LEGISLATIVE GENERAL COUNSEL
₵ Approved for Filing: C.J. Dupont ₵
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H.B. 440

DRUG PRODUCT EQUIVALENT AMENDMENTS

2007 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Eric K. Hutchings

Senate Sponsor: _____

LONG TITLE

General Description:

This bill amends Pharmacy Practice Act provisions governing the substitution of a drug product equivalent for a drug specified in a prescription order.

Highlighted Provisions:

This bill:

- amends the Pharmacy Practice Act;
- expands general drug substitution provisions to apply to any type of substitution;
- deletes duplicative language restating the definition of "drug product equivalent," a term defined elsewhere in the Pharmacy Practice Act;
- except as specified, prohibits substitution of a drug product equivalent for a drug prescribed to treat or prevent seizures without the prescribing practitioner's authorization;
- deletes duplicative language permitting a pharmacist or pharmacy intern to substitute a drug product equivalent for another drug without the prescribing practitioner's authorization;
- makes clarifying changes; and
- makes technical corrections.

Monies Appropriated in this Bill:

None

Other Special Clauses:

H.B. 440

None

Utah Code Sections Affected:

AMENDS:

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

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 drug [~~product equivalent~~] for the prescribed drug only if:

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

(b) the [~~substituted~~] substitute drug is a 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~~] prescribed drug;

(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~~] dispensed 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~~] equivalent may not [~~to~~] be substituted for the drug, as provided in Subsection [~~(5)~~] (4); [~~and~~]

(f) if the prescribed drug has been prescribed in this instance to treat or prevent seizures, the pharmacist or pharmacy intern obtains the authorization of the prescribing practitioner, unless:

(i) the drug product equivalent will be paid for, either in whole or in part, by the Department of Health; and

(ii) (A) the drug product equivalent is a generic drug; and

(B) a Department of Health pharmacist has not overridden, pursuant to Subsection

58-17b-606(5), the generic mandate provision of Subsection 58-17b-606(4) and determined that use of a nongeneric drug would result in a financial benefit to the state; or

(iii) in accordance with Subsection 58-17b-606(4), the prescribing practitioner has demonstrated to the Department of Health a medical necessity for dispensing the drug product equivalent; and

[~~(f)~~] (g) 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~~], and in accordance with Subsection (1)(f), prescribing practitioner authorization.

[~~(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)~~] (3) 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)~~] (4) (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 another drug, the practitioner may indicate a prohibition on substitution either by writing "dispense as written" or may sign 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)~~] (5) The substitution, if any, shall be communicated to the purchaser. The container shall be labeled with the name of the drug product equivalent 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)~~] (6) Failure of a licensed medical practitioner to specify that no substitution is authorized does not constitute evidence of negligence.

Legislative Review Note
as of 2-6-07 10:46 AM

Office of Legislative Research and General Counsel

H.B. 440 - Drug Product Equivalent Amendments

Fiscal Note

2007 General Session

State of Utah

State Impact

Enactment of this bill is estimated to increase Medicaid expenditures and would require an ongoing General Fund appropriation to the Department of Health of $499,600 beginning in FY 2008. There would be a related increase of Federal Funds of $1,238,800.

	FY 2007 Approp.	FY 2008 Approp.	FY 2009 Approp.	FY 2007 Revenue	FY 2008 Revenue	FY 2009 Revenue
General Fund	$0	$499,600	$499,600	$0	$0	$0
Federal Funds	$0	$1,238,800	$1,238,800	$0	$0	$0
Total	**$0**	**$1,738,400**	**$1,738,400**	**$0**	**$0**	**$0**

Individual, Business and/or Local Impact

Enactment of this bill likely will not result in direct, measurable costs and/or benefits for individuals, businesses, or local governments.

2/12/2007, 11:44:05 AM, Lead Analyst: Eckersley, S.

Office of the Legislative Fiscal Analyst