



General Assembly

February Session, 2016

## Substitute Bill No. 313



### **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 Section 20-619 of the general statutes is repealed and the  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.

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

**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), "(a)" 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