

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:



28 **58-17b-605**, as enacted by Laws of Utah 2004, Chapter 280

29

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

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

32 **58-17b-605. Drug product equivalents.**

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

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

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

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

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

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

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

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

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

56 (3) Pharmacists or pharmacy interns may not substitute without the prescriber's
57 authorization on trade name drug product prescriptions unless the product is currently
58 categorized in the approved drug products with therapeutic equivalence evaluations prepared

59 by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration
60 as a drug product considered to be therapeutically equivalent to another drug product.

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

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

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

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

80 (7) (a) For purposes of Subsection (7) ~~Ĥ→~~ ~~[(b)]~~ ~~←Ĥ~~ , "substitutes" means to substitute:

81 (i) a generic drug for another generic drug;

82 (ii) a generic drug for a nongeneric drug;

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

84 (iv) a nongeneric drug for a generic drug.

85 (b) ~~Ĥ→~~ **A prescribing practitioner who makes a finding under Subsection (5)(a) for a**
85a **patient with a seizure disorder shall indicate a prohibition on substitution of a drug product**
85b **equivalent in the manner provided in Subsections (5)(a) or (b).**

85c (c) ~~←Ĥ~~ Except as provided in Subsection (7) ~~Ĥ→~~ ~~[(c)]~~ (d) ~~←Ĥ~~ , a pharmacist or pharmacy
85d intern who ~~Ĥ→~~ **cannot dispense the prescribed drug as written, and who needs to substitute**
86 **[substitutes]** ~~←Ĥ~~ a drug product equivalent for ~~Ĥ→~~ ~~[an epilepsy]~~ the ~~←Ĥ~~ drug prescribed to
86a ~~Ĥ→~~ ~~[-a]~~ the ~~←Ĥ~~ patient to treat or
87 prevent seizures shall notify the prescribing practitioner prior to the substitution.

88 ~~Ĥ→~~ ~~[(c)]~~ (d) ~~←Ĥ~~ Notification under Subsection (7) ~~Ĥ→~~ ~~[(b)]~~ (c) ~~←Ĥ~~ is not required if the
88a drug product equivalent is
89 paid for in whole or in part by Medicaid.

90 [~~7~~] (8) Failure of a licensed medical practitioner to specify that no substitution is
91 authorized does not constitute evidence of negligence.

Legislative Review Note
as of 12-13-07 10:43 AM

Office of Legislative Research and General Counsel

H.B. 361 - Anti-seizure Drug Notification

Fiscal Note

2008 General Session

State of Utah

State Impact

Enactment of this bill will not require additional appropriations.

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.
