HOUSE BILL 504

44TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 1999

INTRODUCED BY

John A. Heaton

AN ACT

RELATING TO DRUGS; AMENDING SECTIONS OF THE NMSA 1978 TO BRING NEW MEXICO LAWS PROVIDING FOR LABELING OF PHARMACEUTICALS INTO COMPLIANCE WITH THE FEDERAL FOOD, DRUG AND COSMETICS ACT.

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 by Laws 1997, Chapter 240, Section 1 and by Laws 1997, Chapter 244, Section 1 and also by Laws 1997, Chapter 253, Section 2) 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;

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C. "biological product" means any virus, therapeutic serum, toxin, antitoxin or analogous product 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 [~~but is not limited to~~] 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 [~~which~~] that specifically neutralizes the poisonous substance and [~~which~~] 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 [~~which~~] that specifically neutralizes the toxin against which the animal is immune;

D. "controlled substance" means any drug,

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substance or immediate precursor enumerated in Schedules I through V of the Controlled Substances Act;

E. "drug" means:

(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, [~~and~~] 58 Stat 702, as amended, and 42 U.S.C. 262;

(3) articles other than food [~~which~~] 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, [~~which~~] that because of [~~any~~] 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

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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 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 drug if it:

(1) is a habit-forming drug and contains any quantity of a narcotic or hypnotic substance or [~~any~~] a chemical derivative of such substance [~~which~~] 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 [~~such~~] 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 [~~such~~] the drug;

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

(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 [~~which~~] 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 [~~in fact~~] manufactured, processed, packed or distributed [~~such~~] the drug and [~~which~~] 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;

H. "device", except when used in Subsection P of this section and in Subsection G of Section 26-1-3, Subsection 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, [~~which~~] 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 [~~any~~] a function of the body of man or other animals and [~~which~~] that does not achieve any of its principal intended purposes

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through chemical action within or on the body of man or other animals and [~~which~~] that is not dependent [~~upon~~] 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 oriental medicine, dentist, veterinarian, certified nurse practitioner, clinical nurse specialist, pharmacist clinician, certified nurse-midwife 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

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(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 [~~any~~] 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 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) [~~upon any~~] on an article or [~~any of~~] its containers or wrappers; or

(2) accompanying [~~any~~] an article;

P. "misbranded" means a label to an article [~~which~~] that is misleading. In determining whether the label

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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 [~~which~~] 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 [~~which~~] that are likely to induce, directly or indirectly, the purchase of drugs, devices 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 drug:

(1) [~~any drug~~] 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

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use under the conditions prescribed, recommended or suggested in the labeling thereof; or

(2) [~~any drug~~] 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 [~~which~~] 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 [~~any~~] 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 [~~any~~] a drug, device or cosmetic found to contain [~~any~~] dirt, dust, foreign or injurious 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 [~~any~~] a drug or cosmetic establishment;

V. "color additive" means a material [~~which~~] 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

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other source; or

(2) when added or applied to a drug or cosmetic or to the human body or [~~any~~] 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 [~~which~~] 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 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 [~~which~~] 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 [~~which~~]

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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 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."

Section 2. Section 26-1-11 NMSA 1978 (being Laws 1967, Chapter 23, Section 11, as amended) is amended to read:

"26-1-11. DRUG OR DEVICE--MISBRANDING.--

A. A drug or device shall be deemed to be misbranded:

(1) if its labeling is false or misleading in any particular;

(2) if in package form, unless it bears a label containing the name and place of the business of the manufacturer, packer or distributor and an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; provided that reasonable variations shall be permitted and exemptions as to small packages shall be allowed in accordance with regulations prescribed by the board or issued under the federal act;

(3) if it is a drug subject to the restrictions on sale contained in Subparagraph 1 of Subsection

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(b) of 21 U.S.C. Section 353, which provisions describe those substances commonly referred to as "legend drugs", and if [~~such~~] the drug is in package form, unless it bears a label on its immediate container, and on any outer container if such there be, including the name and place of the business of the manufacturer of the finished dosage form and the name and place of business of the packer or distributor and an accurate statement of the quantity of the contents in terms of weight, measure or numerical count;

(4) if any word, statement or other information required by or under authority of the New Mexico Drug, Device and Cosmetic Act to appear on the label or labeling is not prominently placed with such conspicuousness, as compared with other words, statements, designs or devices in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(5) if it is for use by man and contains any quantity of a narcotic or hypnotic substance or any chemical derivative of such substance, which derivative after investigation has been found to be and designated as habit-forming by regulations issued pursuant to Section 502(d) or 511 of the federal act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning--May be habit-

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forming" and meets labeling requirements of the federal Comprehensive Drug Abuse Prevention and Control Act of 1970; or

(6) if it is a drug, [~~unless~~] and the label bears, to the exclusion of any other nonproprietary name except the applicable systematic chemical name or the chemical formula, the established name, as defined in this section, of the drug, [~~if such there be~~] and in [~~the~~] case it is fabricated from two or more active ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, antipyrine, amidropyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, thyroid or any derivative or preparation of any such substances contained therein; provided that the requirements for stating the quantity of the active ingredients, other than the quantity of those specifically named in this section, shall apply only to prescription drugs; provided, further, that to the extent that compliance with the requirements of this section is impracticable, exemptions shall be allowed under regulations promulgated by the board or under the federal act.

B. As used in this section, the term "established

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name" with respect to a drug or ingredient means:

(1) the applicable official name designated pursuant to Section 508 of the federal act; or

(2) if there is no such name and such drug or such ingredient is an article recognized in an official compendium, then the official title in such compendium or if neither applies, then the common or usual name, if any, of such drug or of such ingredient; provided [~~further~~] that where an article is recognized in the United States pharmacopoeia and in the homeopathic pharmacopoeia under different official titles, the official title used in the United States pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the homeopathic pharmacopoeia shall apply.

C. A drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users; provided that where adequate directions for use as applied to any drug or device are not necessary for the protection of the public health, the board shall promulgate regulations exempting such drug or device from such requirements; provided, further, that

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articles exempted under regulations issued under Section 502 (f) of the federal act may also be exempt.

D. A drug or device shall be deemed to be misbranded if it purports to be a drug the name of which is recognized in an official compendium unless it is packed and labeled as prescribed therein; provided that the method of packing may be modified with the consent of the board. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not those of the United States pharmacopoeia; provided, further, that in the event of inconsistency between the requirements of this subsection and those of Paragraph (6) of Subsection A of this section as to the name by which the drug or its ingredients shall be designated, the requirements of Paragraph (6) of Subsection A of this section shall prevail.

E. A drug or device shall be deemed to be misbranded if it has been found by the board or under the federal act to be a drug liable to deterioration unless it is packaged in such form and manner and its label bears the statement of such precautions as the regulations issued by the

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board or under the federal act require as necessary for the protection of public health. No regulation shall be established for any drug recognized in an official compendium until the board [~~shall have~~] has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body [~~shall have~~] has failed within a reasonable time to prescribe such requirements.

F. A drug or device shall be deemed to be misbranded if it is a drug and its container is so made, formed or filled as to be misleading or if it is an imitation of another drug or if it is offered for sale under the name of another drug or if it bears a copy, counterfeit or colorable imitation of a trademark, label, container or identifying name or design of another drug.

G. A drug or device shall be deemed to be misbranded if it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended or suggested in the labeling.

H. A drug or device shall be deemed to be misbranded if it is or purports to be or is represented as a drug composed wholly or partly of insulin unless it is from a batch with respect to which a certificate or release has been issued pursuant to Section 506 of the federal act and such certificate or release is in effect with respect to such drug.

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I. A drug or device shall be deemed to be misbranded if it is or purports to be or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin or any other antibiotic drug or any derivative thereof unless it is from a batch with respect to which a certificate or release has been issued pursuant to Section 507 [~~or~~] of the federal act and such certificate or release is in effect with respect to such drug; provided that this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under Section 507(c) or (d) of the federal act. For the purpose of this subsection, the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution, including the chemically synthesized equivalent of any such substance.

J. A drug or device shall be deemed to be misbranded if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of Subsection C of Section [~~9C of the New Mexico Drug and Cosmetic Act~~] 26-1-9 NMSA 1978 or of the federal act.

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K. A drug or device shall be deemed to be misbranded, in the case of any dangerous drug distributed or offered for sale in this state, unless the manufacturer, packer, distributor or retailer thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor or retailer with respect to that drug a true statement of:

(1) the established name as defined in Paragraph (6) of Subsection A of this section; [~~and~~]

(2) the formula showing quantitatively each ingredient of [~~such~~] the drug to the extent required for labels under Section 502(e) of the federal act; and

(3) such other information in brief summary relating to side effects and contraindications as [~~shall be~~] are required in regulations issued under the federal act.

L. A drug or device shall be deemed to be misbranded if a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

M. Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally packaged in accordance with requirements of the New Mexico Drug, Device and Cosmetic Act

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[~~provided, that~~] shall be deemed to be misbranded unless such drugs or devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the board or under the federal act.

N. A dangerous drug, except for drugs declared dangerous pursuant to Subsection B of Section 26-1-18 NMSA 1978, shall be deemed to be misbranded if, at any time prior to dispensing, its label fails to bear [~~the statement~~] either of the following legends:

(1) "Caution: federal law prohibits dispensing without prescription."; or

(2) "RX only"."

Section 3. Section 61-11-2 NMSA 1978 (being Laws 1969, Chapter 29, Section 2, as amended) is amended to read:

"61-11-2. DEFINITIONS.--As used in the Pharmacy Act:

A. "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means as a result of an order of a licensed practitioner;

B. "board" means the board of pharmacy;

C. "compounding" means preparing, mixing, assembling, packaging or labeling a drug or device as the result of a licensed practitioner's prescription or for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing.

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"Compounding" also includes preparing drugs or devices in anticipation of a prescription based on routine, regularly observed prescribing patterns;

D. "confidential information" means information in the patient's pharmacy records accessed, maintained by or transmitted to the pharmacist or communicated to the patient as part of patient counseling and may be released only to the patient or as the patient directs; or to those licensed practitioners and other authorized health care professionals as defined by regulation of the board when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being; or to such other persons authorized by law to receive such information, regardless of whether such information is on paper, preserved on microfilm or stored on electronic media;

E. "consulting pharmacist" means a pharmacist whose services are engaged on a routine basis by a hospital or other health care facility and who is responsible for the distribution, receipt and storage of drugs according to the state and federal regulations;

F. "custodial care facility" means a nursing home, retirement care, mental care or other facility that provides extended health care;

G. "dangerous drug" means a drug that is required by an applicable federal or state law or rule to be dispensed

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pursuant to a prescription or is restricted to use by licensed practitioners; or that is required by federal law to be labeled with [~~either~~] any of the following statements prior to being dispensed or delivered:

(1) "Caution: federal law prohibits dispensing without [~~a~~] prescription."; [~~or~~]

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

(3) "RX only";

H. "device" means an instrument, apparatus, implement, machine, contrivance, implant or similar or related article, including a component part or accessory, that is required by federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician.";

I. "dispense" means the evaluation and implementation of a prescription, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to or use by a patient;

J. "distribute" means the delivery of a drug or device other than by administering or dispensing;

K. "drug" means:

(1) an article recognized as a drug in any

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official compendium or its supplement that is designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;

(2) an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or other animals;

(3) an article, other than food, that affects the structure or any function of the body of humans or other animals; and

(4) an article intended for use as a component of an article described in Paragraph (1), (2) or (3) of this subsection;

L. "drug regimen review" includes an evaluation of a prescription and patient record for:

(1) known allergies;

(2) rational therapy contraindications;

(3) reasonable dose and route of administration;

(4) reasonable directions for use;

(5) duplication of therapy;

(6) drug-drug interactions;

(7) adverse drug reactions; and

(8) proper use and optimum therapeutic outcomes;

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M. "electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment;

N. "hospital" means an institution that is licensed as a hospital by the department of health;

O. "labeling" means the process of preparing and affixing a label to any drug container exclusive of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged prescription drug or device; and which label includes all information required by federal or state law or regulations adopted pursuant to federal or state law;

P. "licensed practitioner" means a person engaged in a profession licensed by any state, territory or possession of the United States who, within the limits of his license, may lawfully prescribe, dispense or administer drugs for the treatment of a patient's condition;

Q. "manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes packaging or repackaging, labeling or relabeling and the promotion and marketing of such drugs or devices. "Manufacturing" also

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includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, licensed practitioners or other persons;

R. "nonprescription drugs" means non-narcotic medicines or drugs that may be sold without a prescription and are prepackaged for use by a consumer and are labeled in accordance with the laws and regulations of the state and federal governments;

S. "nonresident pharmacy" means any pharmacy located outside New Mexico that ships, mails or delivers, in any manner, drugs into New Mexico;

T. "patient counseling" means the oral communication by the pharmacist of information to a patient or his agent or caregiver regarding proper use of a drug or device;

U. "person" means an individual, corporation, partnership, association or other legal entity;

V. "pharmaceutical care" means the provision of drug therapy and other patient care services related to drug therapy intended to achieve definite outcomes that improve a patient's quality of life, including identifying potential and actual drug-related problems, resolving actual drug-related problems and preventing potential drug-related problems;

W. "pharmacist" means a person who is licensed as a pharmacist in this state;

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X. "pharmacist in charge" means a pharmacist who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of the pharmacy and its personnel;

Y. "pharmacy" means a licensed place of business where drugs are compounded or dispensed and pharmaceutical care is provided;

Z. "pharmacist intern" means a person licensed by the board to train under a pharmacist;

AA. "pharmacy technician" means a person who is registered to perform repetitive tasks not requiring the professional judgment of a pharmacist;

BB. "practice of pharmacy" means the evaluation and implementation of a lawful order of a licensed practitioner; the dispensing of prescriptions; the participation in drug and device selection or drug administration that has been ordered by a licensed practitioner, drug regimen reviews and drug or drug-related research; the provision of patient counseling and pharmaceutical care; the responsibility for compounding and labeling of drugs and devices; the proper and safe storage of drugs and devices; and the maintenance of proper records;

CC. "prescription" means an order given

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individually for the person for whom prescribed, either directly from a licensed practitioner or his agent to the pharmacist, including electronic transmission or indirectly by means of a written order signed by the prescriber, that bears 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;

DD. "significant adverse drug reaction" means a drug-related incident that may result in harm, injury or death to the patient; and

EE. "wholesale drug distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, manufacturer's warehouses, distributor's warehouses, chain drug warehouses, wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distribution."

Section 4. Section 61-11B-2 NMSA 1978 (being Laws 1993, Chapter 191, Section 2, as amended) is amended to read:

"61-11B-2. DEFINITIONS.--As used in the Pharmacist Prescriptive Authority Act:

A. "administer" means the direct application of a drug by any means to the body of a person;

B. "board" means the board of pharmacy;

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C. "dangerous drug" means a drug that, because of any potentiality for harmful effect or the methods 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 the drug prior to dispensing is required by federal law and state law to bear the manufacturer's legend of "Caution: federal law prohibits dispensing without [~~a~~] prescription." or "RX only";

D. "guidelines or protocol" means a written agreement between a pharmacist clinician or group of pharmacist clinicians and a practitioner or group of practitioners that delegates prescriptive authority;

E. "monitor dangerous drug therapy" means the review of the dangerous drug therapy regimen of patients by a pharmacist clinician for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. "Monitor dangerous drug therapy" includes:

(1) collecting and reviewing patient dangerous drug histories;

(2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to dangerous drug therapy, including

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blood chemistries and cell counts, controlled substance therapy levels, blood, urine, tissue or other body fluids, culture and sensitivity tests when performed in accordance with guidelines or protocols applicable to the practice setting;

F. "pharmacist" means a person duly licensed by the board [~~of pharmacy~~] to engage in the practice of pharmacy pursuant to the Pharmacy Act;

G. "pharmacist clinician" means a pharmacist with additional training, at least equivalent to the training received by a physician assistant, required by regulations adopted by the board in consultation with the New Mexico board of medical examiners and the New Mexico academy of physician assistants, who exercises prescriptive authority in accordance with guidelines or protocol;

H. "practitioner" means a physician duly authorized by law in New Mexico to prescribe controlled substances; and

I. "prescriptive authority" means the authority to prescribe, administer or modify dangerous drug therapy."

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FORTY-FOURTH LEGISLATURE

FIRST SESSION, 1999

February 23, 1999

Mr. Speaker:

Your BUSINESS AND INDUSTRY COMMITTEE, to whom has been referred

HOUSE BILL 504

has had it under consideration and reports same with recommendation that it DO PASS, amended as follows:

1. On page 13, line 4, strike the brackets and line through "unless" and strike "and".,

and thence referred to the JUDICIARY COMMITTEE.

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Respectfully submitted,

_____

Debbie A. Rodella, Chairwoman

Adopted _____ Not Adopted _____

(Chief Clerk) (Chief Clerk)

Date _____

The roll call vote was 9 For 0 Against

Yes: 9

Excused: Hobbs, Sanchez

Absent: Kissner

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FORTY-FOURTH LEGISLATURE
FIRST SESSION, 1999

March 6, 1999

Mr. Speaker:

Your JUDICIARY COMMITTEE, to whom has been referred

HOUSE BILL 504, as amended

has had it under consideration and reports same with recommendation that it DO PASS.

Respectfully submitted,

R. David Pederson, Chairman

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[~~bracketed material~~] = delete

Adopted _____ Not Adopted _____

(Chief Clerk) (Chief Clerk)

Date _____

The roll call vote was 9 For 0 Against

Yes: 9

Excused: Garcia, Luna, Thompson

Absent: None

J:\99BillsWP\H0504

underscored material = new
[~~bracketed material~~] = delete