



# House of Representatives

General Assembly

**File No. 148**

February Session, 2010

House Bill No. 5307

*House of Representatives, March 25, 2010*

The Committee on Public Health reported through REP. RITTER of the 38th Dist., Chairperson of the Committee on the part of the House, that the 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 Section 20-619 of the general statutes is repealed and the  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, 2010*):

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 name drug product with the same strength,  
33 quantity, dose and dosage form as the prescribed drug product which  
34 is, in the pharmacist's professional opinion, therapeutically equivalent.  
35 When the prescribing practitioner is not reasonably available for  
36 consultation and the prescribed drug does not use a unique delivery  
37 system technology, the pharmacist may substitute an oral tablet,  
38 capsule or liquid form of the prescribed drug as long as the form  
39 dispensed has the same strength, dose and dose schedule and is  
40 therapeutically equivalent to the drug prescribed. The pharmacist shall  
41 inform the patient or a representative of the patient, and the  
42 practitioner of the 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 name 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 product or a generic name drug product, and (2) fill the  
101 prescription by using a new drug manufacturer or distributor of the  
102 prescribed drug, unless the pharmacist provides prior notice of such  
103 substitution or use of a new drug manufacturer or distributor to, and  
104 obtains the written consent of, the patient's practitioner. For purposes  
105 of obtaining the consent of the patient's practitioner required by this  
106 subsection, a pharmacist shall notify the patient's practitioner via  
107 electronic mail or facsimile transmission. If the patient's practitioner  
108 does not provide the necessary consent, the pharmacist shall fill the  
109 prescription without such substitution or use of a new drug

110 manufacturer or distributor or return the prescription to the patient or  
 111 to such patient's representative for filling at another pharmacy. If a  
 112 pharmacist is unable to contact the patient's practitioner after making  
 113 reasonable efforts to do so, such pharmacist may exercise professional  
 114 judgment in refilling a prescription in accordance with the provisions  
 115 of subsection (b) of section 20-616. For purposes of this subsection,  
 116 "pharmacy" means a place of business where drugs and devices may  
 117 be sold at retail and for which a pharmacy license was issued pursuant  
 118 to section 20-594, including a hospital-based pharmacy when such  
 119 pharmacy is filling prescriptions for employees and outpatient care,  
 120 and a mail order pharmacy licensed by this state to distribute in this  
 121 state. "Pharmacy" does not include a pharmacy serving patients in a  
 122 long-term care facility, other institutional facility or a pharmacy that  
 123 provides 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, 2010	20-619

**PH**      *Joint Favorable*

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.

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***OFA Fiscal Note******State Impact:*** None***Municipal Impact:*** None***Explanation***

The bill prohibits retail pharmacists from substituting any alternative drug for a prescribed antiepileptic drug without the prior written approval of the prescribing practitioner. As the bill does not require coverage of these drugs it is not anticipated to impact costs to state or municipal prescription drug plans.

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

**OLR Bill Analysis****HB 5307*****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 name drug for any brand name one.

EFFECTIVE DATE: October 1, 2010

**BANNING SUBSTITUTIONS FOR ANTI-EPILEPTIC DRUGS**

The bill bans certain pharmacists, without the prescriber's written consent, from (1) substituting another brand name or generic name drug product 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 drugs 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 patient by email or fax

in order to obtain consent. If the prescriber does not consent, the pharmacist must fill the prescription without substitution or return it 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 the 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 this way just once.

## **BACKGROUND**

### ***Drug Substitution***

Under existing law, which the bill does not change, a prescriber may tell a pharmacist not to substitute a generic name 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 that 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 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

Yea 29    Nay 0    (03/15/2010)