OLR Bill Analysis

sSB 11

AN ACT CONCERNING PRESCRIPTION DRUG ACCESS AND AFFORDABILITY.

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SUMMARY

This bill includes several provisions on prescription drugs, including setting manufacturer and wholesaler price caps for certain drugs, requiring UConn Health to negotiate bulk prices for state agencies, restricting limits on 340B drugs, expanding required reporting, and establishing a Canadian Prescription Drug Importation program, a prescription drug affordability council, a prescription drug shortage task force, and a vaccine and related biological products advisory committee.

It also makes several changes in Medicaid laws, including on nursing home spending requirements, emergency Medicaid expansions, HUSKY C asset limits, and weight loss drugs and treatments.

And, it makes changes in insurance laws, including provisions addressing private insurance coverage of anesthesia, stop-loss insurance policies, reporting requirements, insulin coverage, and pharmacy benefit managers.

These provisions are described in the section-by-section analysis below.

EFFECTIVE DATE: Various; see below.

§§ 1-3 — IDENTIFIED PRESCRIPTION DRUGS

Caps the price for the sale of identified prescription drugs in the state; generally imposes a civil penalty on pharmaceutical manufacturers and wholesale distributors who violate the cap and requires the DRS commissioner to impose and collect it; and creates a process for penalty disputes

The bill sets a (1) cap on the prices for which pharmaceutical manufacturers and wholesale distributors can sell an identified prescription drug in the state and (2) civil penalty for violators, except for those that made less than $250,000 in total annual sales in the state for the calendar year for which the penalty is being imposed. It also creates a process by which an aggrieved person can request a hearing to dispute the penalty. An "identified prescription drug" is a (1) brand-name drug or biological product for which the patent has expired for at least 24 months, or (2) generic drug or interchangeable biological product.

EFFECTIVE DATE: July 1, 2025

Price Cap on Identified Prescription Drugs (§§ 1 & 2(a))

Increase Based on Consumer Price Index. Starting January 1, 2026, regardless of state statute, the bill prohibits pharmaceutical manufacturers and wholesale distributors from selling an identified prescription drug in the state for more than its reference price, adjusted for any increase in the consumer price index.

Under the bill a "pharmaceutical manufacturer" is a person that manufactures a prescription drug and sells it, directly or through another person, for distribution in the state.

A "wholesale distributor" is a person engaged in the wholesale distribution of prescription drugs. This includes a repacker, own-label distributor, private-label distributor, or independent wholesale drug trader.

A "reference price" is the drug or biological product's wholesale acquisition price. For brand-name drugs or biological products, the reference price is the wholesale acquisition cost on January 1, 2025, or the date the patent expires, whichever is later. For generic drugs or interchangeable biological products, the reference price is the wholesale

acquisition cost on January 1, 2025, or the date the drug or product is first commercially marketed in the U.S., whichever is later.

Drug Shortage. The bill makes one exception by allowing manufacturers and distributors to exceed this price, starting January 1, 2026, if the federal Health and Human Services secretary determines that there is a shortage of the drug in the United States and includes it on the drug shortage list.

Civil Penalty for Violating Price Cap (§ 2(b))

The bill imposes a civil penalty on pharmaceutical manufacturers and wholesale distributors that violate the price cap provision above. The civil penalty must be imposed, calculated, and collected by the state on a calendar year basis by the Department or Revenue Services (DRS) commissioner.

Penalty Calculation. The civil penalty amount for a calendar year must be equal to 80% of the difference between the revenue that the pharmaceutical manufacturer or wholesale distributor:

1. earned from all sales of the identified prescription drug in the state during the calendar year; and

2. would have earned from these sales if the manufacturer or distributor had not sold the drug at a price over the bill's price cap.

Exception. The bill exempts from liability for the above civil penalty, pharmaceutical manufacturers or wholesale distributors of an identified prescription drug that made less than $250,000 in total annual sales in the state for the calendar year for which the civil penalty would otherwise be imposed.

Penalty Payment and Statement Filing (§ 2(c))

For calendar years starting January 1, 2026, each pharmaceutical manufacturer or wholesale distributor that violates the identified prescription drug price cap during any calendar year must, by March 1 immediately following the end of the calendar year:

1. pay the DRS commissioner the civil penalty for that calendar year; and

2. file with the DRS commissioner a statement for that calendar year.

The commissioner must prescribe the statement's form and manner and required information.

Electronic Filing and Wire Transfer. The manufacturer and distributor must file the statement electronically and pay the penalty by electronic funds transfer in the same way as filing and paying tax returns, regardless of whether they would have otherwise been required to do so under the law.

If no statement is filed as required above, the bill allows the DRS commissioner to make the statement at any time according to the best obtainable information and the prescribed form.

Record Examination and Retention (§ 2(d) & (e))

DRS Commissioner's Examination. The commissioner may, as he deems necessary, examine the records of any pharmaceutical manufacturer or wholesale distributor subject to the civil penalty imposed for an identified prescription drug price cap violation described above.

Billing Due to Failure to Pay. After the examination, if the DRS commissioner determines that the pharmaceutical manufacturer or wholesale distributor failed to pay the full amount of the civil penalty, he must bill the pharmaceutical manufacturer or wholesale distributor for the full amount of the civil penalty.

Records Retention. Under the bill, to provide or secure information pertinent to the civil penalty enforcement and collection, the DRS commissioner may require each pharmaceutical manufacturer or wholesale distributor subject to penalty to (1) keep records as the commissioner may prescribe and (2) produce books, papers, documents, and other data.

Investigation. To verify the accuracy of any statement made or, to determine the amount of the civil penalty due if a statement was not made, the DRS commissioner or his authorized representative may (1) examine the books, papers, records, and equipment of anyone subject to the identified prescription drug price cap provisions and (2) investigate the character of their business.

Aggrieved Company's Request for a Hearing (§ 2(f))

Hearing Application. Any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty and aggrieved by the DRS commissioner's actions above (i.e. making a statement, billing, records examination, and investigation) may apply to the commissioner for a hearing. This must be done in writing within 60 days after the notice of the action is delivered or mailed to the manufacturer or distributor.

The aggrieved pharmaceutical manufacturer or wholesale distributor must state in the application (1) why the hearing should be granted and (2) if they believe they are not liable for the civil penalty or the full amount of the civil penalty, the (a) grounds for the belief and (b) amount by which they believe the civil penalty should be reduced.

Hearing Denied or Granted. The DRS commissioner must promptly consider each application and notify the pharmaceutical manufacturer or wholesale distributor (1) immediately of a hearing denial or (2) of the date, time, and place for a hearing that is granted.

DRS Commissioner's Orders. After the hearing, the commissioner may make orders as appears just and lawful to him and must give a copy to the pharmaceutical manufacturer or wholesale distributor.

Hearing on the DRS Commissioner's Initiative. By notice and in writing, the commissioner may order a hearing on his own initiative and require a pharmaceutical manufacturer or wholesale distributor, or any other person the commissioner believes has relevant information, to appear before him, or his authorized agent, with any specified books of account, papers, or other documents for examination under oath.

Aggrieved Company's Appeal to Superior Court (§ 2(g))

Time Period to Appeal. Within 30 days after the aggrieved pharmaceutical manufacturer or wholesale distributor is served notice of the DRS commissioner's order, decision, determination, or disallowance, the manufacturer or distributor may appeal to the Superior Court for the New Britain judicial district.

Accompanying Citation. The appeal must be accompanied by a citation to the DRS commissioner to appear before the court. The citation must be signed by the same authority and the appeal must be returnable at the same time and served and returned in the same way as required for a summons in a civil action.

Bond or Recognizance With Surety. The authority issuing the citation must take from the appellant a bond or recognizance to the state, with surety, to prosecute the appeal to effect and to comply with the court's orders and decrees.

Equitable Relief. Unless there is a reason otherwise, the appeals must be preferred cases and heard at the first session by the court or by a committee it appoints. The court may (1) grant equitable relief, and (2) if the civil penalty was paid before the relief was granted, order the state treasurer to pay the amount of the relief.

Costs Taxed. If the appeal was made without probable cause, the court may tax double or triple costs, as appropriate. For appeals that are denied, costs may be taxed against the pharmaceutical manufacturer or wholesale distributor, but not against the state, at the court's discretion.

DRS Commissioner's Authority (§ 2(h))

Administer Oaths. The commissioner may administer oaths and take testimony under oath for any inquiry or investigation. The commissioner's agent duly authorized to conduct any inquiry, investigation, or hearing under the provisions above also has these powers.

Subpoena Witnesses and Require Record Production. At any hearing the commissioner ordered, he may subpoena witnesses and

require the production of books, papers, and documents relevant to the inquiry or investigation. The commissioner's agent authorized to conduct the hearing and having authority by law to issue the process also has these powers.

A witness under any subpoena authorized to be issued under these provisions must not be excused from testifying or from producing books, papers, or documentary evidence on the ground that the testimony or the production would tend to incriminate the witness, but the books, papers, or documentary evidence produced must not be used in any criminal proceeding against the witness.

Commitment to Community Correctional Center. If anyone disobeys the process or appears but refuses to answer the commissioner's or his agent's questions, the commissioner or the agent may apply to the Superior Court of the judicial district where the pharmaceutical manufacturer or wholesale distributor resides or where the business was conducted, or to any judge of the court if it is not in session, stating the disobedience to process or refusal to answer.

The court or judge must cite the person to appear to answer the question or produce the books, papers, or other documentary evidence and, if they refuse to do so, must commit the person to a community correctional center until they testify, but not for more than 60 days.

Regardless of the person serving the term of commitment, the DRS commissioner may continue the inquiry and examination as if the witness had not previously been called to testify.

Fees and Compensation. Officers who serve subpoenas issued by the DRS commissioner or under his authority and witnesses attending hearings conducted by the commissioner under this provision must receive fees and compensation at the same rates as officers and witnesses in the state courts. This must be paid on vouchers of the DRS commissioner on order of the state comptroller from the proper appropriation for the administration of this provision.

State Collection and Attorney General's Lien Foreclosure (§ 2(i))

State Collection Agency Process. The amount of any unpaid civil penalty under the bill's price cap violations-related provisions may be collected using the process under existing law used by the state collection agency (i.e. the state treasurer; DRS commissioner; any other state official, board, or commission authorized to collect taxes payable to the state; and their duly authorized agents). Under the bill, the warrant issued under the collection process must be signed by the DRS commissioner or his authorized agent.

Lien on Real Property. The amount of the civil penalty must be a lien on the pharmaceutical manufacturer's or wholesale distributor's real property from the last day of the month next preceding the civil penalty's due date until it is paid.

The DRS commissioner may record the lien in the records of the town in which the real property is located, but the lien is not enforceable against a bona fide purchaser or qualified encumbrancer of the real property.

Certificate of Discharge. When the civil penalty for which a lien was recorded is satisfied, the DRS commissioner must, upon request of any interested party, issue a certificate discharging the lien. The discharge certificate must be recorded in the same office in which the lien was recorded.

Foreclosure of the Lien. Any action for the foreclosure of the lien must be brought by the attorney general in the name of the state in the Superior Court for the judicial district in which the real property subject to the lien is located. If the real property is in two or more judicial districts, the action must be brought in the Superior Court for any one of the judicial districts.

The court may limit the time for redemption or order the sale of the real property or make any other decree as it judges equitable.

All civil penalties imposed under this provision can generally be applied as a reduction against any amount payable by the state to the person, as under existing law related to penalties due from taxpayers.

Officer's and Employee's Liability (§ 2(j))

Willful Failure to Perform. An officer or employee of a pharmaceutical manufacturer or wholesale distributor, who (1) owes a duty, on the manufacturer's or distributor's behalf, to pay the civil penalty, file the required statement with the commissioner, keep records, or supply information to the commissioner and (2) willfully fails to do so must, in addition to any other penalty provided by law, be fined up to $1,000, imprisoned up to one year, or both.

Regardless of existing limitations of prosecution for certain violations or offenses, the bill sets a three-year statute of limitations for prosecuting officers or employees for violations of these provisions committed on or after January 1, 2026.

Willful Delivery or Disclosure of Fraudulent or False Material. Any officer or employee of a pharmaceutical manufacturer or wholesale distributor who owes a duty, on the manufacturer's or distributor's behalf, to deliver or disclose to the commissioner, or his authorized agent, any list, statement, return, account statement, or other document and willfully delivers or discloses one the officer or employee knows is fraudulent or false in any material matter is guilty of a class D felony, in addition to any other penalty provided by law. (A class D felony is punishable by a fine up to $5,000, up to five years in prison, or both.)

Under the bill, an officer or employee may not be charged with an offense under both provisions above in relation to the same civil penalty but may be charged and prosecuted for both offenses based on the same information.

Waiver and Tax Credit Prohibited (§ 2(k))

The civil penalty imposed under the bill for violating the identified prescription drug price cap:

1. is excluded from Medicaid provider tax calculations,

2. cannot be waived by the Penalty Review Committee under existing law or any other applicable law, and

3. cannot be reduced by applying a tax credit.

List of Violators and Implementing Regulations (§ 2(l) & (m))

Starting by July 1, 2027, the bill requires the DRS commissioner to (1) annually prepare a list of the pharmaceutical manufacturers or wholesale distributors that violated the identified prescription drug price cap-related provisions during the preceding calendar year and (2) make each annual list publicly available.

The bill authorizes the commissioner to adopt regulations to implement its provisions related to identified prescription drug pricing and sales.

Withdrawal of Identified Prescription Drug (§ 3)

Required Notice to OHS. If a pharmaceutical manufacturer or wholesale distributor intends to withdraw an identified prescription drug from sale in the state, it must send written notice to the Office of Health Strategy (OHS) disclosing that intention at least 180 days before the withdrawal.

Withdrawal to Avoid Penalty Prohibited. The bill prohibits a pharmaceutical manufacturer or wholesale distributor of an identified prescription drug from withdrawing the identified prescription drug from sale in the state to avoid the bill's civil penalty.

Penalty. Any pharmaceutical manufacturer or wholesale distributor that violates the withdrawal provisions above is liable to the state for a $500,000 civil penalty.

Background — Related Bill

sSB 6870 (File 308), §§ 11-13, favorably reported by the Insurance and Real Estate Committee, has substantially similar provisions on the sale of identified prescription drugs by pharmaceutical manufacturers and wholesale distributors in the state, including establishing a price cap and civil penalties for violating it.

§§ 4 & 5 — STATE DRUG PURCHASING AGENCY PRICE NEGOTIATIONS

Requires UConn Health to negotiate bulk prices for prescription drugs on behalf of the state's drug purchasing agencies in order to buy them at lower cost; requires drug purchasing agencies, when negotiating drug prices with manufacturers, to incorporate the maximum fair price negotiated by CMS; allows drug purchasing agencies to enter compacts with other states for these purposes

The bill requires the UConn Health Center to negotiate bulk prices for prescription drugs on behalf of itself and other drug purchasing agencies, including the judicial branch and the departments of Children and Families (DCF), Developmental Services, Mental Health and Addiction Services, and Public Health (DPH). UConn Health must do so with the goal to buy these drugs at lower prices than if the agencies each purchased them. The UConn Health Executive Director or his designee must report by September 1, 2025, to the General Law, Human Services, and Public Health committees on any savings achieved through bulk purchasing.

The bill requires these drug purchasing agencies, when negotiating with drug manufacturers to supply drugs for state-subsidized health care programs, to incorporate by reference the maximum fair price negotiated by the federal Centers for Medicare and Medicaid Services (CMS) for certain drugs under the federal Inflation Reduction Act (see *Background — Maximum Fair Price*).

The bill allows these drug purchasing agencies, either when negotiating bulk prices or referencing CMS's maximum fair price, to enter into a compact with officials in other states to increase the state's purchasing power in negotiations.

It also requires these drug purchasing agencies to consider the Prescription Drug Affordability Council's recommendations (see § 6) in these negotiations.

EFFECTIVE DATE: July 1, 2025

Background — Maximum Fair Price

Federal law requires the CMS secretary to negotiate with manufacturers on the maximum fair price of certain drugs covered under Medicare. The secretary must do so for 10 drugs starting in 2026, 15 more for each of the next two years, and 20 additional per year

starting in 2028. For the first two years, this only applies to certain drugs under Medicare Part D; in the third year, it extends to Medicare Part B (42 U.S.C. § 1320f et seq.).

§ 6 — PRESCRIPTION DRUG AFFORDABILITY COUNCIL

Creates a council to advise the UConn Health Executive Director and drug purchasing agencies on prescription drug negotiations

The bill establishes a Prescription Drug Affordability Council to advise the UConn Health executive director and drug purchasing agencies on drug negotiations (see §§ 4 & 5).

EFFECTIVE DATE: Upon passage

Council Members, Administration, and Reporting Requirement

The council includes eight members appointed by legislative leaders, as shown in the following table.

Table: Council Appointed Members

Appointing Authority	*Appointee Qualifications*
House speaker	Hospital organization representative Physician organization representative
Senate president pro tempore	Academic who has researched prescription drug affordability Representative of organization representing the state's seniors
House majority leader	Representative of physicians who treat patients with rare diseases
Senate majority leader	Unspecified qualifications
House minority leader	Unspecified qualifications
Senate minority leader	Unspecified qualifications

The council also includes the DCF, Consumer Protection (DCP), OHS, Insurance, and Social Services (DSS) commissioners or their designees.

Any of the legislative leaders' appointed members may be legislators. 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 Human Services Committee's administrative staff must serve in that capacity for the council.

The bill requires the council, starting by January 1, 2026, to annually report its findings and recommendations to the OHS commissioner and the General Law, Human Services, and Public Health committees.

§ 7 — NURSING HOME SPENDING ON DIRECT CARE

Generally requires nursing homes, starting in FY 26, to spend at least 80% of their funding on direct resident care provided by nursing personnel; starting in FY 28, allows DSS to decrease Medicaid rates for nursing homes that do not comply

The bill requires the DSS commissioner, beginning with fiscal year 2026, to require nursing homes to spend at least 80% of their funding from Medicaid, Medicare, and all other payment sources on residents' direct care. However, it allows the commissioner to adjust this percentage for nursing homes with a capital improvement project or fair rent increase DSS approved. Beginning with fiscal year 2028, the commissioner may decrease Medicaid reimbursement for any nursing home that does not comply.

Under the bill, "direct care" means hands-on care nursing personnel provide to facility residents (e.g., help with feeding, bathing, toileting, dressing, lifting or moving residents, or administering medication). It also includes nursing personnel's salary and fringe benefits and the cost of supplies to provide hands-on care. Nursing personnel include advanced practice registered nurses, registered or practical nurses, and nurse's aides.

EFFECTIVE DATE: July 1, 2025

Background — Related Bills

SB 805, favorably reported by the Human Services Committee, also requires nursing homes to spend at least 80% of their funding on residents' direct care.

SB 1417, favorably reported by the Human Services Committee, establishes a nursing home workforce standards board to set standards

for wages and other matters for nursing home employees.

sSB 1415, favorably reported by the Human Services Committee, requires nursing homes to increase the minimum hourly wage for certain employees to $22.50 by January 1, 2026, and $25.00 by January 1, 2027.

§ 8 — EMERGENCY MEDICAID EXPANSION

Requires DSS to expand emergency Medicaid coverage for certain conditions and create a system allowing people to apply in advance for emergency coverage for treatment in outpatient settings for these conditions

The bill requires the DSS commissioner to expand, in a way consistent with federal law, Medicaid coverage for treating emergency medical conditions (i.e. emergency Medicaid, see *Background — Emergency Medicaid Coverage*). Under the bill, an "emergency medical condition" is a medical condition, including emergency labor and delivery, with acute symptoms severe enough that it can be expected to result in the following without treatment:

1. placing the patient's health in serious jeopardy,
2. serious impairment to bodily functions, or
3. serious dysfunction of an organ or body part.

The bill lists several conditions that must qualify for emergency Medicaid coverage under the expansion.

The bill also requires the DSS commissioner, by July 1, 2026, to create an administrative system for people to apply in advance for emergency Medicaid coverage for outpatient treatment for emergency medical conditions. The commissioner must include (1) a link to the application and list of covered emergency medical conditions on the DSS website and (2) information about advance applications for emergency Medicaid and a list of covered conditions in DSS forms and policy manuals.

EFFECTIVE DATE: July 1, 2025

Emergency Medical Conditions

Under the bill, DSS's emergency Medicaid expansion must include coverage for the following conditions to the extent allowed by federal law:

1. high-risk pregnancy;
2. type 1 diabetes in people under age 21;
3. diabetic emergencies, including diabetic ketoacidosis;
4. renal failure requiring ongoing dialysis;
5. a skull, arm, neck, leg, spine, or pelvis fracture that occurred in the two-month period before an emergency Medicaid request;
6. hypertensive emergencies in people with symptoms of end organ damage and systolic blood pressure of at least 180 or diastolic blood pressure of at least 120;
7. unstable seizure disorder with at least five minutes of uncontrollable seizures or at least two discrete seizures where the person does not regain consciousness between them;
8. active cancer treatment;
9. ventilator dependency;
10. labor and delivery; and
11. acute inpatient or outpatient psychiatric treatment.

Background — Emergency Medicaid Coverage

Under current state policy, emergency Medicaid coverage is generally limited to treatment after the sudden onset of a medical emergency. It does not cover treatment for chronic conditions, even if the condition may be life threatening. Emergency Medicaid cannot be preapproved, and instead a bill for emergency treatment is submitted to DSS for review.

However, federal law gives states flexibility to define what treatments or conditions qualify for emergency Medicaid coverage within the parameters of the "emergency medical condition" definition above. For example, in 2021 DSS determined that ongoing dialysis for end stage renal disease qualifies for emergency Medicaid coverage because without dialysis, the condition will likely become a medical emergency.

Emergency Medicaid allows hospitals to receive federal Medicaid reimbursement for care that may otherwise be uncompensated. Any person, regardless of immigration status, can qualify for emergency Medicaid coverage if he or she meets Medicaid income and asset limits.

Background — Related Bill

SB 806, favorably reported by the Human Services Committee, also requires DSS to expand Medicaid coverage for treating emergency medical conditions.

§ 9 — PHASEOUT OF HUSKY C ASSET LIMIT

Requires DSS to increase and then eliminate the HUSKY C asset limit over a five-year period

The bill requires the DSS commissioner to increase and then eliminate the HUSKY C asset limit over a five-year period, as shown in the table below. HUSKY C provides Medicaid coverage to people who are age 65 or older, blind, or living with a disability.

Table: HUSKY C Asset Limit Changes Under the Bill

Time Period	*Single Person*	*Married Couple*
Current law	$1,600	$2,400
FY 26	$10,000	$15,000
FY 27	$25,000	$40,000
FY 28	$75,000	$100,000
FY 29	$100,000	$150,000
FY 30	No Limit	No Limit

The bill also requires the commissioner to allow a person to spend down income that exceeds HUSKY C income limits on incurred medical

bills in accordance with federal regulations on Medicaid spend-downs, so long as the person otherwise qualifies for HUSKY C, generally conforming to current practice.

Lastly, the bill requires the commissioner, starting by July 1, 2026, to report annually to the Appropriations and Human Services committees on (1) the number of people eligible for HUSKY C for the prior fiscal year and (2) any increased costs incurred by the state that are attributable to the bill's changes in asset limits.

EFFECTIVE DATE: July 1, 2025

Background — Related Bills

SB 807, favorably reported by the Human Services Committee, also requires DSS to eliminate the asset limit for HUSKY C over a five-year period.

SB 981, favorably reported by the Human Services Committee, requires DSS to disregard certain Social Security income for disabled adult children when determining income eligibility for HUSKY C.

sHB 6911 (File 110), favorably reported by the Aging Committee, requires DSS, starting July 1, 2025, to increase HUSKY C asset limits by at least the same percentage increase as the national consumer price index.

§§ 10 & 11 — REIMBURSEMENT FOR GENERAL ANESTHESIA

Prohibits health insurance policies from imposing (1) arbitrary time limits on reimbursement for medically necessary general anesthesia or (2) unilateral arbitrary limitations on reimbursement for medically necessary ancillary services

The bill prohibits certain individual and group health insurance policies that cover general anesthesia from (1) imposing arbitrary time limits on reimbursement for general anesthesia during a medically necessary procedure or (2) denying, reducing, terminating, or not providing reimbursement for general anesthesia solely because its duration exceeded the insurer's predetermined time limit for the care. It also prohibits the policies from imposing unilateral arbitrary limitations on reimbursement for medically necessary ancillary services.

The bill requires the attending board-certified anesthesiologist to determine the medical necessity of general anesthesia during a medical procedure.

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut on or after January 1, 2026, that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including those provided under an HMO plan. Because of the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

EFFECTIVE DATE: January 1, 2026

Background — Related Bill

sSB 10, §§ 17 & 18, favorably reported by the Insurance and Real Estate Committee, includes the same requirements for medically necessary general anesthesia and ancillary services reimbursements as this bill.

§ 12 — STOP-LOSS INSURANCE POLICIES WITH SELF-FUNDED EMPLOYEE HEALTH PLANS

Requires any stop-loss insurance policies used in conjunction with self-funded employee health benefit plans to either (1) provide specified benefits or (2) have a set minimum individual and aggregate attachment point

Generally, employers use stop-loss insurance policies under self-funded plans to protect against catastrophic losses. The threshold for stop-loss coverage is generally referred to as the "attachment point."

The bill requires any stop-loss insurance policy used along with a self-funded employee health benefit plan to either:

1. provide essential health benefits required under the federal Affordable Care Act and the group state-mandated coverage requirements under state health insurance laws or

2. have a minimum individual attachment point of at least $75,000 and an aggregate attachment point of at least $250,000.

(It is unclear whether the first provision above could be enforced, because federal law (ERISA) preempts the state from regulating a self-insured plan's benefits.)

Current Insurance Department guidelines (Bulletin HC-126) prohibit a stop-loss policy from:

1. having an annual individual attachment point less than $20,000;
2. for a small employer (i.e. 50 or fewer group members), having an annual aggregate attachment point less than the greater of $20,000, $4,000 times the number of covered individuals, or 120% of expected claims;
3. for a large employer, having an annual aggregate attachment point less than 110% of expected claims; or
4. providing direct coverage for an individual's health care or medical expenses.

EFFECTIVE DATE: January 1, 2026

§ 13 — GENERIC GLP-1 DRUGS FOR WEIGHT LOSS

Requires DSS to take certain steps to increase access to generic, lower cost forms of GLP-1 drugs

The bill requires DSS, within 30 days after the bill's passage, to petition the federal Department of Health and Human Services (HSS) secretary to authorize generic, lower cost forms of glucagon-like peptide GLP-1 drugs (e.g., Ozempic) that are FDA approved to treat obesity or diabetes. (Currently, there are two generic versions of GLP-1 drugs approved to treat diabetes, but none specifically approved to treat obesity.)

Under the bill, if HHS approves the petition, the DSS commissioner must contract with a manufacturer to supply the state with a generic form of these drugs for HUSKY Health members. The commissioner may enter into a consortium with other states in such a contract.

The bill requires the commissioner to develop a strategic plan to

maximize access to these drugs and minimize their cost. By December 31, 2025, she must report on the plan to the Human Services Committee and the Obesity Drug Advisory Committee created under the bill (see below).

EFFECTIVE DATE: Upon passage

§ 14 — OBESITY DRUG ADVISORY COMMITTEE

Creates an advisory committee to study and make recommendations on ways to maximize access to cost-effective, FDA-approved prescription drugs to treat obesity

The bill establishes an advisory committee to study ways to maximize access to cost-effective, FDA-approved prescription drugs to treat obesity and make recommendations to DSS.

The committee includes six members, as shown in the following table.

Table: Obesity Drug Advisory Committee Members

Appointing Authority	*Appointee Qualifications*
Council on Medical Assistance Program Oversight chairperson	Two patient advocates
DSS commissioner	Two Medicaid-enrolled pharmacists
Human Services Committee chairpersons	Two medical professionals, including at least one doctor certified by the American Board of Obesity Medicine

The bill requires the committee to meet within 30 days after the bill's passage, choose a chairperson, and meet at least bimonthly.

Under the bill, the committee must review DSS's strategic plan on generic GLP-1 drugs (see § 13) and make recommendations to DSS on implementing the plan and the results of its study by January 31, 2026. The committee ends when it submits its recommendations to DSS or on January 31, 2026, whichever is later.

EFFECTIVE DATE: Upon passage

§ 15 — MEDICAID COVERAGE OF WEIGHT LOSS DRUGS

Expands Medicaid coverage for weight loss drugs by requiring DSS to cover glucagon-like peptide 1 (GLP-1) prescription drugs to treat obesity under certain circumstances

Current law requires DSS to provide medical assistance for medical services for Medicaid and HUSKY B beneficiaries with a body mass index over 35, so long as the beneficiaries otherwise meet conditions set by CMS. By law, medical services include FDA-approved prescription drugs to treat obesity on an outpatient basis and nutritional counseling provided by a registered dietitian.

The bill expands this coverage by (1) removing the requirement that beneficiaries meet CMS conditions and (2) specifying that medical services include GLP-1 prescription drugs approved by the FDA for weight loss or commonly used for weight loss, sleep apnea, or to reduce risks of cardiovascular disease. The bill requires the DSS commissioner to continue providing Medicaid coverage for beneficiaries treated with GLP-1 prescription drugs in cases where their BMI drops below 35 if a physician certifies that their BMI would increase above 35 if GLP-1 drugs were discontinued. Existing law and the bill authorize DSS to amend the Medicaid state plan or the Children's Health Insurance Program state plan if needed to implement this coverage.

EFFECTIVE DATE: July 1, 2025

Background — Related Bills

sSB 1474, favorably reported by the Human Services Committee, also expands Medicaid coverage for weight loss drugs.

§ 16 — 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

sHB 7192, § 3, favorably reported by the Human Services Committee, has identical provisions on rebate annual reporting.

§§ 17 & 18 — 340B PROGRAM

Generally prohibits drug manufacturers from (1) limiting access to 340B drugs for pharmacies contracting with covered entities and (2) requiring pharmacies or covered entities to submit claims or utilization data as a condition for receiving 340B drugs; establishes a hearing process and penalties for violators

Section 340B of the federal Public Health Service Act (i.e. the 340B Drug Pricing Program) requires drug manufacturers participating in Medicaid to sell certain outpatient prescription drugs at discounted prices to health care organizations that care for uninsured and low-income patients. Pharmacies may contract with 340B-participating healthcare organizations to also purchase reduced-price outpatient drugs.

The bill prohibits drug manufacturers (including biologics manufacturers), and their agents or affiliates, from directly or indirectly taking any of the following actions:

1. denying or limiting access to 340B drugs for a pharmacy contracting or otherwise working with a covered entity (see below) to obtain them on the entity's behalf, 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.

For these restrictions, "covered entities" are the UConn Health

Center, federally qualified health centers, family planning clinics, and Ryan White clinics (i.e. clinics that receive specified HIV and AIDS-related federal funding). (Federal law allows other organizations to participate in the 340B program, such as hospitals that serve a disproportionate number of low-income patients.)

Also, under these provisions, 340B drugs are those that a covered entity (1) purchases under the program and that are subject to the program's pricing requirements or (2) would purchase except for the prohibited conduct.

The bill subjects violators to civil penalties (see below). It also requires the DCP commissioner to adopt implementing regulations.

The bill specifies that its 340B provisions must not be applied in a way that conflicts with, or is less restrictive than, applicable state and federal laws (including the federal law on drug risk evaluation and mitigation strategies (REMSs); see *Background — REMS*).

EFFECTIVE DATE: Upon passage

Violations

Beginning July 1, 2025, the bill subjects manufacturers (or their agents or affiliates) to a civil penalty of up to $50,000 per violation if the DCP commissioner has a reasonable belief, based on received information, that they have violated these provisions or regulations.

The commissioner must issue the violation notice by first-class mail or personal service, and it must include:

1. a reference to the law or regulation that has allegedly been violated;

2. a short and plain language statement of the matter;

3. a description of the activity to cease;

4. the penalty amount that may be imposed; and

5. an explanation of the right to request, in writing to DCP, a hearing within 10 business days after receiving the notice.

Under the bill, DCP must hold requested hearings as contested case hearings under the Uniform Administrative Procedure Act (UAPA). If after a hearing, DCP finds, by a preponderance of the evidence, that a violation has occurred or that the entity has violated any DCP order, the department must issue a final cease and desist order in addition to any civil penalty imposed.

If the manufacturer, agent, or affiliate does not timely request a hearing, DCP must issue a cease and desist order or impose a civil penalty.

Background — REMS

Federal law authorizes the FDA to require a drug safety program (called "REMS") for certain prescription medications with serious safety concerns to ensure that the medications are used safely and the risks of serious or life-threatening side effects are minimized for patients, pharmacies, and providers (21 U.S.C. § 355-1).

§ 19 — "PAY TO DELAY" REPORTING

Requires pharmaceutical manufacturers to annually report to DCP any agreements with a competitor to delay the launch of generic drugs; allows DCP to set penalties for the failure to report

The bill requires pharmaceutical manufacturers doing business in the state to annually report to DCP any "pay to delay" agreements with a competitor and the prescription drugs included in the agreement. Under the bill, these are agreements between a pharmaceutical manufacturer and a competitor to delay launching a generic drug based on an expiring or expired patent for one of the manufacturer's drugs. Manufacturers must report in a form and manner DCP sets.

The bill also requires DCP to adopt implementing regulations. The department also may establish penalties and an administrative hearing process under the UAPA for manufacturers that violate the reporting requirement.

EFFECTIVE DATE: July 1, 2025

§§ 20-22 — INSULIN PRODUCT INSURANCE COVERAGE

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 to make available to beneficiaries an eligible insulin product at the lowest wholesale acquisition cost in a preferred tier with no copayment or other out-of-pocket cost. This applies unless a collective bargaining agreement requires otherwise for the state employee plan. 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, commercial health benefit plans generally must cap the out-of-pocket cost of insulin at $25 per 30-day supply.

The bill also allows state entities and health benefit plans to (1) cover more than one eligible insulin product in a preferred tier with no out-of-pocket costs and (2) offer, with no out-of-pocket costs, another eligible insulin product if it has a net cost lower than the lowest wholesale acquisition cost. Under the bill, an insulin product's net cost takes into account rebates or discounts, excluding those required under state or federal law or those related to portfolio agreements for purchasing multiple insulin products or other drugs.

For commercial plans, the bill applies the above requirement to high deductible health plans (HDHP) to the maximum extent permitted by federal law. If the HDHP is used to establish a health savings or similar account, the bill applies to the maximum extent permitted by federal law that does not affect the account's tax preferred status.

Because of ERISA, state insurance benefit mandates do not apply to self-insured benefit plans.

EFFECTIVE DATE: January 1, 2026

§ 23 — 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

sHB 7192, § 1, favorably reported by the Human Services Committee, contains the same provisions on PBMs' fiduciary duty and carrier contracts.

§ 24 — 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

sHB 7192, § 2, favorably reported by the Human Services Committee, has identical provisions on pharmacy services contracts.

§ 25 — 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 on the department's website to these reports.

EFFECTIVE DATE: July 1, 2025

Background — Related Bill

sHB 7192, § 4, favorably reported by the Human Services Committee, also requires this annual reporting on carrier pricing.

§§ 26-35 — CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

Establishes a Canadian prescription drug importation program; requires the DCP commissioner, on behalf of the state, to seek federal approval to import prescription drugs from Canada for distribution in the state; establishes testing, safety, and quality requirements; drug standards and tracking; establishes requirements for participating suppliers and wholesalers, including documentation, records retention, administrative proceedings, and penalties for violations; and authorizes DCP emergency actions (e.g., recalls), 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. ("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 (§ 27)

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 (§ 28)

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 (§§ 26, 29 & 30)

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 (§§ 26 & 31)

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 (§§ 26 & 32(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 (§ 32(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 (§ 32(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 (§ 32(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 (§ 33)

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 (§§ 34 & 35)

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

sHB 6870 (File 308), §§ 1-10, favorably reported by the Insurance and Real Estate Committee, and sHB 7192, §§ 5-14, favorably reported by the Human Services Committee, both have substantially similar provisions related to establishing a Canadian prescription drug importation program.

§ 36 — 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

Appointing Authority	*Appointee Qualifications*
	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 Human Services 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

sHB 7192, § 15, favorably reported by the Human Services Committee, has substantially similar provisions creating a prescription drug shortages task force.

§ 37 — 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 § 36).

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

HB 7192, § 16, favorably reported by the Human Services Committee, has identical provisions on DECD's Strategic Supply Chain Initiative.

§ 38 — VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Requires DPH to convene an advisory committee to coordinate seasonal vaccine production along with drug manufacturers

The bill requires the public health commissioner to establish and convene a Vaccines and Related Biological Products Advisory Committee to coordinate seasonal vaccine production with pharmaceutical manufacturers.

Under the bill, the commissioner must appoint representatives of the following groups:

1. pharmaceutical manufacturers, including one large manufacturer and one small or start-up one;

2. health systems, including at least one large or statewide hospital system and one federally qualified health center; and

3. physicians, including at least one expert each in infectious disease epidemiology, disease ecology, biostatistics or infectious

disease modeling, and an expert in immunology or virology.

The bill requires the committee to meet within 30 days after the bill's passage. The committee has two chairpersons: the DPH commissioner or her designee, and another elected by the committee. The commissioner must fill any vacancy.

Starting by September 1, 2025, the commissioner must annually file a report with the Human Services and Public Health committees on the advisory committee's activities and recommendations and its impact on state preparedness for the annual flu season.

EFFECTIVE DATE: Upon passage

COMMITTEE ACTION

Human Services Committee

Joint Favorable Substitute
Yea 15 Nay 7 (03/13/2025)