



General Assembly

February Session, 2018

**Raised Bill No. 197**

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:

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 Section 20-619 of the general statutes is repealed and the  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

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;

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 biological product" means a biological product  
14 that: (A) The federal Food and Drug Administration has licensed and

15 determined to meet the standards for interchangeability pursuant to 42  
16 USC 262(k)(4), or (B) is therapeutically equivalent to another biological  
17 product, as set forth in the latest edition of or supplement to the  
18 federal Food and Drug Administration's publication "Approved Drug  
19 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; and

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

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

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

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

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

74 [(c)] (f) A prescribing practitioner may specify in writing or by a  
75 telephonic or other electronic communication that there shall be no  
76 substitution for the specified brand name drug product or prescribed  
77 biological product specified on any prescription form, provided (1) for

78 written prescriptions, the practitioner shall specify on the prescription  
79 form that the drug product or prescribed biological product is "brand  
80 medically necessary" or "no substitution", (2) for prescriptions  
81 transmitted by telephonic means, the pharmacist shall specify "brand  
82 medically necessary" or "no substitution" on the prescription form in  
83 the pharmacist's handwriting or in the electronic prescription record  
84 and shall record on the prescription form the time the telephonic  
85 authorization was received and the name of the person who  
86 communicated the telephonic authorization to the pharmacist, and (3)  
87 for prescriptions transmitted by any other electronic communication,  
88 the practitioner shall select the dispense as written code on the  
89 certified electronic prescription form to indicate that a substitution is  
90 not allowed by the practitioner. No prescription form for written  
91 prescriptions, and no prescription form for prescriptions transmitted  
92 pursuant to subdivision (2) or (3) of this subsection, may default to  
93 "brand medically necessary" or "no substitution".

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

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

107 [(f)] (i) Except as provided in subsection [(g)] (j) of this section, when  
108 a pharmacist dispenses a substitute drug product as authorized by  
109 subsection (b) of this section or an interchangeable biological product  
110 as authorized by subsection (c) of this section, the pharmacist shall

111 label the prescription container with the name of the dispensed drug  
112 product or interchangeable biological product. If the dispensed drug  
113 product or interchangeable biological product does not have a brand  
114 name, the prescription label shall indicate the generic name of the drug  
115 product or the nonproprietary name of the interchangeable biological  
116 product dispensed along with the name of the manufacturer of the  
117 drug [manufacturer or distributor] product or interchangeable  
118 biological product.

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

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

128 [(i)] (l) Upon the initial filling or renewal of a prescription that  
129 contains a statistical information code based upon the most recent  
130 edition of the International Classification of Diseases indicating the  
131 prescribed drug is used for the treatment of epilepsy or to prevent  
132 seizures, a pharmacist shall not fill the prescription by using a different  
133 drug manufacturer or distributor of the prescribed drug or biological  
134 product, unless the pharmacist (1) provides prior notice of the use of a  
135 different drug or biological product manufacturer or distributor to the  
136 patient and the prescribing practitioner, and (2) obtains the written  
137 consent of the patient's prescribing practitioner. For purposes of  
138 obtaining the consent of the patient's prescribing practitioner required  
139 by this subsection, a pharmacist shall notify the prescribing  
140 practitioner via electronic mail or facsimile transmission. If the  
141 prescribing practitioner does not provide the necessary consent, the  
142 pharmacist shall fill the prescription without such substitution or use  
143 of a different drug or biological product manufacturer or distributor or

144 return the prescription to the patient or to the patient's representative  
145 for filling at another pharmacy. If a pharmacist is unable to contact the  
146 patient's prescribing practitioner after making reasonable efforts to do  
147 so, such pharmacist may exercise professional judgment in refilling a  
148 prescription in accordance with the provisions of subsection (b) of  
149 section 20-616. For purposes of this subsection, "pharmacy" means a  
150 place of business where drugs and devices may be sold at retail and for  
151 which a pharmacy license was issued pursuant to section 20-594,  
152 including a hospital-based pharmacy when such pharmacy is filling  
153 prescriptions for employees and outpatient care, and a mail order  
154 pharmacy licensed by this state to distribute in this state. "Pharmacy"  
155 does not include a pharmacy serving patients in a long-term care  
156 facility, other institutional facility or a pharmacy that provides  
157 prescriptions for inpatient hospitals.

158 (m) Not later than forty-eight hours following the dispensing of an  
159 interchangeable biological product, the dispensing pharmacist or the  
160 pharmacist's designee shall make an entry of the specific product  
161 provided to the patient, including the name of the product and the  
162 manufacturer of the product. The entry shall be made in a manner that  
163 provides notice to the prescriber and may be made through one of the  
164 following means: (1) An interoperable electronic medical records  
165 system, (2) an electronic prescribing technology, (3) a pharmacy benefit  
166 management system, or (4) a pharmacy record. If the entry is not made  
167 by any of the means specified in subdivision (1), (2), (3) or (4) of this  
168 subsection, the pharmacist shall communicate the product dispensed  
169 to the prescriber using either facsimile, telephone or electronic  
170 transmission, provided such communication shall not be required  
171 when a refill prescription is not changed from the product dispensed  
172 on the prior filling of the prescription. The provisions of this  
173 subsection shall not apply to interchangeable biological products  
174 dispensed by a pharmacy operated by a hospital licensed in  
175 accordance with the provisions of chapter 368v.

176 (n) From the effective date of this section until December 31, 2019,

177 no person shall deliver an interchangeable biological product to a  
178 patient through mail, shipment or parcel delivery service.

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

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

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

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

**GL**      *Joint Favorable*