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**FIRST ENGROSSMENT**

Sixtieth
Legislative Assembly
of North Dakota

# ENGROSSED HOUSE BILL NO. 1431

Introduced by

Representatives Damschen, Kaldor, Weisz

Senator Warner

A BILL for an Act to amend and reenact section 19-02.1-14.1 of the North Dakota Century Code, relating to restricting pharmacists from dispensing substitute epilepsy drugs.

**BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

**SECTION 1. AMENDMENT.** Section 19-02.1-14.1 of the North Dakota Century Code is amended and reenacted as follows:

**19-02.1-14.1. Definitions - Label of prescription drugs - Selecting and dispensing generic name drugs - Identification of prescription drugs.**

1. As used in this section, unless the subject matter or context otherwise requires:
   a. "Anti-epileptic drug" means any drug for the treatment of epilepsy or a drug that is used to treat or prevent seizures. The term does not include an anti-epileptic drug that is used to treat conditions other than epilepsy or to treat or prevent seizures.
   b. "Brand name" means the registered trademark name given to a drug or medicine by its manufacturer, labeler, or distributor.
   ~~b.~~ c. "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer or distributor of the drug, or both.
   ~~c.~~ d. "Distributor" means a person who distributes for resale a drug in solid dosage form under that person's own label even though that person is not the actual manufacturer of the drug.
   e. "Epilepsy" means a neurological condition characterized by recurrent seizures.
   ~~d.~~ f. "Generic name" means the established name or official chemical name of the drug, drug product, or medicine.

g. "Interchange" means the substitution of one version of the same anti-epileptic drug, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed anti-epileptic drug, or a different anti-epileptic drug for the anti-epileptic drug originally prescribed.

~~e.~~ h. "Prescription drug" means a drug defined by section 503(b) of the federal act and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription" or "Rx Only".

i. "Seizure" means an acute clinical change secondary to a brief disturbance in the electrical activity of the brain.

~~f.~~ j. "Solid dosage form" means capsules or tablets intended for oral use.

~~g.~~ k. "Therapeutically equivalent" means a generic name drug product that would elicit the same therapeutic response from the same person as a brand name drug product.

2. Drugs or medicines dispensed pursuant to a prescription must bear a label permanently affixed to the immediate container in which the drug or medicine is dispensed or delivered and which is received by the purchaser or patient. The label must bear the brand name or the generic name, strength, quantity, serial number, date of dispensing, patient name, and directions for use of the drug or medicine, except when the physician or other health care provider authorized by law to prescribe drugs or medicine has notified the pharmacist that the appearance of the name on the label would be alarming to or detrimental to the well-being of the purchaser of the prescription.

3. If a practitioner prescribes a drug by its brand name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated therapeutical equivalency as the one prescribed for dispensing and sale to the patient unless the practitioner specifically indicates in the practitioner's own handwriting "brand necessary" on a written prescription or expressly indicates that an oral prescription is to be dispensed as communicated. The pharmacist shall note the instructions on the file

copy of the prescription. A reminder legend must be placed on all prescription forms. The legend must state "In order to require that a brand name product be dispensed, the practitioner must handwrite the words 'brand necessary'.". The legend printed on the prescription form must be in at least six-point uppercase print. The pharmacist may not substitute a generic name drug product unless its price to the purchaser is less than the price of the prescribed drug product. In addition, a pharmacist may not substitute drug products in the following dosage forms: enteric coated tablets, controlled release products, injectable suspensions other than antibiotics, suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity, and different delivery systems for aerosol and nebulizer drugs. In the event that any drug listed above is, subsequent to January 1, 1982, determined to be therapeutically equivalent, then the previously mentioned substitution ban is automatically removed for that drug. The pharmacist shall inform the person receiving the drug when a prescription for a brand name drug product does not require that the prescribed drug be dispensed and of the person's right to refuse a generic name drug product selected by the pharmacist. The pharmacy file copy of every prescription must include the brand name, if any, or the name of the manufacturer, packer, or distributor of the generic name drug dispensed. A pharmacist who selects and dispenses a therapeutically equivalent generic name drug product shall assume no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its generic name. The practitioner is not liable for the substitution made by a pharmacist.

4. In the case of a prescription for which a maximum allowable cost program for purposes of reimbursement has been established under title XIX of the federal Social Security Act, the following also apply:

   a. If the practitioner has instructed the pharmacist to dispense as written, the words "brand necessary" must also be written on the prescription in the practitioner's own handwriting. The pharmacist may dispense a therapeutically equivalent generic name drug product if this handwritten instruction does not appear on the prescription.

b. If the pharmacist is instructed orally to dispense a brand name drug as prescribed, the pharmacist shall reduce the prescription to writing and shall note the instructions on the file copy of the prescription. The prescription must then be signed by the practitioner and the words "brand necessary" must also be written on the prescription in the practitioner's own handwriting.

c. If the practitioner has not instructed the pharmacist to dispense a brand name drug or medicine and the patient specifically requests a brand name drug or medicine, the patient shall pay the difference between the price to the patient of the brand name drug or medicine and the therapeutically equivalent generic name drug or medicine if the price of the brand name drug or medicine is higher.

5. A pharmacist may not select and dispense a different drug product for a prescribed drug product unless it has been manufactured with the following minimum manufacturing standards and practices by a manufacturer who:

a. Marks capsules and tablets with identification code or monogram.

b. Labels products with their expiration date.

c. Provides reasonable services to accept return goods that have reached their expiration date.

d. Provides the pharmacist with information from which it can be determined whether a drug product is therapeutically equivalent.

e. Maintains recall capabilities for unsafe or defective drugs.

6. Notwithstanding any other provision of this section or other provision of law, a pharmacist may not interchange an anti-epileptic drug or formulation of an anti-epileptic drug for the treatment of seizures or epilepsy without notification of the prescribing practitioner and the signed informed consent of the interchange from the patient or the consent of the patient's parent, legal guardian, or spouse. If a pharmacist dispenses a refill of a prescription drug for epilepsy or for the treatment or prevention of convulsions upon the expiration of a prescription order for the same epilepsy drug, the pharmacist shall dispense the same prescription drug product from the same manufacturer that was last dispensed, unless the pharmacist obtains and documents the consent of the practitioner who issued the

prescription and the consent of the patient or the consent of the patient's parent, legal guardian, or spouse.

7. No prescription drug in solid dosage form may be manufactured or distributed in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug.

~~7.~~ 8. All manufacturers and distributors of prescription drugs in solid dosage form shall provide to the department or board of pharmacy, upon request, a listing of all such prescription drugs identifying by code imprint the manufacturer and the specific type of drug. The listing must at all times be kept current by all manufacturers and distributors subject to the provisions of this section.

~~8.~~ 9. The board of pharmacy may grant exemptions from the requirements of this section upon application by any drug manufacturer or distributor which shows size, physical characteristics, or other unique characteristics of a drug that render the use of a code imprint on the drug impractical or impossible. Any exemption granted by the board of pharmacy must be included by the manufacturer or distributor in the listing required by this section. The listing must describe the physical characteristics and type of drug to which the exemption relates.

~~9.~~ 10. All prescription drugs in solid dosage form that are possessed, distributed, sold, or offered for sale in violation of the provisions of this section must be deemed misbranded and must be seized by the department or board of pharmacy.