SENATE BILL 870

47TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2005

INTRODUCED BY

John T. L. Grubesic

AN ACT

RELATING TO DRUGS; PROVIDING FOR PEDIGREES AND REVISING DEFINITIONS IN THE NEW MEXICO DRUG, DEVICE AND COSMETIC ACT; CHANGING PENALTIES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

Section 1. Section 26-1-2 NMSA 1978 (being Laws 1967, Chapter 23, Section 2, as amended) is amended to read:

"26-1-2. DEFINITIONS.--As used in the New Mexico Drug, Device and Cosmetic Act:

A. "board" means the board of pharmacy or its duly authorized agent;

B. "person" includes individual, partnership, corporation, association, institution or establishment;

C. "biological product" means [~~any~~] a virus, therapeutic serum, toxin, antitoxin or analogous product

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applicable to the prevention, treatment or cure of diseases or injuries of man and domestic animals and, as used within the meaning of this definition:

(1) a "virus" is interpreted to be a product containing the minute living cause of an infectious disease and includes filterable viruses, bacteria, rickettsia, fungi and protozoa;

(2) a "therapeutic serum" is a product obtained from blood by removing the clot or clot components and the blood cells;

(3) a "toxin" is a product containing a soluble substance poisonous to laboratory animals or man in doses of one milliliter or less of the product and having the property, following the injection of nonfatal doses into an animal, or causing to be produced therein another soluble substance that specifically neutralizes the poisonous substance and that is demonstrable in the serum of the animal thus immunized; and

(4) an "antitoxin" is a product containing the soluble substance in serum or other body fluid of an immunized animal that specifically neutralizes the toxin against which the animal is immune;

D. "controlled substance" means [~~any~~] a drug, substance or immediate precursor enumerated in Schedules I through V of the Controlled Substances Act;

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E. "drug" means articles:

(1) [~~articles~~] recognized in an official compendium;

(2) [~~articles~~] intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals and includes the domestic animal biological products regulated under the federal Virus-Serum-Toxin Act, 37 Stat 832-833, 21 U.S.C. 151-158, and the biological products applicable to man regulated under Federal 58 Stat 690, as amended, 42 U.S.C. 216, Section 351, 58 Stat 702, as amended, and 42 U.S.C. 262;

(3) [~~articles~~] other than food that affect the structure or any function of the body of man or other animals; and

(4) [~~articles~~] intended for use as a component of Paragraph (1), (2) or (3) of this subsection, but does not include devices or their component parts or accessories;

F. "dangerous drug" means a drug, other than a controlled substance enumerated in Schedule I of the Controlled Substances Act, that because of a potentiality for harmful effect or the method of its use or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug and hence for which adequate directions for use cannot be prepared. "Adequate directions for use" means directions under

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which the layman can use a drug or device safely and for the purposes for which it is intended. A drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe [~~such~~] the drug if it:

(1) is a habit-forming drug and contains any quantity of a narcotic or hypnotic substance or a chemical derivative of such substance that has been found under the federal act and the board to be habit forming;

(2) because of its toxicity or other potential for harmful effect or the method of its use or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer or prescribe the drug;

(3) is limited by an approved application by Section 505 of the federal act to the use under the professional supervision of a practitioner licensed by law to administer or prescribe the drug;

(4) bears the legend: "Caution: federal law prohibits dispensing without prescription.";

(5) bears the legend: "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."; or

(6) bears the legend "RX only";

G. "counterfeit drug" means [~~a drug other than a controlled substance that, or the container or labeling of~~

~~which, without authorization, bears the trademark, trade name or other identifying mark, imprint or device or any likeness of a drug manufacturer, processor, packer or distributor other than the person who manufactured, processed, packed or distributed the drug and that falsely purports or is represented to be the product of or to have been packed or distributed by such other drug manufacturer, processor, packer or distributor~~] drugs that are deliberately and fraudulently mislabeled with respect to their identities, ingredients or sources. Types of pharmaceutical counterfeits may include:

(1) "identical copies", which are counterfeits made with the same ingredients, formulas and packaging as the originals but not made by the original manufacturer;

(2) "look-alikes", which feature high-quality packaging and convincing appearances but contain little or no active ingredients and may contain harmful substances;

(3) "rejects", which are drugs that have been rejected by the manufacturer for not meeting quality standards; and

(4) "re-labels", which have passed their expiration dates or have been distributed by unauthorized foreign sources and may include placebos created for late-phase clinical trials;

H. "device", except when used in Subsection P of this section and in Subsection G of Section 26-1-3, Subsection

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L and Paragraph (4) of Subsection A of Section 26-1-11 and Subsection C of Section 26-1-24 NMSA 1978, means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, that is:

(1) recognized in an official compendium;

(2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals; or

(3) intended to affect the structure or a function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and that is not dependent on being metabolized for achievement of any of its principal intended purposes;

I. "prescription" means an order given individually for the person for whom prescribed, either directly from the prescriber to the pharmacist or indirectly by means of a written order signed by the prescriber, and bearing the name and address of the prescriber, his license classification, the name and address of the patient, the name and quantity of the drug prescribed, directions for use and the date of issue. No person other than a practitioner shall prescribe or write a prescription;

J. "practitioner" means a physician, doctor of

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oriental medicine, dentist, veterinarian, certified nurse practitioner, clinical nurse specialist, pharmacist, pharmacist clinician, certified nurse-midwife, physician assistant, prescribing psychologist or other person licensed or certified to prescribe and administer drugs that are subject to the New Mexico Drug, Device and Cosmetic Act;

K. "cosmetic" means:

(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; and

(2) articles intended for use as a component of any articles enumerated in Paragraph (1) of this subsection, except that the term shall not include soap;

L. "official compendium" means the official United States pharmacopoeia national formulary or the official homeopathic pharmacopoeia of the United States or any supplement to either of them;

M. "label" means a display of written, printed or graphic matter upon the immediate container of an article. A requirement made by or under the authority of the New Mexico Drug, Device and Cosmetic Act that any word, statement or other information appear on the label shall not be considered to be complied with unless the word, statement or other information

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also appears on the outside container or wrapper, if any, of the retail package of the article or is easily legible through the outside container or wrapper;

N. "immediate container" does not include package liners;

O. "labeling" means all labels and other written, printed or graphic matter:

(1) on an article or its containers or wrappers; or

(2) accompanying an article;

P. "misbranded" means a label to an article that is misleading. In determining whether the label is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or any combination of the foregoing, but also the extent to which the label fails to reveal facts material in the light of such representations or material with respect to consequences that may result from the use of the article to which the label relates under the conditions of use prescribed in the label or under such conditions of use as are customary or usual;

Q. "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of drugs, devices

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or cosmetics;

R. "antiseptic", when used in the labeling or advertisement of an antiseptic, shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder or such other use as involves prolonged contact with the body;

S. "new drug" means [~~any~~] a drug:

(1) the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and efficacy of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof; or

(2) the composition of which is such that the drug, as a result of investigation to determine its safety and efficacy for use under such conditions, has become so recognized, but that has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions;

T. "contaminated with filth" applies to a drug, device or cosmetic not securely protected from dirt, dust and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations, or a drug, device or cosmetic found to contain dirt, dust, foreign or injurious

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contamination or infestation;

U. "selling of drugs, devices or cosmetics" shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale and the sale and the supplying or applying of any such article in the conduct of a drug or cosmetic establishment;

V. "color additive" means a material that:

(1) is a dye, pigment or other substance made by a process of synthesis or similar artifice or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, mineral, animal or other source; or

(2) when added or applied to a drug or cosmetic or to the human body or a part thereof, is capable, alone or through reaction with other substances, of imparting color thereto; except that such term does not include any material that has been or hereafter is exempted under the federal act;

W. "federal act" means the Federal Food, Drug and Cosmetic Act;

X. "restricted device" means a device for which the sale, distribution or use is lawful only upon the written or oral authorization of a practitioner licensed by law to administer, prescribe or use the device and for which the

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federal food and drug administration requires special training or skills of the practitioner to use or prescribe. This definition does not include custom devices defined in the federal act and exempt from performance standards or premarket approval requirements under Section 520(b) of the federal act; [~~and~~]

Y. "prescription device" means a device that, because of its potential for harm, the method of its use or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed in this state to direct the use of such device and for which "adequate directions for use" cannot be prepared, but that bears the label: "Caution: federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "doctor of oriental medicine", "dentist", "veterinarian", "certified nurse practitioner", "clinical nurse specialist", "pharmacist", "pharmacist clinician", "certified nurse-midwife" or with the descriptive designation of any other practitioner licensed in this state to use or order the use of the device; and

Z. "pedigree" means the recorded history of a drug."

Section 2. Section 26-1-16 NMSA 1978 (being Laws 1967, Chapter 23, Section 16, as amended) is amended to read:

"26-1-16. DANGEROUS DRUGS--CONDITIONS FOR SALE--

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PRESCRIPTION REFILLING--LIMITATIONS.--

A. It is unlawful for any person to sell, dispose of or possess any dangerous drugs, except:

(1) manufacturers, wholesalers or distributors or their agents or employees licensed by the board to ship dangerous drugs into the state; or

(2) distributors, wholesalers, hospitals, nursing homes, clinics or pharmacies and other authorized retailers of dangerous drugs in this state licensed by the board, and appropriate records of dangerous drugs receipt, pedigree and disposition are kept. These records shall be open to inspection by any enforcement officer of this state.

B. Practitioners licensed in this state may prescribe, provide samples of and dispense any dangerous drug to a patient where there is a valid physician-patient relationship. A record of all such dispensing shall be kept showing the date the drug was dispensed and bearing the name and address of the patient to whom dispensed. It is the duty of every licensed physician, dentist, veterinarian, pharmacist or person holding a limited license issued under Subsection B of Section 61-11-14 NMSA 1978, when dispensing any dangerous drug, to mark on the dispensing container the name of the patient, the date dispensed, the name and address of the person dispensing the drug, the name and strength of the drug, expiration date where applicable, adequate directions for use

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and the prescription number when applicable. All official compendium requirements for the preservation, packaging, labeling and storage of dangerous drugs are applicable where drugs are held for dispensing to the public, whether by a pharmacy, clinic, hospital or practitioner.

C. Pharmacists are prohibited from selling or disposing of any dangerous drug except on prescription of a practitioner and except as such sale or possession is authorized under Subsection A of this section. It is the duty of all pharmacists to keep an accurate record of all disposals, which record shall be open to inspection by any enforcement officer of this state.

D. No enforcement officer having knowledge by virtue of his office of any prescription, order or record shall divulge such knowledge except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosecution or proceeding the person to whom such prescriptions, orders or records relate is a party.

E. It is unlawful, except as otherwise authorized under Subsection A of this section or the Controlled Substances Act and except for the college of pharmacy of the university of New Mexico or a public health laboratory, for any person to possess any dangerous drug unless such substance has been dispensed to him either directly by a practitioner or on a

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prescription.

F. All records required to be kept under the provisions of the New Mexico Drug, Device and Cosmetic Act shall be preserved for a period of three years; provided that records requirements do not apply to the administration of a drug to a patient upon whom the practitioner personally attends; and provided that records of controlled substances shall be kept in accordance with the provisions of the Controlled Substances Act.

G. No prescription may be lawfully refilled:

(1) if it is marked by the issuing practitioner as not to be refilled;

(2) when the practitioner indicates a specific number of refills or a specific period of time, on the original prescription calling for a dangerous drug, it may be refilled the number of times or for the period of time indicated; provided, the date of refill, the initials of the pharmacist refilling the prescription and the amount of drug dispensed, if it differs from the amount called for on the original prescription, is recorded on the original prescription; and provided that a prescription issued for drugs controlled by the Controlled Substances Act shall comply with that act;

(3) when the practitioner does not indicate refill instructions on the original prescription calling for a dangerous drug, unless:

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(a) the practitioner is contacted orally, by telephone, telegraph or other means of communication for instruction; and

(b) if authorization to refill is given the pharmacist, the following information will be immediately transferred to the original prescription: 1) date; 2) name of person authorizing the refill; 3) pharmacist's initials; and 4) amount dispensed if different than the amount indicated on the original prescription;

(4) when the practitioner indicates on the original prescription calling for dangerous drugs that it may be refilled "prn", the pharmacist may refill it within the limits of the dosage directions for a period of twelve months; provided the date of refilling and the initials of the pharmacist are recorded on the original prescription. At the expiration of the twelve-month period, the practitioner must be contacted for a new prescription; provided that this is not to be construed to apply to those drugs regulated by the Controlled Substances Act; and

(5) the board may adopt and promulgate regulations to permit the use of computer systems for the storage and retrieval of prescription records for the purpose of refilling a prescription.

H. Nothing in this section shall prevent the owner of livestock or his consignee or their employees to be in

possession of drugs for their use in performing routine, accepted livestock management practices in the care of livestock belonging to the owner, and the drugs are labeled as being restricted to animal use only; provided that, if such drugs bear the legend: "CAUTION: federal law restricts this drug to use by or on the order of a licensed veterinarian", the drugs may be used or distributed only as provided in Subsection A of Section 26-1-15 NMSA 1978."

Section 3. Section 26-1-18 NMSA 1978 (being Laws 1972, Chapter 84, Section 50) is amended to read:

"26-1-18. PROMULGATING REGULATIONS--PROCEDURE.--

A. The board of pharmacy may promulgate regulations for the efficient enforcement of the New Mexico Drug, Device and Cosmetic Act. The board shall conform the regulations promulgated under the New Mexico Drug, Device and Cosmetic Act, insofar as practical, with regulations promulgated under the federal act as defined in Section 26-1-2 NMSA 1978.

B. The board of pharmacy shall, by regulation, declare a substance a "dangerous drug" when necessary, and notification shall be sent to all registered pharmacies in the state within sixty days of the adoption of the regulation.

C. The board of pharmacy shall promulgate the requirements for a pedigree.

[~~C.~~] D. All regulations promulgated by the board of pharmacy shall be in accordance with the Uniform Licensing

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Act."

Section 4. Section 26-1-26 NMSA 1978 (being Laws 1967, Chapter 23, Section 26, as amended) is amended to read:

"26-1-26. PENALTIES.--

A. [~~Any~~] A person who knowingly violates any of the provisions of Subsection C, G or H of Section 26-1-3 NMSA 1978 is guilty of a third degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978.

B. A person who knowingly violates any of the provisions of Subsection A, B [~~C~~] or F [~~G or H~~] of Section 26-1-3 NMSA 1978 or Section 26-1-14, 26-1-16, 26-1-22 or 26-1-23 NMSA 1978 is guilty of a fourth degree felony and shall be [~~punished by a fine of not less than one thousand dollars ($1,000) or more than five thousand dollars ($5,000) or by imprisonment for not less than one year or both~~] sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978.

[~~B.~~] C. Except as provided in [~~Subsection~~] Subsections A and B of this section, any person violating any of the provisions of the New Mexico Drug, Device and Cosmetic Act is guilty of a misdemeanor for the first offense and for second and subsequent offenses is guilty of a fourth degree felony."

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