Senate

General Assembly

File No. 96

February Session, 2018

Senate Bill No. 197

Senate, March 28, 2018

The Committee on General Law reported through SEN. LEONE of the 27th Dist. and SEN. WITKOS of the 8th Dist., Chairpersons of the Committee on the part of the Senate, that the bill ought to pass.

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 Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2018*):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

GL *Joint Favorable*

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 19 $	FY 20 $
Consumer Protection, Dept.	GF - Cost	up to $250,000	None

Note: GF=General Fund

Municipal Impact: None e, See Out-Years

Explanation

The substitution provisions of the bill are not anticipated to result in a fiscal impact to the state employee or retiree health plan in FY 19 and FY 20 because biological product substitutions are not anticipated given (1) the structure of the pharmacy benefit and (2) the availability of interchangeable biologics in the market. Under the state employee and retiree plan's four-tiered structure (preferred generic, generic, brand, and preferred brand) currently available biologics are in the preferred brand tier with identical out-of-pocket costs to the consumers. As such, the structure of the pharmacy plan and current classification of available biologics do not provide for savings to be passed on to the consumer (e.g. purchaser), which is a condition of substitution in subsection (h) of the bill. The provisions of the bill are not anticipated to result in a fiscal impact to municipal health plans in the near term.

While substitution is not anticipated in the near term, as discussed above, there could be an impact to the state and municipalities contingent on the recommendations adopted regarding the delivery of interchangeable biologics via mail order and the ability to meet the

bill's substitution requirements. The state employee and retiree health plan utilizes mail order for prescriptions classified as maintenance medications as a cost control mechanism. To the extent mail order is prohibited for interchangeable biologics it will preclude the state from achieving savings. The total estimated annual savings from mail order pharmacy in the state health plan, based on the data available, after adjusting for growth in pharmacy expenditures is approximately $13 million.

Lastly, the bill requires the Commissioner of DCP to conduct a study on the delivery of interchangeable biological products through mail order on patients. The bill will result in a cost of up to $250,000 in FY 19 to the Department of Consumer Protection (DCP) depending on the methods used in the study. DCP does not have research staff or the expertise to conduct the study and will need to hire a consultant.

There is no cost to DCP to adopt regulations regarding substituting biological products as the agency has expertise in this area.

The Out Years

There is no cost to DCP in the out years as the study requirements end as of 12/31/19.

The fiscal impact to the state and municipal health plans in the out years will depend on (1) the availability of interchangeable biologic products in the marketplace, (2) their classification under the pharmacy benefit portion of the state and municipal health plans and (3) the ability for interchangeable biologics to be provide via mail order.

OLR Bill Analysis

SB 197

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

SUMMARY

This bill generally allows pharmacists to substitute a biological product for a prescribed biological product as long as the substitute is an interchangeable biological product and the prescribing practitioner has not prohibited the substitution. It extends to these substitutions many of existing law's provisions on substituting brand name drugs with generic ones.

The bill also establishes requirements applicable only to biological and interchangeable biological products, including requiring (1) practitioners to discuss with patients the treatment methods, alternatives to, and risks associated with using a biological product and (2) a dispensing pharmacist to inform prescribers and patients of a substitution. The bill prohibits, from October 1, 2018 to December 31, 2019, delivering interchangeable biological products to a patient through mail, shipment, or parcel delivery service.

A "biological product" is generally a virus; therapeutic serum; toxin or antitoxin; vaccine; blood or blood component or derivative; allergenic product; protein, but not a chemically synthesized polypeptide; or arsphenamine or a derivative of it, which is used to prevent, treat, or cure a human disease or condition.

The bill also makes minor and technical changes, including (1) eliminating the option for a generic drug prescription label to have the distributor's name instead of the manufacturer's name, (2) allowing prescribers to order a biological product's name to be withheld from the prescription container's label, and (3) removing an unnecessary definition for "antiepileptic drug."

EFFECTIVE DATE: October 1, 2018

PRESCRIBING BIOLOGICAL PRODUCTS

The bill requires practitioners to discuss with patients the treatment methods, alternatives to, and risks associated with using a biological product before prescribing one. Practitioners must document the discussion in the patient's medical record within 24 hours after the discussion.

BIOLOGICAL PRODUCT SUBSTITUTION

Interchangeability

The bill defines "interchangeable biological product" as a biological product that (1) the federal Food and Drug Administration (FDA) has licensed and determined meets the interchangeability standards under federal law or (2) is therapeutically equivalent to another biological product, as set forth in the latest edition of, or supplement to, its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (see BACKGROUND).

Under federal law, a biological product is considered interchangeable if the FDA finds that it is (1) biosimilar (i.e., highly similar, other than minor differences in inactive components, with no meaningful differences in safety, purity, and potency) to the original licensed product and (2) expected to produce the same clinical result in any given patient. For biological products administered to a patient more than once, the risk from switching between the biological product and the original licensed product must be no greater than if only the original product was used.

Notification

Under the bill, upon dispensing an interchangeable biological product, a pharmacist or his or her authorized agent must inform the patient or the patient's representative of the substitution. Additionally, within 48 hours after dispensing the product, the pharmacist must (1) inform the prescribing practitioner and (2) document the substitution by making an entry into an electronic record (see below).

Labeling

As is the case for drug product substitutions, pharmacists must label the prescription container with the name of the interchangeable biological product, or if it doesn't have a brand name, the nonproprietary name of the product, along with the name of the manufacturer.

Prohibited Substitutions

Prescriber order. Under the bill, practitioners may prohibit substitutions for prescribed biological products in the same way that existing law authorizes them to prohibit substitutions for brand name drugs (e.g., specifying on the prescription form "no substitution" or "brand medically necessary").

Cost savings. Under the bill, as is the case for drug product substitutions, there must be a cost savings to the purchaser for an interchangeable biological product substitution to occur. If a patient asks, the pharmacist must disclose the savings amount.

Purchaser objection. Like drug product substitutions, the bill also allows purchasers to reject an interchangeable biological product substitution.

Epilepsy or seizure treatment. The bill extends to biological products existing law's limitations on filling prescriptions for prescribed drugs to treat epilepsy or prevent seizures. Specifically, it prohibits filling a biological product prescription by using a different manufacturer or distributor unless the pharmacist (1) gives the patient and the prescribing practitioner prior notice of the substitution and (2) receives written consent from the practitioner.

ELECTRONIC RECORDS

The bill requires pharmacists, or their designees, within 48 hours after dispensing an interchangeable biological product, to record its name and manufacturer in a way that notifies the prescribing practitioner. The information may be made available through:

1. an interoperable electronic medical records system,
2. an electronic prescribing technology,
3. a pharmacy benefit management system, or
4. a pharmacy record.

If an entry is not made by one of the above means, the pharmacist must let the prescriber know about the dispensed product, by fax, telephone, or electronic transmission. However, no such communication is necessary when (1) a refill prescription is the same as the originally dispensed product or (2) the product is dispensed by a hospital pharmacy.

MISCELLANEOUS PROVISIONS

Signs

Under existing law, pharmacies must post signs, near counters where prescriptions are dispensed, informing purchasers that they may substitute less expensive and therapeutically equivalent drug products. The bill requires the signs to include notice that these rules also apply to interchangeable biological products.

Regulations

The bill requires the consumer protection commissioner, with help from the Commission of Pharmacy, to amend the department's regulations to carry out the bill's provisions.

Study

The bill requires the consumer protection commissioner to study the impact of delivering interchangeable biological products to patients through mail, shipment, or parcel delivery service and report her findings to the General Law Committee by December 31, 2019.

BACKGROUND

Approved Drug Products with Therapeutic Equivalence Evaluations

The *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (i.e., the Orange Book) identifies drug products

approved by the FDA on the basis of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.

COMMITTEE ACTION

General Law Committee

Joint Favorable
Yea 14 Nay 3 (03/15/2018)