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H.B. 69
1st Sub. (Buff)

Representative Rosalind J. McGee proposes the following substitute bill:

PHARMACEUTICAL COST REDUCTION AMENDMENTS

2004 GENERAL SESSION

STATE OF UTAH

Sponsor: Rosalind J. McGee

LONG TITLE

General Description:

This bill requires a pharmacist to dispense a generic drug in substitution of another drug if the generic is less expensive and is a therapeutically equivalent drug product.

Highlighted Provisions:

This bill:

- requires a pharmacist to dispense a generic drug in substitution of another drug if the generic is less expensive and is a therapeutically equivalent drug product;
- requires a pharmacist, pharmacy intern, or pharmacy technician to inform the person presenting the prescription that he may refuse to accept the substitution, unless the pharmacist is being paid for the drug by a governmental agency; and
- does not apply to:
  - any inpatient of a hospital; or
  - a prescription drug if the substitution would make the transaction ineligible for reimbursement by a third party.

Monies Appropriated in this Bill:

None

Other Special Clauses:

This bill provides a coordination clause.

Utah Code Sections Affected:

AMENDS:

58-17a-605.1, as last amended by Chapter 18, Laws of Utah 2002, Fifth Special Session

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

Section 1. Section **58-17a-605.1** is amended to read:

58-17a-605.1. Restrictive drug formulary prohibited -- Dispensing of generic drugs.

(1) As used in this section:

(a) "generic form" means a prescription drug that is available in generic form and has an A rating in the United States Pharmacopeia and Drug Index;

(b) "legend drug" means any drug that requires a prescription under state or federal law; and

(c) "restrictive drug formulary" means a list of legend drugs, other than drugs for cosmetic purposes, that are prohibited by the Utah Department of Health from dispensation, but are approved by the federal Food and Drug Administration.

(2) A practitioner may prescribe legend drugs in accordance with this chapter that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of his patient.

(3) Except as provided in Subsection (4), the Utah Department of Health may not maintain a restrictive drug formulary that restricts a physician's ability to treat a patient with a legend drug that has been approved and designated as safe and effective by the federal Food and Drug Administration, except for drugs for cosmetic purposes.

(4) When a multisource legend drug is available in the generic form, the Department of Health may only reimburse for the generic form of the drug unless the treating physician demonstrates to the Department of Health a medical necessity for dispensing the nongeneric, brand-name legend drug.

(5) This section does not affect the state's ability to exercise the exclusion options available under the federal Omnibus Budget Reconciliation Act of 1990.

(6) (a) Except as otherwise provided in this section, if a practitioner has prescribed a drug by brand name and the practitioner has not indicated, by a method set forth in Subsection

(6)(c), that a substitution is prohibited, the pharmacist or pharmacy intern who fills or refills the prescription shall dispense, in substitution, another drug which is available to him if:

(i) the substituted drug is less expensive than the drug prescribed by brand name;

(ii) the substituted drug is of the same generic type and is designated a 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;

(iii) the substituted drug is permitted to move in interstate commerce; and

(iv) 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;

(b) Before a pharmacist dispenses a drug in substitution for a drug prescribed by brand name, the pharmacist, pharmacy intern, or pharmacy technician shall:

(i) advise the person who presents the prescription that the pharmacist intends to dispense a drug in substitution; and

(ii) advise the person that he may refuse to accept the drug that the pharmacist intends to dispense in substitution, unless the pharmacist is being paid for the drug by a governmental agency, in which case the pharmacist shall dispense the drug as provided in Subsection (4).

(iii) If a person refuses to accept the drug that the pharmacist intends to dispense in substitution, the pharmacist shall dispense the drug prescribed by brand name, unless the pharmacist is being paid for the drug by a governmental agency, in which case the pharmacist shall dispense the drug as provided in Subsection (4).

(c) A pharmacist shall not dispense a drug in substitution for a drug prescribed by brand name:

(i) if the practitioner has indicated that a substitution is prohibited using one or more of the following methods:

(A) by oral communication to the pharmacist; or

(B) by including the handwritten words "Dispense as Written" on a prescription that is given to the pharmacist, or in the case of an electronically transmitted prescription, including faxed prescriptions, the practitioner expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary by indicating "Dispense as Written"; or

(ii) 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.

(d) Subsections (6)(c)(i) and (ii) does not apply to prescriptions paid for by the Department of Health pursuant to Subsection (4).

(e) The provisions of this section also apply to a prescription issued to a person by a practitioner from outside this state if the practitioner has not indicated, by a method set forth in Subsection (6)(c), that a substitution is prohibited or the practitioner has indicated that a specific alternative product is medically necessary.

(f) The provisions of this Subsection (6) do not apply to:

(i) a prescription drug that is dispensed to any inpatient of a hospital by an inpatient pharmacy which is associated with that hospital; or

(ii) a prescription drug that is dispensed to any person by a pharmacist if the substitution:

(A) would violate the terms of a health care plan that maintains a mandatory, exclusive, or closed formulary for its coverage for prescription drugs; or

(B) would otherwise make the transaction ineligible for reimbursement by a third party.

Section 2. **Coordinating H.B. 69 with S.B. 114.**

If this H.B. 69 and S.B. 114, Amendments to Prescribing, Preparation, and Dispensing of Prescription Drugs, both pass, it is the intent of the Legislature that:

(1) Section 58-17a-605.1 in H.B. 69 is repealed; and

(2) Section 58-17b-605 in S.B. 114 shall be 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:

(a) shall substitute another therapeutically equivalent generic drug if:

(i) the therapeutically equivalent generic drug is less expensive than the drug prescribed by brand name;

(ii) the pharmacist, pharmacy intern, or pharmacy technician advises the person who presents the prescription that:

(A) the pharmacist intends to dispense a drug in substitution; and

(B) if the person refuses to accept the drug that the pharmacist intends to dispense in substitution, the pharmacist shall dispense the drug prescribed by brand name, unless the pharmacist is being paid for the drug by a governmental agency, in which case the pharmacist shall dispense the drug as provided in Subsection 59-17b-606(4); and

(iii) the requirements of Subsection (1)(b)(ii) through (vi) are met; and

(b) may substitute another drug product equivalent if the provisions of Subsection (1)(a)(i) do no apply, and if:

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

(ii) the substituted drug is of the same generic type and is designated a 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;

(iii) the substituted drug product is permitted to move in interstate commerce;

(iv) 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;

(v) the prescribing practitioner has not indicated that an equivalent drug product is not to be substituted as provided in Subsection (5); and

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

(2) (a) Each out-of-state mail service pharmacy dispensing a substituted drug product into this state shall notify the patient of 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 substituted, 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 practitioner, it is in the best interest of the patient that an equivalent drug product not be substituted, the practitioner may indicate a prohibition on substitution by writing "dispense as written" or in the case of an electronically transmitted prescription, the practitioner expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary by indicating "dispense as written."

(b) If the prescription is communicated orally by the 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 pharmacy practitioner written after it.

(6) The substitution, if any, shall be communicated to the purchaser. The 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 dispensed in its place.

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

(8) The requirements of Subsection (1)(a) do not apply to:

(a) a prescription drug that is dispensed to any inpatient of a hospital by an inpatient pharmacy which is associated with that hospital; or

(b) a prescription drug that is dispensed to any person by a pharmacist if the substitution:

(i) would violate the terms of a health care plan that maintains a mandatory, exclusive, or closed formulary for its coverage for prescription drugs; or

(ii) should otherwise make the transaction ineligible for reimbursement by a third party."