HOUSE BILL 783

46TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2003

INTRODUCED BY

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AN ACT

RELATING TO PHARMACY; PROVIDING FOR DIRECT PROSECUTION FOR VIOLATIONS OF THE NEW MEXICO DRUG, DEVICE AND COSMETIC ACT; PROVIDING AUTHORITY FOR EMERGENCY PRESCRIPTIVE DISPENSING.

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

Section 1. 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 [~~RIGHT TO BOARD HEARING PRIOR TO CRIMINAL PROCEEDINGS~~].--It [~~shall be~~] 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. [~~Before any~~

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~~violation of this act is reported to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the board or its designated agent, either orally or in writing, in person or by attorney, with regard to such contemplated proceedings.~~]"

Section 2. 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. "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

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

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

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(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. "director" means the executive director of the board hired pursuant to Paragraph (12) of Subsection A of Section 61-11-6 NMSA 1978;

[~~I.~~] J. "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.~~] K. "distribute" means the delivery of a drug or device other than by administering or dispensing;

[~~K.~~] L. "drug" means:

(1) an article recognized as a drug in any 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;

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(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.~~] M. "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;

[~~M.~~] N. "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;

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

[~~O.~~] P. "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.~~] Q. "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.~~] R. "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 includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, licensed practitioners or other persons;

[~~R.~~] S. "nonprescription drugs" means non-narcotic

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

[~~T.~~] U. "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.~~] V. "person" means an individual, corporation, partnership, association or other legal entity;

[~~V.~~] W. "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.~~] X. "pharmacist" means a person who is licensed as a pharmacist in this state;

[~~X.~~] Y. "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

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in full and actual charge of the pharmacy and its personnel;

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

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

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

[~~BB.~~] CC. "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 administering or prescribing of dangerous drug therapy; 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.~~] DD. "prescription" means an order given 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

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

[~~EE.~~] FF. "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 3. 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;

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(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 his 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;

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(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; [~~and~~]

(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) adopt rules for authorization of emergency prescription dispensing by the director.

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; and

(2) provide by regulation for the electronic transmission of prescriptions."

Section 4. Section 61-11-7 NMSA 1978 (being Laws 1969, Chapter 29, Section 6, as amended) is amended to read:

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"61-11-7. DRUG DISPENSATION--LIMITATIONS.--

A. The Pharmacy Act does not prohibit:

(1) any hospital or state or county institution or clinic without the services of a staff pharmacist from acquiring and having in its possession any dangerous drug for the purpose of dispensing if it is in a dosage form suitable for dispensing and if the hospital, institution or clinic employs a consulting pharmacist, and if the consulting pharmacist is not available, the withdrawal of any drug from stock by a licensed professional nurse on the order of a licensed practitioner in such amount as needed for administering to and treatment of his patient;

(2) the extemporaneous preparation by a licensed professional nurse on the order of a licensed practitioner of simple solutions for injection when the solution may be prepared from a quantity of drug that has been prepared previously by a pharmaceutical manufacturer or pharmacist and obtained by a hospital, institution or clinic in a form suitable for the preparation of the solution;

(3) the sale of non-narcotic, nonpoisonous or nondangerous nonprescription medicines or preparations by nonregistered persons or unlicensed stores when sold in their original containers;

(4) the sale of drugs intended for veterinary use; provided that if such drugs bear the legend: "Caution:

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federal law restricts this drug to use by or on the order of a licensed veterinarian", the drug may be sold or distributed only as provided in Subsection A of Section 26-1-15 NMSA 1978, by a person possessing a license issued by the board pursuant to Subsection B of Section 61-11-14 NMSA 1978;

(5) the sale to or possession or administration of topical ocular pharmaceutical agents by licensed optometrists who have been certified by the board of optometry for the use of such agents;

(6) the sale to or possession or administration of oral pharmaceutical agents as authorized in Subsection A of Section 61-2-10.2 NMSA 1978 by licensed optometrists who have been certified by the board of optometry for the use of such agents;

(7) pharmacy technicians from providing assistance to pharmacists;

(8) a pharmacist from prescribing dangerous drug therapy, including vaccines and immunizations, under rules and protocols adopted by the board after approval by the New Mexico board of medical examiners and the board of nursing; [~~or~~]

(9) a pharmacist from exercising his professional judgment in refilling a prescription for a prescription drug, unless prohibited by another state or federal law, without the authorization of the prescribing

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licensed practitioner, if:

(a) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) the pharmacist is unable to contact the licensed practitioner after reasonable effort;

(c) the quantity of prescription drug dispensed does not exceed a seventy-two-hour supply;

(d) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the licensed practitioner is required for future refills; and

(e) the pharmacist informs the licensed practitioner of the emergency refill at the earliest reasonable time; or

(10) a pharmacist from dispensing medications pursuant to Paragraphs (18) and (20) of Subsection A of Section 61-11-6 NMSA 1978.

B. All prescriptions requiring the preparation of dosage forms or amounts of dangerous drugs not available in the stock of a hospital, institution or clinic or a prescription requiring compounding shall be either compounded or dispensed only by a pharmacist."