Senate

General Assembly

File No. 309

February Session, 2024

Substitute Senate Bill No. 8

Senate, April 8, 2024

The Committee on Human Services reported through SEN. LESSER of the 9th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING DRUG AFFORDABILITY.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2024*) For the purposes of this section and sections 2 to 9, inclusive, of this act, unless the context otherwise requires:

(1) "Canadian supplier" means a manufacturer or wholesale drug distributor that is licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs;

(2) "Canadian prescription drug importation program" or "program" means the Canadian prescription drug importation program established by the executive director of the Office of Health Strategy, in consultation with the Commissioners of Social Services, Consumer Protection and Public Health, pursuant to section 2 of this act;

(3) "Drug" means an article that is (A) recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the

United States or official National Formulary, or any supplement thereto, (B) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, (C) not food and intended to affect the structure or any function of the human body, and (D) not a device and intended for use as a component of any article specified in subparagraphs (A) to (C), inclusive, of this subdivision;

(4) "Drug Quality and Security Act" means the federal Drug Quality and Security Act, 21 USC 351, et seq., as amended from time to time;

(5) "Food, Drug and Cosmetic Act" means the federal Food, Drug and Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and Security Act, as both may be amended from time to time;

(6) "Laboratory" means an environmental laboratory as defined in section 19a-29a of the general statutes that is accredited as a testing laboratory in accordance with International Organization for Standardization (ISO) 17025 standards;

(7) "Laboratory testing" means a quantitative and qualitative analysis of a drug consistent with the applicable provisions of the official United States Pharmacopoeia;

(8) "Medical assistance program" means the state's Medicaid program established under Title XIX of the Social Security Act, as amended from time to time, and the Children's Health Insurance Program established under Title XXI of the Social Security Act, as amended from time to time;

(9) "Participating Canadian supplier" means a Canadian supplier that is exporting prescription drugs, in the manufacturer's original container, to a participating wholesaler for distribution in this state under the program;

(10) "Participating wholesaler" means a wholesaler that is (A) designated by the Department of Consumer Protection to distribute prescription drugs, in the manufacturer's original container, obtained from a participating Canadian supplier, and (B) participating in the program;

(11) "Track-and-trace" means the product tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act; and

(12) "Wholesaler" means a wholesaler, as defined in section 21a-70 of the general statutes, that has received a certificate of registration from the Commissioner of Consumer Protection pursuant to said section.

Sec. 2. (NEW) (*Effective July 1, 2024*) (a) The executive director of the Office of Health Strategy, in consultation with the Commissioners of Social Services, Consumer Protection and Public Health, shall establish the "Canadian prescription drug importation program". Notwithstanding any provision of the general statutes, the program shall provide for the importation of safe and effective prescription drugs from Canada for the medical assistance program that have the highest potential for cost savings in this state as determined by the executive director in consultation with said commissioners.

(b) (1) Not later than January 1, 2025, the executive director of the Office of Health Strategy shall submit a request to the federal Food and Drug Administration seeking approval for the program under Section 804 of the federal Food, Drug and Cosmetic Act, 21 USC 384(b) to 21 USC 384(h), inclusive, as amended from time to time. Such request shall, at a minimum:

(A) Describe the state's plans for operating the program;

(B) Demonstrate that any prescription drug that is imported and distributed in this state under the program:

(i) Meets all applicable federal and state standards for safety and effectiveness; and

(ii) Complies with all federal tracing procedures; and

(C) Disclose the costs of implementing the program.

(2) (A) If the federal Food and Drug Administration approves the

request, the executive director of the Office of Health Strategy and the Commissioners of Social Services and Consumer Protection shall:

(i) Submit to the Commissioner of Public Health a notice disclosing that the federal Food and Drug Administration approved such request;

(ii) Submit to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law, human services and public health a notice disclosing that the federal Food and Drug Administration approved such request; and

(iii) Begin operating the program in conjunction with the Commissioners of Social Services, Consumer Protection and Public Health not later than one hundred eighty days after the date of such approval.

(B) The executive director of the Office of Health Strategy shall not operate the program unless the federal Food and Drug Administration approved the request.

Sec. 3. (NEW) (*Effective July 1, 2024*) Each participating wholesaler may import and distribute a prescription drug in this state for use in the medical assistance program from a participating Canadian supplier under the program if:

(1) Such drug meets the United States Food and Drug Administration's standards concerning drug safety, effectiveness, misbranding and adulteration;

(2) Importing such drug would not violate federal patent laws; and

(3) Such drug is not:

(A) A controlled substance, as defined in 21 USC 802, as amended from time to time;

(B) A biological product, as defined in 42 USC 262, as amended from time to time;

(C) An infused drug;

(D) An intravenously injected drug;

(E) A drug that is inhaled during surgery; or

(F) A drug that is a parenteral drug, the importation of which is determined by the federal Secretary of Health and Human Services to pose a threat to the public health.

Sec. 4. (NEW) (*Effective July 1, 2024*) Participating wholesalers may, subject to the provisions of sections 2 to 9, inclusive, of this act, import and distribute drugs in this state for use in the medical assistance program from a participating Canadian supplier under the program to:

(1) A pharmacy or institutional pharmacy, as defined in section 20-571 of the general statutes, solely for prescriptions covered under the medical assistance program; and

(2) A laboratory registered with the Department of Public Health under section 19a-29a of the general statutes to perform analytical testing.

Sec. 5. (NEW) (*Effective July 1, 2024*) The executive director of the Office of Health Strategy shall require that each participating Canadian supplier and participating wholesaler (1) comply with all applicable track-and-trace requirements, and shall not distribute, dispense or sell outside of this state any prescription drug that is imported into this state under the program, and (2) make available to the executive director all track-and-trace records not later than forty-eight hours after the executive director requests such records.

Sec. 6. (NEW) (*Effective July 1, 2024*) (a) The participating wholesaler shall ensure the safety and quality of all drugs that are imported and distributed in this state under the program. The participating wholesaler shall:

(1) For each initial shipment of a drug that is imported into this state

by a participating wholesaler, ensure that a laboratory engaged by the participating wholesaler tests a statistically valid sample size for each batch of each drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

(2) For each shipment of a drug that is imported into this state by a participating wholesaler and has been sampled and tested pursuant to subdivision (1) of this subsection, ensure that a laboratory engaged by the participating wholesaler tests a statistically valid sample of such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

(3) Certify that each drug imported into this state under the program:

(A) Is approved for marketing in the United States and not adulterated or misbranded; and

(B) Meets all of the labeling requirements under 21 USC 352, as amended from time to time;

(4) Maintain laboratory records, including, but not limited to, complete data derived from all tests necessary to ensure that each drug imported into this state under the program is in compliance with the requirements of this section; and

(5) Maintain documentation demonstrating that the testing required by this section was conducted at a laboratory in accordance with the Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations concerning laboratory qualifications.

(b) The participating wholesaler shall maintain all information and documentation that is submitted pursuant to this section for a period of not less than three years from the date of submission.

(c) Each participating wholesaler shall maintain all of the following information for each drug that such participating wholesaler imports and distributes in this state under the program, and submit such information to the executive director of the Office of Health Strategy

upon request by the executive director:

(1) The name and quantity of the active ingredient of such drug;

(2) A description of the dosage form of such drug;

(3) The date on which such participating wholesaler received such drug;

(4) The quantity of such drug that such participating wholesaler received;

(5) The point of origin and destination of such drug;

(6) The price paid by such participating wholesaler for such drug;

(7) A report for any drug that fails laboratory testing; and

(8) Such additional information and documentation that the executive director of the Office of Health Strategy deems necessary to ensure the protection of the public health.

(d) The executive director of the Office of Health Strategy shall require each participating Canadian supplier to maintain the following information and documentation and, upon request by the executive director, submit such information and documentation to the executive director and the Commissioner of Consumer Protection for each drug that such participating Canadian supplier exports into this state under the program:

(1) The original source of such drug, including, but not limited to:

(A) The name of the manufacturer of such drug;

(B) The date on which such drug was manufactured; and

(C) The location where such drug was manufactured;

(2) The date on which such drug was shipped;

(3) The quantity of such drug that was shipped;

(4) The quantity of each lot of such drug originally received and the source of such lot;

(5) The lot or control number and the batch number assigned to such drug by the manufacturer; and

(6) Such additional information and documentation that the executive director of the Office of Health Strategy, in consultation with the Commissioners of Social Services, Consumer Protection and Public Health, deems necessary to ensure the protection of the public health.

Sec. 7. (NEW) (*Effective July 1, 2024*) (a) The executive director of the Office of Health Strategy shall issue a written order:

(1) Suspending importation and distribution of a drug under the program if the executive director discovers that such distribution or importation violates any provision of sections 2 to 9, inclusive, of this act or any other applicable state or federal law or regulation;

(2) Suspending all importation and distribution of drugs by a participating wholesaler under the program if the executive director discovers that the participating wholesaler has violated any provision of sections 2 to 9, inclusive, of this act or any other applicable state or federal law or regulation;

(3) Suspending all importation and distribution of drugs by a participating Canadian supplier under the program if the executive director discovers that the participating Canadian supplier has violated any provision of sections 2 to 9, inclusive, of this act or any other applicable state or federal law or regulation; or

(4) Requiring the recall or seizure of any drug that was imported and distributed under the program and has been identified as adulterated, within the meaning of section 21a-105 of the general statutes, or misbranded.

(b) The executive director of the Office of Health Strategy shall send a notice to each participating Canadian supplier and participating wholesaler affected by an order issued pursuant to subsection (a) of this section notifying such participating Canadian supplier or participating wholesaler that:

(1) The executive director of the Office of Health Strategy has issued such order, and provide the legal and factual basis for such order; and

(2) Such participating Canadian supplier or participating wholesaler may request, in writing, a hearing before the executive director of the Office of Health Strategy, provided such request is received by the executive director not later than thirty days after the date of such notice.

(c) If a hearing is timely requested pursuant to subsection (b) of this section, the executive director of the Office of Health Strategy shall, not later than thirty days after the receipt of the request, convene the hearing as a contested case in accordance with the provisions of chapter 54 of the general statutes. Not later than sixty days after the receipt of such request, the executive director shall issue a final decision vacating, modifying or affirming the order. The participating Canadian supplier or participating wholesaler aggrieved by such final decision may appeal such decision in accordance with the provisions of section 4-183 of the general statutes.

Sec. 8. (NEW) (*Effective July 1, 2024*) The executive director of the Office of Health Strategy may, in consultation with the Commissioners of Social Services, Consumer Protection and Public Health, adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 2 to 9, inclusive, of this act.

Sec. 9. (NEW) (*Effective July 1, 2024*) Not later than one hundred eighty days after the program begins, and annually thereafter, the executive director of the Office of Health Strategy established under section 19a-754a of the general statutes shall submit a report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing

committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law, human services and public health. Such report shall describe the operations of the program established pursuant to section 2 of this act and recommendations for expanding the program to other state-funded and privately funded health care programs.

Sec. 10. (NEW) (*Effective July 1, 2024*) (a) There is established the Prescription Drug Affordability Board to advise the executive director of the Office of Health Strategy on decisions regarding the affordability of prescription drugs. The board shall be within the Office of Health Strategy for administrative purposes only.

(b) The purposes of the Prescription Drug Affordability Board shall be to (1) explore strategies to reduce out-of-pocket drug costs to consumers while supporting innovations in biotechnology and scientific discovery, (2) study the prescription drug supply chain and pharmaceutical pricing strategies to identify opportunities for consumer savings, (3) monitor prescription drug prices in the state, (4) promote innovative strategies for the use of more affordable drugs, (5) take into consideration recommendations of a stakeholder council established pursuant to section 11 of this act, and (6) recommend a range of options of prescription drug cost affordability tools to the executive director of the Office of Health Strategy.

(c) The board shall consist of five members, each of whom shall have an advanced degree and experience or expertise in health care economics, health services research, pharmacoeconomics, pharmacology or clinical medicine. At least one such member shall have direct experience with consumer advocacy and health equity. The members shall be appointed by and serve at the pleasure of the Governor with the advice and consent of either house of the General Assembly. The Governor shall make all initial appointments not later than January 1, 2025. Any vacancy shall be filled for the remainder of the unexpired term by the Governor.

(d) Each member of the board shall serve a term of three years, except

as to the terms of the members who are first appointed to the board. Two such members shall serve an initial term of three years, two such members shall serve an initial term of two years and one such member shall serve an initial term of one year, to be determined by the Governor. The Governor may remove any appointed member of the board for malfeasance in office, failure to regularly attend meetings or any cause that renders the member incapable or unfit to discharge the duties of the member's office. Any such removal is not subject to review.

(e) The Governor shall designate one member of the board to serve as the chairperson of the board. Such chairperson shall schedule the first meeting of the board, which shall be held not later than February 1, 2025.

(f) The board shall meet not less than four times annually to carry out its purposes as set forth in subsection (b) of this section. A majority of the board shall constitute a quorum. The concurrence of a majority of the board in any matter within its powers and duties is required for any determination made by the board. Any conflict of interest involving a member of the board shall be disclosed at the next board meeting after the conflict is identified.

(g) Not later than December 31, 2025, and annually thereafter, the board shall report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to aging, general law, human services, insurance and public health. The report shall include, but need not be limited to: (1) Strategies for identifying and eliminating pricing or business practices that do not support or enhance innovation in drug development, (2) price trends and affordability strategies for any drug identified pursuant to subsection (b) or (c) of section 13 of this act, (3) any recommendations the board may have for legislation needed to make prescription drug products more affordable in the state while supporting and enhancing innovation in drug development, (4) purchasing strategies, cost effectiveness evaluations and the development of new technologies and drugs that increase affordability, and (5) a summary and evaluation of state prescription drug advisory

board activities and recommendations.

(h) Members of the board may engage in private employment, or in a profession or business, subject to any applicable laws, rules and regulations of the state regarding official ethics or conflict of interest. As used in this subsection, (1) "conflict of interest" means (A) an association of a board member, including a financial or personal association, that has the potential to bias or appear to bias a board member's decisions in matters related to the board, and (B) any instance in which a board member, a staff member, a contractor of the division on behalf of the board or an immediate family member of a board member has received or could receive (i) a financial benefit of any amount derived from the results or findings of a study or determination that is reached by or for the board, or (ii) a financial benefit from an individual or company that owns or manufacturers a prescription drug, service or item that is being or will be studied by the board; and (2) "financial benefit" means honoraria, fees, stock or any other form of compensation, including increases to the value of existing stock holdings.

(i) In carrying out its purposes, the board may:

(1) Collect and review publicly available information and information available via private subscriptions regarding prescription drug pricing and business practices of health carriers, health maintenance organizations, managed care organizations, manufacturers, wholesale distributors and pharmacy benefit managers, including, but not limited to, the annual report by pharmacy benefit managers required pursuant to section 38a-479ppp of the general statutes;

(2) Identify innovative strategies that may reduce the cost of prescription drugs to consumers, including importation of certain prescription drugs from Canada and other foreign countries and jurisdictions;

(3) Identify states with innovative programs to lower prescription drug costs and, if approved by the board, enter into memoranda of

understanding with such states to aid in the collection of transparency data for prescription drug products or any other information needed to establish similar programs in this state; and

(4) Receive and accept aid or contributions from any source of money, property, labor or other things of value, to be held, used and applied to carry out the purposes of the board, provided acceptance of such aid or contributions does not present a conflict of interest for any board member or any purpose of the board.

Sec. 11. (NEW) (*Effective July 1, 2024*) (a) There is established a Prescription Drug Affordability Stakeholder Council to advise the Prescription Drug Affordability Board established pursuant to section 10 of this act on decisions regarding the affordability of prescription drugs.

(b) Members of the council shall serve for three years and shall consist of:

(1) Three appointed by the speaker of the House of Representatives, who shall be (A) a representative of a state-wide health care advocacy coalition, (B) a representative of a state-wide advocacy organization for elderly persons, and (C) a representative of a state-wide organization for diverse communities;

(2) Three appointed by the president pro tempore of the Senate, who shall be (A) a representative of a labor union, (B) a health services researcher, and (C) a consumer who has experienced barriers to obtaining prescription drugs due to the cost of such drugs;

(3) Two appointed by the majority leader of the House of Representatives, who shall be (A) a representative of physicians, and (B) a representative of nurses;

(4) Two appointed by the minority leader of the House of Representatives, who shall be (A) a representative of private insurers, and (B) a representative of brand-name drug corporations;

(5) Two appointed by the minority leader of the Senate, who shall be (A) a representative of generic drug corporations, and (B) a representative of an academic institution with expertise in health care costs;

(6) Two appointed by the Governor, who shall be (A) a representative of pharmacists, and (B) a representative of pharmacy benefit managers;

(7) The Secretary of the Office of Policy and Management, or the secretary's designee;

(8) The Commissioner of Social Services, or the commissioner's designee;

(9) The Commissioner of Public Health, or the commissioner's designee;

(10) The Insurance Commissioner, or the commissioner's designee;

(11) The Commissioner of Consumer Protection, or the commissioner's designee;

(12) The executive director of the Office of Health Strategy, or the executive director's designee; and

(13) The Healthcare Advocate, or the Healthcare Advocate's designee.

(c) All initial appointments to the council shall be made not later than November 1, 2024. Any vacancy shall be filled by the appointing authority.

(d) The speaker of the House of Representatives and the president pro tempore of the Senate shall select the chairpersons of the council from among the members of the council. Such chairpersons shall schedule the first meeting of the council, which shall be held not later than sixty days after the effective date of this section.

(e) The administrative staff of the joint standing committee of the

General Assembly having cognizance of matters relating to insurance shall serve as administrative staff of the council.

(f) Not later than September 1, 2025, and annually thereafter, the council shall submit a report to the board, in accordance with the provisions of section 11-4a of the general statutes, on its recommendations concerning prescription drug prices. The council shall also provide recommendations to the board at any time the board requests such recommendations.

Sec. 12. (NEW) (*Effective July 1, 2024*) As used in this section and section 13 of this act:

(1) "Biologic" means a drug licensed under 42 USC 262, as amended from time to time;

(2) "Biosimilar" means a drug that is highly similar to a biologic and is produced or distributed in accordance with a biologics license application approved under 42 USC 262(k), as amended from time to time;

(3) "Board" means the Prescription Drug Affordability Board established pursuant to section 10 of this act;

(4) "Brand-name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 USC 355, as amended from time to time, but does not include an authorized generic drug as defined in 42 CFR 447.502, as amended from time to time;

(5) "FDA breakthrough drug" means a drug granted expedited review by the United States Food and Drug Administration under 21 USC 356, as amended from time to time;

(6) "Generic drug" means (A) a prescription drug product that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 USC 355, as amended from time to time, (B) an authorized generic drug as defined in 42 CFR 447.502, as

amended from time to time, or (C) a drug that entered the market before calendar year 1962 that was not originally marketed under a new prescription drug product application;

(7) "Manufacturer" means an entity that (A) engages in the manufacture of a drug product, or (B) enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name and sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets;

(8) "Orphan drug" has the same meaning as provided in 21 CFR 316.3, as amended from time to time; and

(9) "Prescription drug product" means a brand-name drug, a generic drug, a biologic or biosimilar.

Sec. 13. (NEW) (*Effective July 1, 2024*) (a) To the extent practicable, the Prescription Drug Affordability Board established pursuant to section 10 of this act may assess pricing information for prescription drug products by: (1) Entering into a memorandum of understanding with another state to which a manufacturer reports pricing information, (2) assessing spending for the drug in the state, (3) utilizing data and findings, including consumer affordability strategies, developed by another state's board, (4) utilizing data and findings, including cost containment strategies, developed by any other state or federal entity, (5) utilizing the maximum fair price for a prescription drug for persons eligible for Medicare established pursuant to the federal Inflation Reduction Act of 2022, P.L. No. 117-169, as amended from time to time, and (6) assessing any other available pricing information.

(b) On and after July 1, 2025, the board shall identify prescription drug products that, as adjusted annually for inflation in accordance with the consumer price index for all urban consumers published by the United States Department of Labor, Bureau of Labor Statistics, are:

(1) Brand-name drugs that have a launch wholesale acquisition cost

of thirty thousand dollars or more per year or course of treatment;

(2) Brand-name drugs that have a wholesale acquisition cost increase of three thousand dollars or more in any twelve–month period;

(3) Biosimilars that have a launch wholesale acquisition cost that is not at least fifteen per cent lower than the referenced brand biologic at the time the biosimilars are launched; and

(4) Generic drugs that have:

(A) A wholesale acquisition cost of one hundred dollars or more for (i) a thirty-day supply lasting a patient for a period of thirty consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration, (ii) a supply lasting a patient for fewer than thirty days based on the recommended dosage approved for labeling by the United States Food and Drug Administration, or (iii) one unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage; and

(B) A wholesale acquisition cost that increased by two hundred per cent or more during the immediately preceding twelve-month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding twelve months.

(c) On and after July 1, 2025, the board shall identify any other prescription drug products or pricing practices that may create affordability challenges for the health care system in the state or patients, including, but not limited to, drugs needed to address significant public health priorities.

(d) After identifying prescription drug products as required by subsections (b) and (c) of this section, the board may conduct, within available appropriations, a review for any identified prescription drug product or pricing practice if, after (1) seeking input from relevant stakeholders, and (2) considering the average patient cost share of the

prescription drug product, the board determines such review is in the interest of consumers.

(e) In conducting a review of prescription drugs, the board shall examine any document and research related to the pricing of the prescription drug product, including, but not limited to, (1) net average price in the state, (2) market competition and context, (3) projected revenue to the manufacturer, (4) the estimated value or cost effectiveness, (5) whether and how the prescription drug product represents an innovative therapy or is likely to improve health or health outcomes for the target consumer, and (6) any rebates, discounts, patient access programs or other cost mitigation strategies relevant to the prescription drug product. As part of its review, the board may also examine the costs or potential costs of FDA breakthrough and orphan drugs.

(f) The board shall determine whether use of the prescription drug product, consistent with the labeling approved by the federal Food and Drug Administration or standard medical practice, has led or will lead to affordability challenges for the health care system in the state or high out-of-pocket costs for patients. In determining whether a prescription drug product has led or will lead to an affordability challenge, the board may consider the following factors:

(1) The wholesale acquisition cost for the prescription drug product sold in the state;

(2) The average monetary price concession, discount or rebate provided or expected to be provided to health plans in the state as reported by manufacturers and health plans, expressed as a percentage of the wholesale acquisition cost for the prescription drug product under review;

(3) The total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefits manager operating in the state for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a

percentage of the wholesale acquisition costs;

(4) The price at which therapeutic alternatives have been sold in the state;

(5) The average monetary concession, discount or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefits managers in the state for therapeutic alternatives;

(6) The costs to health plans based on patient access consistent with United States Food and Drug Administration labeled indications and recognized standard medical practice;

(7) The impact on patient access resulting from the cost of the prescription drug product relative to health plan benefit design;

(8) The current or expected dollar value of drug–specific patient access programs that are supported by the manufacturer;

(9) The relative financial impacts to health, medical or social services costs as may be quantified and compared to baseline effects of existing therapeutic alternatives;

(10) The average patient copayment or other cost sharing for the prescription drug product in the state;

(11) Any information a manufacturer chooses to provide; and

(12) Any other factors as determined by the board.

(g) If the board finds that the spending on a prescription drug product reviewed under this section has led or will lead to an affordability challenge, the board shall recommend an upper payment limit to the executive director of the Office of Health Strategy and the Insurance Commissioner after considering: (1) The cost of administering the drug, (2) the cost of delivering the drug to patients, and (3) other relevant administrative costs related to the drug. In its recommendations, the board may utilize (A) upper payment limits set

by similar boards in other states, provided the board finds that the other entity's price justification process is at least as rigorous as the process set forth in state law, (B) upper payment limits set by any other state or federal entity, provided the board finds that the other entity's price justification process is at least as rigorous as the process set forth in state law, and (C) the Medicare maximum fair price for a prescription drug.

Sec. 14. (NEW) (*Effective July 1, 2025*) (a) As used in this section and section 15 of this act, (1) "ERISA plan" means an employee welfare benefit plan subject to the Employee Retirement Income Security Act of 1974, as amended from time to time; (2) "health benefit plan" has the same meaning as provided in section 38a-472f of the general statutes; (3) "state entity" means any state agency, or any individual employed by or acting on the state's behalf that purchases a prescription drug for an individual with health insurance paid for by the state, including health insurance offered by local, state, or federal agencies or through organizations licensed in the state; and (4) "participating ERISA plan" means an ERISA plan that elects to participate in the requirements of this section.

(b) It shall be a violation of this section for a state entity or health benefit plan or participating ERISA plan to purchase drugs with an established upper payment limit to be dispensed or delivered to a consumer in the state, whether directly or through a distributor, for a cost higher than the upper payment limit as determined in subsection (g) of section 13 of this act. Contracts entered into by a state entity, health benefit plan or participating ERISA plan and a third party for the purchase of prescription drugs shall expressly provide that rates paid for drugs may not exceed the upper payment limit.

(c) It shall be a violation of this section for a retail pharmacy licensed in this state to purchase for sale or distribution to a person whose health care is provided by a state entity or health benefit plan or participating ERISA plan a drug for a cost that exceeds the upper payment limit as determined in subsection (g) of section 13 of this act.

Sec. 15. (NEW) (*Effective July 1, 2025*) Any savings generated by a state

entity, health benefit plan, or participating ERISA plan that are attributable to the implementation of an upper payment limit established by the Prescription Drug Affordability Board shall be used to reduce health care costs to consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs. Not later than April 1, 2026, and annually thereafter, each state entity, health benefit plan and participating ERISA plan shall submit to the board and to the executive director of the Office of Health Strategy a report describing the savings achieved as a result of implementing upper payment limits and how those savings were used to reduce health care costs to consumers. Not later than July 1, 2026, and annually thereafter, the executive director, in accordance with the provisions of section 11-4a of the general statutes, shall file a report with the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law, human services, insurance and public health. The report shall include savings achieved and the executive director's recommendations concerning additional savings that may be achieved.

Sec. 16. (NEW) (*Effective July 1, 2025*) (a) As used in this section, "manufacturer" means an entity that (1) engages in the manufacture of a drug product, or (2) enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name and sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets. Any manufacturer that intends to withdraw from sale or distribution within the state a prescription drug for which the Prescription Drug Affordability Board has established an upper payment limit shall provide a notice of withdrawal in writing at least six months before the date of the intended withdrawal of such prescription drug to the board, the Insurance Commissioner, the Attorney General and any entity in the state with which the manufacturer has a contract for the sale or distribution of the drug.

(b) The board shall assess a penalty not to exceed five hundred thousand dollars if the board determines that a manufacturer failed to

provide the notice required by subsection (a) of this section before withdrawing from sale or distribution within the state a prescription drug for which the board has established an upper payment limit as determined in subsection (g) of section 13 of this act.

(c) A representative of a manufacturer that reasonably foresees an impending shortage of a prescription drug it sells or distributes in the state shall notify the board not later than thirty days after determining that a shortage of a prescription drug is imminent.

Sec. 17. (NEW) (*Effective January 1, 2025*) (a) As used in this section:

(1) "Health benefit plan" has the same meaning as provided in section 38a-472f of the general statutes;

(2) "Insulin" means an insulin product, including, but not limited to, an insulin pen or vial, that is licensed under 42 USC 262(a) or 42 USC 262(k), as amended from time to time;

(3) "Eligible insulin" means an insulin product for which at least two licenses have been issued and continues to be marketed pursuant to such licensure;

(4) "Net cost" means the cost of an insulin product taking into account rebates or discounts for that specific product, excluding (A) rebates or discounts required by state or federal law, including Medicaid, Medicare and section 340B of the Public Health Service Act, 42 USC 256b, as amended from time to time, and (B) rebates or discounts related to portfolio agreements that relate to purchase of multiple insulin products or other drugs;

(5) "State entity" means any state agency, or any individual employed by or acting on behalf of the state, that purchases a prescription drug for an individual with health insurance paid for by the state, including health insurance offered by local, state, or federal agencies or through organizations licensed in the state; and

(6) "Wholesale acquisition cost" means the price of a medication set

by a pharmaceutical manufacturer in the United States when selling to a wholesaler.

(b) A state entity and health benefit plan shall, except as otherwise required in any collective bargaining agreement affecting the state employee health plan established pursuant to section 5-259 of the general statutes, make available in a preferred tier with no copayment or out-of-pocket cost an eligible insulin product at the lowest wholesale acquisition cost to a beneficiary. Notwithstanding the provisions of this section, if a state entity or health plan determines that another eligible insulin product has a lower net cost than the lowest wholesale acquisition cost, such entity or health plan may offer that product with no out-of-pocket payment to a beneficiary of such state entity or health benefit plan. Nothing in this section shall prevent such entity or health benefit plan from covering more than one eligible insulin product in a preferred tier with no copayment or out-of-pocket cost to a beneficiary of such entity or health benefit plan.

Sec. 18. Section 38a-492d of the general statutes is amended by adding subsection (e) as follows (*Effective January 1, 2025*):

(NEW) (e) Notwithstanding the provisions of subsection (c) of this section, on and after January 1, 2025, any policy described in subsection (b) of this section shall make available in a preferred tier with no copayment or out-of-pocket cost an eligible insulin product at the lowest wholesale acquisition cost in accordance with section 17 of this act.

Sec. 19. Section 38a-518d of the general statutes is amended by adding subsection (e) as follows (*Effective January 1, 2025*):

(NEW) (e) Notwithstanding the provisions of subsection (c) of this section, on and after January 1, 2025, any policy described in subsection (b) of this section shall make available in a preferred tier with no copayment or out-of-pocket cost an eligible insulin product at the lowest wholesale acquisition cost in accordance with section 17 of this act.

Sec. 20. (NEW) (*Effective July 1, 2024*) (a) As used in this section:

(1) "Eligible drug" means an injectable drug product approved under Section 505(j) or 505(b)(2) of the federal Food, Drug and Cosmetic Act, as amended from time to time, that is on the drug shortage list, or has been on such list during the prior five-year period, established under Section 506E of the federal Food, Drug and Cosmetic Act, 21 USC 356e, as amended from time to time, or which has otherwise been identified as being at risk of shortage;

(2) "Drug purchasing agency" means the Departments of Correction, Social Services and Mental Health and Addiction Services;

(3) "Long-term purchase contract" means an agreement of at least two years' duration that defines price and volume commitments; and

(4) "Hospital" means a hospital licensed pursuant to chapter 368v of the general statutes.

(b) Any hospital or drug purchasing agency shall have a drug shortage prevention strategy covering at least forty eligible drugs, corresponding to at least one-third of the hospital's or agency's expected utilization of each eligible drug. The hospital or agency shall ensure that any long-term purchase contract for prescription drugs requires the entity contracting with the hospital or agency to:

(1) Hold physical reserve inventory in order to buffer supply disruption or demand surge equal to two quarters of contract volume, unless the drug is in shortage or otherwise subject to a supply disruption;

(2) Have a competent quality control unit and have in place processes to evaluate supplier quality;

(3) Have a process to ensure that critical quality attributes have been met and documentation of good manufacturing practices is complete; and

(4) Participate, in accordance with federal law, in the program administered under Section 340B of the Public Health Service Act, 42

USC 256b, as amended from time to time.

(c) Not later than January 1, 2025, and annually thereafter, a hospital shall file a report with the Commissioner of Public Health documenting compliance with the provisions of this section. Not later than February 1, 2025, and annually thereafter, the Commissioners of Correction, Mental Health and Addiction Services, Social Services and Public Health shall each file separate reports on compliance of hospitals, drug purchasing agencies and their contractors, as applicable, with the executive director of the Office of Health Strategy.

(d) The executive director of the Office of Health Strategy shall, not later than April 1, 2025, and annually thereafter, file a comprehensive report, in accordance with the provisions of section 11-4a of the general statutes, on compliance of hospitals, drug purchasing agencies and their contractors with the provisions of this section with the joint standing committees of the General Assembly having cognizance of matters relating to the judiciary, general law, human services and public health.

Sec. 21. (NEW) (*Effective from passage*) As used in this section and section 22 of this act:

(1) "340B drug" means a drug that (A) is a covered outpatient drug within the meaning of 42 USC 256b; (B) has been subject to any offer for reduced prices by a manufacturer under 42 USC 256b(a)(1); and (C) is purchased by a covered entity. "340B drug" includes a drug that would have been purchased but for the restriction or limitation described in subsection (a) of section 22 of this act;

(2) "Biologic" has the same meaning as provided in section 21a-70d of the general statutes;

(3) "Covered entity" has the same meaning as provided in Section 340B of the Public Health Service Act, 42 USC 256b, as amended from time to time;

(4) "Manufacturer" has the same meaning as provided in section 21a-70 of the general statutes, except that such definition shall include

manufacturers of biologics;

(5) "Package" has the same meaning as provided in 21 USC 360eee(11)(A);

(6) "Pharmacy" has the same meaning as provided in section 20-571 of the general statutes;

(7) "Third-party logistics provider" has the same meaning as provided in section 20-571 of the general statutes; and

(8) "Wholesaler" or "distributor" has the same meaning as provided in section 21a-70 of the general statutes.

Sec. 22. (NEW) (*Effective from passage*) (a) A manufacturer, third-party logistics provider, wholesaler or distributor, or an agent or affiliate of such manufacturer, third-party logistics provider, wholesaler or distributor, shall not, either directly or indirectly:

(1) Deny, restrict, prohibit, discriminate against or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services; or

(2) Require a covered entity, or a pharmacy that is under contract with a covered entity, to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, or a pharmacy that is under contract with a covered entity, unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

(b) (1) On and after July 1, 2024, if the executive director of the Office of Health Strategy receives information and has a reasonable belief, after evaluating such information, that any manufacturer, third-party logistics provider, wholesaler or distributor, or an agent or affiliate of

such manufacturer, third-party logistics provider, wholesaler or distributor, has acted in violation of any provision of this section, or rule or regulation adopted thereunder, such manufacturer, third-party logistics provider, wholesaler or distributor, or an agent or affiliate of such manufacturer, third-party logistics provider, wholesaler or distributor, shall be subject to a civil penalty of up to fifty thousand dollars. The executive director may issue a notice of violation and civil penalty by first-class mail or personal service. Such notice shall include: (A) A reference to the section of the general statutes, rule or section of the regulations of Connecticut state agencies believed or alleged to have been violated; (B) a short and plain language statement of the matters asserted or charged; (C) a description of the activity to cease; (D) a statement of the amount of the civil penalty or penalties that may be imposed; (E) a statement concerning the right to a hearing; and (F) a statement that such manufacturer, third-party logistics provider, wholesaler or distributor, or an agent or affiliate of such manufacturer, third-party logistics provider, wholesaler or distributor, may, not later than ten business days after receipt of such notice, make a request for a hearing on the matters asserted.

(2) The manufacturer, third-party logistics provider, wholesaler or distributor, or an agent or affiliate of such manufacturer, third-party logistics provider, wholesaler or distributor, to whom such notice is provided pursuant to subparagraph (A) of subdivision (1) of this subsection may, not later than ten business days after receipt of such notice, make written application to the Office of Health Strategy to request a hearing to demonstrate that such violation did not occur. The failure to make a timely request for a hearing shall result in the issuance of a cease and desist order or imposition of a civil penalty by the office. All hearings held under this subsection shall be conducted in accordance with the provisions of chapter 54 of the general statutes.

(3) Following any hearing before the Office of Health Strategy pursuant to subdivision (2) of this subsection, if the office finds, by a preponderance of the evidence, that any manufacturer, third-party logistics provider, wholesaler or distributor, or an agent or affiliate of

such manufacturer, third-party logistics provider, wholesaler or distributor, violated or is violating any provision of this subsection, any rule or regulation adopted thereunder or any order issued by the office, the office shall issue a final cease and desist order in addition to any civil penalty the office imposes.

(c) Nothing in this section shall be construed or applied to be in conflict with or less restrictive than:

(1) Applicable federal law and related regulations, including 21 USC 355-1, as amended from time to time; or

(2) Other laws of this state to the extent such laws are compatible with applicable federal law.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2024*	New section
Sec. 2	*July 1, 2024*	New section
Sec. 3	*July 1, 2024*	New section
Sec. 4	*July 1, 2024*	New section
Sec. 5	*July 1, 2024*	New section
Sec. 6	*July 1, 2024*	New section
Sec. 7	*July 1, 2024*	New section
Sec. 8	*July 1, 2024*	New section
Sec. 9	*July 1, 2024*	New section
Sec. 10	*July 1, 2024*	New section
Sec. 11	*July 1, 2024*	New section
Sec. 12	*July 1, 2024*	New section
Sec. 13	*July 1, 2024*	New section
Sec. 14	*July 1, 2025*	New section
Sec. 15	*July 1, 2025*	New section
Sec. 16	*July 1, 2025*	New section
Sec. 17	*January 1, 2025*	New section
Sec. 18	*January 1, 2025*	38a-492d(e)
Sec. 19	*January 1, 2025*	38a-518d(e)
Sec. 20	*July 1, 2024*	New section
Sec. 21	*from passage*	New section
Sec. 22	*from passage*	New section

HS *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact: See Below

Municipal Impact: See Below

Explanation

The bill makes changes to address prescription drug affordability that results in various impacts described below.

Sections 1-9 create a Canadian Prescription Drug Importation Program that results in costs to the Office of Health Strategy (OHS) and the Department of Consumer Protection (DCP).

Section 2 requires OHS to submit a request for approval of the importation program to the federal Food and Drug Administration (FDA). OHS will incur a one-time cost of $125,000 in FY 25 to hire a consultant to assist them in preparing a plan. If the program is approved by the FDA, the bill will result in potential costs to a variety of state agencies.

OHS will incur costs of $336,000 in salary and fringe benefits beginning in FY 26 to hire a Staff Attorney 2 and a planning analyst to fulfill the requirements outlined in **Sections 5&7**, which mandate OHS to ensure suppliers and distributors comply with the bill's provisions. The attorney and planning analyst will also assist the executive director with adopting regulations required by **Section 8**.

Section 9 requires OHS to submit an annual report describing the operations of the program. OHS will incur costs of $327,000 in salary and fringe benefits beginning in FY 26 to hire a lead planning analyst

and a planning analyst to create the annual report.

DCP[1] will see a significant increase in regulatory work, and the agency may have to hire two additional employees[2] for a salary and other expenses cost of $203,000, along with associated fringe benefits costs of $82,000, all beginning in FY 26.

Sections 10-13 of the bill establish a Prescription Drug Affordability Board (PDAB) and lay out its administrative responsibilities and capabilities. OHS will incur costs of $527,000 in salary and fringe benefits beginning in FY 26 to hire three new staff to directly support the board in its activities: a planning specialist, a lead planning analyst, and a planning analyst.

Sections 14-15 establish an upper payment limit for state entities, health benefit plans, and participating ERISA plans to purchase drugs. This results in a savings to state entities beginning in FY 25. Any savings will be used to reduce out-of-pocket costs to consumers, resulting in no fiscal impact to the state or municipalities. The plans will also submit a report to the PDAB and OHS describing the savings which will not result in a fiscal impact.

Sections 17-19 result in a potential cost to fully insured municipalities that currently impose cost sharing on insulin products to the extent cost sharing is imposed. Additional costs to municipalities can be incurred if they do not offer insulin products at the lowest wholesale acquisition cost. There is no fiscal impact to the state to impose these provisions as insulin products are currently covered under the state employee health plan with no cost sharing.

Section 20 requires any hospital or drug purchasing agency to have a drug shortage prevention strategy covering at least 40 eligible drugs

[1]DCP is the state regulatory agency responsible for the pharmaceutical industry. DCP is tasked with drug tracking, investigation, and enforcement of this marketplace. The agency will be integrally involved in how the drug supply chains are managed and enforced as well as ensuring compliance with the FDA.

[2] The employees include one drug control agent and one staff attorney.

corresponding to at least one-third of the hospital or agency's expected use of each drug. This includes the Departments of Social Services, Correction, Mental Health and Addiction Services as well as UCONN Health Center. OHS will incur costs of $145,000 in salary and fringe benefits beginning in FY 26 to hire a planning analyst that will develop a comprehensive report on compliance of hospitals, drug purchasing agencies, and their contractors that will be sent to the legislature annually beginning on April 1, 2025.

Sections 21 and 22 regarding 340B entities result in an annual significant positive financial impact to the University of Connecticut Health Center beginning in FY 25. The health center has multiple 340B covered entities, including John Dempsey Hospital, and has not been fully benefiting from the provisions of the 340B program due to manufacturer and pharmacy benefits manager (PBM) practices. The health center estimates that the foregone savings and revenue gain due to these practices has reached approximately $9 million annually and will continue to increase. It is anticipated that the bill will reduce or eliminate the practices it prohibits, and consequently result in greater 340B savings and revenue gain to UConn Health Center.

Section 22 also makes OHS responsible for monitoring compliance by drug manufactures working with covered entities as part of 340b. OHS will incur costs of $146,000 beginning in FY 26 for a staff attorney and related fringe benefits costs to assist in conducting investigations and hearings for violating the provisions of the section. There is a potential revenue gain to the state from this section to the extent OHS renders civil penalties of up to $50,000 on applicable entities.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation and the number of civil penalties administered by OHS.

OLR Bill Analysis

sSB 8

AN ACT CONCERNING DRUG AFFORDABILITY.

TABLE OF CONTENTS:

expects a drug shortage; requires PDAB to fine a manufacturer up to $500,000 for failure to give notice before withdrawing a drug

§§ 17-19 — INSULIN

Requires state entities and health benefit plans to cover certain insulin products at the lowest wholesale acquisition cost in a preferred tier with no copayment or out-of-pocket cost; allows plans to cover and offer more than one insulin product

§ 20 — DRUG SHORTAGE PREVENTION

Requires hospitals and drug purchasing agencies to (1) have drug shortage prevention strategies covering at least one-third of expected use for at least 40 drugs and (2) include in any long-term drug purchasing contract certain drug shortage mitigation strategies

§§ 21 & 22 — 340B DRUGS

Prohibits drug manufacturers, wholesalers, and distributors from (1) limiting a pharmacy's access to 340B drugs and (2) requiring health care organizations or pharmacies to submit claims or utilization data as a condition for receiving 340B drugs; establishes a hearing process and penalties for violators

SUMMARY

This bill takes various steps to address prescription drug affordability and access for Connecticut consumers, including:

1. requiring the Office of Health Strategy (OHS) to establish the Canadian Prescription Drug Importation Program to import from Canada safe and effective drugs with potential cost savings for Connecticut's Medicaid and Children's Health Insurance Program (CHIP) programs;

2. establishing the Prescription Drug Affordability Board (PDAB) and Prescription Drug Affordability Stakeholder Council to review and make recommendations on prescription drugs' costs and affordability;

3. allowing PDAB to review and set upper payment limits for drugs with high inflation or affordability challenges;

4. prohibiting state entities and health insurance plans from purchasing, and pharmacies from distributing to certain consumers, drugs purchased at a price higher than its upper payment limit;

5. requiring state entities and health insurance plans to use cost savings attributable to an upper payment limit to reduce consumers' health care costs;

6. prohibiting manufacturers from withdrawing from distribution in Connecticut a drug with an established upper payment limit without first notifying the state and contracted purchasers;

7. requiring state entities and health insurance plans to cover, in a preferred tier and without copayment or out-of-pocket costs, insulin products at the lowest wholesale acquisition cost;

8. requiring Connecticut hospitals and drug purchasing agencies to have drug shortage prevention strategies that cover at least one-third of the expected use of at least 40 drugs; and

9. prohibiting drug manufacturers, wholesalers, and distributors from limiting, or requiring claims and utilization data as a condition of, a pharmacy or health care organization's access to drugs under the federal 340B drug program.

EFFECTIVE DATE: Various; see below.

§§ 1-9 — CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

Requires OHS to consult with DCP, DPH, and DSS to establish a program to import from Canada prescription drugs with potential cost savings for Medicaid; specifies program participation requirements for suppliers and wholesalers; requires OHS to report annually on the program

The bill requires the OHS executive director, in consultation with the Department of Consumer Protection (DCP), Department of Public Health (DPH), and Department of Social Services (DSS) commissioners, to establish the "Canadian Prescription Drug Importation Program" to import from Canada safe and effective prescription drugs with the highest potential cost savings to the state's medical assistance program (i.e., Medicaid and CHIP).

EFFECTIVE DATE: July 1, 2024

Application for Federal Approval (§ 2)

By January 1, 2025, the OHS executive director must submit a request to the federal Food and Drug Administration (FDA) for approval of the importation program. (Under federal law, drug importation programs require federal approval.)

The request must, at least:

1. describe the state's plans for operating the program,

2. demonstrate that the prescription drugs imported under the program will (a) meet all applicable federal and state safety and effectiveness standards and (b) comply with all federal tracing procedures, and

3. disclose the program's cost.

If the FDA approves the request, the OHS executive director and DCP and DSS commissioners must:

1. notify the DPH commissioner and the Appropriations, General Law, Human Services, and Public Health committees that the request was approved and

2. with the DPH commissioner, begin operating the program within 180 days after the approval date.

The bill prohibits OHS from operating the importation program without federal approval.

Importation (§§ 3 & 4)

Under the bill, a participating wholesaler (i.e., a wholesaler designated by DCP to distribute prescription drugs imported from Canada through the program) may import and distribute drugs if they:

1. meet FDA safety, effectiveness, misbranding, and adulteration standards and

2. are not (a) controlled substances, (b) biologics, (c) infused, (d)

intravenously injected, (e) inhaled during surgery, or (f) parenteral drugs that the federal Health and Human Services secretary determines pose a public health threat.

Wholesalers are also prohibited from importing prescription drugs if doing so violates federal patent laws.

Wholesalers may import and distribute prescription drugs to a pharmacy or institutional pharmacy for the medical assistance program or to a DPH-registered laboratory for analytical testing.

Track-and-Trace (§ 5)

Under the bill, the OHS executive director must require Canadian suppliers and participating wholesalers to comply with all applicable track-and-trace requirements (e.g., document the manufacturer, supply, and distribution chain) and prohibits them from distributing, dispensing, or selling any imported drugs outside of Connecticut.

Under the bill, the suppliers and wholesalers must make track-and-trace records available to the executive director within 48 hours after her request.

Safety (§ 6)

Under the bill, participating wholesalers must ensure the safety and quality of all imported drugs. This includes:

1. for each initial shipment of imported drugs, having a laboratory test a statistically valid sample size for each batch of each drug in the shipment for authenticity and degradation consistent with federal requirements and

2. for subsequent shipments, test a statistically valid sample for authenticity and degradation.

Wholesalers must also:

1. certify that each imported drug is approved for marketing in the United States, is not adulterated or misbranded, and meets

federal labeling requirements;

2. maintain laboratory records, including data from all tests necessary to ensure the drug complies with the bill's requirements; and

3. maintain documentation that the testing required by the bill was done at a laboratory in compliance with federal and state laws and regulations.

The bill requires wholesalers to maintain the records required under the bill for at least three years from the date they are submitted, as noted below.

Wholesaler Records (§ 6)

The bill requires each wholesaler to maintain for each imported drug:

1. the name and quantity of the drug's active ingredient;

2. a description of the drug's dosage form;

3. the quantity of and date on which the wholesaler received the drug, and the price it paid;

4. the drug's origin point and destination;

5. a report for any drug that failed laboratory testing; and

6. any other information and documentation the OHS executive director requires for the protection of public health.

This information must be submitted to OHS upon the executive director's request.

Supplier Records (§ 6)

The bill requires each participating Canadian supplier to maintain the following information for each exported drug:

1. the drug's original source, including the manufacturer's name,

date and location it was manufactured, and shipment date and quantity;

2. the quantity of each lot of drug originally received and its source;

3. the manufacturer-assigned lot or control number and batch number; and

4. any other information and documentation the OHS executive director, in consultation with the DCP, DPH, and DSS commissioners, requires for the protection of public health.

This information must be submitted to the OHS executive director and the DCP commissioner upon request.

Enforcement (§ 7)

The bill requires the OHS executive director to issue a written order suspending the drug's import and distribution, or suspending all importation and distribution of drugs by a wholesaler or Canadian supplier, if she discovers the import or distribution of the drug or the wholesaler or supplier violates any of the bill's provisions or any other applicable state or federal law or regulation.

She must also issue a written order requiring the recall or seizure of any imported drug that has been misbranded or identified as adulterated.

If the executive director issues an order against a wholesaler or supplier, she must notify the wholesaler or supplier (1) of the order, along with its legal and factual basis, and (2) that they may make a written request for a hearing within 30 days after the notice date.

If the executive director receives a timely request for a hearing, she must convene it as a contested case under the Uniform Administrative Procedure Act (UAPA) within 30 days of receiving the request, and must issue a final decision vacating, modifying, or affirming the order within 60 days after the request. Any supplier or wholesaler aggrieved by a final decision may appeal to Superior Court according to existing

UAPA provisions.

Regulations (§ 8)

The bill authorizes the OHS executive director, in consultation with the DCP, DPH, and DSS commissioners, to adopt regulations to implement the drug importation program.

Reporting (§ 9)

Starting no later than 180 days after the program begins, the bill requires the OHS executive director to annually submit a report to the Appropriations, General Law, Human Services, and Public Health committees describing the importation program's operations and recommendations for expanding the program to other state-funded and privately funded health care programs.

§ 10 — PRESCRIPTION DRUG AFFORDABILITY BOARD

Creates the Prescription Drug Affordability Board to advise OHS on prescription drug affordability; requires the board, beginning by December 31, 2025, to report annually to certain legislative committees on drug affordability

The bill establishes PDAB within OHS for administrative purposes to advise the OHS executive director on decisions regarding prescription drug affordability. Specifically, the board must:

1. explore strategies to reduce out-of-pocket drug costs for consumers while supporting biotechnology innovations and scientific discovery,

2. identify opportunities for consumer savings by studying the prescription drug supply chain and pharmaceutical pricing strategies,

3. monitor prescription drug prices in Connecticut,

4. promote innovative strategies for the use of more affordable drugs,

5. consider recommendations from the stakeholder council established by this bill (see § 11), and

6. recommend drug cost affordability tool options to the OHS executive director.

To carry out its duties, the bill authorizes PDAB to do the following:

1. collect and review (a) publicly available information and (b) information available via private subscriptions about various health care organizations' prescription drug pricing and business practices, including the pharmacy benefit managers' annual report required by state law;

2. identify innovative strategies, including importing prescription drugs from Canada or other foreign jurisdictions, to lower prescription drug costs for consumers;

3. identify states with innovative programs to lower prescription drug costs, and, if approved by the board, enter into memoranda of understanding (MOU) with these states to collect data and information to establish similar programs in Connecticut; and

4. receive any aid or contributions from any source, as long as it is not a conflict of interest, to use to carry out its purposes.

EFFECTIVE DATE: July 1, 2024

Membership

Under the bill, PDAB is comprised of five gubernatorial appointees who must have an (1) advance degree and (2) experience or expertise in health care economics, health services research, pharmacoeconomics, pharmacology, or clinical medicine. At least one member must have experience in consumer advocacy and health equity.

The governor, with approval from either legislative chamber, must make initial board appointments by January 1, 2025. The governor must also select the board's chairperson from among its members. Generally, board members will serve three-year terms, except initial appointees' terms will expire as follows:

1. two members will serve three-year terms,

2. two members will serve two-year terms, and

3. one member will serve a one-year term.

The bill allows the governor to assign these term limits among initial board members. Under the bill, the governor may also, without review, remove any board member for malfeasance, failure to regularly attend meetings, or any reason that makes the member incapable of fulfilling PDAB duties. The governor must fill any vacancies, and appointments occurring other than by term expiration are for the unexpired term balance.

The bill allows members to be privately employed, subject to any applicable state ethics rules, but if a member discovers a conflict of interest (i.e., a financial or personal association that may cause bias or a financial benefit related to the board's work), he or she must report it at the next board meeting.

Meetings

The bill requires the chairperson to schedule and hold the board's first meeting by February 1, 2025, and the board must meet at least four times annually. A majority of members constitutes a quorum for conducting business, and any determination the board makes must have majority support.

Reporting Requirement

The bill requires PDAB, beginning by December 31, 2025, to annually report to the Aging, General Law, Human Services, Insurance and Real Estate, and Public Health committees on the following:

1. strategies to identify and eliminate pricing or business practices that do not support drug development innovation;

2. price trends and affordability strategies for specific drugs identified to have recent high-cost increases (see § 13);

3. recommendations for legislation to make prescription drugs more affordable while enhancing drug development innovation;

4. purchasing strategies, cost effectiveness evaluations, and new technology or drug developments that increase affordability; and

5. a summary and evaluation of the board's activities and recommendations.

§ 11 — PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER COUNCIL

Establishes the Prescription Drug Affordability Stakeholder Council to advise PDAB; requires the council to report on prescription drug prices to the board annually beginning by September 1, 2025

The bill establishes the 21-member Prescription Drug Affordability Stakeholder Council to advise PDAB on decisions about prescription drug affordability. Beginning by September 1, 2025, the council must annually report its recommendations on prescription drug prices to PDAB. Additionally, the council must give recommendations to the board at its request.

The bill designates the Insurance and Real Estate Committee's administrative staff as the council's administrative staff. The council must hold its first meeting by August 30, 2024 (i.e., within 60 days after this section's effective date).

EFFECTIVE DATE: July 1, 2024

Membership and Appointments

Under the bill, the council has seven ex officio members and the following 14 appointed members:

1. three members appointed by the House speaker, including a representative from a statewide advocacy organization for (a) a health care coalition, (b) elderly people, and (c) diverse communities;

2. three members appointed by the Senate president pro tempore, including a (a) labor union representative, (b) health services

researcher, and (c) consumer who has experienced barriers to getting prescription drugs due to their cost;

3. two members appointed by the House majority leader, including a representative of (a) physicians and (b) nurses;

4. two members appointed by the House minority leader, including a representative of (a) private insurers and (b) brand-name drug corporations;

5. two members appointed by the Senate minority leader, including a representative of (a) generic drug corporations and (b) an academic institution with expertise in health care costs; and

6. two members appointed by the governor, including a representative of (a) pharmacists and (b) pharmacy benefit managers.

The council's ex officio members are the Office of Policy and Management secretary; DCP, DPH, DSS, and insurance commissioners; OHS executive director; and Healthcare Advocate, or their designees.

Under the bill, initial appointments must be made by November 1, 2024 (though the bill requires the council to hold its first meeting prior to this date), and council members serve three-year terms. The bill requires the House and Senate leaders to select the council's chairpersons from among its members.

§§ 12 & 13 — PRESCRIPTION DRUG PRICING ASSESSMENT

Requires PDAB to (1) identify drugs with high inflation or affordability challenges and (2) recommend upper payment limits for drugs with affordability challenges to OHS; allows PDAB to review drug prices and pricing practices

The bill allows PDAB to assess prescription drug pricing information by doing the following:

1. entering into an MOU with another state to which a drug manufacturer reports pricing information;

2. assessing spending for a drug in Connecticut;

3. using data and findings, including consumer affordability strategies, developed by (a) similar boards in other states or (b) other state or federal entities;

4. using the federally established prescription drug maximum fair price for Medicare members; and

5. assessing any other available pricing information.

EFFECTIVE DATE: July 1, 2024

Annual Inflation-Adjusted Costs

The bill requires PDAB, beginning July 1, 2025, to identify prescription drugs that, when adjusted annually for inflation, are:

1. brand-name drugs with a launch wholesale acquisition cost of at least $30,000 or more per year or treatment course,

2. brand-name drugs with a wholesale acquisition cost increase of at least $3,000 in a 12-month period, or

3. biosimilars (i.e., drugs similar to other licensed drugs) with a launch wholesale acquisition cost not at least 15% lower than the referenced brand biologic.

The board must also identify generic drugs that have:

1. a wholesale acquisition cost of at least $100 for (a) a 30-day dosage supply, (b) a supply lasting a patient fewer than 30 days based on the recommended dosage, or (c) one unit of drug if the FDA does not recommend a finite dosage; or

2. a wholesale acquisition cost that increased by at least 200% in the previous 12-month period.

Affordability Challenges

Beginning July 1, 2025, the bill requires the board to identify other drugs or pricing practices that have created, or may create, affordability challenges for Connecticut's health care system or patients, including

drugs to address significant public health priorities. To do so, the bill allows the board to consider the following:

1. the drug's wholesale acquisition cost;
2. the price of therapeutic alternatives;
3. the price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans and pharmacy benefits managers for (a) the drug under review and (b) therapeutic alternatives;
4. the cost to health plans for patient access based on standard dosage;
5. how the drug's cost relative to health plan benefit design impacts patient access;
6. the current or expected cost for manufacturer-supported patient access programs;
7. the drug's financial impacts on health, medical, or social services costs relative to those for therapeutic alternatives;
8. a Connecticut patient's average copayment or other cost sharing for the drug; and
9. any other factors it deems necessary or any other information the manufacturer provides.

Prescription Drug Review

The bill allows PDAB to review, within available appropriations, any drug or pricing practice that has a high cost when adjusted for inflation or creates an affordability challenge if, after (1) seeking stakeholder input and (2) considering the average patient cost share of the drug, it determines a review is in the interest of consumers.

Under the bill, when doing a review, the board must examine any information related to the drug's pricing, including:

1. net average price in the state;

2. market competition and context;

3. the manufacturer's projected revenue;

4. estimated value or cost effectiveness;

5. if and how the drug is an innovative therapy or likely to improve health for target consumers; and

6. cost mitigation strategies relevant to the drug, such as rebates, discounts, and patient access programs.

The bill also allows the board to examine costs or potential costs of FDA breakthrough and orphan drugs (i.e., drugs to treat rare conditions).

Upper Payment Limits

The bill requires the board to recommend to the OHS executive director and insurance commissioner an upper payment limit for any drug it determines has led or will lead to an affordability challenge. The board must consider (1) the cost of administering the drug, (2) the cost of delivering the drug to patients, and (3) relevant administrative costs when determining its recommended upper payment limit.

To makes its recommendation, the bill allows the board to use:

1. upper payments set by (a) boards in other states and (b) other state or federal entities, as long as their price justification process is as rigorous as that outlined in this bill; and

2. a prescription drug's Medicare maximum fair price.

§ 14 — PAYMENT LIMIT VIOLATIONS

Prohibits state entities, health benefit plans, and participating ERISA plans from purchasing drugs at a price higher than its upper payment limit; prohibits pharmacies from distributing to certain consumers drugs purchased at a price higher than its upper payment limit

The bill makes it a violation for a state entity, health benefit plan (e.g.,

a commercial health insurance policy), or participating Employee Retirement Income Security Act (ERISA) plan (e.g., a health plan subject to federal minimum standards that chooses to participate in the bill's requirements) to purchase drugs for consumers at a price higher than the PDAB-established upper payment limit. The bill requires any contract between a state entity, health benefit plan, or participating ERISA plan and a third party to include that rates paid for drugs may not exceed the upper payment limit.

Similarly, under the bill a Connecticut-licensed retail pharmacy may not purchase drugs meant for people whose health care is provided by a state entity, health benefit plan, or ERISA plan at a price higher than the PDAB's upper payment limit.

The bill is silent on how these violations will be assessed and what penalties may be imposed.

EFFECTIVE DATE: July 1, 2025

§ 15 — COST SAVINGS

Requires state entities, health benefit plans, and participating ERISA plans to (1) use any savings generated by an upper payment limit to lower consumers' costs and (2) annually report to PDAB and OHS on savings achieved; requires OHS to annually report on the savings to certain legislative committees

Under the bill, any savings a state entity, health benefit plan, or participating ERISA plan generates that are attributable to an implemented upper payment limit must be used to reduce consumers' health care costs, prioritizing reducing out-of-pocket prescription drug costs.

Beginning by April 1, 2026, the bill requires the state entities and plans to annually report to PDAB and OHS on savings achieved and how savings were used to reduce consumers' costs.

The bill requires the OHS executive director, beginning by July 1, 2026, to annually report on savings achieved and recommendations to increase savings to the Appropriations, General Law, Human Services, Insurance and Real Estate, and Public Health committees.

EFFECTIVE DATE: July 1, 2025

§ 16 — DRUG WITHDRAWAL

Requires manufacturers to (1) provide six-months' notice before withdrawing from sale a drug with an established upper payment limit and (2) notify PDAB within 30 days if it expects a drug shortage; requires PDAB to fine a manufacturer up to $500,000 for failure to give notice before withdrawing a drug

The bill requires a manufacturer to give at least six-months' written notice before it discontinues distributing a drug for which the board has established an upper payment limit to (1) PDAB, (2) the insurance commissioner, (3) the attorney general, and (4) any entity with which it is contracted with for the drug's sale. The bill also requires a manufacturer that expects a shortage of its drug to notify PDAB within 30 days after making this determination.

Under the bill, PDAB must fine a manufacturer up to $500,000 if it fails to give the required notice before withdrawing a drug.

EFFECTIVE DATE: July 1, 2025

§§ 17-19 — INSULIN

Requires state entities and health benefit plans to cover certain insulin products at the lowest wholesale acquisition cost in a preferred tier with no copayment or out-of-pocket cost; allows plans to cover and offer more than one insulin product

The bill requires state entities and health benefit plans (other than as required in collectively bargained agreements that affect the state employee plan) to make available to beneficiaries an eligible insulin product at the lowest wholesale acquisition cost in a preferred tier with no copayment or out-of-pocket cost. An "eligible insulin product" is an insulin product, including pens or vials, for which at least two licenses have been issued and that continues to be marketed.

Under current law, health benefit plans generally must cap the cost of insulin at $25 per 30-day supply (CGS §§ 38a-492d & -518d).

The bill also allows state entities and health benefit plans to (1) cover more than one eligible insulin product in a preferred tier and (2) offer, without out-of-pocket costs, another eligible insulin product if the product has a net cost lower than the lowest wholesale acquisition cost.

EFFECTIVE DATE: January 1, 2025

§ 20 — DRUG SHORTAGE PREVENTION

Requires hospitals and drug purchasing agencies to (1) have drug shortage prevention strategies covering at least one-third of expected use for at least 40 drugs and (2) include in any long-term drug purchasing contract certain drug shortage mitigation strategies

The bill requires hospitals and drug purchasing agencies (i.e., the departments of correction, mental health and addiction services, and social services) to have a drug shortage prevention strategy that covers at least one-third of the hospital's or agency's expected use of at least 40 eligible drugs. Under the bill, "eligible drugs" are federally approved injectables on the FDA's drug shortage list, on the list within the past five years, or at risk of shortage.

EFFECTIVE DATE: July 1, 2024

Contract Requirements

In any long-term prescription drug purchase contract, a hospital or agency must require the contracting entity to:

1. hold physical reserve inventory equal to two quarters of the contract volume to buffer supply disruption or demand, unless the drug is in shortage or subject to a supply disruption;

2. have a competent quality control unit and processes to evaluate supplier quality;

3. have a process to ensure drug quality and complete documentation of good manufacturing practices; and

4. participate, following federal law, in the 340B Drug Pricing Program.

Reporting Requirements

The bill outlines the following drug shortage prevention compliance reporting requirements:

1. beginning by January 1, 2025, hospitals must annually report to the DPH commissioner documentation of their compliance;

2. beginning by February 1, 2025, the correction, mental health and addiction services, DPH, and DSS commissioners must annually report to OHS on hospitals', drug purchasing agencies', and contractors' compliance; and

3. beginning by April 1, 2025, the OHS executive director must report this information to the General Law, Human Services, Judiciary, and Public Health committees.

§§ 21 & 22 — 340B DRUGS

Prohibits drug manufacturers, wholesalers, and distributors from (1) limiting a pharmacy's access to 340B drugs and (2) requiring health care organizations or pharmacies to submit claims or utilization data as a condition for receiving 340B drugs; establishes a hearing process and penalties for violators

Under federal law, the 340B Drug Pricing Program requires drug manufacturers participating in Medicaid to provide outpatient drugs to eligible healthcare organizations that treat low-income and uninsured patients (i.e., "covered entities") at reduced prices. Pharmacies may contract with 340B-participating healthcare organizations (e.g., hospitals or outpatient clinics) to also purchase reduced-price outpatient drugs.

The bill prohibits manufacturers, third-party logistics providers, wholesalers, or distributors, or their agents or affiliates, from directly or indirectly taking any of the following actions:

1. limiting a 340B-authorized pharmacy's access to 340B drugs, unless the pharmacy's receipt of a drug is federally prohibited; or

2. requiring a covered entity or pharmacy contracted with a covered entity to submit claims or utilization data as a condition for acquiring a 340B drug, unless the claims or data sharing is federally required.

EFFECTIVE DATE: Upon passage

Violations

Beginning July 1, 2024, the bill subjects entities to a civil penalty of up to $50,000 if the OHS executive director receives information or has reasonable belief that the entity has violated these restrictions.

The bill allows the executive director to issue notice of the violation and civil penalty by mail or personal service. The notice must include:

1. reference to the Connecticut law or regulation that has been violated;
2. a short and plain language statement of the violation;
3. a description of the activity to cease;
4. the amount of the imposed civil penalty; and
5. explanation of the right to request, in writing to OHS, a hearing within 10 business days of receiving the notice.

Under the bill, OHS must hold requested hearings following the UAPA. If after a hearing OHS find that a violation has occurred or that the entity has violated any OHS order, the office must issue a final cease and desist order in addition to any civil penalty imposed.

If a timely hearing request is not made, OHS must issue a cease and desist order or impose a civil penalty.

The bill specifies that its 340B drug provisions must not be applied in a way that conflicts with, or is less restrictive than, applicable state and federal laws.

COMMITTEE ACTION

Human Services Committee

Joint Favorable Substitute
Yea 15 Nay 7 (03/19/2024)