



General Assembly

February Session, 2016

Raised Bill No. 313

LCO No. 2130



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 Section 20-619 of the general statutes is repealed and the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, 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 Secretary of the federal Food and Drug
15 Administration has: (A) Determined to be interchangeable, pursuant to
16 42 USC 262 (k) (4), or (B) (i) determined to be therapeutically
17 equivalent to another biological product and (ii) granted an A rating
18 as set for in the latest edition of the federal Food and Drug
19 Administration's publication "Approved Drug Products with
20 Therapeutic Equivalence Evaluations";

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

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

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

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

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

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

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

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

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

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

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

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

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

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

108 the name of the drug or interchangeable biological product
109 manufacturer or distributor.

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

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

119 [(i)] (k) Upon the initial filling or renewal of a prescription that
120 contains a statistical information code based upon the most recent
121 edition of the International Classification of Diseases indicating the
122 prescribed drug is used for the treatment of epilepsy or to prevent
123 seizures, a pharmacist shall not fill the prescription by using a different
124 drug manufacturer or distributor of the prescribed drug or
125 interchangeable biological product, unless the pharmacist (1) provides
126 prior notice of the use of a different drug or interchangeable biological
127 product manufacturer or distributor to the patient and the prescribing
128 practitioner, and (2) obtains the written consent of the patient's
129 prescribing practitioner. For purposes of obtaining the consent of the
130 patient's prescribing practitioner required by this subsection, a
131 pharmacist shall notify the prescribing practitioner via electronic mail
132 or facsimile transmission. If the prescribing practitioner does not
133 provide the necessary consent, the pharmacist shall fill the prescription
134 without such substitution or use of a different drug or interchangeable
135 biological product manufacturer or distributor or return the
136 prescription to the patient or to the patient's representative for filling at
137 another pharmacy. If a pharmacist is unable to contact the patient's
138 prescribing practitioner after making reasonable efforts to do so, such
139 pharmacist may exercise professional judgment in refilling a

140 prescription in accordance with the provisions of subsection (b) of
141 section 20-616. For purposes of this subsection, "pharmacy" means a
142 place of business where drugs and devices may be sold at retail and for
143 which a pharmacy license was issued pursuant to section 20-594,
144 including a hospital-based pharmacy when such pharmacy is filling
145 prescriptions for employees and outpatient care, and a mail order
146 pharmacy licensed by this state to distribute in this state. "Pharmacy"
147 does not include a pharmacy serving patients in a long-term care
148 facility, other institutional facility or a pharmacy that provides
149 prescriptions for inpatient hospitals.

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

167 [(j)] (m) The commissioner, with the advice and assistance of the
168 commission, shall adopt regulations, in accordance with chapter 54, to
169 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 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.]