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 or entities that dispense controlled substances pursuant to prescriptions from practitioners.
[16.19.29.2 NMAC - N, 07-15-04]

16.19.29.3 STATUTORY AUTHORITY: Section 30-31-16 of the Controlled Substance Act. 30-31-1 through 30-31-42 NMSA 1978, authorizes the board of pharmacy to promulgate regulations and charge reasonable fees regarding controlled substances. 30-31-16 authorizes the board to collect information regarding controlled substances.
[16.19.29.3 NMAC - N, 07-15-04]

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

16.19.29.5 EFFECTIVE DATE: 07-15-04, 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 encouraging appropriate treatment of pain and other conditions for which controlled substances are prescribed. The purpose of the system is to improve access to controlled substances 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, appropriate prescribing and use of controlled substances, and the medical treatment options for abusers of controlled substances and pain management.
[16.19.29.6 NMAC - N, 07-15-04]

16.19.29.7 DEFINITIONS:

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

B. "Board of pharmacy" means the state agency responsible for the functions listed in 16.19.29.8 NMAC.

C. "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued and for whom a drug is dispensed.

D. "Dispenser" means the person who delivers a schedule II - V controlled substance as defined in subsection E 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 wholesale distributor of a schedule II - V controlled substance.

E. "Schedule II, III, IV and V controlled substance" means substances that are listed in schedules II, III, IV, and V of the schedules provided under 30-31-5 to 30-31-10 of NMSA or the federal controlled substances regulation (21 U.S.C. 812).

F. "Report" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance.
[16.19.29.7 NMAC - N, 07-15-04]

16.19.29.8 REQUIREMENTS FOR THE PRESCRIPTION MONITORING PROGRAM:

A. The board shall monitor the dispensing of all schedule II, III, and IV controlled substances by all pharmacies 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 reported shall conform to the standards developed by the American society for automation in pharmacy (ASAP) and published in the "ASAP telecommunications format for controlled substances", 1995 edition. Information submitted for each prescription shall include:

(1) dispenser DEA number;
(2) date prescription filled;
(3) prescription number;
(4) whether the prescription is new or a refill;
(5) NDC code for drug dispensed;
(6) quantity dispensed;
(7) patient name;
(8) patient address;
(9) patient date of birth;
(10) prescriber DEA number;
(11) date prescription issued by prescriber;
(12) and if available, the diagnosis code using the current version of the international classification of diseases.

C. Each dispenser shall submit the information in accordance with transmission methods and frequency established by the board; but shall report at least every thirty days, between the 1st and 15th of the month following the month the prescription was dispensed. A record of each controlled substance prescription dispensed must be transmitted to the boards' agent by computer modem, computer disk, cassette tape or other acceptable electronic format monthly.

D. The board may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided that all information required in subsection B of this section is submitted in this alternative format. [16.19.29.8 NMAC - N, 07-15-04]

16.19.29.9 ACCESS TO PRESCRIPTION INFORMATION:

A. Prescription information submitted to the board shall be confidential and not subject to public or open records laws, except as provided in Subsections C, D and E 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 is not disclosed to persons except as in Subsection C, D, and E of this 16.19.29.9 NMAC.

C. After receiving a complaint, the board inspectors shall review the relevant prescription information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the board shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information required for an investigation.

D. The board will establish written protocols for reviewing the prescription data reported. These protocols will be reviewed and approved by the board as needed but at least once every calendar year. These protocols will define information to be screened, frequency and thresholds for screening and the parameters for using the data. Data will be used to notify providers, patients and pharmacies to educate, provide for patient management and treatment options.

E. The board shall be authorized to provide data in the prescription monitoring program 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) an individual who request's their own prescription monitoring information in accordance with procedures established under 61-11-2.D NMSA, 1978 and Subsection G of 16.19.6.23 NMAC.

(3) New Mexico medical board, New Mexico board of nursing, New Mexico board of veterinary medicine, New Mexico board of dental health care, board of examiners in optometry, osteopathic examiners board, acupuncture & oriental medicine board, and podiatry board for their licensees;

(4) professional licensing authorities of other states if their licensees practice in the state or prescriptions provided by their licensees are dispensed in the state;

(5) 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;

(6) human services department regarding medicaid program recipients;
(7) metropolitan, district, state or federal court(s) under grand jury subpoena or criminal court order;
(8) personnel of the board for purposes of administration and enforcement of this regulation, or 16.19.20 NMAC.

F. 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.

[16.19.29.9 NMAC - N, 07-15-04]

16.19.29.10 REPORTS: A written request will be filed with the board prior to release of a report.

A. Persons listed in Paragraphs (1) through (5) of Subsection D of 16.19.29.9 NMAC must submit a written request listing the information for the report. Practitioners, agencies and/or boards or commissions should prepare the request on letterhead.

B. Written reports will be prepared and delivered to the requesting person via U.S. mail.

C. Reports may be provided by secured electronic means after verification of electronic request.

D. The board will develop a system that provides timely access to prescription information to the healthcare providers using current technologies.

E. The board shall receive a quarterly program outcomes report from staff or contractors. A statistical analysis of the data that does not include protected information should be reported on the web site or in the newsletter.

[16.19.29.10 NMAC - N, 07-15-04]

16.19.29.11 AUTHORITY TO CONTRACT: The board is authorized to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contract shall be bound to comply with the provisions regarding confidentiality of prescription information in 16.19.29.9 NMAC of this regulation and shall be subject to the penalties specified in 16.19.29.12 NMAC of this regulation for unlawful regulations.

[16.19.29.11 NMAC - N, 07-15-04]

16.19.29.12 PENALTIES:

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

B. A person authorized to have prescription monitoring information pursuant to this regulation who knowingly discloses such information in violation of this regulation shall be subject to criminal proceedings as described in 26-1-16.D and 26-1-26 NMSA.

C. A person authorized to have prescription monitoring information pursuant to this regulation who uses such information in a manner or for a purpose in violation of this regulation shall be subject to criminal proceedings as described in 26-1-16.D and 26-1-26 NMSA.

[16.19.29.12 NMAC - N, 07-15-04]

16.19.29.13 SEVERABILITY: If any provisions of this regulation or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the regulation which can be given effect without the invalid provisions or applications, and to this end the provisions of this regulation are severable.

[16.19.29.13 NMAC - N, 07-15-04]

HISTORY OF 16.19.29 NMAC: [RESERVED]