

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 29 CONTROLLED SUBSTANCE PRESCRIPTION MONITORING PROGRAM

16.19.29.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
 [16.19.29.1 NMAC - N, 07-15-04]

16.19.29.2 SCOPE: All persons that dispense controlled substances pursuant to prescriptions from practitioners and practitioners who dispense controlled substances directly to a patient under their care. All persons authorized to receive disclosure of prescription monitoring program prescription information.
 [16.19.29.2 NMAC - N, 07-15-04; A, 03-22-15; A, 11-27-16]

16.19.29.3 STATUTORY AUTHORITY: Sections 30-31-1 through 30-31-41 of the Controlled Substance Act NMSA 1978, authorizes the board of pharmacy to promulgate rules and charge reasonable fees regarding controlled substances. Section 30-31-16 of the Controlled Substance Act NMSA 1978 authorizes the board to collect information regarding controlled substances.
 [16.19.29.3 NMAC - N, 07-15-04, A, 03-22-15]

16.19.29.4 DURATION: Permanent.
 [16.19.29.4 NMAC - N, 07-15-04]

16.19.29.5 EFFECTIVE DATE: July 15, 2004, unless a later date is cited at the end of a section.
 [16.19.29.5 NMAC - N, 07-15-04]

16.19.29.6 OBJECTIVE: The objective of Part 29 of Chapter 19 is to promote the public health and welfare by detecting and preventing substance abuse and misuse, and encouraging appropriate treatment of pain and other conditions for which controlled substances are prescribed. The purpose of the program is to improve access to controlled substances prescription information for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. The program's objectives will include education of the public and health care professionals regarding the nature and extent of the problem of drug abuse, and appropriate prescribing and use of controlled substances.
 [16.19.29.6 NMAC - N, 07-15-04; A, 03-22-15; A, 09-25-18]

16.19.29.7 DEFINITIONS:

A. "Audit trail information" means any query based information resulting from an authorized prescription monitoring program user's request for a prescription monitoring program report, which could include the user's name, date and time of the query or other related information.

B. "Board" means the New Mexico board of pharmacy, herein referred to as the board.

C. "Controlled substance" has the meaning given such term in Section 30-31-2 NMSA 1978.

D. "Delegate" means an individual authorized as an agent of a practitioner or pharmacist for the purpose of obtaining data from the PMP for review by the practitioner or pharmacist. The delegate must report directly to said practitioner or pharmacist and the practitioner or pharmacist shall be accountable for the delegate's actions:

(1) a pharmacist's delegate must be a certified pharmacy technician or a registered intern;

(2) a pharmacy technician or pharmacist intern may access information to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing any controlled substance, or for the purposes of a pharmacist providing pharmaceutical care as defined in law.

E. "Dispenser" means the person who delivers a schedule II - V controlled substance as defined in Subsection F of this section to the ultimate user, but does not include the following:

(1) a licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care;

(2) a practitioner, or other authorized person who administers such a substance; or

(3) a practitioner who dispenses to the patient no more than 12 dosage units or 72 hours' worth (whichever is less) of such a substance or;

(4) a wholesale distributor of a schedule II - V controlled substance;

(5) clinics, urgent care or emergency departments dispensing to the patient no more than 12 dosage units or 72 hours' worth (whichever is less) of such a substance or;

(6) a veterinarians or veterinary clinics dispensing to non-human patients.

F. "Patient" means the ultimate user of a drug for whom a prescription is issued and for whom a drug is dispensed.

G. "Person" means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture or any legal or commercial entity.

H. "PMP director" means the individual authorized by the board to administer the prescription monitoring program (PMP).

I. “PMP report” means a compilation of data generated from the PMP concerning a patient, a dispenser, a practitioner, or a schedules II - V controlled substance.

J. “Practitioner” means a person maintaining licensure pursuant to state law that allows him or her to prescribe controlled substance medications in accordance with that licensure.

K. “Prescription monitoring program” (PMP) means a program as described in 16.19.29.6 NMAC which includes a centralized system to collect, monitor, and analyze electronically, for schedules II - V controlled substances, prescribing and dispensing data submitted by dispensers of which the data is to be used to support efforts in education, research, enforcement and abuse prevention.

L. “Schedule II - V controlled substance” means a substance listed in schedules II, III, IV, and V as set forth in the Controlled Substance Act, Sections 30-31-5 through 30-31-10 NMSA 1978 or the federal Controlled Substances Regulation (21 U.S.C. 812).

M. “State” means the state of New Mexico.

[16.19.29.7 NMAC - N, 07-15-04; A, 06-11-11; A, 08-31-12; A, 10-24-14; A, 03-22-15; A, 11-27-16; A, 09-25-18]

16.19.29.8 MANDATORY REPORTING OF PRESCRIPTION INFORMATION TO THE PMP:

A. The board shall monitor the dispensing of all schedule II - V controlled substances by all dispensers licensed to dispense such substances to patients in this state.

B. Each dispenser shall submit to the board by electronic means information regarding each prescription dispensed for a drug included under Subsection A of this section. Information to be submitted for each prescription as well as the standards for how this information shall be formatted, not contrary to law, is defined in the PMP data reporting manual available on the state PMP website at <http://nmpmp.org> shall include at a minimum:

- (1) dispenser NPI number;
- (2) dispenser NCPDP number;
- (3) dispenser DEA number;
- (4) patient name;
- (5) patient address;
- (6) patient date of birth;
- (7) patient gender;
- (8) reporting status (new, revised, void);
- (9) prescription number;
- (10) date prescription written;
- (11) refills authorized;
- (12) date prescription filled;
- (13) refill number;
- (14) product ID (NDC) + product ID qualifier;
- (15) quantity dispensed;
- (16) days' supply;
- (17) drug dosage units;
- (18) transmission form of Rx origin;
- (19) payment type;
- (20) prescriber NPI number; (except veterinarians)
- (21) prescriber DEA number.

C. Dispenser reporting:

(1) each dispenser shall submit the information required under Subsection B of this section in accordance with transmission methods and frequency established by the board; but shall report within one business day of the prescription being filled.

(2) if a dispenser pharmacy did not dispense any schedule II – V controlled substances during an operating business day, the dispenser shall submit a “zero report” within one business day. Information to be submitted with each zero report as well as the standards for how this information shall be formatted, not contrary to law, is defined in the PMP data reporting manual available on the state PMP website at <http://nmpmp.org> shall include at a minimum:

- (a) dispenser DEA number;
- (b) reporting start date; and
- (c) reporting end date.

(3) the PMP director shall have the authority to approve submission schedules that exceed one business day.

D. Corrections to information submitted to the PMP must be addressed including:

- (1) file upload or “outstanding uncorrected errors” as defined in the PMP data reporting manual;
- (2) prescriptions that were not dispensed to the patient must be voided from the PMP;
- (3) incorrect information in prescriptions records submitted to the PMP must be submitted to the PMP

database within five business days once the dispenser has been notified or becomes aware of the incorrect information.

[16.19.29.8 NMAC - N, 07-15-04; A, 06-11-11; A, 08-31-12; A, 03-22-15; A, 03-23-16; A, 09-25-18]

16.19.29.9 DISCLOSURE OF PRESCRIPTION INFORMATION:

A. Prescription information submitted to the board shall not be subject to the Inspection of the Public Records Act, Sections 14-2-1 through 14-2-12 NMSA 1978 and shall be confidential except as provided in Subsections C through G of 16.19.29.9 NMAC.

B. The board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained in the PMP is not disclosed to persons except as provided in Subsection C through G of 16.19.29.9 NMAC.

C. Board inspectors may review prescription information after receiving complaints, and in the course of their enforcement of board administered statutes and regulations.

D. The board shall be authorized to provide PMP information to the following persons:

(1) persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients;

(2) a consultant pharmacist for the purpose of providing pharmaceutical care for a facility's patients; and in ensuring that facility records appropriately account for controlled substance receipt, administration and disposition;

(3) a delegate designated by a practitioner; or pharmacist; who must also maintain an active account, can designate one or more (up to four) delegates for the purpose of requesting and receiving PMP reports for the practitioner or pharmacist; the practitioner or pharmacist shall be responsible for terminating the delegate's access to the PMP within five business days of a delegate's authorization ending;

(4) state practitioner licensing boards whose licensees have prescriptive authority for controlled substances, including the medical board, board of nursing, board of veterinarian medicine, board of dental health care, board of examiners in optometry, board of osteopathic medicine, board of acupuncture and oriental medicine, and board of podiatry, as the PMP information relates to their licensees;

(5) practitioner licensing authorities of other states if their licensees practice in this state or prescriptions provided by their licensees are dispensed in this state;

(6) local, state and federal law enforcement or prosecutorial officials engaged in an ongoing investigation of an individual in the enforcement of the laws governing licit drugs;

(7) the state human services department regarding medicaid program recipients;

(8) a state metropolitan, magistrate and district, or federal court as required by a grand jury subpoena or criminal court order;

(9) state drug court personnel as authorized by the PMP director;

(10) personnel of the board for purposes of administration and enforcement of this rule or of 16.19.20 NMAC;

(11) the prescription monitoring program of another state or group of states with whom the state has established an interoperability agreement;

(12) a living individual who request's his or her own PMP report in accordance with procedures established under the Pharmacy Act, Subsection D of Section 61-11-2 NMSA 1978 and Subsection H of 16.19.6.23 NMAC, or an agent authorized by the living individual along with a valid HIPAA release form or court issued subpoena, or;

(13) a parent to have access to the prescription records about his or her minor child, as his or her minor child's personal representative when such access is not inconsistent with state or other laws;

(14) licensed healthcare professionals (nurses, pharmacists and practitioners) from Medicare, health insurers, workers compensation program/insurers and pharmacy benefit managers for persons enrolled in or covered by their programs, as part of patient care for those persons.

E. The board shall use de-identified data obtained from the PMP database to identify and report to state and local public health authorities the geographic areas of the state where anomalous prescribing dispensing or use of controlled substances is occurring.

F. The board shall share PMP database data with the department of health for the purpose of tracking inappropriate prescribing and misuse of controlled substances, including drug overdose.

G. The board shall provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients and persons who have received prescriptions from dispensers.

H. PMP information gained from other states' prescription monitoring programs shall not be subject to civil subpoena, nor shall such information be disclosed, discoverable, or compelled to be produced in any civil proceeding, nor shall such records be deemed admissible as evidence in any civil proceeding for any reason.

[16.19.29.9 NMAC - N, 07-15-04; A, 06-11-11; A, 08-31-12; A, 03-22-15; A, 11-27-16; A, 09-25-18]

16.19.29.10 DISCLOSURE OF AUDIT TRAIL INFORMATION:

A. Audit trail information maintained by the board shall not be subject to the Inspection of Public Records Act, Sections 14-2-1 through 14-2-12 NMSA 1978, and shall be confidential except as provided in Subsection C and D of 16.19.29.10 NMAC.

B. The board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained in the PMP is not disclosed to persons except as provided in Subsection C and D of 16.19.29.10 NMAC.

C. Board inspectors may review audit trail information after receiving complaints, and in the course of their enforcement of board administered statutes and regulations.

D. The board shall be authorized to provide audit trail information to the following persons:

(1) state practitioner licensing boards whose licensees have prescriptive authority for controlled substances, including the medical board, board of nursing, board of veterinary medicine, board of dental health care, board of optometry, board of osteopathic medicine, board of acupuncture and oriental medicine, and board of podiatry, as the audit trail information relates to their licensees for the purposes of reviewing compliance with PMP utilization;

(2) practitioner licensing authorities of other states if their licensees practice in this state or prescriptions provided by their licensees are dispensed in this state as the audit trail information relates to their licensees for the purposes of reviewing compliance with PMP utilization requirements;

(3) personnel of the board for purposes of administration and enforcement of this rule or of 16.19.20 NMAC;

(4) the board shall share PMP database data with the department of health for the purpose of tracking inappropriate prescribing and misuse of controlled substances, including drug overdose.

E. Audit trail information shall not be subject to civil subpoena, nor shall such information be disclosed, discoverable, or compelled to be produced in any civil proceeding, nor shall such records be deemed admissible as evidence in any civil proceeding for any reason.

[16.19.29.10 NMAC - N, 07-15-04; A, 06-11-11; Repealed, 03-22-15; A, 09-25-18]

16.19.29.11 AUTHORITY TO CONTRACT: The board may contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the PMP. A contractor shall comply with the provisions regarding confidentiality of prescription information in 16.19.29.9 NMAC and shall be subject to the penalties specified in 16.19.29.14 NMAC.

[16.19.29.11 NMAC - N, 07-15-04; A, 03-22-15]

16.19.29.12 REGISTRATION FOR ACCESS TO PRESCRIPTION INFORMATION:

A. Persons authorized for access to PMP information as listed in Paragraphs (1) through (10) and (14) of Subsection D of 16.19.29.9 NMAC must apply for access as described at the PMP website located at <http://nmpmp.org> or as otherwise indicated. Persons granted access must maintain individual accounts and shall not share access information with other persons.

B. All persons authorized for access to PMP information and applying for such access to the PMP shall successfully complete a web based training program as determined by the PMP director.

C. Persons reporting prescription information to the PMP, but not authorized for access to PMP information must also apply for access as described at the PMP website located at <http://nmpmp.org> or as otherwise indicated.

D. The PMP director shall have the authority to set account access and registration renewal requirements necessary for accounts to be considered active and shall also have authority to cancel inactive accounts.

[16.19.29.12 NMAC - N, 07-15-04; 16.19.29.12 NMAC - N, 06-11-11; A, 08-31-12; A, 03-22-15; A, 11-27-16; A, 09-25-18]

16.19.29.13 INFORMATION EXCHANGE WITH OTHER PRESCRIPTION MONITORING PROGRAMS:

A. The board may provide PMP information to other states' prescription monitoring programs and such information may be used by those programs consistent with the provisions of this rule.

B. The board may request and receive PMP information from other states' prescription monitoring programs and may use such information under provisions of this rule.

C. The board may develop the capability to transmit information to and receive information from other prescription monitoring programs employing the standards of interoperability.

D. The board may enter into written agreements with other states' prescription monitoring programs or other persons hosting compatible information sharing technologies for the purpose of describing the terms and conditions for sharing of PMP information under this section.

[16.19.29.13 NMAC - N, 07-15-04; 16.19.29.13 NMAC - N, 06-11-11; A, 03-22-15]

16.19.29.14 PENALTIES:

A. A dispenser who knowingly fails to submit prescription monitoring information to the board as required by this rule or knowingly submits incorrect prescription information shall be subject to disciplinary proceedings as defined in Section 61-11-20 of the Pharmacy Act NMSA 1978.

B. Prescription information submitted to the PMP is protected health information. Persons with access to the PMP shall exercise due diligence in protecting this information and access it only as necessary in the course of legitimate professional regulatory, or law enforcement duties.

C. A person found to be in violation of this section may be subject to one or more of the following actions.

(1) Termination of access to PMP information.

(2) A complaint may be filed with his or her appropriate professional licensing entities.

[16.19.29.14 NMAC - Rn, 16.19.29.12 NMAC, 06-11-11; A, 08-31-12; A, 03-22-15]

16.19.29.15 SEVERABILITY: If any provisions of this rule or its application to any person or circumstance is held invalid or unenforceable, the remainder of this rule shall not be affected and shall be valid and enforceable.

[16.19.29.15 NMAC - Rn, 16.19.29.13 NMAC, 06-11-11; A, 03-22-15]

HISTORY OF 16.19.29 NMAC: [RESERVED]