OLR Bill Analysis

HB 7192

AN ACT IMPLEMENTING RECOMMENDATIONS OF THE BIPARTISAN DRUG TASK FORCE.

TABLE OF CONTENTS:

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)