HOUSE . . . . . No. 4910

Text of amendments, recommended by the committee on Ways and Means (see House document numbered 4891), to the Senate Bill relative to pharmaceutical access, costs and transparency (Senate, No. 2520), as amended by the House. July 24, 2024.

The Commonwealth of Massachusetts

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

By striking out all after the enacting clause and inserting in place thereof the following:–

SECTION 1. Section 1 of chapter 6D, as appearing in the 2022 Official Edition, is hereby amended by striking out the definition of "Payer" and inserting in place thereof the following definition:-

"Payer", any entity, other than an individual, that pays providers for the provision of health care services, including self-insured plans to the extent allowed under the federal Employee Retirement Income Security Act of 1974.

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 is hereby established within the commission an office for pharmaceutical policy and analysis, hereinafter referred to as the office. The office shall: (i) analyze pharmaceutical spending data and information collected by the commission under this chapter and other agencies of the commonwealth pursuant to subsection (b); (ii) produce reports and analyses of issues 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 10B, 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 issues related to access, affordability and spending on pharmaceutical drugs in the commonwealth and other reports as the office may produce from time to time. The annual report shall address trends and underlying factors for pharmaceutical drug spending, including an analysis of: (i) prices and utilization; (ii) drugs or categories of drugs with the highest impact on spending; (iii) trends in patient out-of-pocket spending; and (iv) access and affordability issues for patients with rare diseases and chronic diseases; provided, that any analysis 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 impacts of aggregate rebates, discounts and other price concessions on such cost-sharing; and (v) the impacts 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 10B, 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 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, not later than September 1, the report shall be submitted to the chairs of the house and senate committees on ways and means and the chairs of 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, as so appearing, 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 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, that non-hospital provider organizations shall be assessed not less than 3 per cent nor more than 8 per cent of the assessed amount for 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 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 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 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 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) 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 based on the manufacturer labeler codes used in the MassHealth rebate program to MassHealth's total pharmacy spending.

(e) 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 aggregate revenues of 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 revenues generated by all pharmacy benefit managers attributed to residents of the commonwealth for whom they manage pharmaceutical benefits on behalf of carriers.

SECTION 6. Section 8 of said chapter 6D, as so appearing, is hereby amended by inserting after the word “organization”, in lines 6 and 7, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 7. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by inserting after the word “organizations”, in line 15, the following words:- , pharmacy benefit managers, pharmaceutical manufacturing companies.

SECTION 8. Said section 8 of said chapter 6D, as so appearing, is hereby further amended by striking out, in lines 33 and 34, the words “and (xi) any witness identified by the attorney general or the center” and inserting in place thereof the following words:- (xi) not less than 2 representatives of the pharmacy benefit management industry; (xii) 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 (xiii) any witness identified by the attorney general or the commission.

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 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 (iv) any other matters as determined by the commission.

SECTION 11. Subsection (g) of said section 8 of said chapter 6D, as so appearing, is hereby amended by striking out the second sentence and inserting in place thereof the following sentence:- The report shall be based on the commission's analysis of information provided at the hearings by witnesses, providers, provider organizations, carriers, pharmacy benefit managers and pharmaceutical manufacturing companies, registration data collected pursuant to section 11, data collected or analyzed by the center pursuant to sections 8 to 10B, inclusive, of chapter 12C and any other available information, as defined in regulations promulgated by the commission, that the commission considers necessary to fulfill its duties under this section.

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 adding the following section:-

Section 22. 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 17T of chapter 32A, section 10R of chapter 118E, section 47VV of chapter 175, section 8WW of chapter 176A, section 4WW of chapter 176B and section 4OO 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 "Dispersed service area" the following definition:-

"Drug rebate", any: (i) negotiated price concessions, whether described as a rebate or otherwise, including, but not limited to, base price concessions, and reasonable estimates of any price protection rebates and performance-based price concessions that may accrue, directly or indirectly, to a carrier, pharmacy benefit manager or other party on a carrier's behalf during a carrier's plan year from a pharmaceutical manufacturing company, dispensing pharmacy or other party to the transaction based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter; and (ii) reasonable estimates of any price concessions, fees and other administrative costs that are passed through or are reasonably anticipated to be passed through to the carrier, pharmacy benefit manager or other party on the

carrier's behalf and that serve to reduce the carrier's prescription drug liabilities for the plan year based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter.

SECTION 16. Said section 1 of said chapter 12C, as so appearing, is hereby further amended by inserting after the definition of "Patient-centered medical home" the following 3 definitions:-

"Payer", any entity, other than an individual, that pays providers for the provision of health care services, including self-insured plans to the extent allowed under the federal 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 17. 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. section 1395w-3a(c)(6)(B).

SECTION 18. 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:- , pharmacy benefit managers, pharmaceutical manufacturing companies.

SECTION 19. Said section 3 of said chapter 12C, as so appearing, is hereby further amended by inserting, after the word “provider”, in line 24, the following words:- , pharmacy benefit manager, pharmaceutical manufacturing company.

SECTION 20. 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 21. Said section 5 of said chapter 12C, as so appearing, is hereby further amended by inserting after the word “providers”, in line 15, the following words:- , affected pharmacy benefit managers, affected pharmaceutical manufacturing companies.

SECTION 22. Said chapter 12C is hereby further amended by striking out section 7, as so appearing, 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 and non-hospital provider organization 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 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, that non-hospital provider organizations shall be assessed not less than 3 per cent nor more than 8 per cent of the assessed amount for 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 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 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 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 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) 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 based on the manufacturer labeler codes used in the MassHealth rebate program to MassHealth's total pharmacy spending.

(e) 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 aggregate revenues of 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 revenues generated by all pharmacy benefit managers attributed to residents of the commonwealth for whom they manage pharmaceutical benefits on behalf of carriers.

SECTION 23. Said chapter 12C is hereby further amended by inserting after section 10 the following 2 sections:-

Section 10A. The center shall promulgate regulations necessary to ensure the uniform reporting of information from pharmacy benefit managers that enables 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, utilizations limits, rebates, manufacturer administrative fees and other financial incentives or concessions related to pharmaceutical products or formulary programs; (iv) information regarding the aggregate amount of payments made from a pharmacy benefit manager to pharmacies owned or controlled by the pharmacy benefit manager, and the aggregate amount of payments made from a pharmacy benefit manager to pharmacies that are not owned or controlled by the pharmacy benefit manager; (v) data necessary for monitoring and enforcement of chapter 176Y and regulations promulgated thereof; and (vi) any other additional information deemed reasonably necessary by the center as set forth in the center's regulations.

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

"Cost to the commonwealth", the cost incurred for outpatient prescription drugs by the office of Medicaid and the group insurance commission.

"Substantial net increase", an increase in the wholesale acquisition cost less rebates paid to the state and payers in the commonwealth, of not less than 25 per cent in the immediate prior calendar year.

(b)(1) Annually, not later than March 31, the center shall prepare a list of not more than 10 outpatient prescription drugs that the center determines: (i) are provided at a substantial cost to the commonwealth considering the net cost of such drugs; and (ii) experienced a substantial net increase. The list shall include outpatient prescription drugs from different therapeutic classes and not more than 3 generic outpatient prescription drugs.

(2) Prior to publishing the annual list pursuant to paragraph (1), the center shall prepare a preliminary list that includes outpatient prescription drugs that the center plans to include on such annual list. The center shall make such preliminary list available for public comment for not less than 30 days. During the public comment period, any manufacturer of an outpatient prescription drug included on the preliminary list may produce documentation, as permitted by federal law, to the center to establish that such drug did not experience a substantial net increase. If such documentation establishes, to the satisfaction of the center, that a substantial net increase did not occur, the center shall, not later than 15 days after the closing of the public comment period, remove such drug from the preliminary list before publishing the annual list pursuant to paragraph (1).

(c) The pharmaceutical manufacturing company that manufacturers a prescription drug included on the annual list prepared by the center pursuant to paragraph (1) of subsection (b) shall provide to the center the following:

(i) a written, narrative description, suitable for public release, of factors that caused the increase in the wholesale acquisition cost of the listed prescription drug; and

(ii) aggregate, company-level research and development costs and such other capital expenditures that the center deems relevant for the most recent calendar year for which final audited data is available.

(d) The quality and types of information and data that a pharmaceutical manufacturing company submits to the center pursuant to this section shall be consistent with the quality and types of information and data that the pharmaceutical manufacturing company includes in: (i) such pharmaceutical manufacturing company's annual consolidated report on Securities and Exchange Commission Form 10-K; or (ii) any other public disclosure.

(e) The center shall consult with pharmaceutical manufacturing companies to establish a single, standardized form for reporting information and data pursuant to this section. The form shall minimize the administrative burden and cost imposed on the center and pharmaceutical manufacturing companies.

(f) The center shall compile an annual report based on the information that the center receives pursuant to subsection (c). The center shall publish such report and the information described in this section on the center's website not later than October 1 of each year.

(g) Except as otherwise provided in this section, information and data submitted to the center pursuant to this section shall not be a public record and shall be exempt from disclosure pursuant to clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66. No such information and data shall be disclosed in a manner that may: (i) compromise the financial, competitive or proprietary nature of such information and data; or (ii) enable a third-party to identify: (A) an individual drug, therapeutic class of drugs or pharmaceutical manufacturing company; (B) the prices charged for any particular drug or therapeutic class of drugs; or (C) the value of any rebate provided for any particular drug or class of drugs.

SECTION 24. Said chapter 12C is hereby further amended by striking out section 11, as appearing in the 2022 Official Edition, and inserting in place thereof the following section:-

Section 11. The center shall ensure the timely reporting of information required under sections 8 to 10B, inclusive. The center shall notify payers, providers, provider organizations, pharmacy benefit managers and pharmaceutical manufacturing companies of any applicable reporting deadlines. The center shall notify, in writing, a payer, provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that has failed to meet a reporting deadline of such failure and that failure to respond within 2 weeks of the receipt of the notice may result in penalties. The center may assess a penalty against a payer, provider, provider organization, pharmacy benefit manager or pharmaceutical manufacturing company that fails, without just cause, to provide the requested information not later than 2 weeks following receipt of the written notice required under this section, of not more than $25,000 per week for each week of delay after the 2-week period following receipt of the notice. Amounts collected under this section shall be deposited in the Healthcare Payment Reform Fund established in section 100 of chapter 194 of the acts of 2011.

SECTION 25. Section 12 of said chapter 12C, as so appearing, 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 10B, inclusive.

SECTION 26. 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 pursuant to: (i) sections 8 to 10B, inclusive, concerning health care provider, provider organization, pharmacy benefit manager, pharmaceutical manufacturing company and private and public health care payer costs and cost and price trends; (ii) section 13 of chapter 6D relative to market impact reviews; and (iii) section 15 relative to quality data.

SECTION 27. Chapter 32A of the General Laws is hereby amended by inserting after section 17S the following section:-

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

“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 federal 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 such as 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 most prevalent heart condition 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 reduce hospitalizations or emergency department visits, reduce future exacerbations of illness progression or 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. 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 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, 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 shall make changes in the drugs selected pursuant to this section not more than annually.

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

SECTION 28. 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", as defined in section 1 of chapter 176Y.

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

"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 as between a pharmacy benefit manager and a pharmacist shall prohibit a pharmacist from complying with this section.

SECTION 28A. Chapter 111 of the General Laws is hereby amended by adding the following section:-

Section 245. (a) The department shall implement a provider immunization brand choice requirement as part of the commonwealth's universal immunization program under section 24I, routine childhood immunizations under 24N; the Vaccines for Children Program operated by the department under the authority of 42 U.S.C. §1396s; and in any other existing or future immunization program for children or adults administered by the commonwealth using local, state or federal funds.

(b) For all categories of immunizations included in subsection (a), all participating health care providers shall be able to select any brand or type of immunization, including any combination immunization and dosage form, as long as the immunization is licensed or authorized for emergency use by the federal Food and Drug Administration and recommended by the federal Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. The department shall not limit the ability of such health care providers to provide an immunization by limiting the supply of immunizations purchased by the department. This section shall not apply in the event of a shortage or delay in vaccine availability, disaster or public health emergency, terrorist attack, hostile military or paramilitary action, or extraordinary law enforcement emergency.

(c) The department shall, for the purposes of the purchase, delivery and administration of vaccines, use the Center for Disease Control and Prevention vaccine list established, and periodically reviewed and revised, by the federal Centers for Disease Control and Prevention Advisory Committee on Immunization Practices.

(d) The department shall implement all or part of the provider immunization brand choice requirement as soon as practicable; provided, however, that the department shall complete full implementation of the system not later than July 1, 2025.

SECTION 28B. Chapter 112 of the General Laws is hereby amended by inserting after section 38 the following section:-

Section 38A. (a) For the purposes of this section, a “pharmacy desert” shall mean an area where there is no or limited access to pharmacies due to factors, but not limited to: (i) geographic location, specifically areas where the nearest pharmacy is more than 1 mile away in urban areas,

more than 5 miles away in suburban areas, and more than 10 miles away in rural areas; (ii) distance and travel time, defined as travel time exceeding 15 minutes by car or 30 minutes by public transportation; (iii) limited access to transportation, both public and private, including areas with infrequent public transit services or where at least 20 per cent of the population lacks access to private vehicles.

(b) Any entity that intends to close a pharmacy or pharmacy department registered by the board for the transaction of a "drug business", as defined in section 37, shall notify the board in writing at least 60 days before the proposed closure date. The entity shall send a copy of the notice to the members of the General Court who represent the municipality in which the pharmacy or pharmacy department is located, and the clerk of the municipality in which the pharmacy or pharmacy department is located, who shall distribute the notice to the appropriate local officials. Within 15 days of receipt of the notice of the intended closing, the board shall conduct a review to determine whether the intended closing is likely to result in the creation of a pharmacy desert. If the board finds that the intended closing is likely to result in the creation of a pharmacy desert, the board shall conduct a public hearing not later than 45 calendar days prior to the proposed closure date set out in the entity's notice. At the public hearing, the board shall present information on alternative sources of pharmacy services available to impacted consumers and allow interested parties the opportunity to share comments and concerns about the proposed closure. Such interested parties may include, but not be limited to, impacted residents, municipal government officials, the members of the General Court who represent the municipality in which the pharmacy or pharmacy department is located, local health care providers, and neighborhood associations or other community associations.

SECTION 29. Chapter 118E of the General Laws is hereby amended by inserting after section 10Q the following section:-

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

"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 federal 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 such as 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 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 most prevalent heart condition 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 reduce hospitalizations or emergency department visits, reduce future exacerbations of illness progression or 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 provision shall not apply to health plans providing coverage in the senior care options program to MassHealth-only members who are ages 65 and 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, 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 shall make changes in the drugs selected pursuant to this section not more than annually.

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

SECTION 29A. Said chapter 118E is hereby further amended by striking out section 13L, as so appearing, and inserting in place thereof the following section:-

Section 13L. The secretary of health and human services, hereinafter "the secretary", shall not take any actions, including through managed care entities as defined in section 13D½, that restrict or limit an eligible hospital's access to the discounted purchase of prescription drugs to the full extent permitted under section 340B of the Public Health Service Act, as codified under 42 U.S.C. 256b unless the secretary provides the following not less than 180 days before

the proposed effective date of the limitation or restriction: (i) notice to eligible hospitals of the proposed restriction or limitation; and (ii) a report with the joint committee on health care financing and the senate and house committees on ways and means detailing: (A) the proposed restriction or limitation; (B) the anticipated aggregate savings to the commonwealth; (C) the estimated fiscal impact of the restriction or limitation on each affected hospital; and (D) the manner in which the secretary plans to mitigate the fiscal impact, which may include measures to maintain savings already achieved by providers under said 42 U.S.C. 256b. Notwithstanding the preceding sentence, the secretary shall not designate greater than 25 prescription drugs at any given time to be restricted or limited from the discounts afforded to eligible hospitals under said 42 U.S.C. 256b; provided, that no prescription drug may be designated by the secretary unless the gross cost of such prescription drug is not less than $100,000 per utilizer per year; provided further, that no GLP-1 antagonist drug not already designated by the secretary as of July 1, 2024 shall be so designated.

SECTION 30. Chapter 175 of the General Laws is hereby amended by inserting after section 47UU, added by section 56 of chapter 28 of the acts of 2023, the following section:-

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

“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 federal 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 such as 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) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth, which is considered credible 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 most prevalent heart condition 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 reduce hospitalizations or emergency department visits, reduce future exacerbations of illness progression or 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 credible coverage under section 1 of chapter 111M, shall provide coverage for the brand name drugs and generic drugs identified pursuant to paragraph (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) 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, 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 shall make changes in the drugs selected pursuant to this section not more than annually.

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

SECTION 31. Section 226 of said chapter 175 is hereby repealed.

SECTION 32. Chapter 176A of the General Laws is hereby amended by inserting after section 8VV, added by section 58 of chapter 28 of the acts of 2023, the following section:-

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

"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 federal 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 such as 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) 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 most prevalent heart condition 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 reduce hospitalizations or emergency department visits, reduce future exacerbations of illness progression or 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 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) 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, 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 shall make changes in the drugs selected pursuant to this section not more than annually.

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

SECTION 33. Chapter 176B of the General Laws is hereby amended by inserting after section 4VV, added by section 59 of chapter 28 of the acts of 2023, the following section:-

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

"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 federal 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 such as 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) 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 most prevalent heart condition 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 reduce hospitalizations or emergency department visits, reduce future exacerbations of illness progression or 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. 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, 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 shall make changes in the drugs selected pursuant to this section not more than annually.

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

SECTION 34. Chapter 176G of the General Laws is hereby amended by inserting after section 4NN, added by section 60 of chapter 28 of the acts of 2023, the following section:-

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

"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 federal 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 such as 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) 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 most prevalent heart condition 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 reduce hospitalizations or emergency department visits, reduce future exacerbations of illness progression or 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 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) 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, 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 shall make changes in the drugs selected pursuant to this section not more than annually.

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

SECTION 35. Chapter 176O of the General Laws is hereby amended by adding the following 2 sections:-

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 47VV of chapter 175, section 8WW of chapter 176A, section 4WW of chapter 176B and section 4OO 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 31. (a) As used in this section, the following words shall, unless the context clearly requires otherwise, have the following meanings:

"Cost-sharing", as defined in section 1 of chapter 176Y.

"Estimated rebate", any: (i) negotiated price concessions, whether described as a rebate or otherwise, including, but not limited to, base price concessions, and reasonable estimates of any price protection rebates and performance-based price concessions that may accrue, directly or indirectly, to a carrier, pharmacy benefit manager or other party on a carrier's behalf during a carrier's plan year from a pharmaceutical manufacturing company, dispensing pharmacy or other party to the transaction based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter; and (ii) reasonable estimates of any price concessions, fees and other administrative costs that are passed through, or are reasonably anticipated to be passed through to the carrier, pharmacy benefit manager or other party on the carrier's behalf and that serve to reduce the carrier's prescription drug liabilities for the plan year based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter.

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

"Price protection rebate", a negotiated price concession that accrues directly or indirectly to the carrier, or other party on behalf of the carrier, including a pharmacy benefit manager, in the event of an increase in the wholesale acquisition cost of a drug that is greater than a specified threshold.

(b) A carrier, or any pharmacy benefit manager, shall make available to an insured at least 80 per cent of the estimated rebates received by such carrier, or any pharmacy benefit manager, by reducing the amount of defined cost-sharing that the carrier would otherwise charge at the point of sale, except that the reduction amount shall not result in a credit at the point of sale. Neither the insured nor the carrier shall be responsible for any difference between the estimated rebate amount and the actual rebate amount the carrier receives; provided, that such estimates were calculated in good faith.

(c) Nothing in this section shall preclude a pharmacy benefit manager from decreasing an insured's defined cost-sharing by an amount greater than that required under subsection (b).

(d) Annually, not later than April 1, a carrier shall file with the division a report in the manner and form determined by the commissioner demonstrating the manner in which the carrier has complied with this section. If the commissioner determines that a carrier has not complied with 1 or more requirements of this section, the commissioner shall notify the carrier of such noncompliance and a date by which the carrier must demonstrate compliance. If the carrier does not come into compliance by such date, the division shall impose a fine not to exceed $5,000 for each day during which such noncompliance continues.

(e) In implementing the requirements of this section, the division shall only regulate a carrier or pharmacy benefit manager to the extent permissible under applicable law.

(f) A pharmacy benefit manager, its agent or any third-party administrator shall not publish or otherwise disclose information regarding the actual amount of rebates a carrier receives on a specific product or therapeutic class of products, manufacturer or pharmacy-specific basis. Such information shall be considered to be a trade secret and confidential commercial information, shall not be a public record as defined by clause Twenty-sixth of section 7 of chapter 4 or section 10 of chapter 66, and shall not be disclosed directly or indirectly, or in a manner that would allow for the identification of an individual product, therapeutic class of products or manufacturer, or in a manner that would have the potential to compromise the financial, competitive or proprietary nature of the information. A pharmacy benefit manager shall impose the confidentiality protections and requirements of this section on any agent or third-party administrator that performs health care or administrative services on behalf of the pharmacy benefit manager that may receive or have access to rebate related information.

SECTION 36. The General Laws are hereby amended by inserting after chapter 176X the following chapter:-

CHAPTER 176Y

LICENSURE AND REGULATION OF PHARMACY BENEFIT MANAGERS

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

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

"Clean claim", a claim that has no defect or impropriety, including a lack of any required substantiating documentation, or other circumstance requiring special treatment that prevents timely payment from being made on the claim.

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

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

"Division", the division of insurance.

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

"Independent pharmacy", a pharmacy registered under section 39 of chapter 112 that is under common ownership with not more than 5 other pharmacies.

"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.

"Net price", a price for a prescription drug that takes into account all rebates received or expected to be received in connection with the dispensing or administration of the prescription drug.

"Pharmacy", a facility under the direction or supervision of a registered pharmacist authorized to dispense controlled substances under the supervision of a pharmacist registered in the commonwealth under section 39 of chapter 112.

"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 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 that, pursuant to a contract or under an employment relationship with a carrier, a self-insurance plan or other third-party administrator, either directly or through an intermediary, performs pharmacy benefit management services; provided, however, that "pharmacy benefit manager" shall not include a health benefit plan sponsor that (i) does not contract with a pharmacy benefit manager, (iii) manages its own prescription drug benefits, and (iii) is licensed as a carrier by the division.

"Pharmacy benefit manager network", a network of pharmacies or pharmacists that are offered an agreement or contract to provide pharmacy services for a pharmacy benefit manager or health benefit plan.

"Rebate", any: (i) negotiated price concessions, whether described as a rebate or otherwise, including, but not limited to, base price concessions and reasonable estimates of any price protection rebates and performance-based price concessions that may accrue, directly or indirectly, to a carrier, pharmacy benefit manager or other party on a carrier's behalf during a carrier's plan year from a pharmaceutical manufacturing company, dispensing pharmacy or other party to the transaction based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter; and (ii) reasonable estimates of any price concessions, fees and other administrative costs that are passed through, or are reasonably anticipated to be passed through to the carrier, pharmacy benefit manager or other party on the carrier's behalf, and that serve to reduce the carrier's prescription drug liabilities for the plan year based on the amounts the carrier received in the prior quarter or reasonably expects to receive in the current quarter.

"Spread pricing", model of prescription drug pricing in which the pharmacy benefits manager charges a health benefit plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacy.

"Third-party administrator", any person that directly or indirectly solicits or effects coverage of, underwrites, collects charges or premiums from, arranges alternative access to or funding for prescription drugs, or adjusts or settles claims on behalf of residents of the

commonwealth or residents of another state from offices in this commonwealth, in connection with health insurance coverage.

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

(b) The division shall develop an application for licensure that includes at least the following information: (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; and (iv) the name and address of each person with management or control over the applicant or pharmacy benefit manager.

(c)(1) The division may suspend, revoke or place on probation a pharmacy benefit manager license if: (i) the pharmacy benefit manager has engaged in fraudulent activity that is found by a court of law to be a violation of state or federal law; (ii) the division receives 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; (iv) the pharmacy benefit manager fails to comply with a requirement set forth in this chapter; or (v)

the pharmacy benefit manager fails to comply with reporting requirements of the center for health information and analysis under section 10A of chapter 12C.

(2) The division shall provide written notice to the pharmacy benefit manager and advise in writing of the reason for any suspension, revocation or placement on probation of a pharmacy benefit manager license under this chapter. The 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.

(d) 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 not less than $5,000 per day for each day that the person, business or other entity is found by the division to be in violation.

(e) 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.

Section 3. (a)(1) A pharmacy benefit manager shall have a duty to perform pharmacy benefit management services with care, skill, prudence, diligence and professionalism. Such duty shall extend to both the insured and the health plan for whom the pharmacy benefit manager is performing pharmacy benefit management services.

(2) A pharmacy benefit manager interacting with an insured shall have the same duty to an insured as the health plan for whom it is performing pharmacy benefit services.

(b) A pharmacy benefit manager shall have a duty of good faith and fair dealing with all parties with which it interacts in the performance of pharmacy benefit management services.

Section 4. (a) A pharmacy benefit manager shall provide a reasonably adequate and accessible pharmacy benefit manager network for the provision of prescription drugs, which shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence.

(b) A pharmacy benefit manager shall not deny a pharmacy the opportunity to participate in a pharmacy benefit manager network at preferred participation status if the pharmacy is willing to accept the terms and conditions that the pharmacy benefit manager has established for other pharmacies as a condition of preferred network participation status.

(c) A mail-order pharmacy shall not be included in the calculations for determining pharmacy benefit manager network adequacy.

Section 5. (a) After adjudication of a clean claim for payment made by a pharmacy, a pharmacy benefit manager shall not retroactively reduce payment on the claim, either directly or indirectly, through an aggregated effective rate, direct or indirect remuneration, quality assurance program or otherwise, except if the claim: (i) is found not to be a clean claim during the course of a routine audit performed pursuant to an agreement between the pharmacy benefit manager and the pharmacy; or (ii) was submitted as a result of fraud, waste, abuse or other intentional misconduct.

(b) When a pharmacy adjudicates a claim, the reimbursement amount provided to the pharmacy by the pharmacy benefit manager shall constitute a final reimbursement amount; provided, however, that nothing in this section shall be construed to prohibit any retroactive increase in payment to a pharmacy pursuant to a contract between the pharmacy benefit manager or a pharmacy.

(c) No pharmacy benefit manager shall charge or collect from an insured any cost-sharing amount that exceeds the total contracted amount by the pharmacy for which the pharmacy is paid. If an insured pays a copayment, the pharmacy shall retain the adjudicated costs and the pharmacy benefit manager shall not reduce or recoup the adjudicated cost.

Section 6. (a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:

"Generically equivalent drug", a drug that is pharmaceutically and therapeutically equivalent to the drug prescribed.

"Maximum allowable cost list", a listing of drugs or other methodology used by a pharmacy benefit manager, directly or indirectly, to set the maximum allowable payment to a pharmacy for a generic drug.

"National Drug Code", the numerical code assigned to a prescription drug by the United States Food and Drug Administration.

"Pharmacy acquisition cost", the net amount a pharmacy paid for a pharmaceutical product.

“Pharmacy benefit manager affiliate”, a pharmacy that directly or indirectly, through 1 or more intermediaries, owns or controls, is owned or controlled by or is under common ownership or control with a pharmacy benefits manager.

(b) A drug shall not be placed on a maximum allowable cost list unless:

(i) the drug is a generically equivalent drug, it is listed as therapeutically equivalent and pharmaceutically equivalent A or B rated in the United States Food and Drug Administration's most recent version of the Orange Book or Green Book, it has an NR or NA rating by Medi-Span or Gold Standard, or it has a similar rating by a nationally recognized reference;

(ii) the drug is in stock and available for purchase by each pharmacy in the pharmacy benefit manager’s network from wholesale drug distributors licensed under section 36B of chapter 112; and

(iii) the drug is not obsolete.

(c) A pharmacy benefit manager shall:

(i) provide access to its maximum allowable cost list to each pharmacy in the pharmacy benefit manager’s network that is subject to the maximum allowable cost list;

(ii) update its maximum allowable cost list on a timely basis, but not less than once every 7 calendar days;

(iii) provide a process for each pharmacy subject to the maximum allowable cost list to receive prompt notification of an update to the maximum allowable cost list; and

(iv) provide a reasonable internal grievance process consistent with subsection (d) to allow pharmacies to challenge a maximum allowable cost list as not compliant with this section, and to challenge reimbursements made under a maximum allowable cost list for a specific drug or drugs that are below the pharmacy acquisition cost.

(d)(1) A pharmacy benefit manager shall maintain a formal internal grievance process for pharmacies, in a form approved by the commissioner, and such formal internal grievance process shall provide for adequate consideration and timely resolution of grievances. A pharmacy benefit manager's internal grievance process shall include the following: (i) a dedicated telephone number, email address and website for the purpose of submitting a grievance; (ii) the ability to submit a grievance directly to the pharmacy benefit manager regarding the pharmacy benefits plan or program; and (iii) the ability to file a grievance within not less than 30 business days of the qualifying event.

(2) The pharmacy benefit manager shall respond to a grievance within 30 business days of receipt of the grievance. If the pharmacy benefit manager determines as a result of the internal grievance process that the pharmacy benefit manager's challenged conduct was not compliant with this section, the pharmacy benefit manager shall: (i) provide the pharmacy with the National Drug Code upon which the maximum allowable cost was based; (ii) reprocess the claim; (iii) reimburse the pharmacy in an amount that is not less than the pharmacy acquisition cost; and (iv) to the extent practicable, reprocess claims submitted by similarly situated pharmacies and reimburse said pharmacies an amount that is not less than the pharmacy acquisition cost.

(3) If the pharmacy benefit manager determines as a result of the internal grievance process that the pharmacy benefit manager's challenged conduct was compliant with this section,

the pharmacy benefit manager shall: (i) provide the pharmacy with the National Drug Code upon which the maximum allowable cost was based and the name of any wholesale drug distributors licensed under section 36B of chapter 112 that have the drug currently in stock at a price below the maximum allowable cost; or (ii) if the National Drug Code provided by the pharmacy benefit manager is not available at a price below the pharmacy acquisition cost from the wholesale drug distributor from whom the pharmacy purchases the majority of its prescription drugs for resale, then the pharmacy benefit manager shall adjust the maximum allowable cost as listed on the maximum allowable cost list above the challenging pharmacy's pharmacy acquisition cost, and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the challenged maximum allowable cost.

(e) A pharmacy benefit manager shall not reimburse an independent pharmacy an amount less than the amount that the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for providing the same pharmacist services.

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

Section 7. (a) No pharmacy benefit manager or carrier may, either directly or indirectly through an intermediary, agent or affiliate, engage in spread pricing. A pharmacy benefit manager or carrier that violates this section shall be subject to the surcharge under section 8.

(b) A pharmacy benefit manager shall report to the commissioner on a quarterly basis, for each health benefit plan with which it contracts, the data required to be collected by the center for health information and analysis pursuant to section 10A of chapter 12C.

Section 8. (a) A pharmacy benefit manager or carrier shall be subject to a surcharge payable to the division equal to 10 per cent of the aggregate dollar amount of reimbursements paid by the pharmacy benefit manager or carrier to pharmacies in the previous contract year for prescription drugs in the commonwealth if the pharmacy benefit manager or carrier: (i) engages in spread pricing; or (ii) imposes point-of-sale fees or retroactive fees. A carrier shall be jointly responsible to pay the surcharge amount for violations of this section by its contracted pharmacy benefit manager; provided, however, that a carrier shall not be jointly responsible to pay the surcharge amount for violations of this section by its contracted pharmacy benefit manager unless the contract between the carrier and the pharmacy benefit manager permits conduct prohibited by this section.

(b) A pharmacy benefit manager or carrier subject to enforcement action by the division for a violation of this section shall, upon the filing of a written request with the division, be afforded an adjudicatory hearing pursuant to chapter 30A.

Section 9. (a) When calculating an insured's contribution to any applicable cost-sharing requirement, a carrier shall include any cost-sharing amounts paid by the insured or on behalf of the insured by another person. If under federal law, application of this requirement would result in health savings account ineligibility under section 223 of the federal Internal Revenue Code, this requirement shall apply for health savings account-qualified high deductible health plans with respect to the deductible of such a plan after the insured has satisfied the minimum deductible under section 223 of the federal Internal Revenue Code, except for with respect to items or services that are preventive care pursuant to section 223(c)(2)(C) of the federal Internal Revenue Code, in which case the requirements of this paragraph shall apply regardless of whether the minimum deductible under section 223 has been satisfied.

(b) A carrier, pharmacy benefit manager or third-party administrator shall not directly or indirectly set, alter, implement or condition the terms of health benefit plan coverage, including the benefit design, based in part or entirely on information about the availability or amount of financial or product assistance available for a prescription drug.

(c) The division may promulgate such rules and regulations as it may deem necessary to implement this section.

Section 10. (a)(1) A pharmacy benefit manager shall conduct an audit of the records of a pharmacy with which it contracts.

(2) The contract between a pharmacy and a pharmacy benefit manager shall identify and describe the audit procedures in detail.

(3) With the exception of an investigative fraud audit, the auditor shall give the pharmacy written notice not less than 2 weeks prior to conducting the initial on-site audit for each audit cycle.

(4) A pharmacy benefit manager shall not audit claims beyond 2 years prior to the date of audit.

(5) The auditor shall not interfere with the delivery of pharmacist services to a patient and shall make a reasonable effort to minimize the inconvenience and disruption to the pharmacy operations during the audit process.

(6) Any audit that involves clinical or professional judgment shall be conducted by, or in consultation with, a licensed pharmacist from any state.

(7) A finding of an overpayment or underpayment shall be based on the actual overpayment or underpayment. A statistically sound calculation for overpayment or underpayment may be used to determine recoupment as part of a settlement as agreed to by the pharmacy.

(8) The auditor shall audit each pharmacy under the same standards and parameters with which they audit other similarly situated pharmacies.

(9) An audit shall not be initiated or scheduled during the first 5 calendar days of any month for any pharmacy that averages more than 600 prescriptions per week without the pharmacy's consent.

(10) A preliminary audit report shall be delivered to the pharmacy not later than 30 days after the conclusion of the audit.

(11) The preliminary audit report shall be signed and shall include the signature of any pharmacist participating in the audit.

(12) A pharmacy benefit manager shall not withhold payment to a pharmacy for reimbursement claims as a means to recoup money until after the final internal disposition of an audit, including the appeals process, as provided in subsection (b), unless fraud or misrepresentation is reasonably suspected or the discrepant amount exceeds $15,000.

(13) The auditor shall provide a copy of the final audit report to the pharmacy and plan sponsor within 30 days following the pharmacy's receipt of the signed preliminary audit report or the completion of the appeals process, as provided in subsection (b), whichever is later.

(14) No auditing company or agent shall receive payment based upon a percentage of the amount recovered or other financial incentive tied to the findings of the audit.

(b)(1) Each auditor shall establish an appeal process under which a pharmacy may appeal findings in a preliminary audit.

(2) To appeal a finding, a pharmacy may use the records of a hospital, physician or other authorized prescriber to validate the record with respect to orders or refills of prescription drugs or devices.

(3) A pharmacy shall have 30 days to appeal any discrepancy found during the preliminary audit.

(4) The National Council for Prescription Drug Programs or any other recognized national industry standard shall be used to evaluate claims submission and product size disputes.

(5) If an audit results in the identification of any clerical or record-keeping errors in a required document or record, the pharmacy shall not be subject to recoupment of funds by the pharmacy benefit manager; provided, that the pharmacy may provide proof that the patient received the medication billed to the plan via patient signature logs or other acceptable methods, unless there is financial harm to the plan or errors that exceed the normal course of business.

(c) This section shall not apply to any audit or investigation of a pharmacy that involves potential fraud, willful misrepresentation or abuse, including, but not limited to, investigative audits or any other statutory or regulatory provision which authorizes investigations relating to insurance fraud.

(d) This section shall not apply to a public health care payer, as defined in section 1 of chapter 12C.

(e) The commissioner shall promulgate regulations to enforce this section.

Section 11. (a) The commissioner may make an examination of the affairs of a pharmacy benefit manager when the commissioner deems prudent, but not less 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. A pharmacy benefit manager shall annually report to the commissioner: (i) any state or federal enforcement action taken against the pharmacy benefit manager, and (ii) any civil or criminal process or investigation involving the pharmacy benefit manager within the previous calendar year. The examination shall be conducted in accordance with subsection (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 in accordance with subsection (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. Not later than 30 days

after 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 the examiners to reopen the examination for the purposes of obtaining additional data, documentation or information and re-filing pursuant to the above provisions; or

(iii) calling for an investigatory hearing with no 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 examination 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, so long as the agency or office receiving the information agrees in writing to keep such material confidential. Nothing herein 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 12. A pharmacy benefit manager shall be required to submit to periodic audits by a licensed carrier if the pharmacy benefit manager has entered into a contract with the carrier to provide pharmacy benefits to the carrier or its members. The commissioner shall direct or provide specifications for such audits.

Section 13. (a) A contract between a pharmacy benefit manager and a pharmacy shall not include any provision that prohibits, restricts or limits a pharmacy or its employed pharmacists' ability to provide an insured with information on the amount of the insured's cost-sharing for such insured's prescription drug and the clinical efficacy of a more affordable alternative drug if one is available. No contract shall penalize a pharmacy or an individual pharmacist for disclosing such information to an insured or for dispensing to an insured a more affordable alternative prescription drug if one is available.

(b) A pharmacy benefit manager shall not charge a pharmacy a fee related to the adjudication of a claim unless such fee is set out in a contract between the pharmacy benefit manager and the pharmacist or contracting agent or pharmacy, including, but not limited to, a fee for: (i) the receipt and processing of a pharmacy claim; (ii) the development or management of

claims processing services in a pharmacy benefit manager network; or (iii) participation in a pharmacy benefit manager network.

(c) A contract between a pharmacy benefit manager and a pharmacy shall not include any provision that prohibits, restricts or limits disclosure of information to the division deemed necessary by the division to ensure a pharmacy benefit manager's compliance with the requirements under this section or section 21C of chapter 94C.

SECTION 37. Sections 131 and 226 of chapter 139 of the acts of 2012 are hereby repealed.

SECTION 37A. (a) There shall be a special commission to study and make recommendations on the incidence and impacts of vitiligo and associated light-related diseases and disorders of pigmentation in the commonwealth. The special commission shall consist of: the secretary of the executive office of health and human services or a designee; the commissioner of public health or a designee; the commissioner of insurance or a designee; 2 persons to be appointed by the governor, 1 of whom shall be a primary care provider who treats patients diagnosed with vitiligo, and 1 of whom shall be a physician practicing dermatology and who treats patients diagnosed with vitiligo; 3 persons who shall be appointed by the senate president, 1 of whom shall be the senate chair of the joint committee on public health or a designee, 1 of whom shall be a member of the senate representing a community with an increased prevalence of vitiligo and 1 of whom shall be a patient with vitiligo; 1 member of the senate appointed by the senate minority leader; and 3 persons who shall be appointed by the speaker of the house of representatives, 1 of whom shall be the house chair of the joint committee on public health, or a designee, 1 of whom shall be a member of the house of

representatives representing a community with an increased prevalence of vitiligo and 1 of whom shall be a representative of VITFriends Vitiligo Support Group, Inc. based in the Hyde Park neighborhood of the city of Boston.

(b) The special commission shall: (i) establish a mechanism in order to ascertain the prevalence of vitiligo and associated light-related diseases and disorders of pigmentation in the commonwealth; (ii) study successful models of patient and family education and support programs; (iii) survey the extent of health insurance coverage for treatment and services associated with vitiligo and recommend options to improve patient access to and awareness of innovative, affordable and beneficial treatments and services; and (iv) provide recommendations for additional legislation, support programs and resources necessary to meet the unmet needs of persons with vitiligo and their families.

(c) The special commission shall select by a majority vote a chairperson and vice-chairperson from among its members. The executive office of health and human services shall provide staff support to the commission. The public members shall serve without compensation, but shall be reimbursed for necessary expenses incurred in the performance of their duties.

(d) Not later than December 31, 2025, the commission shall submit the results of its study and its recommendations, if any, together with drafts of legislation necessary to carry its recommendations into effect, to the clerks of the house of representatives and the senate.

SECTION 37B. (a) For the purposes of this section, a “pharmacy desert” shall mean an area where there is no or limited access to pharmacies due to factors such as: (i) geographic location, specifically areas where the nearest pharmacy is more than 1 mile away in urban areas, more than 5 miles away in suburban areas and more than 10 miles away in rural areas; (ii)

distance and travel time, defined as travel time exceeding 15 minutes by car or 30 minutes by public transportation; and (iii) limited access to transportation, both public and private, including areas with infrequent public transit services or where at least 20 per cent of the population lacks access to private vehicles.

(b) Notwithstanding any general or special law to the contrary, the health policy commission, in consultation with the board of registration in pharmacy and the center for health information and analysis, shall conduct an analysis and issue a report on pharmacy deserts, with the objective of identifying the number of pharmacy deserts in the commonwealth and barriers to access to medications for residents in urban and underserved areas. The analysis and report shall include, but not be limited to:

(i) an assessment on impacted neighborhoods and patient populations;

(ii) an assessment on the impact of pharmacy deserts on access to medications and health care outcomes;

(iii) an assessment of the geographical and financial barriers to obtaining medications faced by individuals living in pharmacy deserts;

(iv) an assessment of the average distance and travel time to a pharmacy from an impacted neighborhood, and the transportation options available;

(v) an assessment on the impact of pharmacy deserts on overall health care costs, including the costs of emergency department visits and hospitalizations;

(vi) an assessment on the impact of pharmacy benefit manager business practices in contributing to the closures of pharmacies across the commonwealth; and

(vii) policy recommendations to address current pharmacy deserts and limit the creation of new ones.

(c) Not later than February 1, 2025, the report shall be made available electronically on the health policy commission's website and shall be filed with the clerks of the house of representatives and the senate, the house and senate committees on ways and means and the joint committee on health care financing.

SECTION 37C. (a) The health policy commission shall convene a task force to assess the feasibility of requiring that patient-specific prescription drug benefit and deductible information be made available by payers to requesting providers in real-time, at the point of prescribing, and the potential cost savings to patients as a result of such requirement.

(b) The task force shall consist of: the executive director of the health policy commission or designee, who shall serve as chair; the commissioner for the division of insurance or designee; the house and senate chairs of the joint committee on health care financing; and 5 persons to be appointed by the chair, 1 of whom shall be a representative from the Massachusetts Health and Hospital Association, Inc., 1 of whom shall be a representative from the Massachusetts Association of Health Plans, Inc., 1 of whom shall be a representative from Blue Cross and Blue Shield of Massachusetts, Inc., 1 of whom shall be representative from the Massachusetts Medical Society, and 1 of whom shall be a representative from the Massachusetts Pharmacists Association Corp.

(c) The task force shall submit a report on its findings, along with any legislative recommendations, to the clerks of the house of representatives and the senate and the joint committee on health care financing not later than December 31, 2025.

SECTION 37D. (a) There shall be a special commission to investigate and assess the feasibility of state-sponsored prescription drug manufacturing or distribution in the commonwealth. The special commission shall consist of: the secretary of health and human services or a designee, who shall serve as chair; the commissioner of insurance or a designee; the executive director of the center for health information and analysis or a designee; the executive director of the health policy commission or a designee; the president of the board of registration in pharmacy or a designee; the president of the University of Massachusetts or a designee; and 7 persons selected by the chair, 1 of whom shall be a representative of the Massachusetts Biotechnology Council, Inc., 1 of whom shall be a representative of the Massachusetts Health and Hospital Association, Inc., 1 of whom shall be an individual with expertise in biomedical research, 1 of whom shall be a physician licensed to practice medicine under section 2 of chapter 112 of the General Laws with expertise in the treatment of diabetes and related complications, 1 of whom shall be a physician licensed under said section 2 of said chapter 112 with expertise in the treatment of substance use disorders and related complications, 1 of whom shall be a physician licensed under said section 2 of said chapter 112 with expertise in the treatment of allergic reactions and related complications and 1 of whom shall be a physician licensed under said section 2 of said chapter 112 with expertise in the treatment of asthma and related complications.

(b) The special commission shall study and report on the feasibility of state-sponsored drug manufacturing or distribution in the commonwealth. The special commission shall: (i) study the feasibility of manufacturing commonly used pharmaceutical products and their analogs, including but not limited to insulin, naloxone, albuterol inhalers and epinephrine; (ii) assess the feasibility of providing the drug and drug analogs to low-income residents of the commonwealth

at no-cost or at a reduced cost on a means-tested basis; (iii) assess the feasibility of partnerships between the commonwealth and other entities, including but not limited to, public universities and existing drug manufacturers, or partnerships between other appropriate entities and an existing drug manufacturer to leverage existing research and manufacturing capacity; (iv) study the example of the state of California's state-sponsored drug manufacturing and distribution initiative; and (v) issue a report on the commission's findings and policy recommendations.

(c) In its assessment, the commission shall consider the following factors: (i) the number of low-income residents who currently require the drugs listed in clause (i) of subsection (b); (ii) the ability of the commonwealth, the public university system or other appropriate entity, by themselves or in partnership with existing drug manufacturers, to produce the drugs listed in clause (i) of subsection (b); (iii) any long-term cost savings and revenue generation for the commonwealth; (iv) any long-term cost savings and other benefits to low-income residents of the commonwealth who would receive the drugs listed in clause (i) of subsection (b); (v) any costs to the commonwealth to produce the drugs listed in clause (i) of subsection (b), including additional administrative costs; (vi) state and federal regulatory or legal obstacles, including requirements for licensure, to the production and distribution of the drugs listed in clause (i) of subsection (b) within the commonwealth; (vii) available alternative methods for providing the drugs listed in clause (i) of subsection (b) to low-income residents of the commonwealth at low or no cost; (viii) options for capping copayments for the drugs listed in clause (i) of subsection (b) provided through private insurers; (ix) the potential for the commonwealth to engage in volume purchasing of the drugs listed in clause (i) of subsection (b) at reduced cost; (x) the mechanisms by which the commonwealth could establish a program to distribute the drugs listed in clause (i) of subsection (b) to residents of the commonwealth; (xi) opportunities to establish an interstate

compact with other New England states to reduce costs; (xii) opportunities to establish a public entity to manage the manufacturing, purchasing or distribution of the drugs listed in clause (i) of subsection (b); (xiii) opportunities to establish a model facility to affordably manufacture the drugs listed in clause (i) of subsection (b); and (xiv) opportunities to procure dedicated funding to support the manufacture and distribution of the drugs listed in clause (i) of subsection (b) to residents of the commonwealth.

(d) Not later than September 1, 2025, the commission shall submit its report to the clerks of the house of representatives and the senate, the joint committee on health care financing and the joint committee on public health.

SECTION 38. (a) Notwithstanding any general or special law to the contrary, the office of pharmaceutical policy and analysis, in consultation with the office of Medicaid, shall conduct an analysis and issue a report on the future of cell and gene therapy in the commonwealth with the objective of addressing anticipated barriers to access that may exist with respect to such treatments for patients covered by MassHealth programs and other vulnerable populations. The analysis shall be focused on cell and gene therapy products, hereinafter referred to as products, that are expected to come to market in the United States by the year 2035. The analysis and report shall include, but not be limited to:

(i) a projection of the estimated total number of products that are expected to come to market in the United States;

(ii) information on the diseases and conditions such products will be approved to treat, including the total estimated number of impacted individuals in the commonwealth and the total number of impacted individuals enrolled in MassHealth;

(iii) an assessment of anticipated costs of coverage and existing reimbursement frameworks and methodologies that may be employed by MassHealth for the products to the extent the products are purchased by health care facilities for administration to MassHealth beneficiaries during inpatient hospital stays;

(iv) an assessment of whether the reimbursement frameworks and methodologies identified pursuant to clause (iii) would lead to barriers to access to the products in light of the projected costs to the health care system associated with the utilization of the products, and whether such barriers to access, if any, would disproportionately impact MassHealth beneficiaries or other vulnerable populations, including population groups that may be more likely to have adverse health outcomes due to experience with historic disparities or discrimination; and

(v) an assessment of whether the current health care facility infrastructure necessary for the administration of the products is adequate to ensure equitable access for patients in need of treatment with the products.

(b) To the extent that the analysis identifies any barriers to access to the products, the office of pharmaceutical policy and analysis and the office of Medicaid shall analyze and report on the reasons for such barriers and shall propose corrective policy solutions. If any identified barriers are the result of or otherwise related to current MassHealth reimbursement methodologies for the products, the report shall propose modifications designed to eliminate such barriers to such methodologies to the extent authorized under federal law.

(c) In conducting the analysis and producing the report required by this section, the health office of pharmaceutical policy and analysis and the office of Medicaid shall consult with the

Massachusetts Biotechnology Council, Inc., the Massachusetts Health and Hospital Association, Inc., the Conference of Boston Teaching Hospitals, Inc., the Massachusetts Association of Health Plans, Inc., Blue Cross and Blue Shield of Massachusetts, Inc. and the rare disease advisory council established pursuant to section 241 of chapter 111.

(d) The report shall be made available electronically on the commission's website and shall be filed with the secretary of administration and finance, the clerks of the house of representatives and the senate, the house and senate committees on ways and means and the joint committee on health care financing by not later than July 31, 2025.

SECTION 39. Section 17T of chapter 32A of the General Laws, inserted by section 27; section 10R of chapter 118E of the General Laws, inserted by section 29; section 47VV of 175 of the General Laws, inserted by section 30; section 8WW of 176A of the General Laws, inserted by section 32; section 4WW of 176B of the General Laws, inserted by section 33; and section 4OO of chapter 176G of the General Laws, inserted by section 34, shall apply with respect to health benefit plans that are entered into, amended, extended or renewed on or after August 1, 2025.

SECTION 40. The center shall prepare the list required pursuant to section 10B of chapter 12C, inserted by section 23, not later than March 31, 2026.

SECTION 41. Section 31 of chapter 176O of the General Laws, inserted by section 35, shall take effect on April 1, 2025. All carriers shall file the first annual report required by subsection (d) of said section 31 of said chapter 176O of the General Laws not later than April 1, 2026.

SECTION 42. All entities performing pharmacy benefit management services shall be licensed by the division of health insurance as pharmacy benefit managers pursuant to section 2 of chapter 176Y of the General Laws, inserted by section 36, not later than January 1, 2025.

SECTION 43. Sections 7 to 9, inclusive, of chapter 176Y, inserted by section 36, shall apply with respect to health benefit plans that are entered into, amended, extended or renewed on or after August 1, 2025.; and

by striking out the title and inserting in place thereof the following title: “An Act promoting access and affordability of prescription drugs.”.