ANTI-SEIZURE DRUG NOTIFICATION

2008 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Eric K. Hutchings

Senate Sponsor: Curtis S. Bramble

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act by requiring notification of a prescribing practitioner when substituting a drug product equivalent for an epilepsy drug prescribed to treat or prevent seizures.

Highlighted Provisions:

This bill:

- requires a pharmacist or pharmacy intern who substitutes a drug product equivalent for an epilepsy drug prescribed to a patient to treat or prevent seizures to notify the prescribing practitioner prior to the substitution, regardless of whether the substitution is a substitution of a generic drug for another generic drug, a generic drug for a nongeneric drug, a nongeneric drug for another nongeneric drug, or a nongeneric drug for a generic drug;
- provides an exception to the notification requirement; and
- makes technical changes.

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-605, as enacted by Laws of Utah 2004, Chapter 280

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-605** is amended to read:

58-17b-605. Drug product equivalents.

(1) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug by brand or proprietary name may substitute [~~another~~] a drug product equivalent, as defined in Section 58-17b-102, for the prescribed drug only if:

(a) the purchaser specifically requests or consents to the substitution of a drug product equivalent;

(b) the [~~substituted~~] drug product equivalent is of the same generic type and is designated the therapeutic equivalent in the approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration;

(c) the [~~substituted~~] drug product equivalent is permitted to move in interstate commerce;

(d) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed drug, whether a substitute or not, and the substitution is not otherwise prohibited by this chapter;

(e) the prescribing practitioner has not indicated that [~~an equivalent~~] a drug product [~~is not to~~] equivalent may not be substituted for the drug, as provided in Subsection (5); and

(f) the substitution is not otherwise prohibited by law.

(2) (a) Each out-of-state mail service pharmacy dispensing a [~~substituted~~] drug product equivalent as a substitute for another drug into this state shall notify the patient of the substitution either by telephone or in writing.

(b) Each out-of-state mail service pharmacy shall comply with the requirements of this chapter with respect to [~~drugs which may be~~] a drug product equivalent substituted for another drug, including labeling and record keeping[~~, when dispensing substituted drug products~~].

(3) Pharmacists or pharmacy interns may not substitute without the prescriber's authorization on trade name drug product prescriptions unless the product is currently

categorized in the approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration as a drug product considered to be therapeutically equivalent to another drug product.

(4) A pharmacist or pharmacy intern who dispenses a prescription with a drug product equivalent under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.

(5) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that [~~an equivalent~~] a drug product equivalent not be substituted for a prescribed drug, the practitioner may indicate a prohibition on substitution either by writing "dispense as written" or [~~may sign~~] signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted".

(b) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on substitution and that indication shall be noted in writing by the pharmacist or pharmacy intern with the name of the practitioner and the words "orally by" and the initials of the pharmacist or pharmacy [~~practitioner~~] intern written after it.

(6) [~~The~~] A pharmacist or pharmacy intern who substitutes a drug product equivalent for a prescribed drug shall communicate the substitution[~~, if any, shall be communicated~~] to the purchaser. The drug product equivalent container shall be labeled with the name of the drug dispensed, and the pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both the name of the prescribed drug and the name of the drug product equivalent dispensed in its place.

(7) (a) For purposes of Subsection (7), "substitutes" means to substitute:

(i) a generic drug for another generic drug;

(ii) a generic drug for a nongeneric drug;

(iii) a nongeneric drug for another nongeneric drug; or

(iv) a nongeneric drug for a generic drug.

(b) A prescribing practitioner who makes a finding under Subsection (5)(a) for a patient

with a seizure disorder shall indicate a prohibition on substitution of a drug product equivalent in the manner provided in Subsection (5)(a) or (b).

(c) Except as provided in Subsection (7)(d), a pharmacist or pharmacy intern who cannot dispense the prescribed drug as written, and who needs to substitute a drug product equivalent for the drug prescribed to the patient to treat or prevent seizures shall notify the prescribing practitioner prior to the substitution.

(d) Notification under Subsection (7)(c) is not required if the drug product equivalent is paid for in whole or in part by Medicaid.

[~~(7)~~] (8) Failure of a licensed medical practitioner to specify that no substitution is authorized does not constitute evidence of negligence.