House of Representatives

General Assembly

File No. 308

January Session, 2025

Substitute House Bill No. 6870

House of Representatives, March 27, 2025

The Committee on Insurance and Real Estate reported through REP. WOOD of the 29th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT ADDRESSING PATIENTS' PRESCRIPTION DRUG COSTS.

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

Section 1. (*Effective July 1, 2025*) For the purposes of this section and sections 2 to 10, inclusive, of this act, unless the context otherwise requires:

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

(2) "Canadian prescription drug importation program" or "program" means a program under which the state would seek federal approval to import prescription drugs from Canada that have the highest potential for cost savings in the state;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 2. (*Effective July 1, 2025*) The Commissioner of Consumer Protection shall hire, within available resources, a consultant to study the feasibility of establishing a Canadian prescription drug importation program to reduce prescription drug costs in the state. Not later than October 1, 2027, the Commissioner shall file a report, in accordance with the provisions of section 11-4a of the general statutes, with the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law and human services and the Office of Policy and Management on the results of the feasibility study.

Sec. 3. (*Effective October 1, 2027*) (a) If after completion of the study described in section 2 of this act, the Commissioner of Consumer Protection, in consultation with the Secretary of the Office of Policy and Management, determines a Canadian prescription drug importation program is feasible, the Commissioner of Consumer Protection may submit a request to the federal Food and Drug Administration seeking approval for the program under Section 804 of the federal Food, Drug and Cosmetic Act, 21 USC 384(b) to 21 USC 384(h), inclusive, as amended from time to time. If submitted, such request shall, at a minimum:

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

(2) Demonstrate that any prescription drug that is imported and

distributed in this state under the program would:

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

(B) Comply with all federal tracing procedures; and

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

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

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

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

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

Sec. 4. (*Effective October 1, 2027*) If the Canadian prescription drug importation program is established, each participating wholesaler may import and distribute a prescription drug in this state from a participating Canadian supplier under the program if:

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

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

(3) Such drug is not:

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

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

(C) An infused drug;

(D) An intravenously injected drug;

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

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

Sec. 5. (*Effective October 1, 2027*) If a Canadian prescription drug importation program is established, participating wholesalers may, subject to the provisions of sections 1 to 4, inclusive, and sections 6 to 10, inclusive, of this act, import and distribute drugs in this state from a participating Canadian supplier under the program to:

(1) A pharmacy or institutional pharmacy, as defined in section 20-571 of the general statutes; and

(2) A qualifying laboratory.

Sec. 6. (*Effective October 1, 2027*) If a Canadian prescription drug importation program is established, the Commissioner of Consumer Protection shall require that each participating Canadian supplier and participating wholesaler (1) comply with all applicable track-and-trace requirements, and shall not distribute, dispense or sell outside of this state any prescription drug that is imported into this state under the program, and (2) make available to the commissioner all track-and-trace records not later than forty-eight hours after the commissioner requests such records.

Sec. 7. (*Effective October 1, 2027*) (a) A participating wholesaler in any approved Canadian prescription drug importation program shall ensure the safety and quality of all drugs that may be imported and distributed in this state under the program. The participating wholesaler shall, if such program is established:

(1) For each initial shipment of a drug that is imported into this state by a participating wholesaler, ensure that a qualifying laboratory engaged by the participating wholesaler tests a statistically valid sample size for each batch of each drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

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

(3) Only import drugs into this state that are (A) approved for marketing in the United States, (B) not adulterated or misbranded, and (C) meet all of the labeling requirements under 21 USC 352, as amended from time to time;

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

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

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

(c) Each participating wholesaler shall maintain all of the following information for each drug that such participating wholesaler imports and distributes in this state under the program, and submit such information to the Commissioner of Consumer Protection upon request by the commissioner:

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

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

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

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

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

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

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

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

(d) The Commissioner of Consumer Protection shall require each participating Canadian supplier in any approved Canadian prescription drug importation program to maintain the following information and documentation and, upon request by the commissioner, submit such information and documentation to the commissioner for each drug that such participating Canadian supplier exports into this state under the

program:

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

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

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

(C) The location where such drug was manufactured;

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

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

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

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

(6) Such additional information and documentation that the Commissioner of Consumer Protection deems necessary to ensure the protection of the public health.

Sec. 8. (*Effective October 1, 2027*) (a) If the Commissioner of Consumer Protection determines that public health, safety or welfare requires emergency action, the commissioner may order a participating Canadian supplier, participating wholesaler, relabeler, repacker and qualifying laboratory to cease and desist from actions specified in the order that create the need for such emergency action pending administrative proceedings. Such cease and desist order shall be (1) in writing; (2) signed by the Commissioner of Consumer Protection; and (3) effective upon delivery to the respondent. An administrative proceeding conducted in accordance with chapter 54 of the general statutes shall be promptly instituted following a cease and desist order. The commissioner may impose a civil penalty, in an amount not to exceed ten thousand dollars, after a hearing conducted pursuant to chapter 54 of the general statutes.

(b) The commissioner may require the recall, embargo or destruction, pursuant to section 21a-96 of the general statutes, of any drug that was imported and distributed under the program and has been identified as adulterated, within the meaning of section 21a-105 of the general statutes, or misbranded.

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

Sec. 9. (*Effective October 1, 2027*) If a Canadian prescription drug importation program is established, the Commissioner of Consumer Protection may adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 1 to 8, inclusive, and section 10 of this act.

Sec. 10. (*Effective October 1, 2027*) Not later than one hundred eighty days after the first importation of any Canadian prescription drug under the importation program begins, and biannually thereafter, the Commissioner of Consumer Protection shall submit a report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law, human services and public health. Such report shall describe (1) the operation of the program, if established, and (2) any violation of sections 1 to 9, inclusive, of this act that resulted in any action taken by the commissioner pursuant to section 8 of this act and the status of the investigation into such violation.

Sec. 11. (NEW) (*Effective July 1, 2025*) For the purposes of this section and sections 12 to 14, inclusive, of this act:

(1) "Biological product" has the same meaning as provided in section 20-619 of the general statutes;

(2) "Brand-name drug" means a drug that is produced or distributed

in accordance with an original new drug application approved under 21 USC 355, as amended from time to time, but does not include an authorized generic drug as defined in 42 CFR 447.502, as amended from time to time;

(3) "Commissioner" means the Commissioner of Revenue Services;

(4) "Consumer price index" means the consumer price index, annual average, for all urban consumers: United States city average, all items, published by the United States Department of Labor, Bureau of Labor Statistics, or its successor, or, if the index is discontinued, an equivalent index published by a federal authority, or, if no such index is published, a comparable index published by the United States Department of Labor, Bureau of Labor Statistics;

(5) "Generic drug" means (A) a prescription drug product that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 USC 355, as amended from time to time, (B) an authorized generic drug as defined in 42 CFR 447.502, as amended from time to time, or (C) a drug that entered the market before calendar year 1962 that was not originally marketed under a new prescription drug product application;

(6) "Identified prescription drug" means (A) a brand-name drug or biological product for which the patent has expired for at least twenty-four months, or (B) a generic drug or interchangeable biological product;

(7) "Interchangeable biological product" has the same meaning as provided in section 20-619 of the general statutes;

(8) "Person" has the same meaning as provided in section 12-1 of the general statutes;

(9) "Pharmaceutical manufacturer" means a person that manufactures a prescription drug and sells, directly or through another person, the prescription drug for distribution in this state;

(10) "Prescription drug" means a legend drug, as defined in section 20-571 of the general statutes, approved by the federal Food and Drug Administration, or any successor agency, and prescribed by a health care provider to an individual in this state;

(11) "Reference price" means the wholesale acquisition cost, as defined in 42 USC 1395w-3a, as amended from time to time, of (A) a brand-name drug or biological product (i) on January 1, 2025, if the patent for the brand-name drug or biological product expired on or before said date, or (ii) if the patent for the brand-name drug or biological product expires after January 1, 2025, on the date the patent for such brand-name drug or biological product expires, or (B) a generic drug or interchangeable biological product (i) on January 1, 2025, or (ii) if the generic drug or interchangeable biological product is first commercially marketed in the United States after January 1, 2025, on the date such generic drug or interchangeable biological product is first commercially marketed in the United States; and

(12) "Wholesale distributor" means a person, including, but not limited to, a repacker, own-label distributor, private-label distributor or independent wholesale drug trader, engaged in the wholesale distribution of prescription drugs.

Sec. 12. (NEW) (*Effective July 1, 2025*) (a) (1) Notwithstanding any provision of the general statutes and except as provided in subdivision (2) of this subsection, no pharmaceutical manufacturer or wholesale distributor shall, on or after January 1, 2026, sell an identified prescription drug in this state at a price that exceeds the reference price for the identified prescription drug, adjusted for any increase in the consumer price index.

(2) A pharmaceutical manufacturer or wholesale distributor may, on or after January 1, 2026, sell an identified prescription drug in this state at a price that exceeds the reference price for the identified prescription drug, adjusted for any increase in the consumer price index, if the federal Secretary of Health and Human Services determines, pursuant to 21 USC 356e, as amended from time to time, that such identified

prescription drug is in shortage in the United States.

(b) (1) Except as provided in subdivision (2) of this subsection, any pharmaceutical manufacturer or wholesale distributor that violates the provisions of subsection (a) of this section shall be liable to this state for a civil penalty. Such civil penalty shall be imposed, calculated and collected on a calendar year basis by the commissioner, and the amount of such civil penalty for a calendar year shall be equal to eighty per cent of the difference between:

(A) The revenue that the pharmaceutical manufacturer or wholesale distributor earned from all sales of the identified prescription drug in this state during the calendar year; and

(B) The revenue that the pharmaceutical manufacturer or wholesale distributor would have earned from all sales of the identified prescription drug in this state during the calendar year if the pharmaceutical manufacturer or wholesale distributor had sold such identified prescription drug at a price that did not exceed the reference price for such identified prescription drug, as such reference price is adjusted for any increase in the consumer price index.

(2) No pharmaceutical manufacturer or wholesale distributor of an identified prescription drug shall be liable to this state for the civil penalty imposed under subdivision (1) of this subsection unless the pharmaceutical manufacturer or wholesale distributor made at least two hundred fifty thousand dollars in total annual sales in this state for the calendar year for which such civil penalty would otherwise be imposed.

(c) (1) (A) For calendar years commencing on or after January 1, 2026, each pharmaceutical manufacturer or wholesale distributor that violated the provisions of subsection (a) of this section during any calendar year shall, not later than the first day of March immediately following the end of such calendar year:

(i) Pay to the commissioner the civil penalty imposed under

subsection (b) of this section for such calendar year; and

(ii) File with the commissioner a statement for such calendar year in a form and manner, and containing all information, prescribed by the commissioner.

(B) A pharmaceutical manufacturer or wholesale distributor that is required to file the statement and pay the civil penalty pursuant to subparagraph (A) of this subdivision shall electronically file such statement and make such payment by electronic funds transfer in the manner provided by chapter 228g of the general statutes, irrespective of whether the pharmaceutical manufacturer or wholesale distributor would have otherwise been required to electronically file such statement or make such payment by electronic funds transfer under chapter 228g of the general statutes.

(2) If no statement is filed pursuant to subdivision (1) of this subsection, the commissioner may make such statement at any time thereafter, according to the best obtainable information and the prescribed form.

(d) The commissioner may examine the records of any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section as the commissioner deems necessary. If the commissioner determines from such examination that the pharmaceutical manufacturer or wholesale distributor failed to pay the full amount of such civil penalty, the commissioner shall bill such pharmaceutical manufacturer or wholesale distributor for the full amount of such civil penalty.

(e) (1) The commissioner may require each pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section to keep such records as the commissioner may prescribe, and produce books, papers, documents and other data, to provide or secure information pertinent to the enforcement and collection of such civil penalty.

(2) The commissioner, or the commissioner's authorized representative, may examine the books, papers, records and equipment of any person who is subject to the provisions of this section and may investigate the character of the business of such person to verify the accuracy of any statement made or, if no statement is made by such person, to ascertain and determine the amount of the civil penalty due under subsection (b) of this section.

(f) Any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section and aggrieved by any action of the commissioner under subdivision (2) of subsection (c) of this section or subsection (d) of this section may apply to the commissioner, in writing and not later than sixty days after the notice of such action is delivered or mailed to such pharmaceutical manufacturer or wholesale distributor, for a hearing, setting forth the reasons why such hearing should be granted and if such pharmaceutical manufacturer or wholesale distributor believes that such pharmaceutical manufacturer or wholesale distributor is not liable for such civil penalty or the full amount of such civil penalty, the grounds for such belief and the amount by which such pharmaceutical manufacturer or wholesale distributor believes such civil penalty should be reduced. The commissioner shall promptly consider each such application and may grant or deny the hearing requested. If the hearing request is denied, the commissioner shall immediately notify the pharmaceutical manufacturer or wholesale distributor. If the hearing request is granted, the commissioner shall notify the pharmaceutical manufacturer or wholesale distributor of the date, time and place for such hearing. After such hearing, the commissioner may make such order as appears just and lawful to the commissioner and shall furnish a copy of such order to the pharmaceutical manufacturer or wholesale distributor. The commissioner may, by notice in writing, order a hearing on the commissioner's own initiative and require a pharmaceutical manufacturer or wholesale distributor, or any other person who the commissioner believes to be in possession of relevant information concerning such pharmaceutical manufacturer or wholesale distributor, to appear before the commissioner or the

commissioner's authorized agent with any specified books of account, papers or other documents for examination under oath.

(g) Any pharmaceutical manufacturer or wholesale distributor that is aggrieved by any order, decision, determination or disallowance of the commissioner made under subsection (f) of this section may, not later than thirty days after service of notice of such order, decision, determination or disallowance, take an appeal therefrom to the superior court for the judicial district of New Britain, which appeal shall be accompanied by a citation to the commissioner to appear before said court. Such citation shall be signed by the same authority and such appeal shall be returnable at the same time and served and returned in the same manner as is required in case of a summons in a civil action. The authority issuing the citation shall take from the appellant a bond or recognizance to this state, with surety, to prosecute the appeal to effect and to comply with the orders and decrees of the court. Such appeals shall be preferred cases, to be heard, unless cause appears to the contrary, at the first session, by the court or by a committee appointed by the court. Said court may grant such relief as may be equitable and, if the civil penalty was paid prior to the granting of such relief, may order the Treasurer to pay the amount of such relief. If the appeal was taken without probable cause, the court may tax double or triple costs, as the case demands and, upon all such appeals that are denied, costs may be taxed against such pharmaceutical manufacturer or wholesale distributor at the discretion of the court but no costs shall be taxed against this state.

(h) The commissioner, and any agent of the commissioner duly authorized to conduct any inquiry, investigation or hearing pursuant to this section, shall have power to administer oaths and take testimony under oath relative to the matter of inquiry or investigation. At any hearing ordered by the commissioner, the commissioner, or the commissioner's agent authorized to conduct such hearing and having authority by law to issue such process, may subpoena witnesses and require the production of books, papers and documents pertinent to such inquiry or investigation. No witness under any subpoena

authorized to be issued under the provisions of this section shall be excused from testifying or from producing books, papers or documentary evidence on the ground that such testimony or the production of such books, papers or documentary evidence would tend to incriminate such witness, but such books, papers or documentary evidence so produced shall not be used in any criminal proceeding against such witness. If any person disobeys such process or, having appeared in obedience thereto, refuses to answer any pertinent question put to such person by the commissioner, or the commissioner's authorized agent, or to produce any books, papers or other documentary evidence pursuant thereto, the commissioner, or such agent, may apply to the superior court of the judicial district wherein the pharmaceutical manufacturer or wholesale distributor resides or wherein the business was conducted, or to any judge of such court if the same is not in session, setting forth such disobedience to process or refusal to answer, and such court or such judge shall cite such person to appear before such court or such judge to answer such question or to produce such books, papers or other documentary evidence and, upon such person's refusal to do so, shall commit such person to a community correctional center until such person testifies, but not for a period longer than sixty days. Notwithstanding the serving of the term of such commitment by any person, the commissioner may proceed in all respects with such inquiry and examination as if the witness had not previously been called upon to testify. Officers who serve subpoenas issued by the commissioner or under the commissioner's authority and witnesses attending hearings conducted by the commissioner pursuant to this section shall receive fees and compensation at the same rates as officers and witnesses in the courts of this state, to be paid on vouchers of the commissioner on order of the Comptroller from the proper appropriation for the administration of this section.

(i) The amount of any civil penalty unpaid under the provisions of this section may be collected under the provisions of section 12-35 of the general statutes. The warrant provided under section 12-35 of the general statutes shall be signed by the commissioner or the commissioner's authorized agent. The amount of any such civil penalty

shall be a lien on the real property of the pharmaceutical manufacturer or wholesale distributor from the last day of the month next preceding the due date of such civil penalty until such civil penalty is paid. The commissioner may record such lien in the records of any town in which the real property of such pharmaceutical manufacturer or wholesale distributor is situated, but no such lien shall be enforceable against a bona fide purchaser or qualified encumbrancer of such real property. When any civil penalty with respect to which a lien was recorded under the provisions of this subsection is satisfied, the commissioner shall, upon request of any interested party, issue a certificate discharging such lien, which certificate shall be recorded in the same office in which such lien was recorded. Any action for the foreclosure of such lien shall be brought by the Attorney General in the name of this state in the superior court for the judicial district in which the real property subject to such lien is situated, or, if such real property is located in two or more judicial districts, in the superior court for any one such judicial district, and the court may limit the time for redemption or order the sale of such real property or make such other or further decree as the court judges equitable. The provisions of section 12-39g of the general statutes shall apply to all civil penalties imposed under this section.

(j) (1) Any officer or employee of a pharmaceutical manufacturer or wholesale distributor who owes a duty to the pharmaceutical manufacturer or wholesale distributor to pay the civil penalty imposed under subsection (b) of this section on behalf of such pharmaceutical manufacturer or wholesale distributor, file a statement with the commissioner pursuant to subsection (c) of this section on behalf of such pharmaceutical manufacturer or wholesale distributor, keep records or supply information to the commissioner on behalf of such pharmaceutical manufacturer or wholesale distributor pursuant to this section and wilfully fails, at the time required under this section, to pay such civil penalty, file such statement, keep such records or supply such information on behalf of such pharmaceutical manufacturer or wholesale distributor shall, in addition to any other penalty provided by law, be fined not more than one thousand dollars or imprisoned not more than one year, or both. Notwithstanding the provisions of section

54-193 of the general statutes, no such officer or employee shall be prosecuted for a violation of the provisions of this subdivision committed on or after January 1, 2026, except within three years next after such violation is committed.

(2) Any officer or employee of a pharmaceutical manufacturer or wholesale distributor who owes a duty to the pharmaceutical manufacturer or wholesale distributor to deliver or disclose to the commissioner, or the commissioner's authorized agent, any list, statement, return, account statement or other document on behalf of such pharmaceutical manufacturer or wholesale distributor and wilfully delivers or discloses to the commissioner, or the commissioner's authorized agent, any such list, statement, return, account statement or other document that such officer or employee knows to be fraudulent or false in any material matter shall, in addition to any other penalty provided by law, be guilty of a class D felony.

(3) No officer or employee of a pharmaceutical manufacturer or wholesale distributor shall be charged with an offense under both subdivisions (1) and (2) of this subsection in relation to the same civil penalty, but such officer or employee may be charged and prosecuted for both such offenses upon the same information.

(k) Each civil penalty imposed under subsection (b) of this section shall be deemed to constitute a civil fine or penalty within the meaning of 42 USC 1396b(w), as amended from time to time. No portion of any civil penalty imposed under subsection (b) of this section shall be waived under section 12-3a of the general statutes or any other applicable law. No tax credit shall be allowable against any civil penalty imposed under subsection (b) of this section.

(l) Not later than July 1, 2027, and annually thereafter, the commissioner shall prepare a list containing the name of each pharmaceutical manufacturer or wholesale distributor that violated subsection (a) of this section during the preceding calendar year. The commissioner shall make each such list publicly available.

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

Sec. 13. (NEW) (*Effective July 1, 2025*) (a) No pharmaceutical manufacturer or wholesale distributor of an identified prescription drug shall withdraw the identified prescription drug from sale in this state for the purpose of avoiding the civil penalty established in subsection (b) of section 12 of this act.

(b) Any pharmaceutical manufacturer or wholesale distributor that intends to withdraw an identified prescription drug from sale in this state shall, at least one hundred eighty days before such withdrawal, send advance written notice to the Office of Health Strategy disclosing such pharmaceutical manufacturer's or wholesale distributor's intention.

(c) Any pharmaceutical manufacturer or wholesale distributor that violates the provisions of subsection (a) or (b) of this section shall be liable to this state for a civil penalty in the amount of five hundred thousand dollars.

Sec. 14. (NEW) (*Effective July 1, 2025*) All civil penalties collected from pharmaceutical manufacturers or wholesale distributors under sections 11 to 13, inclusive, of this act shall be deposited in the General Fund and expended for the purposes of promoting access to affordable health care, and reducing the health care costs borne by patients, in this state.

Sec. 15. (NEW) (*Effective January 1, 2026*) (a) As used in this section:

(1) "Enrollee" has the same meaning as provided in section 38a-478 of the general statutes;

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

(3) "Health carrier" has the same meaning as provided in section 38a-591a of the general statutes.

(b) Each insurer, health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues an individual or a group health insurance policy or health benefit plan in this state on or after January 1, 2026, providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes in this state, shall, when calculating an insured's or enrollee's in-network liability for such insured's or enrollee's annual coinsurance, copayment, deductible or other in-network out-of-pocket expense, give credit for any out-of-pocket expense such insured or enrollee pays directly to any pharmacy licensed pursuant to section 20-594 of the general statutes, or health care provider licensed in this state, for any prescription drug, provided (1) no claim for such prescription drug was submitted to such insurer, center, corporation, society, or other entity, and (2) such out-of-pocket expense paid by such insured or enrollee to such pharmacy or health care provider is less than the average discounted rate for such prescription drug paid to an in-network health care provider pursuant to the terms of such health insurance policy or health benefit plan.

(c) If any insured or enrollee purchases a prescription drug from any out-of-network health care provider for a lower amount than the average amount paid by such insured's or enrollee's health carrier to any in-network health care provider for the same prescription drug, such health carrier, when calculating such insured's or enrollee's liability for such insured's or enrollee's in-network annual coinsurance, copayment, deductible or other out-of-pocket expense, shall give credit for such purchase, provided such insured or enrollee provides such health carrier with proof of payment for such prescription drug in accordance with the provisions of subsection (d) of this section. Nothing in this subsection shall be construed to restrict any health insurance policy or health benefit plan from requiring a prior authorization or precertification otherwise provided for in the insured's or enrollee's health insurance policy or health benefit plan.

(d) Each health carrier shall (1) develop a proof of payment form and

publish such form on such health carrier's Internet web site for insureds and enrollees to submit proof of payment for any out-of-network prescription drug purchase pursuant to subsection (c) of this section, and (2) annually provide to such insureds and enrollees written notice of, and instructions for downloading or electronic submission of, such proof of payment form.

(e) Upon receipt of any such proof of payment form submitted by any insured or enrollee pursuant to subsection (d) of this section, each health carrier shall give credit for any out-of-pocket payments that such insured or enrollee paid to any out-of-network pharmacy or health care provider in accordance with the provisions of subsection (c) of this section, provided (1) the prescription drug purchased by such insured or enrollee is included under such insured's or enrollee's health insurance policy or health benefit plan, and (2) such insured or enrollee purchased such prescription drug for a lower price than the average amount paid by such insured or enrollee's health carrier to an in-network health care provider for the same prescription drug.

(f) The total amount credited toward any insured's or enrollee's annual coinsurance, copayment, deductible or other out-of-pocket expense pursuant to subsection (e) of this section shall not (1) exceed the total amount that such insured or enrollee is required to pay out-of-pocket under the terms of the health insurance policy or health benefit plan during a policy period, and (2) carry over to a new policy period.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2025*	New section
Sec. 2	*July 1, 2025*	New section
Sec. 3	*October 1, 2027*	New section
Sec. 4	*October 1, 2027*	New section
Sec. 5	*October 1, 2027*	New section
Sec. 6	*October 1, 2027*	New section
Sec. 7	*October 1, 2027*	New section
Sec. 8	*October 1, 2027*	New section
Sec. 9	*October 1, 2027*	New section

Sec. 10	*October 1, 2027*	New section
Sec. 11	*July 1, 2025*	New section
Sec. 12	*July 1, 2025*	New section
Sec. 13	*July 1, 2025*	New section
Sec. 14	*July 1, 2025*	New section
Sec. 15	*January 1, 2026*	New section

Statement of Legislative Commissioners:

In Section 5, "sections 1 to 4, inclusive, and sections 6 to 10, inclusive, of" was added for accuracy, in Section 8(a), "proceeding in accordance" was changed to "proceeding conducted in accordance" for clarity, in Section 12(i), "such property" was changed to "such real property" for consistency, and in Section 15(b)(1), "entity or company" was changed to "other entity" for consistency.

INS *Joint Favorable Subst. -LCO*

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

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 26 $	FY 27 $
Consumer Protection, Dept.	GF - Cost	100,000	None
Consumer Protection, Dept.	GF - Potential Cost	None	84,010
State Comptroller - Fringe Benefits[1]	GF - Potential Cost	None	31,147
Department of Revenue Services	GF - Cost	32,990	131,958
State Comptroller - Fringe Benefits[2]	GF - Cost	13,430	53,720
Department of Revenue Services	GF - Revenue Gain	Potential	Potential

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill makes various changes regarding prescription drug costs resulting in the costs and revenue gain described below.

Sections 1-10 create a Canadian Prescription Drug Importation Program (CPDIP) resulting in costs to the Department of Consumer Protection (DCP) and the Office of the State Comptroller (OSC). The bill requires DCP to hire a consultant to study the feasibility of establishing a CPDIP resulting in a cost of $100,000 in FY 26.

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

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

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

Sections 11-14 establish a prescription drug cost containment initiative to be administered by the Department of Revenue Services (DRS). This results in a General Fund cost of $46,420 in FY 26 (partial year) and $185,678 in FY 27. The cost is associated with two Revenue Examiner positions within DRS to administer the program ($65,979 and $26,860 each for salary and fringe benefit costs, respectively).

Section 12 imposes a civil penalty for violation of the price cap provision which results in a potential General Fund revenue gain beginning in FY 26, the magnitude of which is dependent on the violator's price differential in excess of the price cap. The bill specifies any penalties be expended for the purposes of promoting access to affordable health care, and reducing patients' health care costs, in the state.

Section 15 requires health carriers to credit enrollees for certain prescription drug costs resulting in no fiscal impact to the state.

The Out Years

The full-year potential costs to run the CPDIP (see sections 1-10 above) will begin in FY 28. To run the program there is a potential annual cost to DCP of $313,538 for salaries and other expenses, along with an associated fringe benefit potential cost of $124,588.

The annualized ongoing fiscal impact identified above would continue into the future subject to if the CPDIP is implemented, the number of violations, and inflation.

OLR Bill Analysis
HB 6870

AN ACT ADDRESSING PATIENTS' PRESCRIPTION DRUG COSTS.

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 (§§ 1-10). ("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.)

The bill also (1) caps the prices pharmaceutical manufacturers and wholesale distributors can sell an identified prescription drug for in the state and (2) imposes a civil penalty for violators, with exceptions. The civil penalties are calculated, imposed, and collected by the Department of Revenue Services (DRS) commissioner. 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 (§§ 11-14).

Lastly, the bill requires health carriers to credit enrollees for certain prescription drug costs when determining liability for out-of-pocket expenses. It requires proof of payment if, for example, the insured or enrollee purchased prescription drugs from an out-of-network health care provider (§ 15).

EFFECTIVE DATE: July 1, 2025, except (1) January 1, 2026, for the provision on health carriers' out-of-pocket expense calculation and the related proof of payment requirements (§ 15); and (2) October 1, 2027,

for most provisions establishing the Canadian prescription drug importation program (§§ 3-10).

§§ 1-10 — CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

Feasibility Study and Report (§ 2)

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 (§ 3)

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 (§§ 1, 4 & 5)

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 (§§ 1 & 6)

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 (§§ 1 & 7(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 (§ 7(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 (§ 7(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 (§ 7(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 (§ 8)

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 (§§ 910)

If a Canadian prescription drug importation program is established, the bill requires 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.

§§ 11-14 — IDENTIFIED PRESCRIPTION DRUGS

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.

Price Cap on Identified Prescription Drugs (§§ 1 & 12(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 (§ 12(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 (§ 12(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 (§ 12(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 (§ 12(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 (§ 12(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 (§ 12(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 (§ 12(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 (§ 12(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 (§ 12(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.

4.

List of Violators and Implementing Regulations (§ 12(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 (§ 13)

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 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.

Civil Penalties to Be Deposited in the General Fund (§ 14)

All civil penalties collected from pharmaceutical manufacturers or wholesale distributors for violating the identified prescription drugs-related provisions of the bill (§§ 11-13) must be (1) deposited in the General Fund and (2) expended to promote access to affordable health care, and reduce patients' health care costs, in the state.

§ 15 — INDIVIDUAL AND GROUP HEALTH INSURANCE POLICIES AND HEALTH BENEFIT PLANS

Calculation of In-Network Liability for Out-of-Pocket Expense

Under the bill, when calculating an insured's or enrollee's in-network liability for his or her out-of-pocket expense (i.e. annual coinsurance, copayment, deductible, or other in-network out-of-pocket expense), each health carrier (see below) that delivers, issues for delivery, renews, amends or continues an individual or a group health insurance policy or health benefit plan in the state on or after January 1, 2026, must give credit for any out-of-pocket expense the insured or enrollee pays directly to any state-licensed pharmacy or health care provider licensed in this state, for any prescription drug, as long as:

1. no claim for the prescription drug was submitted to the insurer, center, corporation, society, or other entity; and

2. the out-of-pocket expense paid by the insured or enrollee to the pharmacy or health care provider is less than the average discounted rate for the prescription drug paid to an in-network health care provider according to the terms of the policy or plan.

Applicability. Under the bill, this applies to insurers, health care centers, hospital service corporations, medical service corporations, fraternal benefit societies or other entities ("health carriers") providing (1) basic hospital expense coverage, (2) basic medical-surgical expense coverage, (3) major medical expense coverage, (4) hospital or medical service plan contract, and (5) hospital and medical coverage to subscribers of a health care center. Because of the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

Prescription Drug From Out-of-Network Health Care Provider

Under the bill, if any insured or enrollee purchases a prescription drug from any out-of-network health care provider for a lower amount than the average amount paid by the insured's or enrollee's health carrier to any in-network health care provider for the same prescription

drug, the health carrier, when calculating the insured's or enrollee's liability for in-network annual out-of-pocket expense, must give credit for the purchase, if the insured or enrollee provides the health carrier with proof of payment following the requirements below.

Preauthorization and Precertification. The bill specifies that it must not be construed to restrict any health insurance policy or health benefit plan from requiring a prior authorization or precertification otherwise provided for in the insured's or enrollee's health insurance policy or health benefit plan.

Proof of Payment to Out-of-Network Provider

Proof of Payment Form and Instructions. The bill requires health carriers to (1) develop a proof of payment form and publish it on their website for insureds and enrollees to submit proof of payment for any out-of-network prescription drug purchase as described above, and (2) annually give them written notice of, and instructions for downloading or electronic submission of, the proof of payment form.

Credit Upon Receipt of Proof of Payment Form. Upon receipt of a proof of payment form from an insured or enrollee, each health carrier must give credit for any out-of-pocket payments that the insured or enrollee paid to any out-of-network pharmacy or health care provider under the provision above, if the:

1. prescription drug the insured or enrollee purchased is included under his or her health insurance policy or health benefit plan, and

2. insured or enrollee purchased the prescription drug for a lower price than the average amount paid by the health carrier to an in-network health care provider for the same prescription drug.

Out-of-Pocket Maximum and Prohibited Carryover

Under the bill, the total amount credited toward any insured's or enrollee's annual out-of-pocket expense for prescription drugs purchased from an out-of-network health care provider must not (1)

exceed the total amount that the insured or enrollee is required to pay out-of-pocket under the terms of the health insurance policy or health benefit plan during a policy period, and (2) carry over to a new policy period.

BACKGROUND

Related Bills

sSB 11, favorably reported by the Human Services Committee, has substantially similar provisions related to the (1) establishment of a Canadian prescription drug importation program and (2) sale of identified prescription drug by pharmaceutical manufacturers and wholesale distributors, including a price cap and civil penalties for violations.

sHB 7192, favorably reported by the Human Services Committee, has substantially similar provisions related to the establishment of a Canadian prescription drug importation program.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 12 Nay 1 (03/11/2025)