AN ACT

RELATING TO HEALTH CARE; AMENDING THE NEW MEXICO DRUG, DEVICE AND COSMETIC ACT; EXPANDING BOARD POWERS UNDER THE PHARMACY ACT; CHANGING DEFINITIONS IN THE CONTROLLED SUBSTANCES ACT AND IN THE NEW MEXICO DRUG, DEVICE AND COSMETIC ACT; PROVIDING FOR PEDIGREES; AMENDING AND REPEALING CERTAIN SECTIONS OF THE NMSA 1978.

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 an individual, partnership, corporation, association, institution or establishment;

C. "biological product" means a 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 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 a drug, substance or immediate precursor enumerated in Schedules I through V of the Controlled Substances Act;

E. "drug" means articles:

(1) recognized in an official compendium;

(2) 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) other than food that affect the structure or any function of the body of man or other animals; and

(4) 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 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 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 that is deliberately and fraudulently mislabeled with respect to its identity, ingredients or sources. Types of such 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 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 a licensed practitioner or the practitioner's agent to the pharmacist, including by means of electronic transmission, 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;

J. "practitioner" means a physician, doctor of 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 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 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 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 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 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;

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;

Z. "valid practitioner-patient relationship" means a professional relationship, as defined by the practitioner's licensing board, between the practitioner and the patient; and

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

Section 2. Section 26-1-7 NMSA 1978 (being Laws 1967, Chapter 23, Section 7) is amended to read:

"26-1-7. ATTORNEY GENERAL OR DISTRICT ATTORNEY TO INSTITUTE PROSECUTIONS.--It is the duty of the attorney general or the various district attorneys of this state to whom the board reports any violation of the New Mexico Drug, Device and Cosmetic Act to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law."

Section 3. 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--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, 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 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 practitioner-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 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 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; provided, 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:

(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 prescriptions, records for the purpose of refilling prescriptions, receipt records, drug distribution records, drug withdrawals from stock, drug compounding records, drug disposition records and drug disposal records.

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 4. Section 26-3-3 NMSA 1978 (being Laws 1976, Chapter 60, Section 4, as amended) is amended to read:

"26-3-3. DRUG PRODUCT SELECTION PERMITTED--CONDITIONS--EXCEPTION FOR PROHIBITION--LABELING.--

A. Upon receipt of a prescription written by a licensed practitioner who may prescribe drugs for a drug for which one or more multiple-source drugs are recognized, listed as final determinations and published in the federal register by the federal department of health and human services, a pharmacist may dispense any one of the drugs that

satisfies the final determinations so recognized and listed by the federal department of health and human services and is sold at a lower cost than the drug listed in the prescription.

B. Upon receipt of a prescription written by a licensed practitioner for a drug that appears on the federal food and drug administration's approved prescription drug products with therapeutic equivalence evaluation list as supplemented, a pharmacist may dispense any of the therapeutically equivalent drugs that appears on that list and which is lower in cost than the drug listed in the prescription.

C. Drug product selection shall be permitted only under circumstances and conditions set forth in Subsections A and B of this section unless the licensed practitioner prescribing prohibits drug product selection. A licensed practitioner shall prohibit drug product selection by writing with his hand the words "no substitution" or the diminution "no sub" on the face of a prescription.

D. If drug product selection occurs as permitted in Subsections A and B of this section, the pharmacist shall indicate on the label of the dispensed container the brand of drug prescribed and the name of the drug dispensed.

E. A pharmacist may not select a therapeutically equivalent drug unless he passes on to the patient all

savings between the net cost of the product prescribed and the product dispensed.

F. For purposes of this section, "multiple-source drug" means a drug marketed or sold by two or more manufacturers, formulators or labelers.

G. For purposes of this section, "therapeutically equivalent" means drug products which have the same amount of the active drug in the same dosage form which when administered can be expected to provide the same therapeutic effect."

Section 5. Section 61-11-6 NMSA 1978 (being Laws 1969, Chapter 29, Section 5, as amended) is amended to read:

"61-11-6. POWERS AND DUTIES OF BOARD.--

A. The board shall:

(1) adopt, amend or repeal rules and regulations necessary to carry out the provisions of the Pharmacy Act in accordance with the provisions of the Uniform Licensing Act;

(2) provide for examinations of applicants for licensure as pharmacists;

(3) provide for the issuance and renewal of licenses for pharmacists;

(4) require and establish criteria for continuing education as a condition of renewal of licensure for pharmacists;

(5) provide for the issuance and renewal of licenses for pharmacist interns and for their training, supervision and discipline;

(6) provide for the licensing of retail pharmacies, nonresident pharmacies, wholesale drug distributors, drug manufacturers, hospital pharmacies, nursing home drug facilities, industrial and public health clinics and all places where dangerous drugs are stored, distributed, dispensed or administered and provide for the inspection of the facilities and activities;

(7) enforce the provisions of all laws of the state pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs or cosmetics and their standards of strength and purity;

(8) conduct hearings upon charges relating to the discipline of a registrant or licensee or the denial, suspension or revocation of a registration or a license in accordance with the Uniform Licensing Act;

(9) cause the prosecution of any person violating the Pharmacy Act, the New Mexico Drug, Device and Cosmetic Act or the Controlled Substances Act;

(10) keep a record of all proceedings of the board;

(11) make an annual report to the governor;

(12) appoint and employ, in the board's

discretion, a qualified person who is not a member of the board to serve as executive director and define the executive director's duties and responsibilities; except that the power to deny, revoke or suspend any license or registration authorized by the Pharmacy Act shall not be delegated by the board;

(13) appoint and employ inspectors necessary to enforce the provisions of all acts under the administration of the board, which inspectors shall be pharmacists and have all the powers and duties of peace officers;

(14) provide for other qualified employees necessary to carry out the provisions of the Pharmacy Act;

(15) have the authority to employ a competent attorney to give advice and counsel in regard to any matter connected with the duties of the board, to represent the board in any legal proceedings and to aid in the enforcement of the laws in relation to the pharmacy profession and to fix the compensation to be paid to the attorney; provided, however, that the attorney shall be compensated from the money of the board, including that provided for in Section 61-11-19 NMSA 1978;

(16) register and regulate qualifications, training and permissible activities of pharmacy technicians;

(17) provide a registry of all persons

licensed as pharmacists or pharmacist interns in the state;

(18) adopt rules and regulations that prescribe the activities and duties of pharmacy owners and pharmacists in the provision of pharmaceutical care, emergency prescription dispensing, drug regimen review and patient counseling in each practice setting;

(19) adopt, after approval by the New Mexico board of medical examiners and the board of nursing, rules and protocols for the prescribing of dangerous drug therapy, including vaccines and immunizations, and the appropriate notification of the primary or appropriate physician of the person receiving the dangerous drug therapy; and

(20) have the authority to authorize emergency prescription dispensing.

B. The board may:

(1) delegate its authority to the executive director to issue temporary licenses as provided in Section 61-11-14 NMSA 1978;

(2) provide by regulation for the electronic transmission of prescriptions; and

(3) delegate its authority to the executive director to authorize emergency prescription dispensing procedures during civil or public health emergencies."

Section 6. 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 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 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 shall promulgate the requirements for a pedigree.

D. All regulations promulgated by the board shall be in accordance with the Uniform Licensing Act."

Section 7. Section 61-11-11.1 NMSA 1978 (being Laws 1997, Chapter 131, Section 12) is amended to read:

"61-11-11.1. PHARMACY TECHNICIAN--QUALIFICATIONS--DUTIES.--

A. The classification of pharmacy technician is established. An applicant for registration as a pharmacy technician shall:

(1) be at least eighteen years of age and not addicted to drugs or alcohol;

(2) complete initial training as required by

regulations of the board that includes on-the-job and related education commensurate with the tasks to be performed by the pharmacy technician; and

(3) if the potential duties of the pharmacy technician will include the preparation of sterile products, complete an additional one hundred hours of experiential training as required by regulations of the board.

B. Permissible activities for pharmacy technicians under the supervision of a pharmacist include:

(1) the preparation, mixing, assembling, packaging and labeling of medications;

(2) processing routine orders of stock supplies;

(3) preparation of sterile products;

(4) filling of a prescription or medication order that entails counting, pouring, labeling or reconstituting medications; and

(5) tasks assigned by the supervising pharmacist that do not require his professional judgment.

C. The supervising pharmacist shall observe and direct the pharmacy technician to a sufficient degree to assure the accurate completion of the activities of the pharmacy technician and shall provide a final check of all aspects of the prepared product and document the final check before dispensing.

D. The supervising pharmacist shall be responsible for the tasks performed by the pharmacist technician and subject to discipline for failure to appropriately supervise the performance of the pharmacist technician."

Section 8. Section 61-11-14 NMSA 1978 (being Laws 1969, Chapter 29, Section 13, as amended) is amended to read:

"61-11-14. PHARMACY LICENSURE--WHOLESALE DRUG DISTRIBUTION BUSINESS LICENSURE--REQUIREMENTS--FEES--REVOCATION.--

A. Any person who desires to operate or maintain the operation of a pharmacy or who engages in a wholesale drug distribution business in this state shall apply to the board for the proper license and shall meet the requirements of the board and pay the fee for the license and its renewal.

B. The board shall issue the following classes of licenses that shall be defined and limited by regulation of the board:

(1) retail pharmacy;

(2) nonresident pharmacy;

(3) wholesale drug distributor;

(4) drug manufacturer;

(5) hospital pharmacy;

(6) industrial health clinic;

(7) community health clinic;

(8) department of health public health

offices;

(9) custodial care facility;

(10) home care services;

(11) emergency medical services;

(12) animal control facilities;

(13) wholesaler, retailer or distributor of veterinary drugs bearing the legend: "caution: federal law restricts this drug to use by or on the order of a licensed veterinarian". Such drugs may be sold or dispensed by any person possessing a retail pharmacy license, wholesale drug distributor's license or drug manufacturer's license issued by the board, without the necessity of acquiring an additional license for veterinary drugs;

(14) returned drugs processors;

(15) drug research facilities;

(16) drug warehouses;

(17) contact lens sellers;

(18) medicinal gas repackagers; and

(19) medicinal gas sellers.

C. Every application for the issuance or biennial renewal of:

(1) a license for a retail pharmacy, nonresident pharmacy, hospital pharmacy or drug research facility shall be accompanied by a fee set by the board in an amount not to exceed three hundred dollars ($300) per year;

(2) a license for a wholesale drug distributor, drug manufacturer or drug warehouse shall be accompanied by a fee not to exceed five thousand dollars ($5,000) per year; provided that the fee shall not exceed one thousand dollars ($1,000) per year upon the implementation of a medicare prescription drug benefit program, pursuant to Sections 1860D-1 through 1860D-24, except Section 1860D-4, of Public Law 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

(3) a license for a custodial care facility or a returned drugs processor business shall be accompanied by a fee set by the board in an amount not to exceed two hundred dollars ($200) per year; and

(4) a license for an industrial health clinic; a community health clinic; a department of health public health office; home care services; emergency medical services; animal control facilities; or wholesaler, retailer or distributor of veterinary drugs shall be accompanied by a fee set by the board in an amount not to exceed two hundred dollars ($200) per year.

D. If it is desired to operate or maintain a pharmaceutical business at more than one location, a separate license shall be obtained for each location.

E. Each application for a license shall be made on forms prescribed and furnished by the board.

F. Any person making application to the board for a license to operate a facility or business listed in Subsection B of this section in this state shall submit to the board an application for licensure indicating:

(1) the name under which the business is to be operated;

(2) the address of each location to be licensed and the address of the principal office of the business;

(3) in the case of a retail pharmacy, the name and address of the owner, partner or officer or director of a corporate owner;

(4) the type of business to be conducted at each location;

(5) a rough drawing of the floor plan of each location to be licensed;

(6) the proposed days and hours of operation of the business; and

(7) other information the board may require.

G. After preliminary approval of the application for a license for any facility or business listed in Paragraphs (1) through (8) and (10) through (16) of Subsection B of this section, a request for an inspection, together with an inspection fee not to exceed two hundred dollars ($200), shall be submitted to the board for each

business location, and an inspection shall be made of each location by the board or its agent.

H. Following a deficiency-free inspection, the executive director of the board may issue a temporary license to the applicant. The temporary license shall expire at the close of business on the last day of the next regular board meeting.

I. Licenses, except temporary licenses provided pursuant to Subsection H of this section, issued by the board pursuant to this section are not transferable and shall expire on the expiration date set by the board unless renewed. Any person failing to renew a license on or before the expiration date set by the board shall not have the license reinstated except upon reapplication and payment of a reinstatement fee set by the board in an amount not to exceed one hundred dollars ($100) and all delinquent renewal fees.

J. The board, after notice and a refusal or failure to comply, may suspend or revoke any license issued under the provisions of the Pharmacy Act at any time examination or inspection of the operation for which the license was granted discloses that the operation is not being conducted according to law or regulations of the board.

K. Pharmaceutical sales representatives who carry dangerous drugs shall provide the board with a written statement from the representative's employer that describes

the employer's policy relating to the safety and security of the handling of dangerous drugs and to the employer's compliance with the federal Prescription Drug Marketing Act of 1987. Pharmaceutical sales representatives are not subject to the licensing provisions of the Pharmacy Act."

Section 9. Section 30-31-2 NMSA 1978 (being Laws 1972, Chapter 84, Section 2, as amended) is amended to read:

"30-31-2. DEFINITIONS.--As used in the Controlled Substances Act:

A. "administer" means the direct application of a controlled substance by any means to the body of a patient or research subject by a practitioner or his agent;

B. "agent" includes an authorized person who acts on behalf of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman;

C. "board" means the board of pharmacy;

D. "bureau" means the narcotic and dangerous drug section of the criminal division of the United States department of justice, or its successor agency;

E. "controlled substance" means a drug or substance listed in Schedules I through V of the Controlled Substances Act or rules adopted thereto;

F. "counterfeit substance" means a controlled substance that bears the unauthorized trademark, trade name,

imprint, number, device or other identifying mark or likeness of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the controlled substance;

G. "deliver" means the actual, constructive or attempted transfer from one person to another of a controlled substance or controlled substance analog, whether or not there is an agency relationship;

H. "dispense" means to deliver a controlled substance to an ultimate user or research subject pursuant to the lawful order of a practitioner, including the administering, prescribing, packaging, labeling or compounding necessary to prepare the controlled substance for that delivery;

I. "dispenser" means a practitioner who dispenses and includes hospitals, pharmacies and clinics where controlled substances are dispensed;

J. "distribute" means to deliver other than by administering or dispensing a controlled substance or controlled substance analog;

K. "drug" or "substance" means substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States or official national formulary or any respective supplement to those publications. It does not

include devices or their components, parts or accessories;

L. "hashish" means the resin extracted from any part of marijuana, whether growing or not, and every compound, manufacture, salt, derivative, mixture or preparation of such resins;

M. "manufacture" means the production, preparation, compounding, conversion or processing of a controlled substance or controlled substance analog by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance:

(1) by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(2) by a practitioner, or by his agent under his supervision, for the purpose of or as an incident to research, teaching or chemical analysis and not for sale;

N. "marijuana" means all parts of the plant cannabis, including any and all varieties, species and subspecies of the genus Cannabis, whether growing or not, the seeds thereof and every compound, manufacture, salt, derivative, mixture or preparation of the plant or its seeds.

It does not include the mature stalks of the plant, hashish, tetrahydrocannabinols extracted or isolated from marijuana, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil or cake, or the sterilized seed of the plant that is incapable of germination;

O. "narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(1) opium and opiate and any salt, compound, derivative or preparation of opium or opiate;

(2) any salt, compound, isomer, derivative or preparation that is a chemical equivalent of any of the substances referred to in Paragraph (1) of this subsection, except the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw, including all parts of the plant of the species Papaver somniferum L. except its seeds; or

(4) coca leaves and any salt, compound, derivative or preparation of coca leaves, any salt, compound, isomer, derivative or preparation that is a chemical equivalent of any of these substances except decocainized

coca leaves or extractions of coca leaves that do not contain cocaine or ecgonine;

P. "opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. "Opiate" does not include, unless specifically designated as controlled under Section 30-31-5 NMSA 1978, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts, dextromethorphan. "Opiate" does include its racemic and levorotatory forms;

Q. "person" means an individual, partnership, corporation, association, institution, political subdivision, government agency or other legal entity;

R. "practitioner" means a physician, doctor of oriental medicine, dentist, physician assistant, certified nurse practitioner, clinical nurse specialist, certified nurse-midwife, prescribing psychologist, veterinarian, pharmacist, pharmacist clinician or other person licensed or certified to prescribe and administer drugs that are subject to the Controlled Substances Act;

S. "prescription" means an order given individually for the person for whom is prescribed a controlled substance, either directly from a licensed practitioner or the practitioner's agent to the pharmacist,

including by means of electronic transmission, or indirectly by means of a written order signed by the prescriber, 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 and in accordance with the Controlled Substances Act or rules adopted thereto;

T. "scientific investigator" means a person registered to conduct research with controlled substances in the course of his professional practice or research and includes analytical laboratories;

U. "ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal under the care, custody and control of the person or by a member of his household;

V. "drug paraphernalia" means all equipment, products and materials of any kind that are used, intended for use or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body a controlled substance or controlled substance analog in violation of the Controlled

Substances Act. It includes:

(1) kits used, intended for use or designed for use in planting, propagating, cultivating, growing or harvesting any species of plant that is a controlled substance or controlled substance analog or from which a controlled substance can be derived;

(2) kits used, intended for use or designed for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances or controlled substance analogs;

(3) isomerization devices used, intended for use or designed for use in increasing the potency of any species of plant that is a controlled substance;

(4) testing equipment used, intended for use or designed for use in identifying or in analyzing the strength, effectiveness or purity of controlled substances or controlled substance analogs;

(5) scales or balances used, intended for use or designed for use in weighing or measuring controlled substances or controlled substance analogs;

(6) diluents and adulterants, such as quinine hydrochloride, mannitol, mannite dextrose and lactose, used, intended for use or designed for use in cutting controlled substances or controlled substance analogs;

(7) separation gins and sifters used, intended for use or designed for use in removing twigs and seeds from, or in otherwise cleaning and refining, marijuana;

(8) blenders, bowls, containers, spoons and mixing devices used, intended for use or designed for use in compounding controlled substances or controlled substance analogs;

(9) capsules, balloons, envelopes and other containers used, intended for use or designed for use in packaging small quantities of controlled substances or controlled substance analogs;

(10) containers and other objects used, intended for use or designed for use in storing or concealing controlled substances or controlled substance analogs;

(11) hypodermic syringes, needles and other objects used, intended for use or designed for use in parenterally injecting controlled substances or controlled substance analogs into the human body;

(12) objects used, intended for use or designed for use in ingesting, inhaling or otherwise introducing marijuana, cocaine, hashish or hashish oil into the human body, such as:

(a) metal, wooden, acrylic, glass, stone, plastic or ceramic pipes, with or without screens, permanent screens, hashish heads or punctured metal bowls;

(b) water pipes;

(c) carburetion tubes and devices;

(d) smoking and carburetion masks;

(e) roach clips, meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small to hold in the hand;

(f) miniature cocaine spoons and cocaine vials;

(g) chamber pipes;

(h) carburetor pipes;

(i) electric pipes;

(j) air-driven pipes;

(k) chilams;

(l) bongs; or

(m) ice pipes or chillers; and

(13) in determining whether an object is drug paraphernalia, a court or other authority should consider, in addition to all other logically relevant factors, the following:

(a) statements by the owner or by anyone in control of the object concerning its use;

(b) the proximity of the object, in time and space, to a direct violation of the Controlled Substances Act or any other law relating to controlled substances or controlled substance analogs;

(c) the proximity of the object to controlled substances or controlled substance analogs;

(d) the existence of any residue of a controlled substance or controlled substance analog on the object;

(e) instructions, written or oral, provided with the object concerning its use;

(f) descriptive materials accompanying the object that explain or depict its use;

(g) the manner in which the object is displayed for sale; and

(h) expert testimony concerning its use;

W. "controlled substance analog" means a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in Schedule I, II, III, IV or V or that was specifically designed to produce effects substantially similar to that of controlled substances in Schedule I, II, III, IV or V. Examples of chemical classes in which controlled substance analogs are found include the following:

(1) phenethylamines;

(2) N-substituted piperidines;

(3) morphinans;

(4) ecgonines;

(5) quinazolinones;

(6) substituted indoles; and

(7) arylcycloalkylamines.

Specifically excluded from the definition of "controlled substance analog" are those substances that are generally recognized as safe and effective within the meaning of the Federal Food, Drug and Cosmetic Act or have been manufactured, distributed or possessed in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of Section 505 of the Federal Food, Drug and Cosmetic Act;

X. "human consumption" includes application, injection, inhalation, ingestion or any other manner of introduction;

Y. "drug-free school zone" means a public school or property that is used for public school purposes and the area within one thousand feet of the school property line, but it does not mean any post-secondary school; and

Z. "valid practitioner-patient relationship" means a professional relationship, as defined by the practitioner's licensing board, between the practitioner and the patient."

Section 10. Section 30-31-18 NMSA 1978 (being Laws 1972, Chapter 84, Section 18) is amended to read:

"30-31-18. PRESCRIPTIONS.--

A. No controlled substance listed in Schedule II,

which is a prescription drug as determined by the federal food and drug administration, may be dispensed without a written prescription of a practitioner, unless administered directly to an ultimate user. No prescription for a Schedule II substance may be refilled. No person other than a practitioner shall prescribe or write a prescription.

B. Prescriptions for Schedules II through IV shall contain the following information:

(1) the name and address of the patient for whom the drug is prescribed;

(2) the name, address and registry number of the person prescribing the drug; and

(3) the identity of the pharmacist of record.

C. A controlled substance included in Schedules III or IV, which is a prescription drug as determined under the New Mexico Drug and Cosmetic Act, shall not be dispensed without a written or oral prescription of a practitioner, except when administered directly by a practitioner to an ultimate user. The prescription shall not be filled or refilled more than six months after the date of issue or be refilled more than five times, unless renewed by the practitioner and a new prescription is placed in the file. Prescriptions shall be retained in conformity with the regulations of the board.

D. The label affixed to the dispensing container of a drug listed in Schedules II, III or IV, when dispensed to or for a patient, shall contain the following information:

(1) date of dispensing and prescription number;

(2) name and address of the pharmacy;

(3) name of the patient;

(4) name of the practitioner; and

(5) directions for use and cautionary statements, if any.

E. The label affixed to the dispensing container of a drug listed in Schedule II, III or IV, when dispensed to or for a patient, shall contain a clear concise warning that it is a crime to transfer the drug to any person other than the patient.

F. No controlled substance included in Schedule V, which is a proprietary nonprescription drug, shall be distributed, offered for sale or dispensed other than for a medical purpose and a record of the sale shall be made in accordance with the regulations of the board.

G. In emergency situations, as defined by regulation, Schedule II drugs may be dispensed upon oral prescription of a practitioner, if reduced promptly to writing and filed by the pharmacy in accordance with regulations of the board."

Section 11. REPEAL.--Section 26-1-3.1 NMSA 1978 (being Laws 1987, Chapter 270, Section 4) is repealed.