HOUSE BILL 93

56TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2023

INTRODUCED BY

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FOR THE LEGISLATIVE HEALTH AND HUMAN SERVICES COMMITTEE

AN ACT

RELATING TO PROFESSIONAL LICENSURE; AMENDING AND ENACTING SECTIONS OF THE PHARMACY ACT; REPEALING THE IMPAIRED PHARMACISTS ACT.

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

SECTION 1. 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

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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 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 other persons authorized by law to receive the information, regardless of whether the 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

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extended health care as defined by board rule; "custodial care facility" does not mean a home:

(1) the principal function of which is to care for no more than sixteen children on a twenty-four-hour-a-day residential basis, and that:

(a) does not receive funds directly from or through the children, youth and families department; and

(b) is a member of any state or national association that requires it to observe standards comparable to pertinent recognized state or national group home standards for the care of children or that is certified by any such organization as complying with the standards; or

(2) maintained by an individual having the care and control, for periods exceeding twenty-four hours, of a child or children not placed for adoption;

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.";

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

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(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 an 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 a function of the body of humans or other

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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;

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 a drug container exclusive of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged prescription drug or device; and

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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 a state, territory or possession of the United States who, within the limits of the person's 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 the 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. "nonprescription drugs" means nonnarcotic 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

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any manner, drugs into New Mexico;

T. "outsourcing facility" means a facility at one geographic location or address that engages in the compounding of sterile drugs, is licensed by the board and, in accordance with board rules, is currently registered with the United States food and drug administration as an outsourcing facility;

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

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

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;

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

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

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

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

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

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;

DD. "prescription" means an order given individually for the person for whom prescribed, either directly from a licensed practitioner or the licensed practitioner's 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, the prescriber's license classification, the name

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and address of the patient, the name and quantity of the drug prescribed, directions for use and the date of issue;

EE. "repackager" means a person that repackages a drug, including a medicinal gas, and that, in accordance with board rules, has a valid registration as a drug establishment with the United States food and drug administration;

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

GG. "third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of a product but which person does not take ownership of the product nor have responsibility to direct the sale or disposition of the product; and

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

SECTION 2. Section 61-11-5 NMSA 1978 (being Laws 1969, Chapter 29, Section 4, as amended) is amended to read:

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"61-11-5. BOARD MEETINGS--QUORUM--OFFICERS--BONDS--EXPENSES.--

A. The board shall annually elect a [~~chairman~~] chair, vice [~~chairman~~] chair and secretary-treasurer from its membership.

B. The board shall meet at least once every three months. Special meetings may be called by the [~~chairman~~] chair and shall be called upon the written request of two or more members of the board. Notification of special meetings shall be made by [~~certified~~] regular mail [~~unless the notice is waived by the entire board and noted in the minutes~~] or electronic mail. Notice of all regular meetings shall be made by regular mail or electronic mail at least ten days prior to the meeting, and copies of the minutes of all meetings shall be mailed to each board member within forty-five days after any meeting.

C. A majority of the board constitutes a quorum.

D. Members of the board shall be reimbursed as provided in the Per Diem and Mileage Act and shall receive no other compensation, perquisite or allowance."

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) promulgate rules in accordance with the

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provisions of the State Rules Act 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

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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

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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) promulgate rules 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) promulgate, after [~~approval by~~] consultation with the New Mexico medical board 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;

(21) enforce and administer the provisions of

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the Impaired Health Care Provider Act and may promulgate rules to implement the provisions of that act as it relates to pharmacists, pharmacist interns, pharmacy technicians and applicants for license or registration; and

(22) have the authority to promulgate rules requiring reporting of particular dispensed non-controlled dangerous drugs to the prescription monitoring program when the board determines that lack of reporting may create a hazard to patients.

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 rule 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 4. Section 61-11-7 NMSA 1978 (being Laws 1969, Chapter 29, Section 6, as amended by Laws 2016, Chapter 45, Section 2 and by Laws 2016, Chapter 47, Section 2) is amended to read:

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

A. The Pharmacy Act does not prohibit:

(1) a hospital or state or county institution

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or clinic without the services of a staff pharmacist from acquiring and having in its possession a 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 a 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 a 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 nonnarcotic, 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 the drugs bear the legend: "Caution: 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,

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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 the 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 the 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~~] consultation with the New Mexico medical board and the board of nursing;

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

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

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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~~] thirty-day supply;

(d) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without 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) the possession, storage, distribution, dispensing, administration or prescribing of an opioid antagonist in accordance with the provisions of Section 24-23-1 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."

SECTION 5. Section 61-11-9.1 NMSA 1978 (being Laws 2007, Chapter 79, Section 4, as amended) is amended to read:

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"61-11-9.1. SURETY BONDS.--

A. The board may require surety bonds or other equivalent means of security, as approved by the board, that are provided by a third party such as insurance, an irrevocable letter of credit or funds deposited in a trust account or financial institution, to secure payment for any administrative or judicial penalties that may be imposed by the board or the state and for any penalties or costs required by board rule or disciplinary action.

B. Surety bonds or other equivalent means of security as approved by the board and required in this section shall apply to initial applicants or renewal applicants as a condition for obtaining or maintaining licensure as a drug manufacturer, nonresident pharmacy, wholesale drug distributor, outsourcing facility, repackager or third-party logistics provider.

C. The board [~~shall~~] may set by rule the amount and conditions of the surety bond or other equivalent means of security authorized in this section.

D. The board may waive the surety bond or other requirements of this section if it determines that it is in the best interest of the public to do so. Such waivers may be granted under conditions established by board rule.

E. Manufacturers distributing their own products that have been licensed or approved by the food and drug

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administration and pharmacy warehouses that are engaged only in intracompany transfers are exempt from this section.

F. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies or groups when such separate locations or affiliated companies or groups are required to apply for or renew their drug manufacturer, nonresident pharmacy, wholesale drug distributor, outsourcing facility, repackager or third-party logistics provider license with the board."

SECTION 6. Section 61-11-14.1 NMSA 1978 (being Laws 1992, Chapter 19, Section 7, as amended) is amended to read:

"61-11-14.1. NONRESIDENT PHARMACY LICENSURE--TOLL-FREE TELEPHONE SERVICE.--

A. Any person making application to the board for a nonresident pharmacy license shall submit to the board an application for licensure that discloses the following information:

(1) the address of the principal office of the nonresident pharmacy and the names and titles of all principal corporate officers [~~and all pharmacists who are dispensing controlled substances or dangerous drugs to residents of this state. A report containing this information shall be made on an annual basis and within thirty days after any change of office location, corporate officer or pharmacist in charge~~];

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(2) that the nonresident pharmacy complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is a resident, as well as with requests for information made by the board pursuant to this section;

(3) that the nonresident pharmacy maintains, at all times, a valid license, permit or registration to operate the pharmacy in compliance with the laws of the state in which it is a resident;

(4) a copy of the most recent inspection report resulting from an inspection of the nonresident pharmacy conducted by the regulatory or licensing agency of the state in which it is a resident; and

(5) that the nonresident pharmacy maintains its records of controlled substances or dangerous drugs that are dispensed to patients in this state so that the records are readily retrievable.

B. A nonresident pharmacy licensed under this section shall provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the nonresident pharmacy who has access to the patient's records. A nonresident pharmacy shall provide the toll-free telephone service during its regular hours of operation, but not less than six days a week and for a minimum of forty hours a week. The toll-free telephone number shall be

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disclosed on a label affixed to each container of drugs dispensed to patients in this state.

C. Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacies."

SECTION 7. A new section of the Pharmacy Act is enacted to read:

"[NEW MATERIAL] PROTECTED ACTIONS--COMMUNICATION.--

A. No current or former member of the board, officer, administrator, staff member, committee member, examiner, representative, agent, employee, consultant, witness or any other person serving or having served the board shall bear liability or be subject to civil damages or criminal prosecutions for any action or omission undertaken or performed within the scope of the board's duties.

B. All written and oral communications made by any person to the board relating to actual and potential disciplinary action shall be confidential communications and are not public records for the purposes of the Inspection of Public Records Act. All data, communications and information acquired by the board relating to actual or potential disciplinary action shall not be disclosed except to the extent necessary to carry out the board's purposes or in a judicial appeal from the board's actions or in a referral of cases made to law enforcement agencies, national database clearinghouses

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or other licensing boards.

C. Prescription monitoring program information, including prescription information and audit trail information, shall be confidential and are not public records for the purposes of the Inspection of Public Records Act or subject to subpoena or disclosure by court order, except as allowed by board rule.

D. No person or legal entity providing information to the board in good faith, whether as a report, a complaint or testimony, shall be subject to civil damages or criminal prosecution."

SECTION 8. REPEAL.--Sections 61-11A-1 through 61-11A-8 NMSA 1978 (being Laws 1987, Chapter 284, Sections 1 through 8) are repealed.

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