General Assembly

Raised Bill No. 5366

February Session, 2020

LCO No. **2027**

Referred to Committee on INSURANCE AND REAL ESTATE

Introduced by:
(INS)

AN ACT CONCERNING THE COST OF PRESCRIPTION DRUGS.

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

Section 1. (NEW) (*Effective January 1, 2021*) No 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 group health insurance policy in this state on or after January 1, 2021, that provides coverage of the type specified in subdivisions (1), (2), (4), (11), (12) and (16) of section 38a-469 of the general statutes and includes coverage for prescription drugs shall impose coinsurance, copayments, deductibles and out-of-pocket expenses for covered prescription drugs that, in the aggregate, exceed two hundred fifty dollars per insured per month.

Sec. 2. (NEW) (*Effective January 1, 2021*) For each year beginning on or after January 1, 2021, the wholesale cost of an outpatient prescription drug sold in this state shall not exceed one hundred two per cent of the consumer price index for all urban consumers as published by the United States Department of Labor, Bureau of Labor Statistics, for the preceding year.

Sec. 3. (NEW) (*Effective July 1, 2020*) For the purposes of this section and sections 4 to 8, 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) "Laboratory testing" means a quantitative and qualitative analysis of a prescription drug consistent with the official United States Pharmacopoeia;

(5) "Legend drug" means a drug that (A) any applicable federal or state law requires to 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;

(6) "Participating Canadian supplier" means a manufacturer or wholesale drug distributor that is (A) licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs, (B) exporting legend drugs, in the manufacturer's original container, to a participating wholesaler for distribution in this state under the program, and (C) properly registered, if such Canadian

supplier is required to be registered, with the United States Food and Drug Administration, or any successor agency;

(7) "Participating wholesaler" means a wholesaler, as defined in section 21a-70 of the general statutes, that (A) has received a certificate of registration from the Commissioner of Consumer Protection pursuant to said section, and (B) is designated by the commissioner to participate in the program;

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

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

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

(11) "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. 4. (NEW) (*Effective July 1, 2020*) (a) The Commissioner of Consumer Protection shall establish a program to be known as the "Canadian legend drug importation program". Under such program, the commissioner shall, notwithstanding any contrary provision of the general statutes:

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

(2) Designate one or more participating wholesalers to distribute legend drugs in this state:

(A) In the manufacturer's original container;

(B) From a participating Canadian supplier; and

(C) To a pharmacy or institutional pharmacy, as both terms are defined in section 20-571 of the general statutes, or a qualified laboratory.

(b) (1) Not later than July 1, 2021, the Commissioner of Consumer Protection shall submit a request to the federal Secretary of Health and Human Services seeking approval for the 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 program;

(B) Demonstrate that the legend drugs that will be imported and distributed in this state under the 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 program.

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

(i) Submit to the Commissioner of Public Health a notice disclosing that the federal Secretary of Health and Human Services has approved such request;

(ii) Submit to 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

(iii) Begin operating the 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 program unless the federal Secretary of Health and Human Services approves the commissioner's request.

Sec. 5. (NEW) (*Effective July 1, 2020*) (a) Each participating wholesaler may, subject to the provisions of this section and sections 4 and 7 of this act, import into this state a legend drug from a participating Canadian supplier, and distribute such legend drug to a pharmacy or institutional pharmacy, as both terms are defined in section 20-571 of the general statutes, or a qualified laboratory in this state, under the 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 has been 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 injected drug;

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

(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.

(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, distribute, dispense or sell in this state any legend drugs under the program except in accordance with the provisions of this section and sections 4 and 7 of this act;

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

(4) Ensure the safety and quality of the legend drugs that are imported and distributed in this state under the program;

(5) For each initial shipment of a 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 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;

(7) Certify to the Commissioner of Consumer Protection that each legend drug imported into this state under the 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 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 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 any 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; and

(11) 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. 6. (NEW) (*Effective July 1, 2020*) 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 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 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. 7. (NEW) (*Effective July 1, 2020*) (a) The Commissioner of Consumer Protection shall issue a written order:

(1) Suspending importation and distribution of a legend drug under the program if the commissioner discovers that such distribution or importation violates any provision of sections 4 to 6, 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 program if the commissioner discovers that the participating wholesaler has violated any provision of section 4 or 5 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 program if the commissioner discovers that the participating Canadian supplier has violated any provision of section 4 or 6 of this act or any other applicable state or federal law or regulation; or

(4) Requiring the recall or seizure of any legend 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.

(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. A participating Canadian supplier or participating wholesaler aggrieved by a final decision may appeal such decision in accordance with the provisions of section 4-183 of the general statutes.

Sec. 8. (NEW) (*Effective July 1, 2020*) 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 3 to 7, inclusive, of this act.

Sec. 9. (NEW) (*Effective October 1, 2020*) (a) Each pharmaceutical manufacturer doing business in this state that manufactures a brand name prescription drug and enters into an agreement with another pharmaceutical manufacturer for the purpose of delaying or preventing such other manufacturer from introducing a generic substitute for such drug into the marketplace shall, not later than thirty days after entering into such agreement, send notice to the Insurance Commissioner, in a form and manner prescribed by the commissioner, disclosing the name of such drug.

(b) (1) The commissioner shall, not later than thirty days after receiving a notice pursuant to subsection (a) of this section, send notice to each health carrier, as defined in section 38a-1080 of the general statutes, and pharmacy benefits manager, as defined in section 38a-479aaa of the general statutes, doing business in this state. Such notice shall, at a minimum:

(A) Disclose the name of the brand name prescription drug that is the subject of the notice the commissioner received pursuant to subsection (a) of this section; and

(B) Instruct such health carrier, if such health carrier includes such drug on such health carrier's drug formulary or list of covered drugs, or pharmacy benefits manager, if such pharmacy benefits manager administers a prescription drug benefit that includes such drug, to immediately reduce the cost of such drug to covered individuals by an amount that is equal to fifty per cent of the manufacturer's wholesale list price for such drug.

(2) For the purposes of this subsection, "manufacturer's wholesale list price" has the same meaning as provided in section 21a-126 of the general statutes.

(c) The provisions of this section shall apply to the maximum extent permitted by applicable law.

(d) The commissioner may adopt regulations, in accordance with

chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 10. (NEW) (*Effective October 1, 2020*) (a) There is established a Critical Drug Shortage Review Board, which shall be part of the Executive Department.

(b) The board shall consist of the following members:

(1) The Commissioner of Correction;

(2) The Commissioner of Mental Health and Addiction Services;

(3) The Commissioner of Social Services; and

(4) The executive director of the Office of Health Strategy, established under section 19a-754a of the general statutes.

(b) A majority of the board shall constitute a quorum for the transaction of any business.

(c) The members of the board shall serve without compensation, but shall, within the limits of available funds, be reimbursed for expenses necessarily incurred in the performance of their duties.

(d) The board shall have the following powers and duties: (1) To evaluate the cost of prescription drugs in this state; (2) to declare a prescription drug pricing emergency and recommend that the Commissioner of Public Health request that the federal government exercise its powers under 28 USC 1498; (3) obtain from any executive department, board, commission or other agency of the state such assistance and data as necessary and available to carry out the purposes of this section; (4) accept any gift, donation or bequest for the purpose of performing the duties described in this section; and (5) perform such other acts as may be necessary and appropriate to carry out the duties described in this section.

(e) The board shall meet as often as deemed necessary by a majority

of the board.

(f) The board may enter into such contractual agreements as may be necessary for the discharge of its duties, within the limits of its appropriated funds and in accordance with established procedures.

Sec. 11. (NEW) (*Effective January 1, 2021*) (a) For the purposes of this section:

(1) "Affordable Care Act" has the same meaning as provided in section 38a-1080 of the general statutes;

(2) "Health benefit plan" has the same meaning as provided in section 38a-1080 of the general statutes, except that such term shall not include a grandfathered health plan as such term is used in the Affordable Care Act; and

(3) "Health carrier" has the same meaning as provided in section 38a-1080 of the general statutes.

(b) Notwithstanding any provision of the general statutes and except as provided in subsection (c) of this section, no health carrier offering a health benefit plan in this state on or after January 1, 2021, that includes a pharmacy benefit and uses a drug formulary or list of covered drugs may:

(1) Remove a prescription drug from the drug formulary or list of covered drugs during a plan year; or

(2) Move a prescription drug from a cost-sharing tier that imposes a lesser coinsurance, copayment or deductible for the prescription drug to a cost-sharing tier that imposes a greater coinsurance, copayment or deductible for the prescription drug during a plan year, unless the prescription drug is subject to an in-network coinsurance, copayment or deductible that is not greater than forty dollars per prescription per month in any tier.

(c) A health carrier offering a health benefit plan in this state on or

after January 1, 2021, that includes a pharmacy benefit and uses a drug formulary or list of covered drugs may:

(1) Remove a prescription drug from the drug formulary or list of covered drugs, upon at least ninety days' advance notice to a covered person and the covered person's treating physician, if:

(A) The federal Food and Drug Administration issues an announcement, guidance, notice, warning or statement concerning the prescription drug that calls into question the clinical safety of the prescription drug, unless the covered person's treating physician states, in writing, that the prescription drug remains medically necessary despite such announcement, guidance, notice, warning or statement; or

(B) The prescription drug is approved by the federal Food and Drug Administration for use without a prescription; and

(2) Move a brand name prescription drug from a cost-sharing tier that imposes a lesser coinsurance, copayment or deductible for the brand name prescription drug to a cost-sharing tier that imposes a greater coinsurance, copayment or deductible for the brand name prescription drug if the health carrier adds to the drug formulary or list of covered drugs a generic prescription drug that is:

(A) Approved by the federal Food and Drug Administration for use as an alternative to such brand name prescription drug; and

(B) In a cost-sharing tier that imposes a coinsurance, copayment or deductible for the generic prescription drug that is lesser than the coinsurance, copayment or deductible that is imposed for such brand name prescription drug.

(d) Nothing in this section shall prevent or prohibit a health carrier from adding a prescription drug to a formulary or list of covered drugs at any time.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2021*	New section
Sec. 2	*January 1, 2021*	New section
Sec. 3	*July 1, 2020*	New section
Sec. 4	*July 1, 2020*	New section
Sec. 5	*July 1, 2020*	New section
Sec. 6	*July 1, 2020*	New section
Sec. 7	*July 1, 2020*	New section
Sec. 8	*July 1, 2020*	New section
Sec. 9	*October 1, 2020*	New section
Sec. 10	*October 1, 2020*	New section
Sec. 11	*January 1, 2021*	New section

Statement of Purpose:

To: (1) Cap aggregate monthly cost-sharing for prescription drugs covered under certain individual and group health insurance policies; (2) cap the cost of generic drugs in this state; (3) require the Commissioner of Consumer Protection to submit a request to the federal Secretary of Health and Human Services to implement a Canadian prescription drug reimportation program in this state and, if the secretary approves such request, implement such program in this state; (4) require pharmaceutical manufacturers to send notice to the Insurance Commissioner regarding "pay-for-delay" agreements, and require health carriers and pharmacy benefits managers to reduce the cost of brand name prescription drugs that are the subject of such agreements; (5) establish a Critical Drug Shortage Review Board; and (6) limit the circumstances in which a health carrier may remove a prescription drug from a drug formulary or list of covered drugs, or move a prescription drug to a different cost-sharing tier, during a plan year.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]