCC of chapter 175, section 8DDD of chapter 176A, section 4DDD of chapter 176B and section 4VV of chapter 176G. The commissioner shall review the drugs to verify that the selected drugs meet the criteria identified in those sections. Should a selected drug be deemed by the commissioner to not meet the criteria, the commissioner may require a different drug to be selected. The commissioner shall disclose the list of drugs selected by each entity annually on the division's website.

SECTION 37. The General Laws are hereby amended by inserting after chapter 176X the following chapter:-

CHAPTER 176Y

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", as defined in section 1 of chapter 176O.

"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.

"Insured", as defined in section 1 of chapter 176O.

"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.

"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 management services", services performed by a pharmacy benefit manager, including: (i) negotiating the price of prescription drugs, including negotiating and contracting for direct or indirect rebates, discounts or other price concessions; (ii) managing any aspects of a prescription drug benefit, including, but not limited to, formulary administration, mail-order pharmacy and specialty drug pharmacy services, clinical, safety and adherence programs for pharmacy service, the processing and payment of claims for prescription drugs, arranging alternative access to or funding for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs and managing or providing data relating to the prescription drug benefit or the provision of services related thereto; (iii) performance of any administrative, managerial, clinical, pricing, financial, reimbursement, data administration or reporting or billing service related to a health benefit plan's prescription drug benefit; and (iv) such other services as the division may define in regulation.

"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 manager" shall not include a health benefit plan sponsor unless otherwise specified by the division.

Section 2. (a) No person, business or other entity shall establish or operate as a pharmacy benefit manager without obtaining a license from the division pursuant to this section. A license may be granted only when the division is satisfied that the entity possesses the necessary

organization, background expertise financial integrity to supply the services sought to be offered. A pharmacy benefit manager license shall be valid for a period of 3 years and shall be renewable for additional 3-year periods. The commissioner shall charge application and renewal fees in the amount of $25,000.

(b) A license granted pursuant to this section and any rights or interests therein shall not be transferable.

(c) A person, business or other entity licensed as a pharmacy benefit manager shall submit data and reporting information to the center according to the standards and methods specified by the center pursuant to section 10A of chapter 12C.

(d) The division may issue or renew a license pursuant to this section, subject to restrictions in order to protect the interests of consumers. Such restrictions may include: (i) limiting the type of services that a license holder may provide or (ii) limiting the activities in which the license holder may be engaged.

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

contained in its application, certified by an officer of the pharmacy benefit manager, within 30 days of such a change.

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

The division shall provide written notice to the applicant or pharmacy benefit manager and advise in writing of the reason for any suspension, revocation, refusal to issue or renew or placement on probation of a pharmacy benefit manager license under this chapter. A copy of the notice shall be forwarded to the center. The applicant or pharmacy benefit manager may make written demand upon the division within 30 days of receipt of such notification for a hearing before the division to determine the reasonableness of the division's action. The hearing shall be held pursuant to chapter 30A.

The division shall not suspend or cancel a license unless the division has first afforded the pharmacy benefit manager an opportunity for a hearing pursuant to said chapter 30A.

(g) If a person, business or other entity performs the functions of a pharmacy benefit manager in violation of this chapter, the person, business or other entity shall be subject to a fine of $5,000 per day for each day that the person, business or other entity is found to be in violation.

(h) A pharmacy benefit manager that violates this chapter or any rule or regulation promulgated pursuant to this chapter shall be subject to a fine of not less than $5,000 for each violation.

(i) A pharmacy benefit manager licensed under this section shall notify a 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 carrier client.

(j) The division shall promulgate rules and regulations necessary for the implementation, administration and enforcement of this chapter.

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

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

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

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

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

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

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

(e) Notwithstanding any general or special law to the contrary, including clause Twenty-sixth of section 7 of chapter 4 and section 10 of chapter 66, the records of any such audit, examination or other inspection and the information contained in the records, reports or books of any pharmacy benefit manager examined pursuant to this section shall be confidential and open only to the inspection of the commissioner, or the examiners and assistants. Access to such confidential material may be granted by the commissioner to law enforcement officials of the commonwealth or any other state or agency of the federal government at any time if the agency or office receiving the information agrees in writing to keep such material confidential. Nothing in this subsection shall be construed to prohibit the required production of such records, and information contained in the reports of such company or organization before any court of the commonwealth or any master or auditor appointed by any such court, in any criminal or civil proceeding, affecting such pharmacy benefit manager, its officers, partners, directors or employees. The final report of any such audit, examination or any other inspection by or on behalf of the division of insurance shall be a public record.

Section 4. (a) A pharmacy benefit manager shall not make payments to a pharmacy benefit consultant or broker whose services were obtained by a health benefit plan sponsor to work on the pharmacy benefit bidding or contracting process if the payment constitutes a conflict of interest, as determined by the commissioner. For purposes of this section, payments from a pharmacy benefit manager to a pharmacy benefit consultant or broker shall include, but not be limited to: (i) shared rebates from pharmaceutical manufacturers; (ii) per prescription fees; (iii) per member fees; (iv) referral fees; (v) bonuses; or (vi) any other financial arrangement the commissioner considers to be a conflict of interest.

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

SECTION 38. The assessments in section 6 of chapter 6D of the General Laws, as amended by section 5, and in section 7 of chapter 12C of the General Laws, as amended by section 21, shall apply to the budgets for the health policy commission and the center for health information and analysis, respectively, beginning in fiscal year 2026; provided, however, that each pharmaceutical manufacturing company and each pharmacy benefit manager shall make a preliminary payment to the commission on October 1, 2025 in an amount equal to 1/2 of the initial year's total assessment, as determined by the commission and center, respectively, and thereafter shall pay, within 30 days of receiving notice, the balance of the total assessment for the initial year.

SECTION 39. Sections 26, 28, 31, 33, 34, and 35 shall apply to all contracts entered into, renewed or amended on or after July 1, 2025.

SECTION 40. The commissioner of insurance shall promulgate regulations to implement chapter 176Y of the General Laws not later than October 1, 2025.

SECTION 41. All pharmacy benefit managers operating within the commonwealth shall be licensed in accordance with said chapter 176Y not later than January 1, 2026.