



Senate

General Assembly

File No. 218

February Session, 2016

Substitute Senate Bill No. 313

Senate, March 24, 2016

The Committee on General Law reported through SEN. LEONE of the 27th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

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

1 Section 1. Section 20-619 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2016*):

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

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

6 [(1)] (2) "Brand name" means the proprietary or trade name selected
7 by the manufacturer and placed upon a drug product, its container,
8 label or wrapping at the time of packaging;

9 [(2)] (3) "Generic name" means the established name designated in
10 the official United States Pharmacopoeia-National Formulary, official
11 Homeopathic Pharmacopoeia of the United States, or official United
12 States Adopted Names or any supplement to any of said publications;

13 (4) "Interchangeable" means, with respect to a biological product, a
14 product that the federal Food and Drug Administration has: (A)
15 Determined to be interchangeable, pursuant to 42 USC 262(k)(4), or (B)
16 (i) determined to be therapeutically equivalent to another biological
17 product, and (ii) granted an A rating as set for in the latest edition of
18 the federal Food and Drug Administration's publication "Approved
19 Drug Products with Therapeutic Equivalence Evaluations";

20 [(3)] (5) "Therapeutically equivalent" means drug products that are
21 approved under the provisions of the federal Food, Drug and
22 Cosmetic Act for interstate distribution and that will provide
23 essentially the same efficacy and toxicity when administered to an
24 individual in the same dosage regimen;

25 [(4)] (6) "Dosage form" means the physical formulation or medium
26 in which the product is intended, manufactured and made available
27 for use, including, but not limited to, tablets, capsules, oral solutions,
28 aerosol, inhalers, gels, lotions, creams, ointments, transdermals and
29 suppositories, and the particular form of any physical formulation or
30 medium that uses a specific technology or mechanism to control,
31 enhance or direct the release, targeting, systemic absorption, or other
32 delivery of a dosage regimen in the body;

33 [(5)] (7) "Epilepsy" means a neurological condition characterized by
34 recurrent seizures;

35 [(6)] (8) "Seizures" means a disturbance in the electrical activity of
36 the brain; and

37 [(7)] (9) "Antiepileptic drug" means a drug prescribed for the
38 treatment of epilepsy or a drug used to prevent seizures.

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

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

52 (c) Except as limited by subsections (e), (g) and (k) of this section,
53 unless the purchaser instructs otherwise, the pharmacist may
54 substitute a biological product for a prescribed biological product if:
55 (A) The federal Food and Drug Administration has determined that
56 the biological product to be substituted is interchangeable with the
57 prescribed biological product, and (B) the practitioner has not
58 specified, in the manner described in subsection (e) of this section, that
59 there shall be no substitution for the prescribed biological product.

60 (d) The pharmacist shall inform the prescribing practitioner and the
61 patient or a representative of the patient at the earliest reasonable time
62 of the substitution of a biological product for a prescribed biological
63 product.

64 [(c)] (e) A prescribing practitioner may specify in writing or by a
65 telephonic or other electronic communication that there shall be no
66 substitution for the specified brand name drug product or
67 interchangeable biological product specified on any prescription form,
68 provided (1) for written prescriptions, the practitioner shall specify on
69 the prescription form that the drug product or interchangeable
70 biological product is "brand medically necessary" or "no substitution",
71 (2) for prescriptions transmitted by telephonic means, the pharmacist
72 shall specify "brand medically necessary" or "no substitution" on the
73 prescription form in the pharmacist's handwriting or in the electronic
74 prescription record and shall record on the prescription form the time
75 the telephonic authorization was received and the name of the person
76 who communicated the telephonic authorization to the pharmacist,

77 and (3) for prescriptions transmitted by any other electronic
78 communication, the practitioner shall select the dispense as written
79 code on the certified electronic prescription form to indicate that a
80 substitution is not allowed by the practitioner. No prescription form
81 for written prescriptions, and no prescription form for prescriptions
82 transmitted pursuant to subdivision (2) or (3) of this subsection, may
83 default to "brand medically necessary" or "no substitution".

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

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

97 [(f)] (h) Except as provided in subsection [(g)] (i) of this section,
98 when a pharmacist dispenses a substitute drug product as authorized
99 by subsection (b) of this section or interchangeable biological product
100 as authorized by subsection (c) of this section, the pharmacist shall
101 label the prescription container with the name of the dispensed drug
102 product or interchangeable biological product. If the dispensed drug
103 product or interchangeable biological product does not have a brand
104 name, the prescription label shall indicate the generic name of the drug
105 product or interchangeable biological product dispensed along with
106 the name of the drug or interchangeable biological product
107 manufacturer or distributor.

108 [(g)] (i) A prescription dispensed by a pharmacist shall bear upon
109 the label the name of the drug or interchangeable biological product in

110 the container unless the prescribing practitioner writes "DO NOT
111 LABEL", or words of similar import, on the prescription or so
112 designates in an oral or electronic transmission of the prescription.

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

117 [(i)] (k) Upon the initial filling or renewal of a prescription that
118 contains a statistical information code based upon the most recent
119 edition of the International Classification of Diseases indicating the
120 prescribed drug is used for the treatment of epilepsy or to prevent
121 seizures, a pharmacist shall not fill the prescription by using a different
122 drug manufacturer or distributor of the prescribed drug or
123 interchangeable biological product, unless the pharmacist (1) provides
124 prior notice of the use of a different drug or interchangeable biological
125 product manufacturer or distributor to the patient and the prescribing
126 practitioner, and (2) obtains the written consent of the patient's
127 prescribing practitioner. For purposes of obtaining the consent of the
128 patient's prescribing practitioner required by this subsection, a
129 pharmacist shall notify the prescribing practitioner via electronic mail
130 or facsimile transmission. If the prescribing practitioner does not
131 provide the necessary consent, the pharmacist shall fill the prescription
132 without such substitution or use of a different drug or interchangeable
133 biological product manufacturer or distributor or return the
134 prescription to the patient or to the patient's representative for filling at
135 another pharmacy. If a pharmacist is unable to contact the patient's
136 prescribing practitioner after making reasonable efforts to do so, such
137 pharmacist may exercise professional judgment in refilling a
138 prescription in accordance with the provisions of subsection (b) of
139 section 20-616. For purposes of this subsection, "pharmacy" means a
140 place of business where drugs and devices may be sold at retail and for
141 which a pharmacy license was issued pursuant to section 20-594,
142 including a hospital-based pharmacy when such pharmacy is filling
143 prescriptions for employees and outpatient care, and a mail order

144 pharmacy licensed by this state to distribute in this state. "Pharmacy"
 145 does not include a pharmacy serving patients in a long-term care
 146 facility, other institutional facility or a pharmacy that provides
 147 prescriptions for inpatient hospitals.

148 (l) Not later than five business days following the dispensing of a
 149 biological product, the dispensing pharmacist or the pharmacist's
 150 designee shall make an entry of the specific biological product
 151 provided to the patient, including the name of the biological product
 152 and the manufacturer of the biological product. The entry shall be
 153 made in a manner that is electronically accessible to the prescriber
 154 through one of the following means: (1) An interoperable electronic
 155 medical records system, (2) an electronic prescribing technology, (3) a
 156 pharmacy benefit management system, or (4) a pharmacy record.
 157 Entry into an electronic medical records system is presumed to
 158 provide notice to the prescriber. The pharmacist may communicate the
 159 biological product dispensed to the prescriber using facsimile,
 160 telephone or electronic transmission, provided such communication
 161 shall not be required when there is no federal Food and Drug
 162 Administration approved interchangeable biological product for the
 163 product prescribed or when a refill prescription is not changed from
 164 the product dispensed on the prior filling of the prescription.

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

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| This act shall take effect as follows and shall amend the following sections: | | |
| Section 1 | October 1, 2016 | 20-619 |

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| Section 1 | October 1, 2016 | 20-619 |
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Statement of Legislative Commissioners:

In Section 1(a) and (c), "Secretary of the" was deleted, in Section 1(c)(d) and (l), "biologic" was changed to "biological", in Section 1(h), "(g)" was changed to "[(g)] (i)", in Section 1(j), "(d)" was changed to "[(d)] (f)", and in Section 1(l), Subdiv. designators (A), (B), (C) and (D) were changed to (1), (2), (3) and (4) for accuracy.

GL *Joint Favorable Subst. -LCO*

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:*** None***Municipal Impact:*** None***Explanation***

There is no cost to the Department of Consumer Protection adopting regulations to carry out the requirements for substituting biological products as the agency has expertise in this area.

The Out Years***State Impact:*** None***Municipal Impact:*** None

OLR Bill Analysis**sSB 313*****AN ACT CONCERNING BIOLOGICAL PRODUCTS.*****SUMMARY:**

This bill sets conditions under which pharmacists can substitute biological products for prescribed biological products. In general, the substitution may occur if the (1) product to be substituted is interchangeable with the prescribed product and (2) practitioner has not explicitly prohibited the substitution. The bill's requirements are similar to those under existing law for substituting generics for prescribed brand name drugs.

The bill also requires pharmacists to electronically record certain information about the biological products they dispense and make it accessible to prescribing practitioners.

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.

EFFECTIVE DATE: October 1, 2016

BIOLOGICAL PRODUCT SUBSTITUTION***Interchangeability***

The bill specifies that a biological product is interchangeable if the federal Food and Drug Administration (FDA) determines (1) it to be or (2) that it is "therapeutically equivalent" to another biological product, meaning that federal law allows for its interstate distribution and it will provide the same efficacy and toxicity, and the FDA gave it an "A" rating in its most recent edition of "Approved Drug Products with

Therapeutic Equivalence Evaluations.” (“A” rated products are those that the FDA considers therapeutically equivalent to other pharmaceutically equivalent products.)

Under federal law, which the bill incorporates, 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, and 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, there must be no greater risk of switching between the biological product and the original licensed product than if only the original product is used.

When Substitution May Occur

Under the bill, a pharmacist may generally substitute a biological product for a prescribed biological product if the (1) product to be substituted is interchangeable with the prescribed product, according to the FDA, and (2) prescribing practitioner has not explicitly prohibited the substitution (see below).

If a substitution occurs, the pharmacist must inform the prescribing practitioner and the patient, or the patient’s representative, of the substitution at the earliest reasonable time. Unlike existing law for drug product substitutions, the bill does not prohibit pharmacists from using the failure to provide this notice as defense to a lawsuit by a purchaser.

When Substitution is Not Allowed

Prescribing practitioner. As under existing law for substituting generics for brand name drugs, a prescribing practitioner may specify that no substitution may occur for an interchangeable biological product the practitioner specifies on the prescription form (presumably meaning the biological product, not the substituted version).

If prescribed in writing, the practitioner must state on the

prescription form that the interchangeable biological product is “brand medically necessary” or “no substitution.”

If done telephonically, the pharmacist must (1) specify “brand medically necessary” or “no substitution” on the prescription form in the pharmacist’s handwriting or in the electronic prescription record and (2) record the time the telephonic authorization was received and who gave the authorization.

If the prescription is electronically transmitted, the practitioner must select the “dispense as written” code on the electronic prescription form.

No cost savings. Under the bill, as is the case for drug product substitutions, there must be a cost savings to the purchaser for a substitution of an interchangeable biological product to occur. If a patient asks, the pharmacist must disclose the savings amount.

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

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

ELECTRONIC RECORDS

The bill requires pharmacists, or their designees, within five business days after dispensing a biological product, to record the name and manufacturer of the specific product provided to the patient. The information must be electronically accessible to the prescribing practitioner through:

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

It specifies that entering the information into an electronic medical records system is presumed to notify the prescriber.

The bill also allows pharmacists to communicate to prescribers about dispensed products through fax, telephone, or electronic means. But no such communication is necessary when no federally approved interchangeable biological product for the prescribed product exists or when a refill prescription is the same as the originally dispensed product.

MISCELLANEOUS PROVISIONS

Labels

As is the case with drug product substitutions, the bill requires pharmacists to label the prescription containers of dispensed interchangeable biological products with the name of the products. If the product has no “brand name”, the label must include the product’s “generic name” and its manufacturer or distributor. But prescribing practitioners may instruct pharmacists to withhold the name of the interchangeable biological product from the prescription label.

Signs

Under the bill, pharmacies must amend their signs informing purchasers of the ability to substitute less expensive drug products to include the ability to substitute less expensive interchangeable biological products unless they disapprove of the substitutions. By law, the signs must be located near counters where prescriptions are dispensed so that they may be easily seen.

Regulations

The bill allows the consumer protection commissioner, with help from the Commission on Pharmacy, to adopt regulations to carry out the requirements for substituting biological products, as they may do for drug product substitutions.

COMMITTEE ACTION

General Law Committee

Joint Favorable

Yea 17 Nay 0 (03/11/2016)