General Assembly

Raised Bill No. 197

February Session, 2018

LCO No. **1273**

Referred to Committee on GENERAL LAW

Introduced by:
(GL)

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

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

Section 1. Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2018*):

(a) For the purposes of section 20-579 and this section:

(1) "Biological product" has the same meaning as provided in 42 USC 262;

[(1)**]** (2) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

[(2)**]** (3) "Generic name" means the established name designated in the official United States Pharmacopoeia-National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States Adopted Names or any supplement to any of said publications;

(4) "Interchangeable biological product" means a biological product

that: (A) The federal Food and Drug Administration has licensed and determined to meet the standards for interchangeability pursuant to 42 USC 262(k)(4), or (B) is therapeutically equivalent to another biological product, as set forth in the latest edition of or supplement to the federal Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations";

[(3)**]** (5) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetic Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen;

[(4)**]** (6) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body;

[(5)**]** (7) "Epilepsy" means a neurological condition characterized by recurrent seizures; and

[(6)**]** (8) "Seizures" means a disturbance in the electrical activity of the brain. **[**; and**]**

[(7) "Antiepileptic drug" means a drug prescribed for the treatment of epilepsy or a drug used to prevent seizures.**]**

(b) Except as limited by subsections **[**(c), (e) and (i)**]** (f), (h) and (l) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent.

When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) Except as limited by subsections (f), (h) and (l) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a biological product for a prescribed biological product if: (1) It is an interchangeable biological product, and (2) the practitioner has not specified, in the manner described in subsection (f) of this section, that there shall be no substitution for the prescribed biological product.

(d) Upon the dispensing of an interchangeable biological product to a patient, the pharmacist or a duly authorized agent of the pharmacist shall inform the patient or a representative of the patient of a substitution of an interchangeable biological product for a prescribed biological product. Not later than forty-eight hours after the pharmacist has informed the patient or representative of the patient of the substitution, the pharmacist shall make an entry documenting the substitution in a manner authorized pursuant to subsection (m) of this section.

(e) Upon the dispensing of an interchangeable biological product, but not later than forty-eight hours following the dispensing of such product, the pharmacist shall inform the prescribing practitioner by facsimile, telephone or electronic transmission of the substitution of such interchangeable biological product for a prescribed biological product.

[(c)**]** (f) A prescribing practitioner may specify in writing or by a

telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product or prescribed biological product specified on any prescription form, provided (1) for written prescriptions, the practitioner shall specify on the prescription form that the drug product or prescribed biological product is "brand medically necessary" or "no substitution", (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify "brand medically necessary" or "no substitution" on the prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3) for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to "brand medically necessary" or "no substitution".

[(d)**]** (g) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

[(e)**]** (h) A pharmacist may substitute a drug product under subsection (b) or interchangeable biological product under subsection (c) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

[(f)**]** (i) Except as provided in subsection **[**(g)**]** (j) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section or an interchangeable biological product as authorized by subsection (c) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product or interchangeable biological product. If the dispensed drug product or interchangeable biological product does not have a brand name, the prescription label shall indicate the generic name of the drug product or the nonproprietary name of the interchangeable biological product dispensed along with the name of the manufacturer of the drug **[**manufacturer or distributor**]** product or interchangeable biological product.

[(g)**]** (j) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug or biological product in the container unless the prescribing practitioner writes "DO NOT LABEL", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

[(h)**]** (k) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection **[**(d)**]** (g) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

[(i)**]** (l) Upon the initial filling or renewal of a prescription that contains a statistical information code based upon the most recent edition of the International Classification of Diseases indicating the prescribed drug is used for the treatment of epilepsy or to prevent seizures, a pharmacist shall not fill the prescription by using a different drug manufacturer or distributor of the prescribed drug or biological product, unless the pharmacist (1) provides prior notice of the use of a different drug or biological product manufacturer or distributor to the patient and the prescribing practitioner, and (2) obtains the written consent of the patient's prescribing practitioner. For purposes of obtaining the consent of the patient's prescribing practitioner required

by this subsection, a pharmacist shall notify the prescribing practitioner via electronic mail or facsimile transmission. If the prescribing practitioner does not provide the necessary consent, the pharmacist shall fill the prescription without such substitution or use of a different drug or biological product manufacturer or distributor or return the prescription to the patient or to the patient's representative for filling at another pharmacy. If a pharmacist is unable to contact the patient's prescribing practitioner after making reasonable efforts to do so, such pharmacist may exercise professional judgment in refilling a prescription in accordance with the provisions of subsection (b) of section 20-616. For purposes of this subsection, "pharmacy" means a place of business where drugs and devices may be sold at retail and for which a pharmacy license was issued pursuant to section 20-594, including a hospital-based pharmacy when such pharmacy is filling prescriptions for employees and outpatient care, and a mail order pharmacy licensed by this state to distribute in this state. "Pharmacy" does not include a pharmacy serving patients in a long-term care facility, other institutional facility or a pharmacy that provides prescriptions for inpatient hospitals.

(m) Not later than forty-eight hours following the dispensing of an interchangeable biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer of the product. The entry shall be made in a manner that provides notice to the prescriber and may be made through one of the following means: (1) An interoperable electronic medical records system, (2) an electronic prescribing technology, (3) a pharmacy benefit management system, or (4) a pharmacy record. If the entry is not made by any of the means specified in subdivision (1), (2), (3) or (4) of this subsection, the pharmacist shall communicate the product dispensed to the prescriber using either facsimile, telephone or electronic transmission, provided such communication shall not be required when a refill prescription is not changed from the product dispensed

on the prior filling of the prescription. The provisions of this subsection shall not apply to interchangeable biological products dispensed by a pharmacy operated by a hospital licensed in accordance with the provisions of chapter 368v.

(n) From the effective date of this section until December 31, 2019, no person shall deliver an interchangeable biological product to a patient through mail, shipment or parcel delivery service.

(o) The commissioner shall study the impact of the delivery of interchangeable biological products to patients through mail, shipment or parcel delivery service. Not later than December 31, 2019, the commissioner, in accordance with the provisions of section 11-4a, shall report the results of such study to the joint standing committees of the General Assembly having cognizance of matters relating to controlled substances and consumer protection.

[(j)**]** (p) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

Sec. 2. (NEW) (*Effective October 1, 2018*) Prior to prescribing a biological product, as defined in section 20-619 of the general statutes, as amended by this act, a prescribing practitioner shall discuss with the patient or a representative of the patient the treatment methods, alternatives to and risks associated with the use of such biological product. The prescribing practitioner shall document such discussion in the patient's medical record not later than twenty-four hours after such discussion has taken place.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2018*	20-619
Sec. 2	*October 1, 2018*	New section

Statement of Purpose:

To add biological products to existing law regarding substitution of generic 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.]