General Assembly

Raised Bill No. 1355

January Session, 2025

LCO No. **5153**

Referred to Committee on GENERAL LAW

Introduced by:
(GL)

AN ACT CONCERNING PRESCRIPTION DRUGS.

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

Section 1. (NEW) (*Effective from passage*) (a) As used in this section:

(1) "Component" means any active or nonactive ingredient of a drug product;

(2) "Nonsterile compounded pharmaceutical product" means a drug product produced by compounding one or more components; and

(3) "Nonsterile compounding pharmacy" means a pharmacy that is licensed pursuant to section 20-594 of the general statutes and dispenses nonsterile compounded pharmaceutical products.

(b) The Commissioner of Consumer Protection, in consultation with the Commission of Pharmacy, shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to:

(1) Ensure that nonsterile compounding pharmacies are able to engage in nonsterile compounding (A) in accordance with (i) the laws

and regulations of this state, and (ii) all applicable provisions of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations, as amended from time to time, and (B) to maintain patients' ability to readily access nonsterile compounded pharmaceutical products that include (i) levonorgestrel, mifepristone or misoprostol as an active ingredient, or (ii) an active ingredient that is similar to levonorgestrel, mifepristone or misoprostol; and

(2) Provide for the Department of Consumer Protection, or one or more public-private partnerships between the department and one or more private entities, to import levonorgestrel, mifepristone and misoprostol as a drug product and as a component, and to import drug products and components that are similar to levonorgestrel, mifepristone and misoprostol, to ensure that patients are able to readily access drug products, including, but not limited to, nonsterile compounded pharmaceutical products, that include (A) levonorgestrel, mifepristone or misoprostol as an active ingredient, or (B) an active ingredient that is similar to levonorgestrel, mifepristone or misoprostol.

(c) Notwithstanding the requirements of sections 4-168 to 4-172, inclusive, of the general statutes, in order to effectuate this section, prior to adopting regulations pursuant to subsection (b) of this section, the Commissioner of Consumer Protection shall issue policies and procedures to implement the provisions of this section that shall have the force and effect of law. The commissioner shall post all policies and procedures on the Department of Consumer Protection's Internet web site and submit such policies and procedures to the Secretary of the State for posting on the eRegulations System, at least fifteen days prior to the effective date of any such policy or procedure. Any such policy or procedure shall no longer be effective upon the earlier of either the adoption of the policy or procedure as a final regulation under section 4-172 of the general statutes or forty-eight months after the effective date of this section, if such regulation has not been submitted to the legislative regulation review committee for consideration under section 4-170 of the general statutes.

Sec. 2. Section 21a-70i of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) On and after October 1, 2023, a pharmaceutical manufacturer that employs a pharmaceutical representative shall register annually with the department as a pharmaceutical marketing firm, in a form and manner prescribed by the commissioner. No pharmaceutical manufacturer shall authorize an individual to perform the duties of a pharmaceutical representative on such manufacturer's behalf unless such manufacturer has obtained a pharmaceutical marketing firm registration from the department pursuant to this section. Registrations issued pursuant to this section shall expire annually on June thirtieth.

(b) The nonrefundable fee for registration as a pharmaceutical marketing firm and for annual renewal of such registration shall be one hundred fifty dollars. Any pharmaceutical marketing firm that fails to renew its registration on or before June thirtieth shall pay a late fee of one hundred dollars for each year that such firm did not renew, in addition to the annual renewal fee required under this section.

(c) On the date of its initial registration, and annually thereafter, each pharmaceutical marketing firm shall provide to the department a list of all pharmaceutical representatives employed or compensated by such firm. Each pharmaceutical marketing firm shall notify the department, in a form and manner prescribed by the commissioner, of each individual who is no longer employed or compensated as a pharmaceutical representative or who was hired or compensated as a pharmaceutical representative after the date on which such firm provided such annual list, not later than two weeks after such individual leaves employment or was hired or otherwise compensated.

[(d) The department shall prominently post on its Internet web site the most recent list provided by each pharmaceutical marketing firm pursuant to subsection (c) of this section.**]**

[(e)**]** (d) Any person who is not identified to the department pursuant

to subsection (c) of this section shall not perform the duties of a pharmaceutical representative on behalf of the pharmaceutical marketing firm.

[(f)**]** (e) Not later than July 1, 2024, and annually thereafter, each pharmaceutical marketing firm shall provide the commissioner with the following information regarding the performance for the previous calendar year of each of its pharmaceutical representatives identified to the department pursuant to subsection (c) of this section at any time during the previous calendar year, in a form and manner prescribed by the commissioner:

(1) The aggregate number of contacts such pharmaceutical representative had with prescribing practitioners and pharmacists;

(2) The specialty of such prescribing practitioner and each pharmacist with whom such pharmaceutical representative made contact;

(3) Whether product samples, materials or gifts of any value were provided to a prescribing practitioner or such practitioner's staff in a prescribing practitioner's office or to a pharmacist; and

(4) An aggregate report of all free samples, by drug name and strength, in a form and manner prescribed by the commissioner.

[(g)**]** (f) The department shall annually compile a report on the activities of pharmaceutical marketing firms in the state. Not later than December 31, 2024, and annually thereafter, the department shall post such report on its Internet web site and submit such report to the Secretary of the Office of Policy and Management.

Sec. 3. (NEW) (*Effective from passage*) (a) A veterinarian licensed in accordance with the provisions of chapter 384 of the general statutes may authorize a person to dispense a prescription veterinary drug, provided:

(1) The prescription veterinary drug is dispensed (A) upon the lawful

written or oral order of the veterinarian acting in the course of the veterinarian's professional practice, as required under Section 503(f) of the Federal Food, Drug and Cosmetic Act, as amended from time to time, (B) in accordance with all applicable state and federal laws and regulations concerning the dispensing of prescription veterinary drugs, and (C) for an animal for which the veterinarian, or another veterinarian in the same practice who is licensed in accordance with the provisions of chapter 384 of the general statutes and has access to the animal's medical records, has established a veterinarian-client-patient relationship; and

(2) The person is working under the direct supervision of the veterinarian or another veterinarian described in subparagraph (C) of subdivision (1) of this subsection.

(b) A veterinarian who authorizes a person to dispense a prescription veterinary drug in accordance with the provisions of subsection (a) of this section shall be responsible for ensuring that all applicable requirements for dispensing such prescription veterinary drug are satisfied.

(c) The Commissioner of Public Health, in consultation with the Connecticut Board of Veterinary Medicine and 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 this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	New section
Sec. 2	*from passage*	21a-70i
Sec. 3	*from passage*	New section

Statement of Purpose:

To (1) require the Commissioner of Consumer Protection to adopt regulations to (A) ensure that nonsterile compounding pharmacies are

able to engage in nonsterile compounding of drug products that include levonorgestrel, mifepristone, misoprostol or a similar component as an active ingredient, and (B) provide for the Department Consumer Protection, or one or more public-private partnerships, to import levonorgestrel, mifepristone, misoprostol and similar drug products and components, (2) eliminate a provision requiring the department to prominently post on its Internet web site certain information concerning pharmaceutical representatives, and (3) authorize certain persons working under the direct supervision of veterinarians to dispense prescription veterinary drugs.

[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.]