SENATE BILL

52ND LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2015

INTRODUCED BY

DISCUSSION DRAFT

AN ACT

RELATING TO PRESCRIPTION DRUGS; AMENDING AND ENACTING SECTIONS OF THE PHARMACY ACT TO REQUIRE THE BOARD OF PHARMACY TO ESTABLISH A PEDIATRIC PSYCHOTROPIC DRUG MONITORING PROGRAM TO MONITOR THE PRESCRIBING OF PSYCHOTROPIC DRUGS TO MINORS; ESTABLISHING THE PEDIATRIC PSYCHOTROPIC DRUG REVIEW PANEL; MAKING AN APPROPRIATION.

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 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

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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.";

(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

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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 [~~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;

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(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 [~~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

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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~~] 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. "minor" means an individual under twenty-one years of age;

[~~R.~~] S. "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.~~] 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~~] 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 of drug therapy and other patient care services related to drug

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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 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

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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. "psychotropic drug" means a dangerous drug for which the primary indication for use has been approved by the federal food and drug administration for the treatment of mental disorders and that is listed as a psychotherapeutic agent in *Drug Facts and Comparisons* or in the American hospital formulary service publication, *Drug Information*;

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

[~~EE.~~] GG. "wholesale drug distributor" means a person engaged in the wholesale distribution of prescription

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

"[NEW MATERIAL] PEDIATRIC PSYCHOTROPIC DRUG MONITORING PROGRAM--DATABASE--PORTAL--ACCESS TO PSYCHOTROPIC INFORMATION.--

A. The board shall adopt and promulgate rules to establish a pediatric psychotropic drug monitoring program to monitor the dispensing of psychotropic drugs to minors in the state. The program shall establish:

(1) a database to collect information about each psychotropic drug dispensed in the state, accessible via a web site portal maintained by the board;

(2) a requirement that pharmacists that dispense psychotropic drugs to minors shall enter information into the database established pursuant to Paragraph (1) of this subsection;

(3) a requirement that licensed practitioners with authority to prescribe psychotropic drugs to minors check the database to survey any other prescriptions for psychotropic

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drugs dispensed to a minor for whom the practitioner is considering prescribing a psychotropic drug before issuing a prescription for a psychotropic drug to that minor; and

(4) a system for notifying the pediatric psychotropic drug review panel whenever two or more psychotropic drugs have been dispensed to a particular minor.

B. With each notification made pursuant to Subsection A of this section, the board shall provide to the pediatric psychotropic drug review panel the following information about each psychotropic drug dispensed:

(1) the pharmacist's federal drug enforcement administration number;

(2) the date of the prescription;

(3) the prescription number;

(4) whether the prescription for each psychotropic drug is a new prescription or a refill;

(5) the national drug code;

(6) the quantity dispensed;

(7) the name of the patient;

(8) the address of the patient;

(9) the patient's date of birth;

(10) the federal drug enforcement administration number of the prescribing licensed practitioner;

(11) the payment classification of the prescription; and

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(12) if available, the indication for which the psychotropic drug was prescribed.

C. A pharmacist shall submit to the board by electronic means information regarding each psychotropic drug dispensed in the state that has been prescribed for a minor. Board rules shall provide that a pharmacist submit information at least as often as every seven days.

D. Information to be reported shall conform in format, content and frequency to rules promulgated and adopted by the board.

E. In accordance with state and federal law, board rules shall provide for the sharing of information collected pursuant to the pediatric psychotropic drug monitoring program with the pediatric psychotropic drug review panel.

F. Prescription information submitted to the board pursuant to this section shall be confidential and not subject to public or open records laws. The board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to persons except as provided in this section.

G. The board may contract with another agency of this state or with a private vendor to ensure the effective operation of the pediatric psychotropic drug monitoring program. The board and any contractor authorized pursuant to

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this subsection shall comply with provisions regarding the confidentiality of prescription information in accordance with state and federal law."

SECTION 3. A new section of the Pharmacy Act is enacted to read:

"[NEW MATERIAL] PEDIATRIC PSYCHOTROPIC DRUG REVIEW PANEL--ESTABLISHMENT--MEMBERSHIP.--

A. The "pediatric psychotropic drug review panel" is created. The board shall appoint the following members of the panel:

(1) at least two licensed practitioners authorized to prescribe psychotropic drugs to minors pursuant to their scopes of practice and status as practitioners under the New Mexico Drug, Device and Cosmetic Act;

(2) at least three individuals with expertise in child development; and

(3) at least two individuals with expertise in child psychology or child psychosocial well-being who are licensed pursuant to the Professional Psychologist Act, the Counseling and Therapy Practice Act or the Social Work Practice Act.

B. In addition to the members appointed pursuant to Subsection A of this section, the pediatric psychotropic drug review panel shall include one representative from the children, youth and families department and one representative

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from the human services department with expertise in the administration of publicly funded behavioral health services for minors, appointed by the secretary of their respective departments.

C. The board shall provide administrative support to the pediatric psychotropic drug review panel.

D. The chair of the board shall call the first meeting of the pediatric psychotropic drug review panel. At that meeting, the members shall elect a chair and a vice chair of the panel, as well as any other officers it deems necessary. Members shall serve for terms of three years. The chair, vice chair and any other officers of the panel shall serve no more than two consecutive terms in their respective offices.

E. Members of the pediatric psychotropic drug review panel who are not public officers or public employees may receive per diem and mileage pursuant to the Per Diem and Mileage Act for attendance at panel meetings in person or by means of telecommunication technology.

F. A member of the pediatric psychotropic drug review panel or a member's spouse, parent or child shall not be employed or have any financial interest in a wholesale drug distributor."

SECTION 4. A new section of the Pharmacy Act is enacted to read:

"[NEW MATERIAL] PEDIATRIC PSYCHOTROPIC DRUG REVIEW PANEL--

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DUTIES.--

A. The pediatric psychotropic drug review panel shall:

(1) establish standards for the prescribing and dispensing of psychotropic drugs to minors;

(2) conduct outreach and education to licensed practitioners with authority to prescribe psychotropic drugs; and

(3) review information received pursuant to Paragraph (2) of Subsection A of Section 2 of this 2015 act and conduct outreach and education with licensed practitioners who prescribe a psychotropic drug to a minor when that minor has already been prescribed at least one other psychotropic drug. The panel may contact the licensed practitioner's licensing authority and conduct joint education and outreach efforts with the licensed practitioner on the risks associated with psychotropic drugs for minors.

B. In accordance with state and federal law, the board shall establish by rule requirements for licensed practitioners with authority to prescribe psychotropic drugs to comply with the pediatric psychotropic drug review panel's requests for information related to a physical or behavioral health diagnosis or service provided to a minor."

SECTION 5. A new section of the Pharmacy Act is enacted to read:

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"[NEW MATERIAL] FEE--PEDIATRIC PSYCHOTROPIC DRUG MONITORING PROGRAM--PEDIATRIC PSYCHOTROPIC DRUG REVIEW PANEL.--The board may by rule establish a reasonable fee to cover the cost of administering the pediatric psychotropic drug monitoring program and the activities of the pediatric psychotropic drug review panel."

SECTION 6. APPROPRIATION.--One hundred thousand dollars ($100,000) is appropriated from the general fund to the board of pharmacy for expenditure in fiscal year 2016 to establish and administer the pediatric psychotropic drug monitoring program and to establish and administer the activities of the pediatric psychotropic drug review panel. Any unexpended or unencumbered balance remaining at the end of fiscal year 2016 shall revert to the general fund.

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