LEGISLATURE OF NEBRASKA

ONE HUNDREDTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 631

Introduced by Dierks, 40

Read first time January 17, 2007

Committee: Health and Human Services

A BILL

FOR AN ACT relating to the Nebraska Drug Product Selection Act; to amend section 71-5401.01, Reissue Revised Statutes of Nebraska, and sections 71-5402 and 71-5403, Revised Statutes Cumulative Supplement, 2006; to prohibit interchange of anti-epileptic drugs; to define terms; to harmonize provisions; and to repeal the original sections.

Be it enacted by the people of the State of Nebraska,

Section 1. Section 71-5401.01, Reissue Revised Statutes of Nebraska, is amended to read:

71-5401.01 Sections 71-5401.01 to 71-5409 and section 4 of this act shall be known and may be cited as the Nebraska Drug Product Selection Act.

Sec. 2. Section 71-5402, Revised Statutes Cumulative Supplement, 2006, is amended to read:

71-5402 For purposes of the Nebraska Drug Product Selection Act, unless the context otherwise requires:

(1) Anti-epileptic drug means any drug prescribed for the treatment of epilepsy or the treatment or prevention of seizures;

(2) Bioequivalent means drug products: (a) That are legally marketed under regulations promulgated by the federal Food and Drug Administration; (b) that are the same dosage form of the identical active ingredients in the identical amounts as the drug product prescribed; (c) that comply with compendial standards and are consistent from lot to lot with respect to (i) purity of ingredients, (ii) weight variation, (iii) uniformity of content, and (iv) stability; and (d) for which the federal Food and Drug Administration has established bioequivalent standards or has determined that no bioequivalence problems exist;

~~(2)~~ (3) Board means the Board of Pharmacy;

~~(3)~~ (4) Brand name means the proprietary or trade name selected by the manufacturer, distributor, or packager for a drug product and placed upon the labeling of such product at the time

of packaging;

~~(4)~~ (5) Chemically equivalent means drug products that contain amounts of the identical therapeutically active ingredients in the identical strength, quantity, and dosage form and that meet present compendial standards;

~~(5)~~ (6) Department means the Department of Health and Human Services Regulation and Licensure;

~~(6)~~ (7) Drug product means any drug or device as defined in section 71-1,142;

~~(7)~~ (8) Drug product select means to dispense, without the practitioner's express authorization, an equivalent drug product in place of the brand-name drug product contained in a medical order of such practitioner;

~~(8)~~ (9) Epilepsy means a neurological condition characterized by recurrent seizures;

(10) Equivalent means drug products that are both chemically equivalent and bioequivalent;

~~(9)~~ (11) Generic name means the official title of a drug or drug combination as determined by the United States Adopted Names Council and accepted by the federal Food and Drug Administration of those drug products having the same active chemical ingredients in the same strength and quantity;

~~(10)~~ (12) Interchange means the substitution of one version of an anti-epileptic drug for the anti-epileptic drug originally prescribed, including (a) a generic for the prescribed

brand, (b) a brand for the prescribed generic, (c) a generic by one manufacturer for a generic by a different manufacturer, (d) a different formulation of the prescribed anti-epileptic drug, or (e) a different anti-epileptic drug;

(13) Medical order has the definition found in section 71-1,142;

~~(11)~~ (14) Pharmacist means a pharmacist licensed under the Uniform Licensing Law; ~~and~~

~~(12)~~ (15) Practitioner has the definition found in section 71-1,142; and ~~.~~

(16) Seizure means an acute clinical change secondary to a brief disturbance in the electrical activity of the brain.

Sec. 3. Section 71-5403, Revised Statutes Cumulative Supplement, 2006, is amended to read:

71-5403 (1) A pharmacist may drug product select except when:

(a) A practitioner designates that drug product selection is not permitted by specifying on the face of the prescription or by telephonic, facsimile, or electronic transmission that there shall be no drug product selection. For written prescriptions, the practitioner shall specify in his or her own handwriting on the prescription the phrase "no drug product selection", "dispense as written", "brand medically necessary", or "no generic substitution" or the notation "N.D.P.S.", "D.A.W.", or "B.M.N." or words or notations of similar import to indicate that drug product selection

is not permitted. The pharmacist shall note "N.D.P.S." or "No Drug Product Selection" on the face of the prescription to indicate that drug product selection is not permitted if such is communicated orally by the prescribing practitioner; ~~or~~

(b) A patient or designated representative or caregiver of such patient instructs otherwise; or ~~.~~

(c) Prohibited pursuant to section 4 of this act.

(2) A pharmacist shall not drug product select a drug product unless:

(a) The drug product, if it is in solid dosage form, has been marked with an identification code or monogram directly on the dosage unit;

(b) The drug product has been labeled with an expiration date;

(c) The manufacturer, distributor, or packager of the drug product provides reasonable services, as determined by the board, to accept the return of drug products that have reached their expiration date; and

(d) The manufacturer, distributor, or packager maintains procedures for the recall of unsafe or defective drug products.

Sec. 4. A pharmacist may not interchange an anti-epileptic drug without prior notification and the signed, informed consent of the prescribing practitioner and the patient or the patient's parent, legal guardian, or spouse.

Sec. 5. Original section 71-5401.01, Reissue Revised

Statutes of Nebraska, and sections 71-5402 and 71-5403, Revised Statutes Cumulative Supplement, 2006, are repealed.