



Senate

General Assembly

File No. 120

January Session, 2009

Substitute Senate Bill No. 757

Senate, March 19, 2009

The Committee on Public Health reported through SEN. HARRIS of the 5th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING THE FILLING OF PRESCRIPTIONS FOR ANTIEPILEPTIC DRUGS.

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 Section 20-619 of the general statutes is repealed and the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, 2009*):

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

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

7 (2) "Generic name" means the established name designated in the
8 official United States Pharmacopoeia/National Formulary, official
9 Homeopathic Pharmacopoeia of the United States, or official United
10 States adopted names or any supplement to any of them;

11 (3) "Therapeutically equivalent" means drug products that are
12 approved under the provisions of the federal Food, Drug and

13 Cosmetics Act for interstate distribution and that will provide
14 essentially the same efficacy and toxicity when administered to an
15 individual in the same dosage regimen; [and]

16 (4) "Dosage form" means the physical formulation or medium in
17 which the product is intended, manufactured and made available for
18 use, including, but not limited to, tablets, capsules, oral solutions,
19 aerosol, inhalers, gels, lotions, creams, ointments, transdermals and
20 suppositories, and the particular form of any physical formulation or
21 medium that uses a specific technology or mechanism to control,
22 enhance or direct the release, targeting, systemic absorption, or other
23 delivery of a dosage regimen in the body;

24 (5) "Epilepsy" means a neurological condition characterized by
25 recurrent seizures;

26 (6) "Seizures" means a disturbance in the electrical activity of the
27 brain; and

28 (7) "Antiepileptic drug" means a drug prescribed for the treatment
29 of epilepsy or a drug used to prevent seizures.

30 (b) Except as limited by subsections (c), [and] (e) and (i) of this
31 section, unless the purchaser instructs otherwise, the pharmacist may
32 substitute a generic drug product with the same strength, quantity,
33 dose and dosage form as the prescribed drug product which is, in the
34 pharmacist's professional opinion, therapeutically equivalent. When
35 the prescribing practitioner is not reasonably available for consultation
36 and the prescribed drug does not use a unique delivery system
37 technology, the pharmacist may substitute an oral tablet, capsule or
38 liquid form of the prescribed drug as long as the form dispensed has
39 the same strength, dose and dose schedule and is therapeutically
40 equivalent to the drug prescribed. The pharmacist shall inform the
41 patient or a representative of the patient, and the practitioner of the
42 substitution at the earliest reasonable time.

43 (c) A prescribing practitioner may specify in writing or by a

44 telephonic or other electronic communication that there shall be no
45 substitution for the specified brand name drug product in any
46 prescription, provided (1) in any prescription for a Medicaid, state-
47 administered general assistance, or ConnPACE recipient, such
48 practitioner specifies the basis on which the brand name drug product
49 and dosage form is medically necessary in comparison to a chemically
50 equivalent generic drug product substitution, and (2) the phrase
51 "BRAND MEDICALLY NECESSARY", shall be in the practitioner's
52 handwriting on the prescription form or on an electronically-produced
53 copy of the prescription form or, if the prohibition was communicated
54 by telephonic or other electronic communication that did not
55 reproduce the practitioner's handwriting, a statement to that effect
56 appears on the form. The phrase "BRAND MEDICALLY NECESSARY"
57 shall not be preprinted or stamped or initialed on the form. If the
58 practitioner specifies by telephonic or other electronic communication
59 that did not reproduce the practitioner's handwriting that there shall
60 be no substitution for the specified brand name drug product in any
61 prescription for a Medicaid, state-administered general assistance, or
62 ConnPACE recipient, written certification in the practitioner's
63 handwriting bearing the phrase "BRAND MEDICALLY NECESSARY"
64 shall be sent to the dispensing pharmacy within ten days.

65 (d) Each pharmacy shall post a sign in a location easily seen by
66 patrons at the counter where prescriptions are dispensed stating that,
67 "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS
68 EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY
69 EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR
70 UNLESS YOU DO NOT APPROVE." The printing on the sign shall be
71 in block letters not less than one inch in height.

72 (e) A pharmacist may substitute a drug product under subsection
73 (b) of this section only when there will be a savings in cost passed on
74 to the purchaser. The pharmacist shall disclose the amount of the
75 savings at the request of the patient.

76 (f) Except as provided in subsection (g) of this section, when a

77 pharmacist dispenses a substitute drug product as authorized by
78 subsection (b) of this section, the pharmacist shall label the
79 prescription container with the name of the dispensed drug product. If
80 the dispensed drug product does not have a brand name, the
81 prescription label shall indicate the generic name of the drug product
82 dispensed along with the name of the drug manufacturer or
83 distributor.

84 (g) A prescription dispensed by a pharmacist shall bear upon the
85 label the name of the drug in the container unless the prescribing
86 practitioner writes "DO NOT LABEL", or words of similar import, on
87 the prescription or so designates in an oral or electronic transmission
88 of the prescription.

89 (h) Neither the failure to instruct by the purchaser as provided in
90 subsection (b) of this section nor the fact that a sign has been posted as
91 provided in subsection (d) of this section shall be a defense on the part
92 of a pharmacist against a suit brought by any such purchaser.

93 (i) Upon the initial filling or renewal of a prescription that contains a
94 statistical information code based upon the most recent edition of the
95 International Classification of Diseases indicating the prescribed drug
96 is used for the treatment of epilepsy or to prevent seizures, a
97 pharmacist shall not: (1) Substitute for the prescribed drug another
98 antiepileptic drug or formulation of another antiepileptic drug,
99 irrespective of whether such other antiepileptic drug is a brand name
100 drug or a generic drug name, and (2) fill the prescription by using a
101 new drug manufacturer or distributor of the prescribed drug, unless
102 the pharmacist provides prior notice of such substitution or use of a
103 new drug manufacturer or distributor to, and obtains the written
104 consent of, the patient's practitioner. For purposes of obtaining the
105 consent of the patient's practitioner required by this subsection, a
106 pharmacist shall notify the patient's practitioner via electronic mail or
107 facsimile transmission. If the patient's practitioner does not provide the
108 necessary consent, the pharmacist shall fill the prescription without
109 such substitution or use of a new drug manufacturer or distributor or

110 return the prescription to the patient or to such patient's representative
 111 for filling at another pharmacy. If a pharmacist is unable to contact the
 112 patient's practitioner after making reasonable efforts to do so, such
 113 pharmacist may exercise professional judgment in refilling a
 114 prescription in accordance with the provisions of subsection (b) of
 115 section 20-616. For purposes of this subsection, "pharmacy" means a
 116 place of business where drugs and devices may be sold at retail and for
 117 which a pharmacy license was issued pursuant to section 20-594,
 118 including a hospital-based pharmacy when such pharmacy is filling
 119 prescriptions for employees and outpatient care, and a mail order
 120 pharmacy licensed by this state to distribute in this state. "Pharmacy"
 121 does not include a pharmacy serving patients in a long-term care
 122 facility, other institutional facility or a pharmacy that provides
 123 prescriptions for inpatient hospitals.

124 [(i)] (j) The commissioner, with the advice and assistance of the
 125 commission, shall adopt regulations, in accordance with chapter 54, to
 126 carry out the provisions of this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2009	20-619

PH *Joint Favorable Subst.*

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

OLR Bill Analysis**sSB 757*****AN ACT CONCERNING THE FILLING OF PRESCRIPTIONS FOR ANTIEPILEPTIC DRUGS.*****SUMMARY:**

This bill prohibits retail pharmacists from substituting any alternative for a drug prescribed to treat epilepsy or prevent seizures without the prior written approval of the prescribing practitioner. The law already permits a prescriber to tell a pharmacist not to substitute a generic drug for any brand name one.

EFFECTIVE DATE: October 1, 2009

BANNING SUBSTITUTIONS FOR ANTI-EPILEPTIC DRUGS

The bill bans covered pharmacists, without the prescriber's written consent, from (1) substituting another brand name or generic drug or drug formulation for the prescribed drug and (2) filling the prescription with a product from a new manufacturer or distributor. It applies to new and renewal prescriptions that contain an International Classification of Diseases statistical code indicating the drug is used to treat epilepsy or prevent seizures.

The ban applies to community pharmacies, hospital pharmacies that serve employees and outpatients, and mail order pharmacies licensed to distribute in Connecticut. It does not apply to pharmacies (1) in long-term care facilities such as nursing homes, chronic disease hospitals, and intermediate care facilities for people with mental retardation; (2) serving hospital in-patients; and (3) in other institutions.

The bill requires the pharmacist to notify the prescriber by electronic

mail or fax in order to obtain consent. If the prescriber does not consent, the pharmacist must fill the prescription without substitution or give the prescription back to the patient or his or her representative for filling at another pharmacy.

If, after making reasonable efforts, a pharmacist cannot contact the prescriber, he or she may refill a prescription with a 72-hour supply if, in his or her professional judgment, failure to do so might interrupt the patient’s therapeutic regimen or cause the patient to suffer. When dispensing this refill, the pharmacist must tell the patient or the patient’s representative that the prescriber did not authorize it and inform the prescriber that he or she must authorize future refills. The pharmacist may refill a prescription in this way just once.

Under existing law, which the bill does not change, a prescriber may tell a pharmacist not to substitute a generic for any brand name drug. The prescriber must do this by writing “Brand Medically Necessary” on the prescription form or, if the prescriber calls in the prescription or electronically transmits it in a way the does not reproduce his or her handwriting, by stating so on the communication. For Medicaid, State-Assisted General Assistance, and ConnPACE clients, the prescriber must (1) specify why the name brand and dosage form is medically necessary and (2) send the “brand medically necessary” certification to the pharmacist in writing within 10 days if it was not on the prescription form. This law applies to all pharmacies.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute
Yea 30 Nay 0 (03/09/2009)