

Following the definitions will be the section on Pharmacist Clinicians.

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 4 PHARMACIST

16.19.4.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, Albuquerque, NM.
[02-15-96; 16.19.4.1 NMAC - Rn, 16 NMAC 19.4.1, 03-30-02; A, 12-15-02; A, 08-16-10]

16.19.4.2 SCOPE: All designations of pharmacists subject to licensure and regulation by the Board of Pharmacy.
[02-15-96; 16.19.4.2 NMAC - Rn, 16 NMAC 19.4.2, 03-30-02]

16.19.4.3 STATUTORY AUTHORITY: Section 61-11-6.A.(1) authorizes the board of pharmacy to adopt, regularly review and revise rules and regulations necessary to carry out the provisions of the Pharmacy Act, Sections 61-11-1, 61-11-2, 61-11-4 to 61-11-28 NMSA 1978. Those provisions include the authority to (i) deny or take disciplinary action with respect to any certificate of registration or license held or applied for under the Pharmacy Act, Sections 61-11-20 NMSA 1978; (ii) require and establish criteria for continuing education as a condition of renewal of a pharmacist license, Sections 61-11-6.A.(4) NMSA 1978; (iii) issue permits or licenses, as defined and limited by board regulation, to nursing homes, industrial and public health clinics and home care services, Sections 61-11-6.A.(6), 61-11-14 NMSA 1978; (iv) provide for the annual renewal of licenses for pharmacists, Sections 61-11-6.A.(3), 61-11-13 NMSA 1978; (v) provide for the registration of pharmacist interns, their certification, annual renewal of certification, training, supervision, and discipline, Sections 61-11-6.A.(5) NMSA 1978; and (vi) adopt rules and regulations that establish patient counseling requirements, 61-11-6.A.(18) NMSA 1978. Under the Pharmacist Prescriptive Authority Act, Sections 61-11B-1 to 61-11B-3 NMSA 1978, the board is required to establish regulations governing certification as a pharmacist clinician. The Impaired Pharmacists Act, Sections 61-11A-1 to 61-11A-8 NMSA 1978, requires the establishment by the board of a plan for treatment and rehabilitation of impaired pharmacists.
[03-14-98; 16.19.4.3 NMAC - Rn, 16 NMAC 19.4.3, 03-30-02]

16.19.4.4 DURATION: Permanent
[02-15-96; 16.19.4.4 NMAC - Rn, 16 NMAC 19.4.4, 03-30-02]

16.19.4.5 EFFECTIVE DATE: February 15, 1996, unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.
[03-14-98; 16.19.4.5 NMAC - Rn, 16 NMAC 19.4.5, 03-30-02]

16.19.4.6 OBJECTIVE: The objective of Part 4 of Chapter 19 is to promote the delivery of quality pharmaceutical services by establishing comprehensive regulations governing pharmacists, conduct, continuing education and requirements, criteria for specialized certification, and duties and responsibilities.
[02-15-96; 16.19.4.6 NMAC - Rn, 16 NMAC 19.4.6, 03-30-02]

16.19.4.7 DEFINITIONS:

- A. “A year”** begins with the first day of the pharmacist’s birth month and ends the last day of the pharmacist’s birth month the following year.
- B. “Activity”** as used in the ACPE criteria for quality and these regulations, the term refers to an individual educational experience or program such as a lecture, home study course, workshop, seminar, symposium, etc.
- C. “Alternate supervising physician”** means a physician who holds a current unrestricted license, is a cosignatory on the notification of supervision, agrees to act as the supervising physician in the supervising physician’s absence, or expand the “scope of practice or sites of practice” of the pharmacist clinician and is approved by the board.
- D. “Approved provider”** means an institution, organization or agency that has been recognized by the accreditation council for pharmaceutical education (ACPE) as having met its criteria indicative of the ability to

provide quality continuing pharmaceutical education, and is listed in the ACPE annual publication of approved providers.

E. “**Board**” means the New Mexico board of pharmacy.

F. “**Consultation**” means communication in person, telephonically, by two-way radio, by e-mail or by other electronic means.

G. “**Contact hour**” means a unit of measure equivalent to 60 minutes of participation in an approved organized learning experience or activity.

H. “**Continuing education unit (CEU)**” means ten contact hours of participation or its equivalent in an organized continuing education activity sponsored by an approved provider.

I. “**Continuing pharmacy education (CPE)**” means a structured education activity offered by an approved provider, designed or intended to support the continuing development of pharmacies or pharmacy technicians to maintain and enhance their competence. Continuing pharmacy education should promote problem-solving and critical thinking and be applicable to the practice of pharmacy.

J. “**Continuing professional development (CPD)**” means the responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional, throughout their careers.

K. “**Criteria for quality**” means continuing education provider shall show evidence of adherence to the criteria adopted by the American council on pharmaceutical education as indicative of the ability to provide continuing pharmaceutical education activities; areas include: administrative and organization; budget and resources; teaching staff; educational content management of activity; method of delivery; facilities; evaluation mechanism.

L. “**Dangerous drug**” means a drug that, because of any potentiality for harmful effect or the methods of its use or the collateral measures necessary to its use, is not safe except under the supervision of a physician licensed by law to direct the use of such drug and the drug prior to dispensing is required by federal law and state law to bear the manufacturer’s legend “Caution: Federal law prohibits dispensing without a prescription”.

M. “**Guidelines or protocol**” means a written agreement between a pharmacist clinician or group of pharmacist clinicians and a physician or group of physicians that delegates prescriptive authority.

N. “**Initial pharmacist licensure**” means the license issued shall be valid for no less than 24 months. The license will expire the last date of his/her birth month that immediately follows the minimum 24 month time period.

O. “**Live programs**” means CPE activities that provide for direct interaction between faculty and participants and may include lectures, symposia, live teleconferences, workshops, etc.

P. “**Mediated forms**” means learning transmitted via intermediate mechanism such as audio and/visual tape, telephonic transmission, etc.

Q. “**Monitor dangerous drug therapy**” means to review the dangerous drug therapy regimen of patients by a pharmacist clinician for the purpose of evaluating and rendering advice to the prescribing physician regarding adjustment of the regimen. “Monitor dangerous drug therapy” includes:

(1) collecting and reviewing patient dangerous drug histories;

(2) measuring and reviewing routine patient vital signs including pulse, temperature, blood pressure and respiration;

(3) ordering and evaluating the results of laboratory tests relating to dangerous drug therapy, including blood chemistries and cell counts, controlled substance therapy levels, blood, urine, tissue or other body fluids, culture and sensitivity tests when performed in accordance with guidelines or protocols applicable to the practice setting and;

(4) evaluating situations that require the immediate attention of the physician and instituting or modifying treatment procedures when necessary.

R. “**Oversight committee**” means a joint committee made up of four members to hear issues regarding pharmacist clinicians’ prescriptive authority activities and supervising physicians’ direction of these activities.

S. “**Patient safety**” means the prevention of healthcare errors and the elimination or mitigation of patient injury caused by healthcare errors.

T. “**Pharmaceutical care**” means the provision 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.

U. “Pharmacist” means a person duly licensed by the board to engage in the practice of pharmacy pursuant to the Pharmacy Act, Sections 61-11-1, 61-11-2, 61-11-4 to 61-11-28 NMSA 1978.

V. “Pharmacist clinician” means a pharmacist with additional training required by regulations adopted by the board in consultation with the New Mexico medical board and the New Mexico academy of physician assistants, who exercises prescriptive authority in accordance with guidelines or protocol.

W. “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.

X. “Practice of pharmacy” means continually optimizing medication safety, patient wellness, and quality of services through the effective use of pharmaceutical care and emerging technologies and competency-based and performance-based training.

(1) Pharmaceutical dispensing including product selection. Practice of pharmacy may include, but is not limited to:

(2) specialty pharmacy practice including pharmacists working for licensed pharmaceutical manufacturers or wholesalers;

(3) practice of telepharmacy within and across state lines;

(4) engaging in health care educational activities;

(5) pharmacy-specific academia;

(6) provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care including patient counseling, prescriptive authority, drug administration, primary care, medication therapy management, collaborative practice, and monitoring dangerous drug therapy;

(7) inspecting on a full time basis to ensure compliance with the practice of pharmacy;

(8) provision of pharmaceutical and drug information services, as well as consultant pharmacy services;

(9) engaging in other phases of the pharmaceutical profession including those with research or investigational or dangerous drugs; or

(10) engaging in functions that relate directly to the administrative, advisory, or executive responsibilities pursuant to the practice of pharmacy in this state;

(11) the responsibility for compounding and labeling of drugs and devices;

(12) the proper and safe storage of drugs and devices; and

(13) the maintenance of proper records.

Y. “Practitioner” means a physician duly authorized by law in New Mexico to prescribe dangerous drugs including controlled substances in schedules II through V.

Z. “Prescriptive authority” means the authority to prescribe, administer, monitor or modify dangerous drug therapy.

AA. “Professional judgment” means a cognitive process, by a licensed pharmacist, that takes education, experience and current standards of practice into consideration when drawing conclusions and reaching decisions.

BB. “Renewal period” means continuing education programs or activities must be completed during the 24 month time period occurring between the first day of the pharmacist’s birth month and the last day of his/her birth month 2 years later.

CC. “Scope of practice” means those duties and limitations of duties placed upon a pharmacist clinician and/or the alternate supervising physician(s) and the board; includes the limitations implied by the field of practice of the supervising physician and/or the alternate supervising physician(s) and the board.

DD. “Supervising physician” means a doctor, or group of doctors, of medicine or osteopathy approved by the respective board to supervise a pharmacist clinician; “supervising physician includes a physician approved by the respective board as an alternate supervising physician.

[02-15-96; 16.19.4.7 NMAC - Rn, 16 NMAC 19.4.7, 03-30-02; A, 01-31-07; A, 08-16-10; A, 10-25-12; A, 11-13-18]

16.19.4.17 PHARMACIST CLINICIAN:

A. Purpose: The purpose of these regulations is to implement the Pharmacist Prescriptive Authority Act, Sections 61-11B-1 through 61-11B-3 NMSA 1978 by providing minimum standards, terms and conditions for the certification, registration, practice, and supervision of pharmacist clinicians. These regulations are adopted pursuant to Section 61-11B-3 NMSA 1978 of the Pharmacist Prescriptive Authority Act.

B. Initial certification and registrants.

(1) The board may certify and register a pharmacist as a pharmacist clinician upon completion of an application for certification and satisfaction of the requirements set forth in these regulations.

(2) A pharmacist who applies for certification and registration as a pharmacist clinician shall complete application forms as required by the board and shall pay a fee. The fee shall be set by the board to defray the cost of processing the application, which fee is not returnable.

(3) To obtain initial certification and registration as a pharmacist clinician, the following must be submitted:

(a) proof of completion of 60 hour board approved physical assessment course, followed by a 150 hour, 300 patient contact preceptorship supervised by a physician or other practitioner with prescriptive authority, with hours counted only during direct patient interactions;

(b) the applicant will submit a log of patient encounters as part of the application;

(c) patient encounters must be initiated and completed within two years of the application;

(d) a pharmacist clinician requesting a controlled substance registration to prescribe controlled substance in schedule II or schedule III shall be trained in responsible opioid prescribing practices. Educational programs shall include an understanding of the pharmacology and risks of controlled substances, a basic awareness of the problems of abuse, addiction, and diversion, and awareness of the state and federal regulations of the prescribing of controlled substances.

(4) The board shall register each pharmacist certified as a pharmacist clinician.

(5) Upon certification and registration by the board, the name and address of the pharmacist clinician, (name of the supervising physician if applicable), and other pertinent information shall be enrolled by the board on a roster of pharmacist clinicians.

C. Biennial renewal of registration.

(1) Renewal applications shall be submitted prior to the license expiration.

(2) Applications for renewal must include:

(a) after January 1, 2013, documentation of continuing education hours, including proof of completion of 2.0 CEU 20 contact hours of live CPE or continuing medical education (CME) approved by (ACPE) or AACME (live programs provided by other continuing education providers may be submitted for review and approval to the board), beyond the required hours in 16.19.4.10 NMAC (as amended), as required by the board; and

(b) effective January 1, 2015, a pharmacist clinician with a controlled substance registration to prescribe controlled substances listed in schedule II or schedule III shall complete a minimum of 0.2 CEU (two contact hours) per renewal period in the subject area of responsible opioid prescribing practices, and

(c) a current protocol of collaborative practice signed by the supervising physician (if prescriptive authority is sought); and

(d) a copy of the pharmacist clinicians registration with the supervising physicians board (if prescriptive authority is sought); and

(e) other additional information as requested by the board.

D. Prescriptive authority, guidelines or protocol.

(1) Only a registered pharmacist clinician with current protocols, registered with the New Mexico medical board or the New Mexico board of osteopathic medical examiners, may exercise prescriptive authority.

(2) A pharmacist clinician seeking to exercise prescriptive authority shall submit an application to the board. The application must include the supervising physicians' name and current medical license, protocol of collaborative practice and other information requested by the board. A pharmacist may submit the application with the initial application for certification or as a separate application after becoming certified and registered as a pharmacist clinician.

(3) The protocol will be established and approved by the supervising physician as set forth in these regulations and will be kept on file at each practice site of the pharmacist clinician and with the board.

(4) The protocol must include:

(a) name of the physician(s) authorized to prescribe dangerous drugs and name of the pharmacist clinician;

(b) statement of the types of prescriptive authority decisions the pharmacist clinician is authorized to make, including, but not limited to:

(i) types of diseases, dangerous drugs or dangerous drug categories involved and the type of prescriptive authority authorized in each case;

(ii) ordering lab tests and other tests appropriate for monitoring of drug therapy;

(iii) procedures, decision criteria or plan the pharmacist clinician is to follow when exercising prescriptive authority;

(c) activities to be followed by the pharmacist clinician while exercising prescriptive authority, including documentation of feedback to the authorizing physician concerning specific decisions made; documentation may be made on the prescriptive record, patient profile, patient medical chart or in a separate log book;

(d) description of appropriate mechanisms for consulting with the supervising physician, including a quality assurance program for review of medical services provided by the pharmacist clinician, (this quality assurance program will be available for board review); and

(e) description of the scope of practice of the pharmacist clinician.

(5) Pharmacist clinicians shall not prescribe dangerous drugs including controlled substances for self-treatment or treatment of immediate family members, except under emergency situations. This will not apply to medications that may be prescribed under 16.19.26 NMAC. Pharmacist clinicians shall not write a recommendation for the use of medical cannabis.

E. Scope of practice.

(1) A pharmacist clinician shall perform only those services that are delineated in the protocol and are within the scope of practice of the supervising physician or alternate supervising physician(s).

(2) A pharmacist clinician may practice in a health care institution within the policies of that institution.

(3) A pharmacist clinician may prescribe controlled substances provided that the pharmacist clinician:

(a) has obtained a New Mexico controlled substances registration and a drug enforcement agency registration, and

(b) prescribes controlled substances within the parameters of written guidelines or protocols established under these regulations and Subsection A of 61-11B-3 NMSA 1978 of the Pharmacist Prescriptive Authority Act.

(4) The board may, in its discretion after investigation and evaluation, place limitations on the tasks a pharmacist clinician may perform under the authority and direction of a supervising physician or alternate supervising physician(s).

F. Prescription monitoring program:

(1) A pharmacist clinician exercising prescriptive authority in the prescribing of a controlled substance;

(a) shall register with the board to become a regular participant in PMP inquiry and reporting;

(b) may authorize delegate(s) to access the PMP report consistent with 16.19.29 NMAC; while a pharmacist clinician's delegate may obtain a report from the states' PMP, pharmacist clinician is solely responsible for reviewing the PMP report and documenting the receipt and review of a report in the patient's medical record;

(c) before a pharmacist clinician prescribes for the first time, a controlled substance in schedule II, III or IV to a patient for a period greater than four days, or if there is a gap in prescribing the controlled substance for 30 days or more, the pharmacist clinician shall review a PMP report for the patient for the preceding 12 months; when available, the pharmacist clinician shall review similar reports from adjacent states; the pharmacist clinician shall document the receipt and review of such reports in the patient's medical record;

(d) a PMP report shall be;

(i) reviewed a minimum of once every three months during the continuous use of an opioid, benzodiazepine, or carisoprodol for each patient; and

(ii) reviewed a minimum of once every six months during the continuous use of a controlled substance in schedule II, III or IV which is not an opioid, benzodiazepine, or carisoprodol for each patient; and

(iii) the pharmacist clinician shall document the review of these reports in the patient's medical record; nothing in this section shall be construed as preventing a pharmacist clinician from reviewing PMP reports with greater frequency than that required by this section;

(e) a pharmacist clinician does not have to obtain and review a PMP report before prescribing, ordering, or dispensing a controlled substance in schedule II, III or IV;

(i) to a patient in a nursing facility; or

(ii) to a patient in hospice care.

(f) upon review of a PMP report for a patient, the pharmacist clinician shall identify and be aware of a patient currently receiving:

(i) opioids from multiple prescribers;

(ii) opioids and benzodiazepines concurrently;

(iii) opioids for more than 12 consecutive weeks;

(iv) more than one controlled substance analgesic;

(v) opioids totaling more than 90 morphine milligram equivalents per

day;

(vi) exhibiting potential for abuse or misuse of opioids and other controlled substances, such as over-utilization, requests to fill early, requests for specific opioids, requests to pay cash when insurance is available, receiving opioids from multiple pharmacies.

(g) upon recognizing any of the above conditions described in Subparagraph (f) of Paragraph (1) of Subsection F of 16.19.4.17 NMAC, the pharmacist clinician using professional judgement based on prevailing standards of practice, shall take action as appropriate to prevent, mitigate, or resolve any potential problems or risks that may result in opioid misuse, abuse, or overdose; these steps may involve counseling the patient on known risks and realistic benefits of opioid therapy, prescription and training for naloxone, consultation with or referral to a pain management specialist, offering or arranging treatment for opioid or substance use disorder; the pharmacist clinician shall document actions taken to prevent, mitigate, or resolve the potential problems or risks.

(2) Pharmacist clinician's licensed to practice in an opioid treatment program, as defined in 7.32.8 NMAC, shall review a PMP report upon a patients' initial enrollement into the opioid treatment program and every three months thereafter while prescribing, ordering, administering, or dispensing opioid treatment medications in schedule II for the purpose of treating opioid use disorder. The pharmacist clinician shall document the receipt and review of a report in the patients' medical record.

G. Complaints and appeals.

(1) The chair of the board will appoint two members of the board, and the president of the supervising physician respective board will appoint two members of the respective board to the oversight committee; the oversight committee will review complaints concerning the pharmacist clinician practice; the oversight committee will make a report that may include non-binding recommendations to both the board and respective board(s) regarding disciplinary action. Each board can accept or reject the recommendations.

(2) Any applicant for certification or any pharmacist clinician may appeal a decision of the board in accordance with the provisions of the Uniform Licensing Act, Sections 61-1-1 to 61-1-33 NMSA 1978. [03-14-98; 16.19.4.17 NMAC - Rn, 16 NMAC 19.4.17, 03-30-02; 16.19.4.17 NMAC - Rn, 16.19.4.18 NMAC, 12-15-02; A, 09-30-03; A, 01-31-07; A, 05-14-10; A, 08-16-10; A, 10-25-12; A, 03-23-13; A, 06-29-13; A, 08-12-13; A, 10-19-16]