Senate

General Assembly

File No. 208

February Session, 2022

Substitute Senate Bill No. 13

Senate, March 30, 2022

The Committee on Insurance and Real Estate reported through SEN. LESSER of the 9th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT REDUCING PRESCRIPTION DRUG PRICES.

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

Section 1. (NEW) (*Effective July 1, 2022*) There is established an account to be known as the "Covered Connecticut account" which shall be a separate, nonlapsing account within the General Fund. The account shall be administered by the Office of Health Strategy, established under section 19a-754a of the general statutes, and contain any moneys required by law to be deposited in the account. Moneys in the account shall be expended by the (1) Office of Health Strategy for the purpose of supporting the Covered Connecticut program established under section 19a-754c of the general statutes, and (2) Department of Social Services for the purpose of supporting the state medical assistance program administered by the department.

Sec. 2. (NEW) (*Effective July 1, 2022*) For the purposes of this section and sections 3 and 4 of this act:

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

(2) "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;

(3) "Covered Connecticut account" means the Covered Connecticut account established under section 1 of this act;

(4) "Identified prescription drug" means a prescription drug that is sold at a price that exceeds the sum calculated under subdivision (1) of subsection (a) of section 3 of this act for such drug;

(5) "Legend drug" has the same meaning as provided in section 20-571 of the general statutes;

(6) "Office of Health Strategy" means the Office of Health Strategy established under section 19a-754a of the general statutes;

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

(8) "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;

(9) "Prescription drug" means a legend drug 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;

(10) "Reference price" means the wholesale acquisition cost of a drug (A) on January 1, 2022, or (B) on the date such drug is first commercially marketed in the United States if such drug is first commercially marketed in the United States after January 1, 2022; and

(11) "Wholesale acquisition cost" has the same meaning as provided

in 42 USC 1395w-3a, as amended from time to time.

Sec. 3. (NEW) (*Effective July 1, 2022*) (a) (1) Notwithstanding any provision of the general statutes and except as provided in subdivision (2) of this subsection, no pharmaceutical manufacturer shall, on or after January 1, 2023, sell a prescription drug with a wholesale acquisition cost equal to or greater than one hundred dollars in this state at a price that exceeds the sum of:

(A) The reference price for the prescription drug, adjusted for any increase or decrease in the consumer price index; and

(B) Two per cent of the reference price for the prescription drug for each twelve-month period that has elapsed since the date on which the reference price for such prescription drug was determined, compounded annually on the anniversary of such date.

(2) A pharmaceutical manufacturer may sell a prescription drug in this state at a price that exceeds the sum calculated for the prescription drug under subdivision (1) of this subsection if the federal Secretary of Health and Human Services determines, pursuant to 21 USC 356e, as amended from time to time, that such prescription drug is in shortage in the United States.

(b) (1) Except as provided in subdivision (2) of this subsection, any pharmaceutical manufacturer 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, 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 earned from all sales of the identified prescription drug in this state during the calendar year; and

(B) The revenue that the pharmaceutical manufacturer would have earned from all sales of the identified prescription drug in this state during the calendar year if the pharmaceutical manufacturer had sold

such identified prescription drug at a price that did not exceed the sum calculated under subdivision (1) of subsection (a) of this section for such identified prescription drug.

(2) No pharmaceutical manufacturer 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 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) Not later than March 1, 2024, and annually thereafter, each pharmaceutical manufacturer that violated subsection (a) of this section during the preceding calendar year shall:

(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 that is required to file a statement and pay a 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 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 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 failed to pay the full amount of such civil penalty, the commissioner shall bill such pharmaceutical manufacturer for the full amount of such civil penalty.

(e) (1) The commissioner may require each pharmaceutical manufacturer that is subject to a civil penalty imposed under 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 any person authorized by the commissioner, 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 required to be paid.

(f) Any pharmaceutical manufacturer that is subject to a civil penalty imposed under 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, for a hearing, setting forth the reasons why such hearing should be granted and the amount by which the 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. If the hearing request is granted, the commissioner shall notify the pharmaceutical manufacturer 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. The commissioner may,

by notice in writing, order a hearing on the commissioner's own initiative and require a pharmaceutical manufacturer, or any other person who the commissioner believes to be in possession of relevant information concerning such pharmaceutical manufacturer, 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 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 in the premises. 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 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 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 so to do, 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 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 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 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 it 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 who owes a duty to the pharmaceutical manufacturer to pay a civil penalty imposed under this section on behalf of such pharmaceutical manufacturer, file a statement with the commissioner pursuant to subsection (c) of this section on behalf of such pharmaceutical manufacturer, keep records or supply information to the commissioner on behalf of such pharmaceutical manufacturer 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 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 July 1, 2022, except within three years next after such violation is committed.

(2) Any officer or employee of a pharmaceutical manufacturer who owes a duty to the pharmaceutical manufacturer 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 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 shall be charged with an offense under 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) The proceeds from all civil penalties imposed under this section shall be deposited in the Covered Connecticut account. Each civil penalty imposed under 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 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 this section.

(l) Not later than July 1, 2024, and annually thereafter, the commissioner shall prepare a list containing the name of each pharmaceutical manufacturer 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. 4. (NEW) (*Effective July 1, 2022*) (a) No pharmaceutical manufacturer 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 3 of this act.

(b) Any pharmaceutical manufacturer 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 intention.

(c) Any pharmaceutical manufacturer 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. 5. (NEW) (*Effective July 1, 2022*) For the purposes of this section and sections 6 to 10, inclusive, of this act unless the context otherwise requires:

(1) "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 other article specified in subparagraphs (A) to (C), inclusive, of this subdivision;

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

(3) "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;

(4) "Importation program" means the Canadian legend drug importation program established by the Commissioner of Consumer Protection pursuant to section 6 of this act;

(5) "Institutional pharmacy" has the same meaning as provided in section 20-571 of the general statutes;

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

(7) "Legend drug" means a drug that (A) any applicable federal or state law provides shall only be (i) dispensed pursuant to a prescription, or (ii) used by a prescribing practitioner, or (B) applicable federal law requires to bear the following legend: "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT;

(8) "Participating Canadian supplier" means a manufacturer or wholesale drug distributor that (A) is licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs, (B) exports legend drugs, in the manufacturer's original container, to a participating wholesaler for distribution in this state under the importation program, and (C) is properly registered, if such Canadian supplier is required to be registered, with the United States Food and Drug Administration, or any successor agency;

(9) "Participating wholesaler" means a qualified wholesaler that is designated by the Commissioner of Consumer Protection to participate in the importation program;

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

(11) "Prescription" means a lawful oral, written or electronic order by a prescribing practitioner for a drug for a specific patient;

(12) "Qualified laboratory" means a laboratory that is (A) adequately equipped and staffed to properly perform qualitative and quantitative laboratory testing on legend drugs, and (B) accredited to International Organization for Standardization (ISO) 17025;

(13) "Qualified 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; and

(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.

Sec. 6. (NEW) (*Effective July 1, 2022*) (a) The Commissioner of Consumer Protection shall establish a program to be known as the "Canadian legend drug importation program". Under such importation program, the commissioner shall, notwithstanding any provision of the general statutes:

(1) Provide for the importation from Canada of safe and effective legend drugs that have the highest potential for cost savings for patients in this state;

(2) Develop and implement an application and approval process for qualified wholesalers to be designated as participating wholesalers; and

(3) Designate one or more participating wholesalers to distribute in this state legend drugs, imported from Canada, from a participating Canadian supplier and in the manufacturer's original container, to a licensed pharmacy or institutional pharmacy or a qualified laboratory.

(b) (1) Not later than July 1, 2023, the Commissioner of Consumer Protection shall submit a request to the federal Secretary of Health and Human Services seeking approval for the importation program under 21 USC 384, as amended from time to time. Such request shall, at a minimum:

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

(B) Demonstrate that the legend drugs to be imported and distributed in this state under the importation program shall:

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

(ii) Comply with all federal tracing procedures; and

(C) Disclose the costs of implementing the importation program.

(2) (A) If the federal Secretary of Health and Human Services approves the commissioner's request, the commissioner shall:

(i) Submit to (I) the Commissioner of Public Health a notice disclosing that the federal Secretary of Health and Human Services has approved such request, and (II) the joint standing committees of the General Assembly having cognizance of matters relating to appropriations, general law, human services and public health a notice disclosing that the federal Secretary of Health and Human Services has approved such request; and

(ii) Begin operating the importation program not later than one hundred eighty days after the date of such approval.

(B) Except as otherwise provided in this subsection, the Commissioner of Consumer Protection shall not operate the importation program unless the federal Secretary of Health and Human Services approves the commissioner's request.

Sec. 7. (NEW) (*Effective July 1, 2022*) (a) Each participating wholesaler may, subject to the provisions of this section and sections 6 and 9 of this act, import into this state a legend drug from a participating Canadian supplier, and distribute such legend drug to a licensed pharmacy or institutional pharmacy, or a qualified laboratory in this state, under the importation program if:

(1) Such participating wholesaler:

(A) Is registered with the federal Secretary of Health and Human Services pursuant to Section 510(b) of the Food, Drug and Cosmetic Act, 21 USC 360(b), as amended from time to time; and

(B) Holds a valid labeler code that was issued to such participating wholesaler by the United States Food and Drug Administration, or any successor agency; and

(2) Such legend drug:

(A) May be imported into this state in accordance with applicable federal patent laws;

(B) Meets the United States Food and Drug Administration's, or any successor agency's, standards concerning drug safety, effectiveness, misbranding and adulteration; and

(C) Is not:

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

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

(iii) An infused drug;

(iv) An intravenously, intradermally, intrathecally, intramuscularly or subcutaneously injected drug;

(v) A drug that is inhaled during surgery;

(vi) 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; or

(vii) A drug that is a compound which is not commercially available.

(b) Each participating wholesaler shall:

(1) Comply with all applicable track-and-trace requirements, and make available to the Commissioner of Consumer Protection all track-and-trace records not later than forty-eight hours after the commissioner requests such records;

(2) Not import into, or distribute, dispense or sell, in this state any legend drugs under the importation program except in accordance with the provisions of this section and sections 6 and 9 of this act;

(3) Not distribute, dispense or sell outside of this state any legend drugs that are imported into this state under the importation program;

(4) Ensure the safety and quality of each legend drug that is imported and distributed in this state under the importation program;

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

(6) For each subsequent shipment of a legend drug that is imported into this state by such participating wholesaler, and sampled and tested pursuant to subdivision (5) of this subsection, ensure that a qualified laboratory engaged by such participating wholesaler tests a statistically valid sample of such legend drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act, and quarantine such shipment until the results of such test conducted pursuant to this subdivision indicate that such legend drug is consistent with its labeling;

(7) Certify to the Commissioner of Consumer Protection that each legend drug imported into this state under the importation program:

(A) Is approved for marketing in the United States and not

adulterated or misbranded; and

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

(8) Maintain laboratory records, including, but not limited to, complete data derived from all tests necessary to ensure that each legend drug imported into this state under the importation program satisfies the requirements of subdivisions (5) and (6) of this subsection;

(9) Maintain documentation demonstrating that the testing required by subdivisions (5) and (6) of this subsection was conducted at a qualified laboratory in accordance with the Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations concerning laboratory qualifications;

(10) Maintain the following information for each legend drug that such participating wholesaler imports and distributes in this state under the importation program, and submit such information to the Commissioner of Consumer Protection upon request by the commissioner:

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

(B) A description of the dosage form of such legend drug;

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

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

(E) The point of origin and destination of such legend drug;

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

(G) A report for each legend drug that fails laboratory testing under

subdivision (5) or (6) of this subsection; and

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

(11) Ensure that any legend drug that fails laboratory testing under subdivision (5) or (6) of this subsection is appropriately quarantined and destroyed; and

(12) Maintain all information and documentation that is submitted to the Commissioner of Consumer Protection pursuant to this subsection for a period of not less than three years.

Sec. 8. (NEW) (*Effective July 1, 2022*) Each participating Canadian supplier shall:

(1) Comply with all applicable track-and-trace requirements;

(2) Not distribute, dispense or sell outside of this state any legend drugs that are imported into this state under the importation program; and

(3) Maintain the following information and documentation and, upon request by the Commissioner of Consumer Protection, submit such information and documentation to the commissioner for each legend drug that such participating Canadian supplier exports into this state under the importation program:

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

(i) The name of the manufacturer of such legend drug;

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

(iii) The location where such legend drug was manufactured;

(B) The date on which such legend drug was shipped to a

participating wholesaler;

(C) The quantity of such legend drug that was shipped to a participating wholesaler;

(D) The quantity of each lot of such legend drug that such participating Canadian supplier originally received and the source of such lot;

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

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

Sec. 9. (NEW) (*Effective July 1, 2022*) (a) The Commissioner of Consumer Protection shall issue a written order:

(1) Suspending importation and distribution of a legend drug under the importation program if the commissioner discovers that such importation or distribution violates any provision of sections 6 to 8, inclusive, of this act or any other applicable state or federal law or regulation;

(2) Suspending all importation and distribution of legend drugs by a participating wholesaler under the importation program if the commissioner discovers that the participating wholesaler has violated any provision of section 6 or 7 of this act or any other applicable state or federal law or regulation;

(3) Suspending all importation and distribution of legend drugs by a participating Canadian supplier under the importation program if the commissioner discovers that the participating Canadian supplier has violated any provision of section 6 or 8 of this act or any other applicable state or federal law or regulation;

(4) Requiring the quarantine, recall or seizure of any legend drug that

was imported and distributed under the importation program if such legend drug has been identified as adulterated, within the meaning of section 21a-105 of the general statutes, or misbranded; or

(5) Requiring retesting, at the expense of the participating wholesaler and by a laboratory approved by the commissioner, of any legend drug distributed by the participating wholesaler if the commissioner deems such retesting necessary.

(b) The Commissioner of Consumer Protection shall send a notice to each participating Canadian supplier and participating wholesaler affected by an order issued pursuant to subsection (a) of this section notifying such participating Canadian supplier or participating wholesaler that:

(1) The commissioner has issued such order, and providing the legal and factual basis for such order; and

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

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

Sec. 10. (NEW) (*Effective July 1, 2022*) The Commissioner of Consumer

Protection may, in consultation with the Commissioner of Public Health, adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 5 to 9, inclusive, of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2022*	New section
Sec. 2	*July 1, 2022*	New section
Sec. 3	*July 1, 2022*	New section
Sec. 4	*July 1, 2022*	New section
Sec. 5	*July 1, 2022*	New section
Sec. 6	*July 1, 2022*	New section
Sec. 7	*July 1, 2022*	New section
Sec. 8	*July 1, 2022*	New section
Sec. 9	*July 1, 2022*	New section
Sec. 10	*July 1, 2022*	New section

INS *Joint Favorable Subst.*

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

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 23 $	FY 24 $
Revenue Serv., Dept.	GF - Potential Cost	Less than 500,000	Less than 500,000
State Comptroller - Fringe Benefits[1]	GF - Potential Cost	Less than 202,650	Less than 202,650
Department of Revenue Services	GF - Cost	None	Less than 100,000
Consumer Protection, Dept.	GF - Cost	75,000	90,418
State Comptroller - Fringe Benefits	GF - Cost	30,398	36,646
Department of Revenue Services	GF - Revenue Gain	None	Potential

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill, which establishes certain limitations and requirements regarding prescription drugs and associated penalties for violation, results in the following fiscal impacts:

Section 1 establishes the Covered Connecticut account as a separate, nonlapsing account within the General Fund, administered by the Office of Health Strategy (OHS). The account will contain revenue from civil penalties resulting from any pharmaceutical manufacturer that violates the provisions of the bill. Funding in the account must be used

[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 40.53% of payroll in FY 23.

for the purposes of supporting the Covered Connecticut Program (OHS) and the Department of Social Services (DSS) Medicaid program.

Sections 2 – 4 require pharmaceutical manufacturers that violate the bill's pricing provisions to annually pay the Department of Revenue Services (DRS) commissioner a civil penalty[2]. This results in: 1) a potential revenue gain to the Covered Connecticut account beginning in FY 24, and 2) a one-time cost of less than $100,000 in FY 24 associated with form development, postage costs, and associated updates to the online Taxpayer Service Center and CTax integrated tax administration system.

It is unclear how violations of the bill's provisions by pharmaceutical manufacturers would be determined. To the extent DRS is required to monitor pharmaceutical company sales and investigate potential violations, there is a cost to the agency beginning as early as FY 23. Any potential cost is anticipated to be less than $702,650 annually, inclusive of fringe benefit costs.

Sections 5 through 10 require the Department of Consumer Protection (DCP) to establish a Canadian Legend Drug Importation Program (CLDIP) resulting in costs of approximately $75,000 to DCP (salary) and $30,398 to OSC (fringe benefits) in FY 23, and $90,418 to DCP (salary) and $36,646 to OSC (fringe benefits) in FY 24 and each fiscal year thereafter. In FY 23 only, a six-month durational Project Manager is needed to submit a request to the federal Secretary of Health and Human Services for approval to establish the CLDIP. Assuming federal approval is granted, a full-time Drug Control Agent will be needed to run the program beginning in FY 24.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

[2] The penalty equals 80% of the increased revenue the pharmaceutical company made by selling the drug at the higher price compared to a price allowed under the bill.

OLR Bill Analysis

sSB 13

AN ACT REDUCING PRESCRIPTION DRUG PRICES.

SUMMARY

The bill prohibits pharmaceutical manufacturers from selling a prescription drug for a price higher than the drug's reference price (i.e., the drug's wholesale acquisition cost) adjusted for changes in the consumer price index for urban consumers, plus 2% of the reference price per year compounded annually on the anniversary of the date the drug was first commercially marketed. The price limits apply to drugs with a wholesale acquisition cost of $100 or more.

Under the bill, pharmaceutical manufacturers who violate the price limit are liable to the state for a civil penalty of 80% of the increased revenue the pharmaceutical manufacturer earned by selling the drug higher than allowed. It also establishes procedures and due process for reporting, collecting, and contesting the penalty.

The bill also subjects pharmaceutical manufacturers to a $500,000 civil penalty if they withdraw a drug from the Connecticut market (1) without giving advance written notice or (2) to avoid paying the civil penalty for selling a drug above the price limit.

It exempts (1) from the price limitations, drugs the U.S. Health and Human Services (HHS) secretary determines are in shortage in the United States and (2) from the civil penalty, pharmaceutical manufacturers making less than $250,000 in annual sales in Connecticut in the calendar year the penalty would be imposed.

Lastly, bill establishes a program to import certain legend drugs from Canada and distribute them to Connecticut pharmacies. The program is dependent upon federal approval and requires drug importers and wholesalers to adhere to safety, testing, and tracking standards.

EFFECTIVE DATE: July 1, 2022

§§ 1-4 — PHARMACEUTICAL MANUFACTURER PRICING LIMITS

Price Limit (§§ 2 & 3)

Beginning January 1, 2023, the bill prohibits pharmaceutical manufacturers from selling a prescription drug with a wholesale acquisition cost of $100 or more for more than:

1. the drug's reference price, adjusted for any change in the consumer price index for urban consumers, plus

2. 2% for each 12-month period since the date the reference price was determined, compounded annually on the anniversary of that date.

Under the bill, a "pharmaceutical manufacturer" is anyone manufacturing and selling a prescription drug, either directly or through another person, for distribution in Connecticut. A drug's "reference price" is the drug's wholesale acquisition cost as of January 1, 2022, or for new drugs, the date when it is first commercially marketed in the United States. A drug's "wholesale acquisition cost" is generally the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding discounts, rebates, or reductions, for the most recent month for which data is available.

Drugs that the HHS secretary determines are in shortage are exempt from the pricing limitations.

Civil Penalty (§§ 1 & 3)

Under the bill, a pharmaceutical manufacturer selling a prescription drug above the price limit is subject to a civil penalty, determined and collected on a calendar year basis. The penalty equals 80% of the increased revenue the pharmaceutical company made by selling the drug at the higher price compared to a price allowed under the bill.

Under the bill, all money collected from the civil penalty must be deposited into the Covered Connecticut account, which the bill

establishes as a separate, nonlapsing General Fund account that must contain any money required by law to be deposited into it. Money in the account must be used by (1) the Office of Health Strategy (OHS) to administer the Covered Connecticut program and (2) Department of Social Services to administer the state medical assistance program (e.g., Medicaid). (By law, the Covered Connecticut program provides eligible individuals health insurance at no out-of-pocket cost to them (CGS § 19a-754c).)

The penalties are deemed a civil fine or penalty under federal law (therefore excluding them from state tax revenue for certain federal benefit calculations) and cannot be waived by the Revenue Services Penalty Review Committee or under any other applicable law. Additionally, the bill prohibits tax credits from being applied towards the penalty.

Penalty Payment Provisions. Beginning March 1, 2024, the bill requires pharmaceutical manufacturers that violated the pricing provisions during the previous calendar year to annually pay the Department of Revenue Services (DRS) commissioner the civil penalty the bill imposes.

They must also file with the DRS commissioner a statement containing information in a form and manner he prescribes. The statement and civil penalty must be electronically filed and paid, regardless of how the manufacturer would have otherwise filed with, or paid money to, DRS. If no statement is filed by the due date, the bill authorizes the commissioner to make the statement at any time after the due date according to the best obtainable information and prescribed form.

Tax Warrants and Liens. The bill allows the civil penalty to be collected according to existing law that authorizes DRS and other state collection agencies to (1) issue a tax warrant on the real property or tangible or intangible personal property (e.g., bank accounts, receivables, and securities) of a taxpayer who fails to pay state taxes and (2) serve the warrant on a third party (e.g., bank or payment settlement

entity) who possesses the property or is obligated to it in some way (CGS § 12-35). Under the bill, the warrant must be signed by the DRS commissioner or his authorized agent.

Additionally, the amount of the civil penalty becomes a lien on the pharmaceutical manufacturer's real property, beginning on the last day of the month before the penalty was due, until it is paid. The commissioner may record the lien in the records of the town in which the manufacturer is located, but the bill prohibits the lien from being enforced against a bona fide purchaser or qualified encumbrancer of the property. If the lien is satisfied, the commissioner must discharge it upon request from an interested party.

The bill allows the (1) attorney general to bring a foreclosure action against the lien in the Superior Court in the judicial district where the property is located and (2) court to make any order it deems equitable.

It also applies existing laws on collecting taxes and related penalties from taxpayers to the civil penalties imposed under the bill.

Examination Authority and Record Keeping. If a pharmaceutical manufacturer is subject to the civil penalty, the bill authorizes the DRS commissioner to examine its books and determine if it paid the full penalty amount. If the commissioner determines that it did not, he must bill the pharmaceutical manufacturer for the full amount. The commissioner, or any person he authorizes, may also examine the books, papers, records, and equipment of anyone subject to the bill's provisions, and investigate the character of their business to verify the accuracy of the filed statement (or if no statement is filed, to ascertain and determine the civil penalty amount).

The bill authorizes the commissioner to require all pharmaceutical manufacturers subject to a civil penalty to keep any records he prescribes and produce books, papers, documents, and other data he needs to determine the penalty amount and collect it.

The bill grants the commissioner and his agents the power to

administer oaths and take testimony under oath in matters related to an inquiry or investigation.

Requests for a Hearing and Reduction. Under the bill, an aggrieved pharmaceutical manufacturer may apply in writing to the DRS commissioner for a hearing, laying out why a hearing should be granted and how much the civil penalty should be reduced. The pharmaceutical manufacturer must apply within 60 days after receiving the penalty notice or after it is delivered or mailed to the manufacturer. The commissioner may also order a hearing on his own initiative.

The commissioner must promptly consider and either grant or deny each application. If he denies it, he must immediately notify the applicant; if he approves it, he must provide the hearing date, time, and place. Following the hearing, he must provide the applicant a copy of any order he makes.

Additionally, the bill allows the commissioner to require a pharmaceutical manufacturer or any other person he believes has relevant information to appear, along with any specified documents for examination under oath.

In any hearing, the bill allows the commissioner or his authorized agents to subpoena witnesses and require the production of books, papers, and documents related to the investigation. A witness may not be excused from testifying or from producing documents if doing so would incriminate him or her. However, the bill prevents such evidence from being used in a criminal proceeding against the witness.

The bill allows the commissioner to apply to the Superior Court that has jurisdiction over the pharmaceutical manufacturer being investigated, or another court of competent jurisdiction, to compel any person to obey a subpoena. The bill requires the court to commit an individual still disobeying a subpoena or summons to a community correctional center until they do so, for up to 60 days.

The bill requires that officers serving subpoenas and witnesses

attending hearings receive fees and compensation at the same rate as they would for appearing in court.

Appeals. Any pharmaceutical manufacturer aggrieved by the commissioner's orders, decisions, determinations, or disallowances may appeal, within 30 days after receiving notice of the commissioner's action, to the Superior Court for the New Britain judicial district. The appeal must be accompanied by a citation to the commissioner to appear. It must be signed, served, and returned in the same way existing law requires for a civil summons in a civil action.

The authority issuing the citation must take from the person appealing the case, a bond or recognizance, with surety, to prosecute the appeal to effect and to comply with the court orders and decrees. These appeals must be preferred cases, to be heard at the first session of the court or an appointed committee, unless cause appears to the contrary.

Under the bill, the court may grant equitable relief, and if the civil penalty has already been paid, may order the treasurer to refund it. If the appeal has been taken without probable cause, the court may tax double or triple costs, as the case demands. After an appeal is denied, the court may, at its discretion, tax the manufacturer the costs of the appeal, but no costs must be taxed against the state.

Officer or Employee Penalties (§ 3)

Under the bill, a pharmaceutical manufacturer officer or employee who owes a duty to pay a civil penalty, file statements, or keep or produce records under the bill's provisions and willfully fails to do so is subject to a fine up to $1,000, up to a year in prison, or both. Regardless of other state law, the bill establishes a three-year statute of limitations for officers or employees to be prosecuted after each violation.

Additionally, any officer or employee who willfully delivers or discloses any fraudulent or false list, statement, return, account statement, or other document to the commissioner is guilty of a class D felony, punishable by a fine up to $5,000, up to 5 years in prison, or both.

The bill prohibits an officer or employee from being charged with an offense under both the provisions described above in connection with the same civil penalty. However, it allows the officer or employee to be charged for both offenses upon the same information.

List of Offenders (§ 3)

Beginning by July 1, 2024, the bill requires the DRS commissioner to annually prepare, and make publicly available, a list of each pharmaceutical manufacturer that violated the bill's provisions during the preceding year.

Implementing Regulations (§ 3)

The bill authorizes the DRS commissioner to adopt implementing regulations.

Pharmaceutical Manufacturer's Withdrawing Prescription Drugs (§ 4)

Additionally, the bill prohibits a pharmaceutical manufacturer from withdrawing a prescription drug in Connecticut after it has been identified as being sold above the bill's price limits to avoid the civil penalty. Pharmaceutical manufacturers must notify OHS in writing at least 180 days before withdrawing one of these drugs from the Connecticut market. Under the bill, a pharmaceutical manufacturer that violates either of these provisions is subject to a $500,000 civil penalty.

§§ 5-10 — CANADIAN LEGEND DRUG IMPORTATION PROGRAM

The bill requires the Department of Consumer Protection (DCP) commissioner to establish the "Canadian legend drug importation program" to:

1. import from Canada safe and effective legend drugs with the highest potential cost savings to Connecticut patients,

2. develop and implement an application and approval process for participating wholesalers, and

3. designate one or more participating wholesalers to distribute

imported legend drugs in Connecticut.

Participating wholesalers must distribute legend drugs in the manufacturer's original container; from a participating Canadian supplier; and to a pharmacy, institutional pharmacy, or qualified laboratory.

Under the bill, a "legend drug" is a drug that (1) any federal or state law requires a prescription for or allows to be used by a prescribing practitioner or (2) federal law requires to bear "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT (i.e., the legend).

Application for Federal Approval (§ 6)

By July 1, 2023, the DCP commissioner must submit a request to the HHS secretary for approval of the importation program. (Under federal law, drug importation programs require federal approval.)

The request must, at least:

1. describe the commissioners' plans for operating the program;

2. demonstrate that the prescription drugs imported and distributed through the program will (a) meet all applicable federal and state safety and effectiveness standards and (b) comply with all federal tracing procedures (e.g., a documented supply chain); and

3. disclose the program's cost.

If the HHS secretary approves the request, the DCP commissioner must:

1. notify the public health commissioner and the Appropriations, General Law, Human Services, and Public Health committees of the approval and

2. begin operating the program within 180 days after the approval

date.

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

Importation (§ 7)

Under the bill, a participating wholesaler (i.e., a registered wholesaler designated by DCP to distribute legend drugs imported from Canada through the program) may import and distribute legend drugs from a participating Canadian supplier and distribute them to a licensed pharmacy, institutional pharmacy, or qualified laboratory (i.e., a laboratory accredited by the International Organization for Standardization and staffed and equipped to properly test legend drugs) in accordance with the bill's provisions.

The imported legend drugs:

1. may be imported in accordance with applicable federal patent laws;

2. must meet U.S. Food and Drug Administration (FDA) standards for safety, effectiveness, misbranding, and adulteration; and

3. cannot be (a) controlled substances, (b) biologics, (c) infused, (d) intravenously, intradermally, intrathecally, intramuscularly, or subcutaneously injected, (e) inhaled during surgery, (f) parenteral drugs that HHS determines pose a public health threat, or (g) compounded drugs that are not commercially available.

Track-and-Trace (§ 7)

Importing wholesalers must be registered with HHS and hold a valid FDA labeler code. Additionally, the bill (1) requires them to comply with all applicable track-and-trace requirements (e.g., document the manufacture, supply, and distribution chain) and (2) prohibits them from distributing, dispensing, or selling any imported drugs outside of Connecticut or in any way other than the bill specifies.

Under the bill, wholesalers must make track-and-trace records available to the DCP commissioner within 48 hours of her request.

Safety Testing and Wholesaler Record Keeping (§ 7)

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

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

2. for subsequent shipments, having a qualified laboratory test a statistically valid sample of each shipment for authenticity and degradation.

The bill additionally requires importers to quarantine subsequent shipments until the laboratory test confirms the drug is consistent with its labeling.

Wholesalers must also:

1. certify to the DCP commissioner that each imported drug is approved for marketing in the United States, is not adulterated or misbranded, and meets all federal labeling requirements;

2. maintain laboratory records, including complete data from all authenticity and degradation tests necessary to ensure the drug is safe;

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

4. ensure that any drugs failing laboratory testing are appropriately quarantined and destroyed.

The bill requires each wholesaler to also maintain for each imported

drug:

1. the name and quantity of the drug's active ingredient;
2. a description of the drug's dosage form;
3. the quantity of and date on which the wholesaler received the drug, and the price it paid;
4. the drug's origin point and destination;
5. a report for any drug that failed laboratory testing; and
6. any other information and documentation the DCP commissioner requires to protect public health.

A wholesaler must submit this information to the DCP commissioner upon her request. It must maintain any information submitted to the commissioner for at least three years.

Supplier Record Keeping (§ 8)

Under the bill, Canadian legend drug suppliers must meet all applicable track-and-trace requirements and may not distribute, dispense, or sell outside of Connecticut any legend drugs that are imported under the program. Additionally, the bill requires each participating Canadian supplier to maintain the following information for each exported drug and submit it to the DCP commissioner upon her request:

1. the drug's original source, including the manufacturer's name and the drug's manufactured date and location, shipment date, and quantity shipped;
2. the quantity of each lot of drug the supplier originally received and its source;
3. the manufacturer-assigned lot or control number and batch number; and

4. any other information and documentation the DCP commissioner requires to protect public health.

Commissioner Enforcement (§ 9)

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

The commissioner must also issue a written order requiring (1) the quarantine, recall, or seizure of any imported drug that has been misbranded or identified as adulterated or (2) retesting of a drug, if she deems it necessary, at the wholesaler's expense and by a laboratory the commissioner approves.

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

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

Regulations (§ 10)

The bill authorizes the DCP commissioner, in consultation with the public health commissioner, to adopt implementing regulations.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Substitute
Yea 17 Nay 0 (03/10/2022)