HCF REDRAFT

Joint Committee on Health Care Financing

Bill Summary

BILL NUMBER Senate, No. 0749, *as amended*

TITLE An Act relative to pharmaceutical access, costs and transparency

SPONSORS Senators Friedman, Rausch, Comerford, Lewis, O'Connor, Eldridge, Cyr, Jehlen, Feeney, Moore, and Tarr; Representatives Whipps of Athol, Lewis of Framingham, Gentile of Sudbury, and Howard of Lowell

HEARING DATE Tuesday, June 6, 2023 at 10:00 AM - 01:00 PM, A-1

SIMILAR MATTERS H1176 [Coppinger]; H1201 [Hogan] H1205 [Jones]; H1206 [Jones]; S0732 [Cronin]; S0778 [Mark]; S0783 [Montigny] & S0797 [Oliveira]

PRIOR HISTORY

A refile of S0771 from the 2021-2022 legislative session. Referred to the Joint Committee on Health Care Financing. Public hearing on July 13, 2021. Accompanied by S736, S785, S786, S790, S803, S804 and H729, H1254, H1272, H1278, H1279, H1307 and H3787. Reported Ought to Pass by committee and referred to the committee on Senate Ways and Means on November 17, 2021, passed to be engrossed by the Senate on February 10, 2022. Reported Ought to Pass with an amendment substituting a new draft, S2651, and placed on the Orders of the Day on February 3, 2022. Read second, new draft S2695 substituted as amended, read third and reprinted as amended, see S2695, and passed to be engrossed on February 10, 2022. Read and referred to the Committee on House Ways and Means on February 15, 2022. No further action taken.

CURRENT LAW

M.G.L. Ch. 6A establishes the executive offices that serve under the governor.

M.G.L. Ch. 6D § 1 defines certain terms as they are to be understood within the context of Chapter 6D, which governs the operations and activities of the HPC.

M.G.L. Ch. 6D § 2A directs the HPC to keep confidential all nonpublic clinical, financial, strategic or operational documents or information provided or reported to it in connection with any care delivery or quality improvement process or performance improvement plan activities. Such documents are exempt from public records laws.

M.G.L. Ch. 6D §4 establishes an advisory council to the HPC and directs the executive director of the HPC to appoint representatives of health care interests to the advisory council.

M.G.L. Ch. 6D § 6 governs assessments levied upon hospitals, ambulatory surgical centers, and surcharge payors to cover the estimated operational expenses of the HPC. Acute hospitals and

ambulatory surgical centers must pay “not less than” 33% of the assessment and payors “not less than” 33% of the assessment.

M.G.L. Ch. 6D § 8 directs the HPC to hold annual public hearings, based on the report submitted by the Center for Health Information and Analysis [CHIA] pursuant to section 16 of chapter 12C. The hearing shall examine provider and payer costs, prices, and cost trends, with particular attention to factors that contribute to cost growth. The HPC shall identify witnesses for the hearing, who shall give testimony under oath and be subject to examination and cross examination. Witnesses are required to provide testimony on specific subjects, including testimony concerning costs, payment systems, and relative prices.

M.G.L. Ch. 6D § 9 directs the HPC board to establish a health care cost growth benchmark for the average growth in total health care expenditures. The benchmark for 2018-2022 shall be the growth rate of potential gross state product minus 0.5%. For 2018-2022, the commission may modify the benchmark to be between -0.5% and the growth rate. In making that determination, the statue requires the HPC to hold a public hearing to consider available data, information, and testimony from market participants and other interested parties. The statute also grants the Joint Committee on Health Care Financing the right to participate in the public hearing.

M.G.L. Ch. 12C § 1 defines certain terms as they are to be understood within the context of Chapter 12C, which governs the operations and activities of CHIA.

M.G.L. Ch. 12C §7 governs assessments levied upon hospitals, ambulatory surgical centers, and surcharge payors to cover the estimated operational expenses of the CHIA. Acute hospitals and ambulatory surgical centers must pay “not less than” 33% of the assessment and payors “not less than” 33% of the assessment. M.G.L. Ch. 12C § 10 directs CHIA to ensure uniform reporting by private and public health care payers of information necessary to analyze trends in health insurance costs and utilization.

M.G.L. Ch. 12C § 11 directs CHIA to ensure timely reporting of information required under sections 8, 9 and 10. If a health care entity fails, without just cause, to provide the requested information within 2 weeks of written notice, the center may assess a penalty against of up to $1,000 per week for each week of delay after the 2-week period. The maximum annual penalty shall be $50,000. Amounts collected shall be deposited in the Healthcare Payment Reform Fund.

M.G.L. Ch. 12C § 12 declares CHIA to be the sole repository for health care data collected under sections 8, 9 and 10 of Chapter 12C, and directs CHIA to collect, store and maintain such data in a payer and provider claims database to be accessible to the public as set forth in this section.

M.G.L. Ch. 12C § 16 directs CHIA to publish an annual report based on data collected from payers and providers. The report shall include information on provider price variation, including changes affecting price variation, factors that contribute to price variation, and the impact of price variation.

M.G.L. Ch. 13 § 17 establishes the Drug Formulary Commission within the Department of Public Health [DPH] and directs the commission to prepare a formulary of interchangeable drug products and a formulary of chemically equivalent substitutions for drugs that are opiates and contained in schedule II or III of section 3 of said chapter 94C that the commission has determined have a heightened level of

public health risk due to the drugs' potential for abuse and misuse. The formularies prepared by the commission shall be adopted by regulations of DPH.

Chapter 29 of the General Laws governs state finance.

M.G.L. Ch. 32A § 17G governs items determined to be medically necessary by the GIC in order to treat diabetes.

Chapter 94C of the General Laws, the "Controlled Substances Act," authorizes certain registered and licensed health professionals and providers to possess, prescribe, distribute, and administer controlled substances as permitted under this chapter and applicable sections of Chapter 112.

Chapter 111 of the General Laws directs DPH to establish, maintain, and enforce certain offices, programs, and authorities pertaining to the general health and welfare of the Commonwealth.

M.G.L. Chapter 118E §10E governs items determined to be medically necessary by MassHealth in order to treat diabetes.

Chapter 175 of the General Laws governs the operation, structure, and practices of companies engaged in the principle business of insurance, including insurance products issued for individual or group blanket accident and sickness.

M.G.L. Ch. 175 § 47N governs items determined to be medically necessary by insurance companies in order to treat diabetes.

M.G.L. Ch. 175 § 226, governing pharmacy benefit manager audits of pharmacy records, defines, in subsection (a), the term "pharmacy benefit manager" as follows: "any person or entity that administers the (i) prescription drug, prescription device or pharmacist services or (ii) prescription drug and device and pharmacist services portion of a health benefit plan on behalf of plan sponsors, including, but not limited to, self-insured employers, insurance companies and labor unions. A health benefit plan that does not contract with a pharmacy benefit manager shall be considered a pharmacy benefit manager for the purposes of this section, unless specifically exempted."

M.G.L. Ch. 176A § 8P governs items determined to be medically necessary by Blue Cross in order to treat diabetes.

M.G.L. Ch. 176B § 4S governs items determined to be medically necessary by Blue Shield in order to treat diabetes.

M.G.L. Chapter 176G § 4H governs items determined to be medically necessary by an HMO in order to treat diabetes.

MGL Ch. 176O § 2 establishes a bureau of managed care withing DOI which promulgates regulations related to utilization review, quality management and improvement, credentialing, and preventive health services.

Section 11 of Chapter 133 of the Acts of 2016, the FY2017 General Appropriation Act, requires CHIA, when examining the cost growth trend in the pharmaceutical sector, to consider the effect of drug rebates and other price concessions in the aggregate without disclosure of any product or manufacturer-

specific rebate or price concession information, and without limiting or otherwise affecting the confidential or proprietary nature of any rebate or price concession agreement.

Section 514 of the Employee Retirement Income Security Act of 1974, Public Law 93-406 (ERISA), provides that ERISA supersedes any state law as it relates to an employee benefit plan.

SUMMARY

SECTION 1 adds a new section, 16DD, to chapter 6A which establishes a drug access program, administered by the executive office of health and human services, for the purpose of enhancing access to targeted high-value medications used to treat certain chronic conditions (diabetes, asthma and heart conditions).

SECTIONS 2, 3 and 4 add the following terms to section 1 of Chapter 6D: "Biosimilar"; "Brand name drug"; "Early notice"; "Generic drug".

SECTION 5 amends the term "Payer", as defined in section 1 of Chapter 6D, to expand the definition of payer as used in the Chapter to "include self-insured plans to the extent allowed under the federal Employee Retirement Income Security Act of 1974."

SECTIONS 6, 7 & 8 add the following terms to section 1 of Chapter 6D: "Pharmaceutical manufacturing company"; "Pharmacy benefit manager"; "Pipeline drugs"; "Wholesale acquisition cost".

SECTION 9 amends section 2A of Chapter 6D to extend the existing confidentiality protections afforded to documents and information obtained by the HPC from providers and payers to the documents and information obtained by the HPC from pharmaceutical manufacturing companies and pharmacy benefit managers under the relevant sections of the Chapter, as amended by this Act.

SECTION 10 amends section 4 of Chapter 6D to include a pharmacy benefit manager representative on the HPC's advisory council.

SECTIONS 11, 12 & 13 amend section 6 of Chapter 6D to authorize the HPC to level an assessment on pharmaceutical manufacturing companies & pharmacy benefit managers to cover any additional expenses incurred related to its analysis of pharmaceutical or biopharmaceutical spending trends, including an academic detailing program, and further amends the contribution percentage for the assessed entities so that the HPC collects the total funds required as follows: "not less than" 25% from acute hospitals and ambulatory surgical centers; "not less than" 25% from surcharge payers; and "not less than" 25% from pharmaceutical manufacturing companies and pharmacy benefit managers.

SECTIONS 14, 15, 16, 17, 18 & 19 amend section 8 of Chapter 6D to incorporate pharmaceutical manufacturing companies and pharmacy benefit managers into the HPC's annual cost trend hearings and report.

--- The HPC is directed to identify 1 PBM and 3 pharmaceutical manufacturing companies to participate as witnesses and provide testimony under oath, subject to examination and cross examination during its cost trends hearings. Information obtained under this section and the new section 10A of chapter 12C [added by SECTION 29 of this Act] shall be incorporated into the HPC's annual cost trends report.

--- Participants shall provide information on "factors underlying prescription drug costs and price increases including, but not limited to, the initial prices of drugs coming to market and subsequent price increases, changes in industry profit levels, marketing expenses, reverse payment patent settlements,

the impact of manufacturer rebates, discounts and other price concessions on net pricing, the availability of alternative drugs or treatments and any other matters as determined by the commission."

SECTION 20 amends section 9 of Chapter 6D to direct the HPC to incorporate information related to pharmaceutical manufacturing companies and pharmacy benefit managers into its process to determine the annual health care cost growth benchmark.

SECTION 21 inserts a new section into Chapter 6D, new Section 15A, requiring pharmaceutical manufacturing companies with a new drug or other development coming to market shall be subject to an "early notice" requirement for (1) pipeline drugs; (2) generic drugs and (3) biosimilar drug. Companies shall notify the HPC in writing of such drugs within 60 days of the receipt of an action date from the FDA.

---For each pipeline drug or biosimilar, pharmaceutical manufacturing companies must submit information required by this section not later than 60 days after receipt of the FDA action date, or as soon as is practical in the case of a pipeline drug with an FDA designation as an orphan, fast track, breakthrough therapy, accelerated approval, or priority review for new molecular entities.

---Additionally, pharmaceutical manufacturing companies shall be required to provide early notice to the HPC of a planned price increase and shall report relevant information to the HPC at least 30 days before the effective date of a planned price increase.

--- If a pharmaceutical manufacturing company fails to timely comply with the requirements under this section or otherwise knowingly obstructs the commission's ability to receive early notice under this section, the commission may impose appropriate sanctions against the manufacturer, including reasonable monetary penalties not to exceed $500,000, in each instance.

SECTION 22 inserts 2 new sections into Chapter 6D:

--- New Section 20 directs the HPC to review the price of high cost drugs and establish a "proposed value" of brand name drugs or biologics, biosimilar drugs, or "public health essential drugs" [defined in SECTION 37 of this Act] as identified information submitted under this section, received from CHIA or obtained from third parties. Manufacturers of drugs so identified shall be notified by the HPC and shall be required to disclose to the commission drug pricing data and documentation related to corporate expenditures in specific spending categories. Based on the data and documentation received, the HPC shall determine whether the manufacturer's price "substantially exceeds" the commission's "proposed value", and for such drugs the HPC shall request that the manufacturer enter into an "access improvement plan", pursuant to the new section 21. The HPC shall also request that the manufacturer of a drug enter into an access improvement plan if the commission "identifies patient access and affordability barriers."

--- New Section 21 directs the HPC to establish an "access improvement plan" for drug manufacturers identified by the commission, pursuant to the new section 20, as producing a drug sold at a price that substantially exceeds the commission's proposed value or for which the commission has identified patient access and affordability barriers. Under this Section, an access improvement plan shall be generated by the manufacturer but be subject to HPC approval, identify the reasons for the manufacturer's drug price, and include "specific strategies, adjustment and action steps the manufacturer proposes to implement to address the cost of the drug and improve patient affordability and access". Manufacturers that agree to initiate an access improvement plan shall be subject to

additional reporting requirements as determined by the HPC. The HPC shall notify the public that a manufacturer has agreed to initiate and has received approval for an access improvement plan for a specific drug. The HPC shall provide opportunities for patients who utilize the eligible drug and other members of the public, as well as providers who prescribe the eligible drug, to comment on whether they have been successfully able to access the eligible drug at a lower cost following implementation of an access improvement plan. If a manufacturer declines to enter into an access improvement plan or the HPC determines that a manufacturer is not acting in good faith, the HPC shall issue a public determination on whether the manufacturer's pricing is "unreasonable or excessive in relation to the commission's proposed value."

SECTIONS 23, 24, 25 & 26 add the following terms to section 1 of Chapter 12C: "Average manufacturer price"; "Biosimilar"; "Brand name drug"; "Generic drug"; "Pharmaceutical manufacturing company"; "Pharmacy benefit manager"; "Wholesale acquisition cost".

SECTIONS 27 & 28 amend section 3 of Chapter 12C to grant explicit authorization for the CHIA executive director, subject to appropriation, to appoint officers & employees and establish subdivisions to "collect, analyze and disseminate information" regarding pharmaceutical manufacturing companies & pharmacy benefit managers "to increase the transparency and improve the functioning of the health care system", and to "participate in and provide data and data analysis" at the HPC's annual cost trends hearings concerning pharmaceutical manufacturing companies & pharmacy benefit managers costs, prices and cost trends.

SECTIONS 29 & 30 amend section 5 of Chapter 12C to add pharmaceutical manufacturing companies & pharmacy benefit managers to list of health care industries that CHIA must consult with prior to the adoption of regulations to ensure regulatory reporting requirements are not duplicative or excessive.

SECTIONS 31, 32 & 33 amend section 7 of Chapter 12C to authorize CHIA to level an assessment on pharmaceutical manufacturing companies and pharmacy benefit managers to cover any additional expenses incurred by CHIA related to its analysis of pharmaceutical or biopharmaceutical spending trends. Additionally, these sections amend the contribution percentage for the assessed entities so that CHIA collects the total funds required as follows: "not less than" 25% from acute hospitals and ambulatory surgical centers; "not less than" 25% from surcharge payers; and "not less than" 25% from pharmaceutical manufacturing companies and pharmacy benefit managers.

SECTION 34 inserts a new section into Chapter 12C, new Section 10A, to direct CHIA to issue regulations for "uniform analysis" of and submission of data and information from pharmaceutical manufacturing companies and pharmacy benefit managers.

SECTION 35 amends section 11 of Chapter 12C to extend CHIA's "timely reporting" of information relevant to pharmaceutical manufacturing company and pharmacy benefit manager data collected under the new Section 10A [added by SECTION 33 of this Act], increases the penalty on all entities for noncompliance with CHIA data reporting requirements to $2,000 per week (from $1,000 per week) and eliminates the maximum total penalty of $50,000.

SECTION 36 amends section 12 of Chapter 12C to incorporate pharmaceutical manufacturing company and pharmacy benefit manager data collected under the new Section 10A [added by SECTION 34 of this Act] into CHIA's all-payer claims database.

SECTION 37, 38 & 39 amends section 16 of Chapter 12C to incorporate pharmaceutical manufacturing company and pharmacy benefit manager data collected under the new Section 10A [added by SECTION 30 of this Act] into CHIA's annual report on health care cost trends.

SECTION 40 amends section 13 of Chapter 17 to direct the Drug Formulary Commission to identify and publish a list of "public health essential drugs", defined as "a prescription drug, biologic or biosimilar approved by the federal Food and Drug Administration that: (i) appears in any formulation of the medicines included on the Model List of Essential Medicines most recently adopted by the World Health Organization; or (ii) is deemed an essential medicine by the commission due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living or because limited access to a certain population would pose a public health challenge."

SECTION 41 inserts a new section into Chapter 29, new Section 2RRRRR, establishing the Prescription Drug Cost Assistance Trust Fund administered and expended by the secretary of health and human services to a drug cost assistance program established pursuant section 238 of Chapter 111 [added by SECTION 45 of this Act].

SECTION 42 amends section 17G of chapter 32A to mandate that coverage for insulin is not subject to any deductible or co-insurance and any co-payment must not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's prescription.

SECTION 43 adds a new section, 17S, to chapter 34A which mandates the GIC to provide coverage for the brand name drugs and generic drugs identified by the drug access program established in section 16DD in chapter 6A (See SECTION 1 of this Act).

SECTION 44 inserts a new Chapter into the General Laws, new Chapter 63D, which introduces a penalty system for drug manufacturers who excessively increase the prices of their drugs.

---Any person who manufactures and sells drugs in the state and establishes an excessive price for a drug, either directly or in collaboration with a related party, must pay a penalty per unit of the drug that is ultimately dispensed or administered in the state. The penalty for each unit is set at 80% of the excessive price increase.

---A person who sets an excessive price for a drug must file a return, declaring all units of excessively priced drugs sold for distribution in the state during each calendar quarter. If any units of drugs subject to penalty are ultimately dispensed or administered outside the state, the person can claim a credit for the penalty amounts on the tax return for the period when those units are dispensed or administered.

---The penalty only applies to a person who has a place of business in the state or whose total sales of all products for distribution in the state exceed $100,000 in the calendar year beginning with the reference date. The penalty can only be imposed once for each unit of drug sold.

---If a person subject to the penalty fails to pay the required amounts, a related party that distributes any drug subject to this chapter in the state will be jointly and severally liable for the penalty.

SECTION 45 inserts a new section into chapter 94C, Section 21C, to require retail pharmacies to post notice to consumers that they may request to be informed of the retail price of a prescription drug & inform patients when the retail price of a drug is lower than the patient's cost sharing obligation under

their health plan and prohibits "gag clause" in pharmacy contracts that would prevent a pharmacist from compliance with the new disclosure requirements.

SECTION 46 inserts a new section into Chapter 111, new Section 238, establishing a Prescription Drug Cost Assistance Program to be administered by DPH and funded from revenue generated by the prescription drug sales tax [added by SECTION 41 of this Act] and transferred to DPH from the Prescription Drug Cost Assistance Trust Fund. The program shall provide financial assistance to eligible individuals who require prescription drugs to treat "(1) chronic respiratory conditions, including, but not limited to, chronic obstructive pulmonary disease and asthma; (2) chronic heart conditions, including, but not limited to, heart failure, coronary artery disease, hypertension and high blood pressure; (3) diabetes; and (4) any other chronic condition identified by the department that disproportionally impacts people of color or is a risk factor for increased COVID-19 complications." The program shall cover the full cost of any cost sharing required for the purchase of such drugs. The eligibility requirements for the program are as follows" individual must be a resident of the Commonwealth, have a current prescription for a drug used to treat a qualifying condition, have a family income at or below 500% FPL, and not be enrolled in MassHealth. DPH shall process applications and complete eligibility determinations within 10 days of the receipt of an application. Adverse eligibility determinations shall be made in writing citing the specific reasons an individual was determined to be ineligible for the program. Eligible individuals will be issued a program card valid for 12 months and renewable upon an annual redetermination. Pharmacies who fill a prescription for enrollees shall be reimbursed for cost-sharing owed from the Prescription Drug Cost Assistance Trust Fun. DPH shall submit an annual report o the program to the House and Senate Clerks and the chairs of the House and Senate Committees on Ways & Means and the Joint Committee on Health Care Financing.

SECTION 47 amends section 10C of chapter 118E mandating that MassHealth coverage for insulin is not subject to any deductible or co-insurance and any co-payment must not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's prescription.

SECTION 48 adds a new section, 10O, to chapter 118E which mandates MassHealth to provide coverage for the brand name drugs and generic drugs identified by the drug access program established in section 16DD in chapter 6A (See SECTION 1 of this Act).

SECTION 49 amends section 47N of chapter 175 mandating that insurance coverage for insulin is not subject to any deductible or co-insurance and any co-payment must not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's prescription.

SECTION 50 adds a new section, 47QQ, to chapter 175 which mandates insurance companies to provide coverage for the brand name drugs and generic drugs identified by the drug access program established in section 16DD in chapter 6A (See SECTION 1 of this Act).

SECTION 51 repeals section 226 of chapter 175, governing pharmacy audits conducted by carriers and places it into NEW Chapter 176X [SEE SECTION 61]

SECTION 52 amends section 8P of chapter 176A to mandate that coverage for insulin is not subject to any deductible or co-insurance and any co-payment must not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's prescription.

SECTION 53 adds a new section, 8RR, to chapter 176A which mandates Blue Cross to provide coverage for the brand name drugs and generic drugs identified by the drug access program established in section 16DD in chapter 6A (See SECTION 1 of this Act).

SECTION 54 amends section 4S of chapter 176B to mandate that coverage for insulin is not subject to any deductible or co-insurance and any co-payment must not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's prescription.

SECTION 55 adds a new section, 4RR, to chapter 176B which mandates Blue Cross to provide coverage for the brand name drugs and generic drugs identified by the drug access program established in section 16DD in chapter 6A (See SECTION 1 of this Act).

SECTION 56 amends section 4H of chapter 176G to mandate that coverage for insulin is not subject to any deductible or co-insurance and any co-payment must not exceed $25 per 30-day supply, regardless of the amount or type of insulin needed to fill an insured's prescription.

SECTION 57 adds a new section, 4HH, to chapter 176G which mandates HMOs to provide coverage for the brand name drugs and generic drugs identified by the drug access program established in section 16DD in chapter 6A (See SECTION 1 of this Act).

SECTION 58 amends section 2 of Chapter 176O to require carriers that contract with pharmacy benefit managers to coordinate, at least every 3 years, an audit of contracted pharmacy benefit managers and to examine prices and rebates on drugs provided to the carrier's covered persons.

SECTION 59 inserts a new section into Chapter 176O, new section 22A, directing carriers that contract with pharmacy benefit managers to require such pharmacy benefit managers obtain a license from DOI pursuant to Chapter 176X [added by SECTION 45 of this Act].

SECTION 60 adds a new section, 30, to chapter 176O which directs a pharmacy, a the point of sale, to charge an individual either the appropriate cost-sharing amount or the pharmacy retail price, whichever is lower. However, a carrier or an entity managing or administering benefits for a carrier cannot require an individual to pay an amount at the point of sale that exceeds the lesser of the individual's cost share or the pharmacy retail price. Furthermore, a contract cannot prohibit a pharmacist from complying with this section or impose a penalty on the pharmacist or pharmacy for complying with this section.

SECTION 61 inserts a new chapter into the General Laws, chapter 176X consisting of 14 new sections on PBMs:

---Section 1 adds the following definitions in chapter 176X: "Carrier"; "Cost-sharing requirement"; "Division"; "Health benefit plan"; "Health care services"; "Insured"; "Mail order pharmacy"; "Network pharmacy"; "Person"; "Pharmacy"; "Pharmacy benefit manager"; "Pharmacy benefit services"; "Rebate or fees"; "Retail pharmacy"; "Spread pricing" and"Steering".

---Section 2 directs PBMs to obtain a license from the Department of Insurance (DOI) to operate in the commonwealth. The license is valid for three (3) years and costs $25,000.

- DOI must develop an application for licensure that includes at least the following information: (i) the name of the pharmacy benefit manager; (ii) the address and contact telephone number for

the pharmacy benefit manager; (iii) the name and address of the pharmacy benefit manager's agent for service of process in the commonwealth; (iv) the name and address of each person beneficially interested in the pharmacy benefit manager; and (v) the name and address of each person with management or control over the pharmacy benefit manager.

- DOI may suspend, revoke, or place on probation a pharmacy benefit manager license under any of the following circumstances: (i) the pharmacy benefit manager has engaged in fraudulent activity that constitutes a violation of state or federal law; (ii) the division received consumer complaints that justify an action under this chapter to protect the safety and interests of consumers; (iii) the pharmacy benefit manager fails to pay an application fee for the license; or (iv) the pharmacy benefit manager fails to comply with a requirement set forth in this chapter.
- If an entity performs the functions of a pharmacy benefit manager acts without registering, it will be subject to a fine of $5,000 per day for the period they are found to be in violation.

---Section 3 establishes that PBMs have a fiduciary duty, requiring good faith and fair dealing with all parties, including but not limited to covered individuals and pharmacies, with whom it interacts in the performance of pharmacy benefit services.

---Section 4 requires PBMs to maintain an adequate and accessible pharmacy benefit manager network for the provision of prescription drugs, which provides for convenient patient access to pharmacies within a reasonable distance from a patient's residence.

---Section 5 is an anti-clawback section, that prohibit PBMs from retroactively reduce payment on a cleanclaim by a pharmacy, either directly or indirectly, and prohibits PBMs from charging or collecting from an individual a copayment that exceeds the total submitted charges by the pharmacy for which the pharmacy is paid.

---Section 6 requires PBMs to establish a maximum allowable cost (MAC) list for prescription drugs and requires PBMs to reimburse a pharmacy for generic drugs at a price at least equal to the wholesale invoice amount that the pharmacy paid for the drug inventory. The PBM must update the MAC list on a timely basis and give pharmacies no less than thirty business days to file an administrative appeal to challenge the MAC list.

---Sections 7 -9 prohibit PBMs and health plans from engaging in the practice of "spread pricing," "steering" and imposing point-of-sale fees or retroactive fees. Spread pricing is defined as "the practice of a pharmacy benefit manager retaining an additional amount of money in addition to the amount paid to the pharmacy to fill a prescription." Steering is defined as "a practice employed by a pharmacy benefit manager or carrier that channels a prescription to a pharmacy in which a pharmacy benefit manager or carrier has an ownership interest, and includes but is not limited to retail, mail-order, or specialty pharmacies."

- Any PBM or health plan that engages in any of these practices are subject to a 10% surcharge on the aggregate dollar amount it reimbursed pharmacies in the previous calendar year for prescription drugs in the commonwealth.
- All PBMs and health plans must submit to the commissioner, in a form and manner and by a date specified by the commissioner, data detailing all prescription drug claims it administered in

the commonwealth for insured residents on behalf of each health plan client and any other data the commissioner deems necessary to evaluate whether a pharmacy benefit manager may be engaged in any of the prohibited practices.

- DOI, in consultation with the health policy commission and the center for health information and analysis, shall prepare an aggregate report reflecting the total number of prescriptions administered by the reporting PBM or health plan with the total sum due to the commonwealth, which shall be public record.

---Section 10 requires PBMs to include any cost-sharing amounts paid by an enrollee or another third party on behalf of an enrollee when calculating an enrollee's total cost-sharing contributions/make sure the amounts count towards the calculation of an enrollee's contributions toward their deductible and total out-of-pocket spend.

---Section 11 takes the pharmacy audit language from the repealed section 226 of chapter 175 [See SECTION 51 of this ACT] and inserts it as a new section under 176X. Under the existing law, DOI regulation of this section is not mandatory. The new section will make DOI regulation mandatory.

---Section 12 establishes a procedure for DOI to audit PBMs every three (3) years.

- 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.
- Upon receipt of the verified report, the commissioner shall transmit the report to the pharmacy benefit manager examined with a notice which 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.
- The records of any such audit, examination or other inspection and the information contained in the records, reports or books of any pharmacy benefit manager examined pursuant to this section shall be confidential and open only to the inspection of the commissioner, or the examiners and assistants.
- 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 13 requires PBMs 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 14 prohibits "gag clause" in contracts that would prevent or penalize a pharmacist or pharmacy from providing an insured with cost or clinical information for a drug or selling a patient a more affordable alternative drug.

- PBMs prohibited from charging a pharmacist or pharmacy a fee related to a claim, including, without limitation: (i) a fee for receiving or processing a claim; (ii) a fee for the management of a PBM pharmacy network claims processing service; (iii) a PBM pharmacy network fee that is not set out in the contract between the PBM and the pharmacist or pharmacy.
- No PBM contract shall include a provision that prevents or interferes with compliance with this section or section 21C of chapter 94C [See SECTION 45 of this Act]

SECTION 62 directs the HPC to produce interim and final reports on the use of insulin in the commonwealth and the effects of capping copayments and eliminating deductible to the legislature not later than 18 months after the effective date of this Act.

SECTION 63 directs the Health Connector Authority to report to the legislature, not later than July 1, 2025 on the impact of pharmaceutical pricing on health care costs and outcomes for ConnectorCare and non-group and small group plans offered through the connector and its members.

SECTION 64 establishes a commission to study and evaluate all aspects related to establishing a system for the bulk purchasing and distribution of pharmaceutical products with a significant public health benefit.

SECTION 65 establishes a task force to review the drug supply chain.

SECTION 66 directs the HPC to consult with representatives of identified industries and consumer and patient communities to assist the commission in the development and regulation of the criteria to determine the "proposed value" of brand name drugs or biologics, biosimilar drugs, or "public health essential drugs" under section 20 of Chapter 6D [as added by SECTION 21 of the Act].

SECTIONS 67, 68 & 73 instructs the HPC to define a significant price increase for a generic drug as a generic drug priced at $100 or more per wholesale acquisition cost unit that increases in cost by 100 per cent or more during any 12-month period. This definition sunsets on January 1, 2024.

SECTION 69 instructs the drug access program under SECTION 1 to take a effect no later than 1 year after the effective date of this Act.

SECTION 70 directs DOR to promulgate regulations for the penalty on excessive drug prices (See SECTION 44 of the Act) as soon as practicable after the effective date of this Act.

SECTION 71 requires that the excessive drug price section shall apply to all sales commencing on or after the effective date of this Act.

SECTIONS 72 to 76 set the effective dates for SECTIONS 22, 40, 42, 47, 49 ,52, 54, 56, 59, 61 and 68.