Senate

General Assembly

File No. 329

January Session, 2015

Substitute Senate Bill No. 28

Senate, March 31, 2015

The Committee on General Law reported through SEN. LEONE of the 27th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING MANUFACTURER NAMES AND MEDWATCH REPORTING INFORMATION ON GENERIC DRUG CONTAINERS, THE ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM AND PHARMACIST CHANGES TO PRESCRIPTION DRUGS DISPENSED TO CERTAIN PATIENTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-617 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2016*):

(a) Each pharmacist shall include on the label of each prescription container: (1) The quantity of prescribed drug placed in such container, in addition to any other information required by law, **[**;**]** and (2) a prominently printed expiration date based on the manufacturer's recommended conditions of use and storage that can be read and understood by the ordinary individual. The expiration date required pursuant to subdivision (2) of this **[**section**]** subsection shall be no later than the expiration date determined by the manufacturer.

(b) In addition to the information required to be included on the

label of each prescription container pursuant to subsection (a) of this section, each pharmacist shall include on the label of each prescription container for a drug sold only by generic name, as defined in section 20-14a, and not by brand name, as defined in said section: (1) The name of the manufacturer of the generic drug placed in the container, and (2) the Internet web site address and toll-free telephone number for the United States Food and Drug Administration's safety information and adverse event reporting program (MedWatch).

Sec. 2. Section 21a-317 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2015*):

(a) Every practitioner who distributes, administers or dispenses any controlled substance or who proposes to engage in distributing, prescribing, administering or dispensing any controlled substance within this state shall (1) obtain a certificate of registration issued by the Commissioner of Consumer Protection in accordance with the provisions of this chapter, and (2) register for access to the electronic prescription drug monitoring program established pursuant to subsection (j) of section 21a-254. Registration for access to said program shall be in a manner prescribed by said commissioner.

(b) The commissioner shall not issue or renew a license of a practitioner who distributes, administers or dispenses any controlled substance or who proposes to engage in distributing, prescribing, administering or dispensing any controlled substance within this state unless such practitioner has obtained a certificate of registration and registered for access to the electronic prescription drug monitoring program established pursuant to subsection (j) of section 21a-254.

Sec. 3. (NEW) (*Effective October 1, 2015*) (a) As used in this section:

(1) "Complex or chronic medical condition" means a physical, behavioral or developmental condition that has been diagnosed or is being treated by a prescribing practitioner and: (A) Has no known cure, (B) is progressive, or (C) can be debilitating or fatal if left untreated or undertreated.

(2) "Rare medical condition" means a disease or condition that has been diagnosed or is being treated by a prescribing practitioner and that affects fewer than either: (A) Two hundred thousand persons in the United States, or (B) less than or equal to one out of one thousand five hundred persons worldwide.

(3) "Medically stable" means a determination that a patient's condition is not worsening made by a prescribing practitioner, based on the prescribing practitioner's clinical expertise, taking into account the patient's condition and response to treatment.

(4) "Drug" has the same meaning as provided in section 20-571 of the general statutes.

(5) "Pharmacist" has the same meaning as provided in section 20-571 of the general statutes.

(6) "Prescribing practitioner" has the same meaning as provided in section 20-571 of the general statutes.

(b) If a pharmacist has been informed that a patient is medically stable and diagnosed with a complex or chronic medical condition or a rare medical condition, the pharmacist may not change the drug prescribed to the patient without a medical basis for such change and the express written consent of the prescribing practitioner who prescribed the drug that is subject to the change.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2016*	20-617
Sec. 2	*October 1, 2015*	21a-317
Sec. 3	*October 1, 2015*	New section

GL *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

Explanation

The bill is not anticipated to result in a fiscal impact to the state employee and retiree health plan, the state's Medicaid program or municipalities. The bill does not preempt the state's current authorization or reimbursement process.

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis

sSB 28

AN ACT CONCERNING MANUFACTURER NAMES AND MEDWATCH REPORTING INFORMATION ON GENERIC DRUG CONTAINERS, THE ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM AND PHARMACIST CHANGES TO PRESCRIPTION DRUGS DISPENSED TO CERTAIN PATIENTS.

SUMMARY:

This bill prohibits a pharmacist from changing a patient's prescribed drug without a medical basis for doing so and the prescribing practitioner's express written consent if the pharmacist knows the patient is medically stable and diagnosed with a complex, chronic, or rare medical condition. Current law allows pharmacists to (1) substitute therapeutically equivalent generic drugs for prescribed drugs under certain circumstances and (2) modify prescribed drugs under collaborative drug therapy management agreements (CGS §§ 20-619 and 20-631).

The bill bars the consumer protection (DCP) commissioner from issuing or renewing a license of a practitioner who distributes, administers, or dispenses controlled substances, or seeks to do so, if the practitioner (1) is not properly registered with the agency or (2) failed to register for access to the state's electronic prescription drug monitoring program as existing law requires (see BACKGROUND). These practitioners include certain medical professionals, scientific investigators, hospitals, and other people or institutions that dispense in the course of professional practice or research.

Lastly, the bill expands the information pharmacists must put on generic prescription drug labels to include the manufacturer's name and contact information for MedWatch, a federal drug safety and reporting program.

EFFECTIVE DATE: October 1, 2015, except the prescription label provision takes effect January 1, 2016.

MEDICAL CONDITIONS

A "medically stable" patient is one whose condition the prescribing practitioner determines is not worsening, based on the practitioner's experience and taking into account the patient's condition and response to treatment.

A "complex or chronic medical condition" is a diagnosed or in-treatment condition that (1) has no known cure, (2) is progressive, and (3) can be debilitating or fatal if untreated or undertreated. The condition can be physical, behavioral, or developmental. A "rare medical condition" is a diagnosed or in-treatment disease or condition that affects fewer than (1) 200,000 people in the United States or (2) one in 1,500 people or fewer worldwide.

GENERIC DRUG LABELS

The bill adds to the information pharmacists must include on labels of generic prescription drugs. The law already requires pharmacists to put, on all labels, (1) the quantity of the prescribed drug, (2) an expiration date, and (3) any other information required by law.

Under the bill, for drugs sold only by generic name, pharmacists must also include the (1) manufacturer's name and (2) website and toll-free telephone number for MedWatch, the U.S. Food and Drug Administration's safety information and voluntary adverse event reporting program.

By law, a "generic name" is the chemical name or formula or the established name given by the United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary (CGS § 20-14a).

BACKGROUND

Electronic Prescription Drug Monitoring Program

This program requires DCP to collect prescription information from

pharmacies on certain controlled substances (drugs that are acceptable for medical use but may be abused). Pharmacists are required to electronically report certain information to DCP, including the date a drug was dispensed, dispenser identification and prescription number, and certain patient identification data. The information is made available to medical practitioners and others so that they can track their patients' history and prevent improper or illegal drug use.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 18 Nay 0 (03/12/2015)