



Senate

General Assembly

File No. 431

February Session, 2008

Substitute Senate Bill No. 654

Senate, April 3, 2008

The Committee on Public Health reported through SEN. HANDLEY of the 4th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING THE AVAILABILITY OF PRESCRIBED 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 Section 20-619 of the general statutes is repealed and the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, 2008*):

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 (j) 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) The commissioner, with the advice and assistance of the
94 commission, shall adopt regulations, in accordance with chapter 54, to
95 carry out the provisions of this section.

96 (j) Upon the initial filling or renewal of a prescription, if the patient
97 or a representative of the patient or the patient's practitioner informs
98 the pharmacy, in writing, that the prescription is used for the
99 treatment of epilepsy, a pharmacist shall not substitute an antiepileptic
100 drug or formulation of an antiepileptic drug, brand name or
101 manufacturer of a generic name using the National Drug Code system
102 for the treatment of epilepsy without consent of the patient's
103 practitioner. For purposes of obtaining the consent of the patient's
104 practitioner required for a drug substitution, a pharmacist shall notify
105 the patient's practitioner via facsimile transmission. If the patient, the
106 patient's representative or the patient's practitioner refuses the
107 substitution, the pharmacist shall fill the prescription without such
108 substitution or return the prescription to the patient or to such patient's
109 representative for filling at another pharmacy. For purposes of this
110 subsection, "pharmacy" includes a hospital-based pharmacy when

111 such pharmacy is filling prescriptions for employees and outpatient
112 care, and mail order pharmacies licensed by the state to distribute in
113 state. "Pharmacy" does not include pharmacies in long-term care
114 facilities.

115 Sec. 2. Subsection (a) of section 20-631 of the general statutes is
116 repealed and the following is substituted in lieu thereof (*Effective*
117 *October 1, 2008*):

118 (a) (1) One or more pharmacists licensed under this chapter who are
119 determined eligible in accordance with subsection (c) of this section,
120 and employed by a hospital may enter into a written protocol-based
121 collaborative drug therapy management agreement with one or more
122 physicians licensed under chapter 370 to manage the drug therapy of
123 individual patients receiving inpatient services in a hospital licensed
124 under chapter 368v, in accordance with subsections (b) to (d),
125 inclusive, of this section and subject to the approval of the hospital.
126 Each patient's collaborative drug therapy management shall be
127 governed by a written protocol specific to that patient established by
128 the treating physician in consultation with the pharmacist.

129 (2) One or more pharmacists licensed under this chapter who are
130 determined eligible in accordance with subsection (c) of this section
131 and employed by or under contract with a nursing home facility, as
132 defined in section 19a-521, may enter into a written protocol-based
133 collaborative drug therapy management agreement with one or more
134 physicians licensed under chapter 370 to manage the drug therapy of
135 individual patients receiving services in a nursing home facility, in
136 accordance with subsections (b) to (d), inclusive, of this section and
137 subject to the approval of the nursing home facility. Each patient's
138 collaborative drug therapy management shall be governed by a
139 written protocol specific to that patient established by the treating
140 physician in consultation with the pharmacist. Each such protocol shall
141 be reviewed and approved by the active organized medical staff of the
142 nursing home in accordance with the requirements of section 19-13-
143 D8t(i) of the Public Health Code.

144 (3) One or more pharmacists licensed under this chapter who are
 145 determined eligible in accordance with subsection (c) of this section
 146 and employed by or under contract with a hospital licensed under
 147 chapter 368v may enter into a written protocol-based collaborative
 148 drug therapy management agreement with one or more physicians
 149 licensed under chapter 370 to manage the drug therapy of individual
 150 patients receiving outpatient hospital care or services for diabetes,
 151 asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart
 152 failure or smoking cessation, including patients who qualify as
 153 targeted beneficiaries under the provisions of Section 1860D-
 154 4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with
 155 subsections (b) to (d), inclusive, of this section and subject to the
 156 approval of the hospital. Each patient's collaborative drug therapy
 157 management shall be governed by a written protocol specific to that
 158 patient established by the treating physician in consultation with the
 159 pharmacist.

160 (4) One or more pharmacists licensed under this chapter, who are
 161 determined eligible in accordance with subsection (c) of section 20-
 162 631a and employed by or under contract with a licensed community
 163 pharmacy, as defined in section 20-631a, may enter into a written
 164 protocol-based collaborative drug therapy management agreement
 165 with one or more physicians licensed under chapter 370 to manage a
 166 patient's refills of prescribed medications. Each patient's collaborative
 167 drug therapy management shall be governed by a written protocol
 168 specific to that patient established by the treating physician in
 169 consultation with the pharmacist.

This act shall take effect as follows and shall amend the following sections:

Section 1	October 1, 2008	20-619
Sec. 2	October 1, 2008	20-631(a)

PH Joint Favorable Subst.

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either chamber thereof for any purpose:

OFA Fiscal Note

State Impact: None

Municipal Impact: None

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis**sSB 654*****AN ACT CONCERNING THE AVAILABILITY OF PRESCRIBED ANTIEPILEPTIC DRUGS.*****SUMMARY:**

This bill permits community pharmacists to manage any patient's prescription refills under collaborative drug therapy management agreements with physicians and patient-specific protocols. It also limits pharmacists' ability to substitute another brand or generic form of an antiepileptic drug without consent from the patient's practitioner.

EFFECTIVE DATE: October 1, 2008

COLLABORATIVE AGREEMENTS

The bill permits pharmacists working in a "community pharmacy" either as employees or under contract to enter into protocol-based collaborative drug therapy management agreements with physicians to manage patients' prescription refills. By law, a community pharmacy is one that serves primarily noninstitutionalized patients living in a community setting.

The bill applies to any patient. A two-year pilot program authorized to run through the end of 2008 permits collaborative agreements concerning people with specific conditions, such as diabetes, hypertension, osteoporosis, and congestive heart failure.

Agreement and Protocol Terms

The pharmacist-physician agreement must be based on written protocols, and each patient's drug therapy management collaboration must be governed by a written protocol specific to him or her that the

treating physician establishes in consultation with the pharmacist.

By law, an agreement can authorize a pharmacist to start, modify, or discontinue a drug therapy the physician prescribes; administer drugs; and order associated lab tests. The patient-specific protocol must contain detailed directions about what the pharmacist can do. At a minimum, it must include the:

1. specific drug or drugs the pharmacist will manage;
2. terms and conditions under which the therapy can be implemented, modified, or discontinued;
3. conditions and events that require the pharmacist to contact the physician; and
4. lab tests the pharmacist can order.

A participating pharmacist must notify the treating physician within 24 hours after discontinuing a drug therapy and must report to him at least every 30 days on the patient's therapy. Any action the pharmacist performs under the protocol must be documented in the patient's medical record.

Each agreement and related protocols must be available for inspection at the Public Health and Consumer Protection departments. The patient-specific protocol must be placed in the patient's medical records.

Pharmacist Eligibility

The Pharmacy Commission must determine that a pharmacist is competent to participate in these agreements. In making this determination, the commission must use criteria based on the law's requirements for pharmacists' continuing education—at least 15 contact hours a year, with at least five hours attending a live demonstration and one hour in the area of pharmacy or drug law.

Regulations

The law permits the consumer protection commissioner to adopt regulations governing the minimum content of collaborative agreements and patient protocols.

ANTIEPILEPTIC DRUG SUBSTITUTION

The bill permits a patient or the patient's representative or practitioner to tell a pharmacy filling or refilling a prescription to treat epilepsy not to substitute another antiepileptic drug or formulation or a brand name or generic drug used to treat epilepsy without the practitioner's consent. It defines an antiepileptic drug as one used to treat epilepsy or prevent seizures. The pharmacy must be informed in writing. The bill excludes nursing home pharmacies from these requirements and includes hospital-based pharmacies that fill prescriptions for employees and outpatients.

A pharmacist who wants to substitute another drug must send the practitioner a fax to that effect. If the practitioner, the patient, or the patient's representative refuses the substitution, the pharmacist must fill the prescription or return it to the patient or representative to fill at another pharmacy.

The law already permits a practitioner to tell a pharmacist not to substitute for the brand name drug specified in the prescription. If the patient is a Medicaid, ConnPACE, or state-administered general assistance recipient, the practitioner must specify why the brand and dose is medical necessary and must (1) write "BRAND MEDICALLY NECESSARY" on the prescription form or its electronic equivalent or (2) telephone this message to the pharmacist and then send written certification of the medical necessity within 10 days.

BACKGROUND

Community Pharmacy Collaborative Agreement Pilot Program

PA 05-217 established a two-year pilot program that runs through the end of 2008. The pilot was never implemented.

It authorized collaborative agreements between physicians and 10 community pharmacists to manage the drug therapies of people with

specific conditions, such as diabetes, hypertension, osteoporosis, and congestive heart failure. Physicians and pharmacists had to follow the same agreement and protocol requirements the bill applies, and pharmacists' eligibility is determined in the same way. Records or information collected as part of the pilot program were exempt from disclosure under the Freedom of Information Act for six months after they were created or collected and could not be used as evidence in any judicial or administrative proceeding unless the law otherwise provides for their use (CGS § 20-631a).

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea 30 Nay 0 (03/17/2008)