General Assembly

Substitute Bill No. 28

January Session, 2015

SB00028GL 031615

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 Section 20-617 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2016*):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 Section 21a-317 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2015*):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.*