House of Representatives

General Assembly

File No. 414

January Session, 2025

Substitute House Bill No. 7192

House of Representatives, April 1, 2025

The Committee on Human Services reported through REP. GILCHREST of the 18th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT IMPLEMENTING RECOMMENDATIONS OF THE BIPARTISAN DRUG TASK FORCE.

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

Section 1. (NEW) (*Effective October 1, 2025*) (a) Any pharmacy benefits manager shall owe a fiduciary duty to any health carrier, as defined in section 38a-591a of the general statutes, or other health benefit plan sponsor.

(b) Any pharmacy benefits manager shall notify the health carrier or other health benefit plan sponsor, in writing, of any activity, policy or practice of such pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this section.

(c) Any pharmacy benefits manager shall have an obligation of good faith and fair dealing in performing such pharmacy benefits manager's duties with all parties, including, but not limited to, a health carrier or other health benefit plan sponsor with whom such pharmacy benefits manager interacts in the performance of pharmacy benefit management

services.

(d) Notwithstanding any provision of title 38a of the general statutes and to the maximum extent permitted by applicable law, no contract entered into or amended after October 1, 2025, by a health carrier shall contain any provision that permits or requires any party to such contract to violate the fiduciary duty that such health carrier owes to such health carrier's covered persons.

(e) Any violation of the provisions of this section shall constitute a violation of sections 38a-815 to 38a-819, inclusive, of the general statutes.

(f) The Insurance Commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 2. Section 38a-477cc of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2026*):

(a) No contract for pharmacy services entered into in the state between a health carrier, as defined in section 38a-591a, or pharmacy benefits manager, as defined in section 38a-479aaa, and a pharmacy or pharmacist shall:

(1) On and after January 1, 2018, contain a provision prohibiting or penalizing, including through increased utilization review, reduced payments or other financial disincentives, a pharmacist's disclosure to an individual purchasing prescription medication of information regarding:

(A) The cost of the prescription medication to the individual; or

(B) The availability of any therapeutically equivalent alternative medications or alternative methods of purchasing the prescription medication, including, but not limited to, paying a cash price, that are less expensive than the cost of the prescription medication to the individual; **[**and**]**

(2) On and after January 1, 2020, contain a provision permitting the health carrier or pharmacy benefits manager to recoup, directly or indirectly, from a pharmacy or pharmacist any portion of a claim that such health carrier or pharmacy benefits manager has paid to the pharmacy or pharmacist, unless such recoupment is permitted under section 38a-479iii or required by applicable law;

(3) On and after January 1, 2026, contain a provision permitting the pharmacy benefits manager to charge a health benefit plan in this state a contracted price for any pharmacy services that differs from the amount such pharmacy benefits manager, directly or indirectly, pays the pharmacy for such pharmacy services; and

(4) On and after January 1, 2026, contain a provision permitting the pharmacy benefits manager to charge a health benefit plan, directly or indirectly, a fee that is conditioned on the (A) wholesale acquisition cost or any other price metric for a prescription drug, (B) amount of savings, rebates or other fees charged, realized, collected by or generated based on the business practices of such pharmacy benefits manager, or (C) amount of premiums charged or cost-sharing requirements pursuant to such health benefit plan that are realized or collected by such pharmacy benefits manager from covered persons. For the purposes of this subdivision, "wholesale acquisition cost" means the price of a medication set by a pharmaceutical manufacturer in the United States when selling to a wholesaler.

(b) (1) On and after January 1, 2018, no health carrier or pharmacy benefits manager shall require an individual to make a payment at the point of sale for a covered prescription medication in an amount greater than the lesser of:

(A) The applicable copayment for such prescription medication;

(B) The allowable claim amount for the prescription medication; or

(C) The amount an individual would pay for the prescription medication if the individual purchased the prescription medication

without using a health benefit plan, as defined in section 38a-591a, or any other source of prescription medication benefits or discounts.

(2) For the purposes of this subsection, "allowable claim amount" means the amount the health carrier or pharmacy benefits manager has agreed to pay the pharmacy for the prescription medication.

(c) Any provision of a contract that violates the provisions of this section shall be void and unenforceable. Any general business practice that violates the provisions of this section shall constitute an unfair trade practice pursuant to chapter 735a. The invalidity or unenforceability of any contract provision under this subsection shall not affect any other provision of the contract.

(d) The Insurance Commissioner may:

(1) Enforce the provisions of this section pursuant to chapter 697; and

(2) Upon request, audit a contract for pharmacy services for compliance with the provisions of this section.

Sec. 3. Section 38a-479ttt of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2025*):

Not later than March 1, 2021, and annually thereafter, the commissioner shall prepare a report, for the immediately preceding calendar year, describing the rebate practices of health carriers. The report shall contain (1) an explanation of the manner in which health carriers accounted for rebates in calculating premiums for health care plans delivered, issued for delivery, renewed, amended or continued during such year, (2) a statement disclosing whether, and describing the manner in which, health carriers made rebates available to insureds at the point of purchase during such year, (3) any other manner in which health carriers applied rebates during such year, (4) the percentage of rebate dollars used by health carriers to reduce cost-sharing requirements during such year, (5) an evaluation of rebate practices to reduce cost-sharing for health care plans delivered, issued for delivery, renewed, amended or continued during such year, and **[**(4)**]** (6) such

other information as the commissioner, in the commissioner's discretion, deems relevant for the purposes of this section. The commissioner shall publish a copy of the report on the department's Internet web site.

Sec. 4. (NEW) (*Effective July 1, 2025*) (a) The Insurance Commissioner shall require any health carrier, as defined in section 38a-591a of the general statutes, to report to the commissioner annually on pricing offered to and profit generated between such carrier and any pharmacy benefits manager or mail-order pharmacy doing business with such carrier.

(b) The commissioner shall post a link on the Internet web site of the Insurance Department to the reports filed pursuant to subsection (a) of this section.

Sec. 5. (*Effective July 1, 2025*) For the purposes of this section and sections 6 to 14, 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 a program under which the state would seek federal approval to import prescription drugs from Canada that have the highest potential for cost savings in the state;

(3) "Department" means the Department of Consumer Protection;

(4) "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;

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

(6) "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;

(7) "Qualifying laboratory" has the same meaning as provided in 21 CFR 251.2;

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

(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) "Recall" means a person's removal or correction of a marketed product that the department determines is in violation of this section, but "recall" does not include a market withdrawal or a stock recovery, as such terms are defined in 21 CFR 7.3;

(12) "Relabeler" has the same meaning as provided in 21 CFR 207.1;

(13) "Repacker" has the same meaning as provided in 21 CFR 207.1;

(14) "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

(15) "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. 6. (*Effective July 1, 2025*) The Commissioner of Consumer Protection shall hire, within available resources, a consultant to study the feasibility of establishing a Canadian prescription drug importation program to reduce prescription drug costs in the state. Not later than October 1, 2027, the commissioner shall file a report, in accordance with the provisions of section 11-4a of the general statutes, with the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law and human services and the Office of Policy and Management on the results of the feasibility study.

Sec. 7. (*Effective October 1, 2027*) (a) If after completion of the study described in section 6 of this act, the Commissioner of Consumer Protection, in consultation with the Secretary of the Office of Policy and Management, determines a Canadian prescription drug importation program is feasible, the Commissioner of Consumer Protection may 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. If submitted, such request shall, at a minimum:

(1) Describe the state's plans for operating the program and describe any opportunities to coordinate or operate the program in coordination with other states;

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

(A) Meet all applicable federal and state standards for safety and effectiveness; and

(B) Comply with all federal tracing procedures; and

(3) State the estimated costs of implementing the program.

(b) If the federal Food and Drug Administration approves the request, the Commissioner of Consumer Protection shall:

(1) Submit to the Secretary of the Office of Policy and Management, and the Commissioners of Social Services and Health Strategy, a notice disclosing that the federal Food and Drug Administration approved such request; and

(2) 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.

(c) The Commissioner of Consumer Protection shall not operate the program unless the federal Food and Drug Administration approves the request. Notwithstanding the provisions of this subsection, the department may expend resources in advance of such approval to ensure efficient implementation.

Sec. 8. (*Effective October 1, 2027*) If the Canadian prescription drug importation program is established, each participating wholesaler may import and distribute a prescription drug in this state from a participating Canadian supplier under the program if:

(1) Such drug meets the federal 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. 9. (*Effective October 1, 2027*) If a Canadian prescription drug importation program is established, participating wholesalers may, subject to the provisions of sections 10 and 11 of this act, import and distribute drugs in this state 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; and

(2) A qualifying laboratory.

Sec. 10. (*Effective October 1, 2027*) If a Canadian prescription drug importation program is established, the Commissioner of Consumer Protection 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 commissioner all track-and-trace records not later than forty-eight hours after the commissioner requests such records.

Sec. 11. (*Effective October 1, 2027*) (a) A participating wholesaler in any approved Canadian prescription drug importation program shall ensure the safety and quality of all drugs that may be imported and distributed in this state under the program. The participating wholesaler shall, if such program is established:

(1) For each initial shipment of a drug that is imported into this state by a participating wholesaler, ensure that a qualifying 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 qualifying 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) Only import drugs into this state that are (A) approved for marketing in the United States, (B) not adulterated or misbranded, and (C) meet all of the labeling requirements under 21 USC 352, as amended from time to time;

(4) Maintain qualifying laboratory records, including, but not limited to, complete data derived from all tests necessary to ensure that each drug imported into this state under any approved Canadian prescription drug importation 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 qualifying laboratory in accordance with the Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations concerning qualifying laboratory qualifications.

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

(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 Commissioner of Consumer Protection upon request by the commissioner:

(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 regarding any drug that fails qualifying laboratory testing; and

(8) Such additional information and documentation that the commissioner deems necessary to ensure the protection of the public health.

(d) The Commissioner of Consumer Protection shall require each participating Canadian supplier in any approved Canadian prescription drug importation program to maintain the following information and documentation and, upon request by the commissioner, submit such information and documentation to the commissioner 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 Commissioner of Consumer Protection deems necessary to ensure the protection of the public health.

Sec. 12. (*Effective October 1, 2027*) (a) If the Commissioner of Consumer Protection determines that public health, safety or welfare requires emergency action, the commissioner may order a participating Canadian supplier, participating wholesaler, relabeler, repacker and qualifying laboratory to cease and desist from actions specified in the order that create the need for such emergency action pending administrative proceedings. Such cease and desist order shall be (1) in writing; (2) signed by the Commissioner of Consumer Protection; and (3) effective upon delivery to the respondent. An administrative proceeding in accordance with chapter 54 of the general statutes shall be promptly instituted following a cease and desist order. The commissioner may impose a civil penalty, in an amount not to exceed ten thousand dollars, after a hearing conducted pursuant to chapter 54 of the general statutes.

(b) The commissioner may require the recall, embargo or destruction, pursuant to section 21a-96 of the general statutes, 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.

(c) In the event of a cease and desist, recall, embargo or destruction order, the person adversely impacted by such order shall provide written notice to all other businesses participating in the program, informing them of the order.

Sec. 13. (*Effective October 1, 2027*) If a Canadian prescription drug importation program is established, the Commissioner of Consumer Protection may adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 5 to 12, inclusive, of this act.

Sec. 14. (*Effective October 1, 2027*) Not later than one hundred eighty days after the first importation of any Canadian prescription drug under the importation program begins, and biannually thereafter, the Commissioner of Consumer Protection 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 (1) the operation of the program, if established, and (2) any violation of sections 5 to 13, inclusive, of this act that resulted in any action taken by the commissioner pursuant to section 12 of this act and the status of the investigation into such violation.

Sec. 15. (NEW) (*Effective from passage*) (a) There is established a task force to study emergency preparedness and mitigation strategies for prescription drug shortages. The task force shall identify prescription drugs at risk of shortage in this state and make recommendations pursuant to subsection (g) of this section.

(b) The task force shall consist of the following members:

(1) Two appointed by the speaker of the House of Representatives, one of whom has expertise in prescription drug supply chains and one of whom has expertise in federal law concerning prescription drug shortages;

(2) Two appointed by the president pro tempore of the Senate, one of whom represents hospitals and one of whom represents health care providers who treat patients with rare diseases;

(3) One appointed by the majority leader of the House of Representatives, who represents one of the two federally recognized Indian tribes in the state;

(4) One appointed by the majority leader of the Senate, who represents one of the two federally recognized Indian tribes in the state;

(5) One appointed by the minority leader of the House of Representatives;

(6) One appointed by the minority leader of the Senate;

(7) The Commissioner of Health Strategy, or the commissioner's designee;

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

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

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

(11) The chief executive officer of The University of Connecticut Health Center, or the chief executive officer's designee;

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

(13) The Commissioner of Economic and Community Development, or the commissioner's designee.

(c) Any member of the task force appointed under subdivision (1), (2), (3), (4), (5) or (6) of subsection (b) of this section may be a member

of the General Assembly.

(d) All initial appointments to the task force shall be made not later than thirty days after the effective date of this section. Any vacancy shall be filled by the appointing authority.

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

(f) The administrative staff of the joint standing committee of the General Assembly having cognizance of matters relating to general law shall serve as administrative staff of the task force.

(g) Not later than January 1, 2026, and annually thereafter, the task force shall submit a report on its findings and recommendations to the joint standing committees of the General Assembly having cognizance of matters relating to general law, human services, insurance and real estate and public health, in accordance with the provisions of section 11-4a of the general statutes, including, but not limited to, identification of prescription drugs the task force determines are at risk of shortage and strategies that would mitigate these shortages, including methods to increase in-state production of such drugs deemed both at risk of shortage and critically necessary for the provision of health care within the state.

Sec. 16. (NEW) *(Effective July 1, 2025*) (a) As used in this section, "Strategic Supply Chain Initiative" means a program administered by the Department of Economic and Community Development to help state-based companies to increase their production capacity to win new business and attract out-of-state and international supply chain operations.

(b) The Commissioner of Economic and Community Development shall expand the Strategic Supply Chain Initiative to include efforts to

prevent or mitigate prescription drug shortages, including, but not limited to, incorporating recommendations to prevent or mitigate prescription drug shortages by the task force established pursuant to section 15 of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2025*	New section
Sec. 2	*January 1, 2026*	38a-477cc
Sec. 3	*October 1, 2025*	38a-479ttt
Sec. 4	*July 1, 2025*	New section
Sec. 5	*July 1, 2025*	New section
Sec. 6	*July 1, 2025*	New section
Sec. 7	*October 1, 2027*	New section
Sec. 8	*October 1, 2027*	New section
Sec. 9	*October 1, 2027*	New section
Sec. 10	*October 1, 2027*	New section
Sec. 11	*October 1, 2027*	New section
Sec. 12	*October 1, 2027*	New section
Sec. 13	*October 1, 2027*	New section
Sec. 14	*October 1, 2027*	New section
Sec. 15	*from passage*	New section
Sec. 16	*July 1, 2025*	New section

Statement of Legislative Commissioners:
In Section 1(d), "after October 1, 2025," was added after "amended" for clarity, and in Section 1(e), "sections 38a-815 to 38a-819, inclusive, of the general statutes" was substituted for "the Connecticut Unfair Insurance Practices Act established pursuant to section 38a-815 of the general statutes" for clarity.

HS *Joint Favorable Subst. -LCO*

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:

Agency Affected	Fund-Effect	FY 26 $	FY 27 $
Consumer Protection, Dept.	GF - Cost	100,000	None
Consumer Protection, Dept.	GF - Potential Cost	None	84,010
State Comptroller - Fringe Benefits[1]	GF - Potential Cost	None	31,147
Treasurer, Debt Serv.	GF - Potential Cost	See Below	See Below

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill establishes a Canadian prescription drug importation program (CPDIP) and makes various prescription drug and health care related changes resulting in the costs described below.

Sections 1 - 4 make numerous changes that result in no fiscal impact to the Insurance Department. The bill makes several changes regarding pharmacy benefits managers (PBMs) and rebate practices of health carriers, and health carrier reporting on these topics. No fiscal impact is expected, as the department does not anticipate a meaningful increase in workload and compliance by PBMs and health carriers is expected.

Section 2 creates a new unfair trade practice violation resulting in no fiscal impact to the state. The Department of Consumer Protection

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 40.71% of payroll in FY 26.

(DCP) investigates unfair trade practice violations and has the resources and expertise to meet the requirements of the bill.

Sections 5-14 create the CPDIP resulting in costs to DCP and the Office of the State Comptroller (OSC). The bill requires DCP to hire a consultant to study the feasibility of establishing a CPDIP resulting in a cost of $100,000 in FY 26.

If the consultant reports that it's feasible to establish the CPDIP and the program is approved by the federal Food and Drug Administration there is a cost to DCP and OSC. To run the program, DCP will need to hire two drug control agents and one staff attorney beginning in the last three months of FY 27, for a partial year salary and other expenses costs of $84,010 along with associated fringe benefit costs of $31,147 in FY 27.

Section 15 establishes a task force to study emergency preparedness and mitigation strategies for prescription drug shortages resulting in no fiscal impact to the state because the task force has the expertise to meet the requirements of the bill.

Section 16 expands the Strategic Supply Chain Initiative program, which is funded by General Obligation (GO) bond funds, to include efforts to prevent or mitigate prescription drug shortages.

Future General Fund debt service costs may be incurred sooner under the bill to the degree that it causes authorized GO bond funds to be expended more rapidly than they otherwise would have been.

As of March 1, 2025, there is $25 million in previously allocated bond funds from Manufacturing Assistance Act program that have been set aside by the Department of Economic and Community Development to fund the Strategic Supply Chain Initiative program.

The bill does not change GO bond authorizations relevant to the program.

The Out Years

The full-year potential costs to run the CPDIP (see sections 5-14 above) will begin in FY 28. To run the program there is a potential annual cost to DCP of $313,538 for salaries and other expenses, along with an associated fringe benefit potential cost of $124,588.

The annualized ongoing fiscal impact identified above would continue into the future subject to if the CPDIP is implemented, the terms of any bonds issued, and inflation.

OLR Bill Analysis

HB 7192

AN ACT IMPLEMENTING RECOMMENDATIONS OF THE BIPARTISAN DRUG TASK FORCE.

TABLE OF CONTENTS:

Requires the insurance commissioner to require carriers to annually report on pricing offered to, and profit generated between, the carrier and any PBM or mail-order pharmacy

§ 15 — PRESCRIPTION DRUG SHORTAGES TASK FORCE
Creates a task force to study prescription drug shortage preparedness and mitigation

§ 16 — STRATEGIC SUPPLY CHAIN INITIATIVE
Requires DECD to incorporate prescription drug shortage prevention or mitigation into its Strategic Supply Chain Initiative

SUMMARY

This bill establishes a Canadian prescription drug importation program under which the Department of Consumer Protection (DCP) commissioner, on behalf of the state, would seek federal approval to import prescription drugs from Canada that have the highest potential for cost savings in the state.

It also includes various other provisions on prescription drugs, pharmacy benefits managers (PBMs), health carriers, and related matters.

A section-by-section analysis follows below.

EFFECTIVE DATE: Various, as indicated under each section below.

§§ 5-14 — CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

Establishes a Canadian prescription drug importation program under which the DCP commissioner would seek federal approval to import prescription drugs from Canada for distribution in the state; establishes testing, safety, and quality requirements; drug standards, tracking, tracing, recalls, embargos, and destruction; also establishes requirements for participating Canadian suppliers and participating wholesalers, including documentation, records retention, administrative proceedings and penalties for violations; provides for DCP emergency actions, regulations, and reporting

The bill establishes a Canadian prescription drug importation program under which the DCP commissioner, on behalf of the state, would seek federal approval to import prescription drugs from Canada that have the highest potential for cost savings in the state. Under the bill, "prescription drug" is a legend drug approved by the federal Food

and Drug Administration (FDA), or any successor agency, and prescribed by a health care provider to an individual in the state.

EFFECTIVE DATE: October 1, 2027, except July 1, 2025, for the provisions that define the applicable terms and require the DCP feasibility study.

Feasibility Study and Report (§ 6)

The bill requires the DCP commissioner to:

1. hire, within available resources, a consultant to study the feasibility of establishing a Canadian prescription drug importation program to reduce prescription drug costs in the state; and

2. by October 1, 2027, report the findings to the Appropriations, General Law, and Human Services committees and the Office of Policy and Management (OPM).

Food and Drug Administration Approval (§ 7)

Request for FDA Approval. If the DCP commissioner, in consultation with the OPM secretary, determines the program is feasible, the bill authorizes the commissioner to request program approval from the FDA.

At a minimum, the request to the FDA must do the following:

1. describe (a) the state's plans for operating the program and (b) any opportunities to coordinate with other states,

2. demonstrate that any prescription drug imported and distributed in this state under the program would (a) meet all applicable federal and state standards for safety and effectiveness and (b) comply with all federal tracing procedures, and

3. state the estimated program implementation costs.

The bill authorizes the DCP commissioner to spend resources before

FDA approval to ensure efficient implementation, but it prohibits the commissioner from actually operating the program without FDA approval.

FDA-Approval Received. If the FDA approves the request, the DCP commissioner must submit a notice disclosing it to the OPM secretary; Social Services and Health Strategy commissioners; and Appropriations, General Law, Human Services, and Public Health committees.

Prescription Drug Importation, Distribution, and Standard (§§ 5, 8 & 9)

Importation and Distribution. If a Canadian prescription drug importation program is established under the bill, participating wholesalers may, subject to the bill's provisions and under the program, import and distribute drugs in this state from a participating Canadian supplier to pharmacies, institutional pharmacies, and qualifying laboratories.

Drug. For purposes of the Canadian prescription drug importation program, "drug" means an article that is:

1. recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any of their supplements;

2. intended to diagnose, cure, mitigate, treat, or prevent disease in humans;

3. not food and intended to affect the structure or any function of the human body; and

4. not a device and intended for use as a component of any article specified in those listed above.

Participating Wholesaler. A "participating wholesaler" in the

program is designated by DCP to distribute prescription drugs in the manufacturer's original container, obtained from a participating Canadian supplier.

Participating Canadian Supplier. A "participating Canadian supplier" in the program is a Canadian supplier that is exporting prescription drugs, in the manufacturer's original container, to a participating wholesaler for distribution in the state under the program.

Canadian Supplier. A "Canadian supplier" is a manufacturer or wholesale drug distributor licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs.

An "institutional pharmacy" is the area within a care-giving, correctional, or juvenile training institution where drugs are stored and dispensed under the direct charge of a pharmacist. This area is commonly known as the pharmacy.

Drug Standards. Under the program, participating wholesalers may import and distribute prescription drugs in this state from a participating Canadian supplier under the program if doing so would not violate federal patent laws and the drug meets the FDA's drug safety, effectiveness, misbranding, and adulteration standards.

A drug cannot be imported under the program if it is:

1. considered a controlled substance under federal law;

2. a biological product (e.g., a virus, therapeutic serum, vaccine, blood, or blood component applied to prevent, treat, or cure a human disease or condition);

3. one that is infused, intravenously injected, or inhaled during surgery; or

4. a parenteral drug that the federal Health and Human Services secretary determines would pose a threat to the public health if imported.

Track-and-Trace-Related Requirements (§§ 5 & 10)

Under the program, the DCP commissioner must require participating Canadian suppliers and participating wholesalers to (1) comply with all applicable track-and-trace requirements and (2) make all track-and-trace records available within 48 hours after the commissioner requests them.

"Track-and-trace" is the product tracing process in the federal Drug Quality and Security Act for the components of the pharmaceutical distribution supply chain.

The DCP commissioner must prohibit the distribution, dispensing, or sale outside the state of any prescription drug imported under the program.

Safety and Quality Requirements (§§ 5 & 11(a))

A participating wholesaler under the program must ensure the safety and quality of all drugs imported and distributed in the state under the program.

Drug Requirements. The drugs must (1) be approved for marketing in the United States; (2) not be adulterated or misbranded; and (3) meet all labeling requirements (e.g., content, prominence of information, and designation of established names) under federal law.

Laboratory Testing. Under the bill, "laboratory testing" is a quantitative and qualitative analysis of a drug consistent with the applicable provisions of the official United States Pharmacopoeia.

The bill requires a participating wholesaler to engage a qualifying laboratory (i.e. one in the United States approved by the FDA for purposes of the federal Food, Drug, and Cosmetic Act) to test for authenticity and degradation a (1) statistically valid sample size for each batch of each drug in the initial shipment and (2) statistically valid sample of the shipment.

The laboratory must do testing consistent with the federal Food,

Drug and Cosmetic Act.

Laboratory Records Maintenance and Retention Requirements (§ 11(a) & (b))

Under the program, a participating wholesaler must maintain:

1. qualifying laboratory records, including complete data derived from all tests necessary to ensure that each drug imported under the program complies with the bill's safety and quality requirements; and

2. documentation demonstrating that the required testing was done at a qualifying laboratory consistent with the federal Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations on qualifying laboratory qualifications.

After a qualifying laboratory submits information and documentation to the participating wholesaler, the wholesaler must keep them for at least three years from the submission date.

Participating Wholesaler Documentation Requirements (§ 11(c))

A participating wholesaler must also maintain the following information for each drug the wholesaler imports and distributes in the state under the program:

1. the name and quantity of the drug's active ingredient and a description of the drug's dosage form,

2. the date the participating wholesaler received the drug and the price the wholesaler paid,

3. the quantity the participating wholesaler received and the drug's point of origin and destination,

4. a report on any drug that fails qualifying laboratory testing, and

5. any additional information and documentation that the commissioner deems necessary to protect public health.

The wholesaler must submit the above information and documentation to the commissioner, upon the commissioner's request.

Participating Supplier Documentation Requirements (§ 11(d))

The DCP commissioner must require each participating Canadian supplier to maintain the following information and documentation for each drug the supplier exports into the state under the program:

1. the original source of the drug, including the manufacturer's name and manufacture date and location;

2. the shipping date and quantity;

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

4. the lot or control number and batch number the manufacturer assigned to the drug; and

5. any additional information and documentation that the DCP commissioner deems necessary to ensure public health protection.

The supplier must submit the above information and documentation to the commissioner, upon the commissioner's request.

Authorized Emergency Actions for Public Health or Welfare (§ 12)

The bill authorizes the DCP commissioner to issue cease and desist, recall, embargo, or destruction orders to program participants when warranted and subject to administrative proceedings and penalties.

Cease and Desist Order. If the DCP commissioner determines that public health, safety, or welfare requires emergency action, the commissioner may order a participating Canadian supplier, participating wholesaler, relabeler, repacker, and qualifying laboratory to cease and desist from actions specified in the order pending administrative proceedings. The cease and desist order must be in writing and signed by the commissioner and is effective upon delivery

to the respondent.

Administrative Proceeding and Civil Penalty. After a cease and desist order is issued, an administrative proceeding, done according to the Uniform Administrative Procedures Act, must begin promptly. After a hearing, the commissioner may impose a civil penalty up to $10,000.

Recall, Embargo, or Destruction. The commissioner may require the recall, embargo, or destruction of any drug that was imported and distributed under the program that has been identified as adulterated or misbranded. Any such action must be done according to DCP's process for food, drug, and cosmetic seizures and embargoes in existing law, which includes a hearing and possible civil penalty.

Generally, a drug is deemed adulterated under several circumstances. For example, if it consists of any filthy, putrid, or decomposed substance; or has been produced, prepared, packed, or held under insanitary conditions so that it may have been contaminated with filth or made injurious to health.

Written Notice to Impacted Businesses. If a cease and desist, recall, embargo, or destruction order is issued, the person adversely impacted by the order must notify all other businesses participating in the program of the order. The notice must be in writing.

DCP Regulations and Report to the General Assembly (§§ 13 & 14)

If a Canadian prescription drug importation program is established, the bill allows the DCP commissioner to adopt implementing regulations.

By 180 days after the first importation and biannually after that, the commissioner must submit a report to the Appropriations, General Law, Human Services, and Public Health committees describing the program operation, any violations that resulted in action being taken by the commissioner, and the status of any violation investigations.

Background — Related Bills

sSB 11, §§ 26-35, favorably reported by the Human Services Committee and sHB 6870 (File 308), §§ 1-10, favorably reported by the Insurance Committee, both have substantially similar provisions related to the establishment of a Canadian prescription drug importation program.

§ 1 — PHARMACY BENEFITS MANAGER FIDUCIARY DUTY AND HEALTH CARRIER CONTRACTS

Provides that PBMs owe a fiduciary duty to health carriers or other health plan sponsors and generally prohibits carrier contracts from allowing or requiring a party to violate the carrier's fiduciary duty to insureds

The bill provides that pharmacy benefits managers (PBMs) owe a fiduciary duty to any heath carriers (e.g., insurers) or other health benefit plan sponsors (in other words, have the legal duty to act in the carriers' or sponsors' interests). It also provides that PBMs have an obligation of good faith and fair dealing in performing their duties with all parties, including carriers or other plan sponsors they interact with in performing their management services.

Under the bill, a PBM must notify the carrier or other plan sponsor, in writing, if any of the PBM's activities, policies, or practices directly or indirectly present a conflict of interest with its duties under the bill.

The bill also prohibits any health carrier contracts entered into or amended after October 1, 2025, from allowing or requiring a party to violate the fiduciary duty that the carrier owes to the carrier's covered persons (i.e. insureds). This applies despite any contrary provisions in the state's insurance laws and to the maximum extent allowed by law.

Under the bill, a violation of any of these provisions is an unfair insurance practice (see *Background — Connecticut Unfair Insurance Practices Act*).

The bill allows the insurance commissioner to adopt implementing regulations.

EFFECTIVE DATE: October 1, 2025

Background — Connecticut Unfair Insurance Practices Act

The law prohibits engaging in unfair or deceptive acts or practices in the business of insurance. It authorizes the insurance commissioner to conduct investigations and hearings, issue cease and desist orders, impose fines, revoke or suspend licenses, and order restitution for per se violations (i.e. violations specifically listed in statute). The law also allows the commissioner to ask the attorney general to seek injunctive relief in Superior Court if he believes someone is engaging in other unfair or deceptive acts not specifically defined in statute.

Fines may be up to (1) $5,000 per violation to a $50,000 maximum or (2) $25,000 per violation to a $250,000 maximum in any six-month period if the violation was knowingly committed. The law also imposes a fine of up to $50,000, in addition to or in place of a license suspension or revocation, for violating a cease and desist order (CGS §§ 38a-815 to -819).

Background — Related Bill

sSB 11, § 23, favorably reported by the Human Services Committee, contains the same provisions on PBMs' fiduciary duty and carrier contracts.

§ 2 — PHARMACY SERVICES CONTRACTS

Prohibits certain provisions in pharmacy services contracts, such as those allowing a PBM to charge a health plan a contracted price that differs from what the PBM pays the pharmacy for the services

The bill prohibits a pharmacy services contract between a pharmacist or pharmacy and health carrier or PBM from allowing the PBM to charge an in-state health benefit plan a contracted price for any pharmacy services that differs from what the PBM pays the pharmacy (directly or indirectly) for these services (sometimes called a "spread pricing" arrangement).

It further prohibits these contracts from allowing the PBM to charge a health benefit plan, directly or indirectly, a fee that depends on any of the following:

1. a prescription drug's wholesale acquisition cost or another price metric for these drugs;

2. the amount of savings, rebates, or other fees charged, collected, or generated based on the PBM's business practices; or

3. the amount of charged premiums or cost-sharing requirements under the plan that the PBM collects from covered persons.

As under existing law for prohibited provisions in these contracts:

1. any contract provision that violates the bill is void and unenforceable, but a provision rendered invalid or unenforceable does not affect remaining provisions;

2. any general business practice that violates the bill's provisions is an unfair trade practice under the Connecticut Unfair Trade Practices Act (CUTPA, see *Background — Connecticut Unfair Trade Practices Act*); and

3. the insurance commissioner may enforce the bill's provisions and upon request, audit pharmacy services contracts for compliance.

EFFECTIVE DATE: January 1, 2026

Background — Connecticut Unfair Trade Practices Act

By law, CUTPA prohibits businesses from engaging in unfair and deceptive acts or practices. It allows the DCP commissioner, under specified procedures, to issue regulations defining an unfair trade practice, investigate complaints, issue cease and desist orders, order restitution in cases involving less than $10,000, impose civil penalties of up to $5,000, enter into consent agreements, ask the attorney general to seek injunctive relief, and accept voluntary statements of compliance. It also allows individuals to sue. Courts may issue restraining orders; award actual and punitive damages, costs, and reasonable attorney's fees; and impose civil penalties of up to $5,000 for willful violations and up to $25,000 for a restraining order violation.

Background — Related Bill

sSB 11, § 24, favorably reported by the Human Services Committee, has identical provisions on pharmacy services contracts.

§ 3 — HEALTH CARRIER REBATE ANNUAL REPORTING

Expands the contents of the insurance commissioner's annual report on health carrier rebates to include certain information on how rebates affected cost sharing

Existing law requires the insurance commissioner to annually report on health carrier rebate practices for the prior year and publish the report on the department's website. The bill expands the required contents of this report to include the (1) percentage of rebate dollars health carriers used to reduce cost-sharing requirements and (2) an evaluation of rebate practices to reduce cost-sharing for health care plans delivered, issued, renewed, amended, or continued.

Under existing law, the report must include (1) an explanation of how carriers accounted for rebates when calculating premiums, (2) a statement disclosing whether and how carriers made rebates available to insureds at the point of purchase, (3) any other way carriers applied rebates, and (4) any other information the commissioner deems relevant.

EFFECTIVE DATE: October 1, 2025

Background — Related Bill

sSB 11, § 16, favorably reported by the Human Services Committee, has identical provisions on rebate annual reporting.

§ 4 — HEALTH CARRIER PRICING AND PROFIT REPORTING REQUIREMENTS

Requires the insurance commissioner to require carriers to annually report on pricing offered to, and profit generated between, the carrier and any PBM or mail-order pharmacy

Under the bill, the insurance commissioner must require health carriers to annually report on pricing offered to, and profit generated between, the carrier and any PBM or mail-order pharmacy doing business in Connecticut. The commissioner must post a link to these reports on the department's website.

EFFECTIVE DATE: July 1, 2025

Background — Related Bill

sSB 11, § 25, favorably reported by the Human Services Committee, has identical provisions on health carrier reporting.

§ 15 — PRESCRIPTION DRUG SHORTAGES TASK FORCE

Creates a task force to study prescription drug shortage preparedness and mitigation

The bill creates an ongoing task force to study emergency preparedness and mitigation strategies for prescription drug shortages. The task force must identify drugs at risk of shortage in this state and recommend ways to address that (see below).

EFFECTIVE DATE: Upon passage

Task Force Members, Administration, and Reporting Requirement

The task force includes eight members appointed by the legislative leaders, as shown in the following table. Appointees may be legislators.

Table: Task Force Appointed Members

Appointing Authority	*Appointee Qualifications*
House speaker	Expert in prescription drug supply chains Expert in federal law on prescription drug shortages
Senate president pro tempore	Representative of hospitals Representative of providers who treat patients with rare diseases
House majority leader	Representative of the Mohegan or Mashantucket Pequot tribe
Senate majority leader	Representative of the Mohegan or Mashantucket Pequot tribe
House minority leader	Unspecified qualifications
Senate minority leader	Unspecified qualifications

The task force also includes the following officials or their designees: the DCP, economic and community development (DECD), health strategy, insurance, public health, and social services commissioners and UConn Health Center's chief executive officer.

Appointing authorities must make their initial appointments within 30 days after the bill's passage and fill any vacancy.

The House speaker and Senate president pro tempore must select the task force chairpersons from among its members. The chairpersons must schedule and hold the first meeting within 60 days after the bill's passage. The General Law Committee's administrative staff serves in that capacity for the task force.

The bill requires the task force, starting by January 1, 2026, to annually report its findings and recommendations to the General Law, Human Services, Insurance and Real Estate, and Public Health committees. The reports must identify (1) those drugs the task force determines are at risk of shortage and (2) strategies to mitigate these shortages, including ways to increase in-state production of drugs that are at risk of shortage and critically necessary for health care in the state.

Background — Related Bill

sSB 11, § 36, favorably reported by the Human Services Committee, has substantially similar provisions creating a prescription drug shortages task force.

§ 16 — STRATEGIC SUPPLY CHAIN INITIATIVE

Requires DECD to incorporate prescription drug shortage prevention or mitigation into its Strategic Supply Chain Initiative

The bill requires the DECD commissioner to expand the department's Strategic Supply Chain Initiative to include efforts to prevent or mitigate prescription drug shortages. This must include incorporating the task force's recommendations (see § 15).

Under the bill, this initiative is a DECD-administered program to help state-based companies increase their production capacity to win new business and attract out-of-state and international supply chain operations.

EFFECTIVE DATE: July 1, 2025

Background — Related Bill

sSB 11, § 37, favorably reported by the Human Services Committee, has identical provisions on DECD's Strategic Supply Chain Initiative.

COMMITTEE ACTION

Human Services Committee

Joint Favorable
Yea 19 Nay 3 (03/13/2025)