SENATE BILL 271

54TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2019

INTRODUCED BY

Pete Campos

AN ACT

RELATING TO PROFESSIONAL LICENSURE; AMENDING AND ENACTING SECTIONS OF THE PHARMACY ACT TO ESTABLISH ADDITIONAL LICENSURE AND REGISTRATION COMPLIANCE REQUIREMENTS AND PROVIDE LIABILITY AND COMMUNICATION PROTECTIONS; PROVIDING PENALTIES.

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,

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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 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~~] the information, regardless of whether [~~such~~] 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,

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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.";

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

(3) "RX only";

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

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

J. "distribute" means the delivery of a drug or

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device other than by administering or dispensing;

K. "drug" means:

(1) an article recognized as a drug in [~~any~~] 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 [~~any~~] a function of the body of humans or other animals; and

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

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

(1) known allergies;

(2) rational therapy contraindications;

(3) reasonable dose and route of administration;

(4) reasonable directions for use;

(5) duplication of therapy;

(6) drug-drug interactions;

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(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 [~~any~~] 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 which label includes all information required by federal or state law or regulations adopted pursuant to federal or state law;

P. "licensed practitioner" means a person engaged in a profession licensed by [~~any~~] a state, territory or possession of the United States who, within the limits of [~~his~~] 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

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repackaging, labeling or relabeling and the promotion and marketing of [~~such~~] 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 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;

[~~T.~~] U. "patient counseling" means the oral communication by the pharmacist of information to a patient or [~~his~~] the patient's 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

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

[~~Y.~~] Z. "pharmacy" means a [~~licensed~~] place of business licensed by the board 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

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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~~] 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, [~~his~~] the prescriber's 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;

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;

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

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

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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

[~~EE.~~] HH. "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~~] 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 61-11-9.1 NMSA 1978 (being Laws 2007, Chapter 79, Section 4) is amended to read:

"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

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shall apply to initial applicants or renewal applicants as a condition for obtaining or maintaining licensure as a drug manufacturer, nonresident pharmacy, [~~or~~] wholesale drug distributor, outsourcing facility, repackager or third-party logistics provider.

C. The board shall 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 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 3. Section 61-11-11 NMSA 1978 (being Laws 1969,

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Chapter 29, Section 10, as amended) is amended to read:

"61-11-11. PHARMACIST INTERN--QUALIFICATIONS FOR LICENSURE.--The classification of pharmacist intern is established. An applicant for licensure as a pharmacist intern shall:

A. be not less than eighteen years of age and not be addicted to the use of drugs or alcohol;

B. have satisfactorily completed [~~not less than thirty semester hours or the equivalent thereof~~] educational requirements established by rules of the board in a school or college of pharmacy approved by the board; and

C. meet other requirements established by regulation of the board."

SECTION 4. 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~~] CLASSES OF LICENSES--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~~] an activity in this state requiring licensure by the board 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

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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, outsourcing facility license, repackager 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;

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(15) drug research facilities;

(16) drug warehouses;

(17) contact lens sellers;

(18) medicinal gas repackagers; [~~and~~]

(19) medicinal gas sellers;

(20) outsourcing facilities;

(21) repackagers; and

(22) third-party logistics providers.

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, outsourcing facility, repackager or third-party logistics provider shall be accompanied by a fee not to exceed one thousand dollars ($1,000) per year;

(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

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office; home care services; emergency medical services; animal control facilities; [~~or~~] wholesaler, retailer or distributor of veterinary drugs; contact lens sellers; or medicinal gas sellers 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

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location to be licensed;

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

(7) other information the board may require, including a criminal background check and financial history, provided that manufacturers distributing their own products that have been licensed or approved by the food and drug administration shall be exempt from criminal background check and financial history requirements pursuant to this section.

G. After preliminary approval of the application for a license for any facility or business listed in Paragraphs (1) through (8) and (10) through [~~(19)~~] (22) 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

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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 5. Section 61-11-20 NMSA 1978 (being Laws 1969, Chapter 29, Section 19, as amended) is amended to read:

"61-11-20. DISCIPLINARY PROCEEDINGS--UNIFORM LICENSING ACT.--

A. In accordance with the Uniform Licensing Act,

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the board may deny, withhold, suspend or revoke any registration or license held or applied for under the Pharmacy Act upon grounds that the licensee or applicant:

(1) is guilty of gross immorality or dishonorable or unprofessional conduct as defined by regulation of the board;

(2) is convicted of a violation of [~~any~~] a federal law relating to controlled substances, [~~any~~] a federal food and drug law or [~~any~~] a federal law requiring the maintenance of drug records;

(3) is guilty of a violation of the Controlled Substances Act, the Drug Product Selection Act, the Imitation Controlled Substance Act, the Pharmacy Act, [~~or~~] the New Mexico Drug, Device and Cosmetic Act or the Drug Precursor Act;

(4) is addicted to the use of dangerous drugs or narcotic drugs of any kind;

(5) is habitually intemperate;

(6) is guilty of knowingly or fraudulently adulterating or misbranding or causing to be adulterated or misbranded any drugs;

(7) is guilty of procuring or attempting to procure licensure as a pharmacist or pharmacist intern, registration as a pharmacy technician or licensure for a pharmacy or pharmaceutical business in this state for [~~himself~~] the licensee's or applicant's own self or another by knowingly

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making or causing to be made false representations to the board;

(8) is unfit or unable to practice pharmacy by reason of a physical or mental disease or disability as determined by the board and based on competent medical authority, during the period of such disability;

(9) fails to maintain any drug [~~records~~] record required by [~~any~~] federal law [~~resulting~~] and that failure results in the condemnation of any drugs in [~~his~~] the licensee's or applicant's possession or control;

(10) is convicted of [~~any~~] a felony;

(11) has furnished false or fraudulent material in [~~any~~] an application made in connection with drug or device manufacturing or distribution;

(12) has had [~~any~~] a nonresident pharmacy, drug manufacturer, [~~or~~] wholesale drug distributor, returned drugs processor, outsourcing facility, repackager or third-party logistics provider license or federal registration suspended or revoked;

(13) has obtained [~~any~~] remuneration for professional services by fraud, misrepresentation or deception;

(14) has dealt with drugs or devices that [~~he~~] the licensee or applicant knew or should have known were stolen;

(15) has purchased or received a drug or

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device from a source other than a person or pharmacy licensed pursuant to the Pharmacy Act, unless otherwise provided in that act, the Controlled Substances Act or the New Mexico Drug, Device and Cosmetic Act;

(16) is a wholesale drug distributor, manufacturer, outsourcing facility or repackager other than a pharmacy and dispenses or distributes drugs or devices directly to a patient;

(17) has violated [~~any~~] a rule [~~or regulation~~] adopted by the board pursuant to the Pharmacy Act; or

(18) has divulged or revealed confidential information or personally identifiable information to a person other than a person authorized by the provisions of the Pharmacy Act or regulations adopted pursuant to that act to receive [~~such~~] that information.

B. Disciplinary proceedings may be instituted by [~~any~~] a person, shall be by sworn complaint and shall conform with the provisions of the Uniform Licensing Act. [~~Any~~] A party to the hearing may obtain a copy of the hearing record upon payment of costs for the copy.

C. The board may modify [~~any~~] a prior order of revocation, suspension or refusal to issue a license of a pharmacist or a pharmacist intern or registration of a pharmacy technician but only upon a finding by the board that there no longer exist any grounds for disciplinary action; provided that

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[~~any~~] cessation of the practice of pharmacy for twelve months or more shall require the pharmacist to undergo additional education, internship or examination as the board determines necessary."

SECTION 6. A new section of the Pharmacy Act is enacted to read:

"[NEW MATERIAL] PROTECTED 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. 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.

C. No person or legal entity providing information to the board in good faith, whether as a report, a complaint or

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testimony, shall be subject to civil damages or criminal prosecutions."

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