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HOUSE BILL

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

INTRODUCED BY

DISCUSSION DRAFT

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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1 result of a licensed practitioner's prescription or for the
2 purpose of, or as an incident to, research, teaching or
3 chemical analysis and not for sale or dispensing.

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

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

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

24 F. "custodial care facility" means a nursing home,
25 retirement care, mental care or other facility that provides

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

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

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

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

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

16 G. "dangerous drug" means a drug that is required
17 by an applicable federal or state law or rule to be dispensed
18 pursuant to a prescription or is restricted to use by licensed
19 practitioners; or that is required by federal law to be labeled
20 with any of the following statements prior to being dispensed
21 or delivered:

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

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

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1 (3) "RX only";

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

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

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

15 K. "drug" means:

16 (1) an article recognized as a drug in an
17 official compendium or its supplement that is designated from
18 time to time by the board for use in the diagnosis, cure,
19 mitigation, treatment or prevention of disease in humans or
20 other animals;

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

24 (3) an article, other than food, that affects
25 the structure or a function of the body of humans or other

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1 animals; and

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

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

7 (1) known allergies;

8 (2) rational therapy contraindications;

9 (3) reasonable dose and route of
10 administration;

11 (4) reasonable directions for use;

12 (5) duplication of therapy;

13 (6) drug-drug interactions;

14 (7) adverse drug reactions; and

15 (8) proper use and optimum therapeutic
16 outcomes;

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

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

22 O. "labeling" means the process of preparing and
23 affixing a label to a drug container exclusive of the labeling
24 by a manufacturer, packer or distributor of a nonprescription
25 drug or commercially packaged prescription drug or device; and

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1 which label includes all information required by federal or
2 state law or regulations adopted pursuant to federal or state
3 law;

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

9 Q. "manufacturing" means the production,
10 preparation, propagation, conversion or processing of a drug or
11 device, either directly or indirectly, by extraction from
12 substances of natural origin or independently by means of
13 chemical or biological synthesis and includes packaging or
14 repackaging, labeling or relabeling and the promotion and
15 marketing of the drugs or devices. "Manufacturing" also
16 includes the preparation and promotion of commercially
17 available products from bulk compounds for resale by
18 pharmacies, licensed practitioners or other persons;

19 R. "nonprescription drugs" means nonnarcotic
20 medicines or drugs that may be sold without a prescription and
21 are prepackaged for use by a consumer and are labeled in
22 accordance with the laws and regulations of the state and
23 federal governments;

24 S. "nonresident pharmacy" means any pharmacy
25 located outside New Mexico that ships, mails or delivers, in

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1 any manner, drugs into New Mexico;

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

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

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

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

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

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

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

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

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

9 CC. "practice of pharmacy" means the evaluation and
10 implementation of a lawful order of a licensed practitioner;
11 the dispensing of prescriptions; the participation in drug and
12 device selection or drug administration that has been ordered
13 by a licensed practitioner, drug regimen reviews and drug or
14 drug-related research; the administering or prescribing of
15 dangerous drug therapy; the provision of patient counseling and
16 pharmaceutical care; the responsibility for compounding and
17 labeling of drugs and devices; the proper and safe storage of
18 drugs and devices; and the maintenance of proper records;

19 DD. "prescription" means an order given
20 individually for the person for whom prescribed, either
21 directly from a licensed practitioner or the licensed
22 practitioner's agent to the pharmacist, including electronic
23 transmission or indirectly by means of a written order signed
24 by the prescriber, that bears the name and address of the
25 prescriber, the prescriber's license classification, the name

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

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

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

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

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

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

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1 "61-11-5. BOARD MEETINGS--QUORUM--OFFICERS--BONDS--
2 EXPENSES.--

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

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

17 C. A majority of the board constitutes a quorum.

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

21 SECTION 3. Section 61-11-6 NMSA 1978 (being Laws 1969,
22 Chapter 29, Section 5, as amended) is amended to read:

23 "61-11-6. POWERS AND DUTIES OF BOARD.--

24 A. The board shall:

25 (1) promulgate rules in accordance with the

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1 provisions of the State Rules Act to carry out the provisions
2 of the Pharmacy Act in accordance with the provisions of the
3 Uniform Licensing Act;

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

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

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

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

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

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

25 (8) conduct hearings upon charges relating to

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1 the discipline of a registrant or licensee or the denial,
2 suspension or revocation of a registration or a license in
3 accordance with the Uniform Licensing Act;

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

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

9 (11) make an annual report to the governor;

10 (12) appoint and employ, in the board's
11 discretion, a qualified person who is not a member of the board
12 to serve as executive director and define the executive
13 director's duties and responsibilities; except that the power
14 to deny, revoke or suspend any license or registration
15 authorized by the Pharmacy Act shall not be delegated by the
16 board;

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

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

23 (15) have the authority to employ a competent
24 attorney to give advice and counsel in regard to any matter
25 connected with the duties of the board, to represent the board

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1 in any legal proceedings and to aid in the enforcement of the
2 laws in relation to the pharmacy profession and to fix the
3 compensation to be paid to the attorney; provided, however,
4 that the attorney shall be compensated from the money of the
5 board, including that provided for in Section 61-11-19 NMSA
6 1978;

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

9 (17) provide a registry of all persons
10 licensed as pharmacists or pharmacist interns in the state;

11 (18) promulgate rules that prescribe the
12 activities and duties of pharmacy owners and pharmacists in the
13 provision of pharmaceutical care, emergency prescription
14 dispensing, drug regimen review and patient counseling in each
15 practice setting;

16 (19) promulgate, after [~~approval by~~]
17 consultation with the New Mexico medical board and the board of
18 nursing, rules and protocols for the prescribing of dangerous
19 drug therapy, including vaccines and immunizations, and the
20 appropriate notification of the primary or appropriate
21 physician of the person receiving the dangerous drug therapy;
22 [~~and~~]

23 (20) have the authority to authorize emergency
24 prescription dispensing;

25 (21) enforce and administer the provisions of

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

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

10 B. The board may:

11 (1) delegate its authority to the executive
12 director to issue temporary licenses as provided in Section
13 61-11-14 NMSA 1978;

14 (2) provide by rule for the electronic
15 transmission of prescriptions; and

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

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

23 "61-11-7. DRUG DISPENSATION--LIMITATIONS.--

24 A. The Pharmacy Act does not prohibit:

25 (1) a hospital or state or county institution

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1 or clinic without the services of a staff pharmacist from
2 acquiring and having in its possession a dangerous drug for the
3 purpose of dispensing if it is in a dosage form suitable for
4 dispensing and if the hospital, institution or clinic employs a
5 consulting pharmacist, and if the consulting pharmacist is not
6 available, the withdrawal of a drug from stock by a licensed
7 professional nurse on the order of a licensed practitioner in
8 such amount as needed for administering to and treatment of a
9 patient;

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

17 (3) the sale of nonnarcotic, nonpoisonous or
18 nondangerous nonprescription medicines or preparations by
19 nonregistered persons or unlicensed stores when sold in their
20 original containers;

21 (4) the sale of drugs intended for veterinary
22 use; provided that if the drugs bear the legend: "Caution:
23 federal law restricts this drug to use by or on the order of a
24 licensed veterinarian", the drug may be sold or distributed
25 only as provided in Subsection A of Section 26-1-15 NMSA 1978,

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1 by a person possessing a license issued by the board pursuant
2 to Subsection B of Section 61-11-14 NMSA 1978;

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

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

12 (7) pharmacy technicians from providing
13 assistance to pharmacists;

14 (8) a pharmacist from prescribing dangerous
15 drug therapy, including vaccines and immunizations, under rules
16 and protocols adopted by the board after ~~[approval by]~~
17 consultation with the New Mexico medical board and the board of
18 nursing;

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

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

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1 create patient suffering;

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

4 (c) the quantity of prescription drug
5 dispensed does not exceed a [~~seventy-two-hour~~] thirty-day
6 supply;

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

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

15 (10) the possession, storage, distribution,
16 dispensing, administration or prescribing of an opioid
17 antagonist in accordance with the provisions of Section 24-23-1
18 NMSA 1978.

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

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

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1 "61-11-9.1. SURETY BONDS.--

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

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

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

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

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

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

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

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

13 "61-11-14.1. NONRESIDENT PHARMACY LICENSURE--TOLL-FREE
14 TELEPHONE SERVICE.--

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 or other licensing boards.

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

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

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