

This is an amendment to 16.19.4 NMAC, Section 9, 11, 12, 16 and 17, effective 9/13/2022

16.19.4.9 DEFINING UNPROFESSIONAL OR DISHONORABLE CONDUCT:

A. Preamble: In defining "unprofessional conduct" the definitions of professional conduct and a pharmacist's duty should be considered.

B. Professional conduct may be defined as complying with all the laws and regulations that apply to a given professional activity.

C. Definition: Unprofessional or dishonorable conduct by a pharmacist shall mean, among other things, but not be limited to.

(1) Violation of any provision of the Pharmacy Act as determined by the board.

(2) Violation of the board of pharmacy regulations as determined by the board.

(3) Violation of the Drug and Cosmetic Act as determined by the board.

(4) Violation of the Controlled Substances Act as determined by the board.

(5) Failure of the pharmacist to conduct himself professionally in conformity with all applicable federal, state and municipal laws and regulations to his relationship with the public, other health professions and fellow pharmacists.

(6) Failure to keep his pharmacy and/or area of professional practice clean, orderly, maintained and secured for the proper performance of his professional duties.

(7) Acquiring prescription stock from unlicensed sources.

(8) Failure to hold on the strictest confidence all knowledge concerning patrons, their prescriptions, and other confidence entrusted or acquired of by him; divulging in the interest of the patron only by proper forms, or where required for proper compliance with legal authorities.

(9) Participation in a plan or agreement which compromises the quality or extent of professional services, or facilities at the expense of public health or welfare.

(10) The solicitation of prescription business by providing prescribers with prescription blanks with the name of any licensed pharmacy or pharmacist printed thereon.

(11) ~~the~~ The solicitation of prescription business by providing a prescriber with pre-selected medication on a prescription blank. This does not apply to:

(a) the inpatient, or institutional setting (i.e. long term care or correctional facility) by an in-house or contracted pharmacy; or

(b) a request for therapeutic interchange of a medication prescribed for the patient.

(12) ~~the~~ The solicitation of a prescription whereby the initial prescription request was not initiated by the patient or practitioner. This does not apply to a request for therapeutic interchange of a medication prescribed for the patient.

(13) Failure to report a theft or loss of controlled substances in accordance with 16.19.20.36 NMAC.

(14) Failure to report an impaired licensee in compliance with Subparagraph (a) of Paragraph (1) of Subsection C of 16.19.4.12 NMAC.

(15) Failure to train or supervise adequately supportive personnel or the use of supportive personnel in activities outside the scope of their permitted activities.

(16) Conviction, plea of nolo contendere, or entering into any other legal agreements for any violation of the Pharmacy Act, Controlled Substances Act, Drug Device and Cosmetic Act or any similar act of another state or territory of the United States.

(17) Suspension, revocation, denial, or forfeiture of license to practice or similar disciplinary action by a licensing agency of another state or territory of the United States.

(18) Dispensing a prescription for a dangerous drug to a patient without an established practitioner-patient relationship:

(a) except for the provision of treatment of partners of patients with sexually transmitted diseases when this treatment is conducted in accordance with the expedited partner therapy guidelines and protocol published by the New Mexico department of health;

(b) except for on-call practitioners providing services for a patient's established practitioner;

(c) except for delivery of dangerous drug therapies to patients ordered by a New Mexico department of health physician as part of a declared public health emergency;

(d) except for dispensing the dangerous drug naloxone or other opioid antagonist as authorized in Section 24-23-1 NMSA 1978;

(e) except for the prescribing or dispensing and administering for immunizations programs.

(19) Dispensing a prescription order for a dangerous drug to a patient if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order was issued on the basis of an internet-based questionnaire or an internet-based consultation without a valid practitioner-patient relationship.

(20) Failure to perform a prospective drug review as described in Subsection D of 16.19.4.17 NMAC and document steps taken to resolve potential problems.

[3/1/1993; 16.19.4.9 NMAC - Rn, 16 NMAC 19.4.9, 3/30/2002; A, 7/15/2002; A, 1/15/2008; A, 9/16/2011; A, 8/31/2012; A, 3/23/2016; A, 10/19/2019; A, 11/13/2018; A, 9/13/2022]

16.19.4.11 CONSULTANT PHARMACIST:

A. Duties and responsibilities:

(1) To abide by the code of ethics of the *American society of consultant pharmacists*. Must be qualified to practice as a consultant pharmacist and is to be aware of all federal and state drug laws, rules and regulations related to pharmacy services, and to provide the facility with current information pertaining to drug service.

(2) Ensure that drugs are handled in the facility in which he/she is the consultant pharmacist, in a manner that protect the safety and welfare of the patient.

(3) Set the policy and procedures in the facility as related to all ~~facts~~ facets of drug handling and distribution; these policies and procedures to be reviewed and updated on an annual basis.

(4) To visit the facility, commensurate with his duties, as specified by board regulations relative to the facility or by written contract with the administration of the facility not inconsistent with board regulations.

(5) His/her primary goal and objective shall be the health and safety of the patient, and he/she shall make every effort to assure the maximum level of safety and efficacy in the provision of pharmaceutical services.

(6) The consultant pharmacist shall not condone or participate in any transaction with any practitioner of another health profession, or any other persons whosoever under which fees are divided, or rebates or kickbacks paid or caused to be paid, or which may result in financial exploitation of patients or their families in connection with the provision of drugs and medication or supplies or pharmaceutical services.

B. Consultant pharmacist serving skilled nursing facilities and intermediate care facilities - upper level care - long term care facilities by any other title:

(1) The consultant pharmacist's agreement with the facility shall include but is not limited to the following duties and responsibilities.

(a) Serve as a member of appropriate committees, and attend these meetings.

(b) Development of the drug control procedures manual.

(c) Monitor on a routine basis all aspects of the total drug distribution system - to be accomplished in a manner designed to monitor and safeguard all areas of the drug distribution system.

(d) Maintain active pharmacist status registration in the state.

(e) Assume responsibility for the destruction or removal of unwanted dangerous drugs and any controlled substances as prescribed by law and regulations.

(f) Maintain a log of all visits and activities in the facility indicating dates and other pertinent data; such logs are to be available to inspection by state drug inspectors upon request.

(g) Furnish and replenish emergency drug supply in acceptable containers.

Maintain a log of use and replacement of drugs in the emergency tray.

(h) Make routine inspections of drug storage areas, patient health records, and review drug regimen of each patient at least once a month. Report irregularities, contraindication, drug interactions, etc., to the medical staff.

(i) Provide or make arrangements for provision of pharmacy services to the facility on a 24-hour, seven days a week basis, including stat orders.

(j) Provide in-service training of staff personnel as outlined in the procedures manual.

(k) Meet all other responsibilities of a consultant pharmacist as set forth in the board regulations and federal or state laws and which are consistent with quality patient care.

(l) The contract consultant pharmacist to a SNF or ICF facility, that is required to review patients' drug regimen as set forth in Subparagraph h of Paragraph (1) of Subsection B of 16.19.4.11 NMAC, who is under contract as sole supplier of unit-doses/state of the art medications, shall be exempt from charges of unprofessional conduct under Paragraph (10) of Subsection B of 16.19.4.9 NMAC.

(m) The consultant pharmacist to a SNF or ICF facility who delivers drugs in a unit-dose system, approved by an agent of the board, which is a tightly sealed, unopened, individual dose, shall be exempt from the requirements of 16.19.6.14 NMAC. The regulation shall not prohibit the return to the pharmacy stock, where partial credit may be given in accordance with any federal or state law or regulation, to the patient for such medication, when the physician discontinues the drug therapy, the patient expires or for any other reason, other than an outdated drug.

(n) **Customized patient medication packages;** In lieu of dispensing one, two, or more prescribed drug products in separate containers or standard vial containers, a pharmacist may, with the consent of the patient, the patient's care-giver, the prescriber, or the institution caring for the patient, provide a customized patient medication package. The pharmacist preparing a patient medication package must abide by the guidelines as set forth in the current edition of the U.S. pharmacopoeia for labeling, packaging and record keeping.

(o) **Repackaging of patient medication packages;** In the event a drug is added to or discontinued from a patient's drug regimen, when a container within the patient medication package has more than one drug within it, the pharmacist may repackage the patient's patient medication package and either add to or remove from the patient medication packaged as ordered by the physician. The same drugs returned by the patient for repackaging must be reused by the pharmacist in the design of the new patient medication package for the new regimen, and any drug removed must either be destroyed, returned to the DEA or returned to the patient properly labeled. Under no circumstances may a drug within a container of a patient medication package which contains more than one drug be returned to the pharmacy stock.

(p) Return of patient medication package drugs.

(i) Patient medication ~~[package's]~~ packages with more than one drug within a container: Patient medication packages with more than one drug within a container may not under any circumstances be returned to a pharmacy stock.

(ii) Patient medication ~~[package's]~~ packages with only one drug within a container: 1 Non-Institutional: A patient medication package stored in a non-institutional setting where there is no assurance of storage standards may not be returned to pharmacy stock. 2 Institutional: A patient medication package stored in an institutional setting where the storage and handling of the drugs are assured and are consistent with the compendia standards may be returned to the pharmacy stock provided the following guidelines are followed: (1) the drug is to be kept within the patient medication package and it is to remain sealed and labeled until dispensed; (2) the expiration date of drug shall become fifty percent of the time left of the expiration for the drug; and (3) no schedule II - V drugs may be returned to inventory [~~;- and (4) proper record keeping for the addition of other scheduled drugs into inventory must be done~~].

(2) When a consultant pharmacist enters into a written contractual agreement with a facility to which he/she will provide service.

(a) The consultant pharmacist whose practice is not in the immediate vicinity of the facility for which he has entered into a written service agreement, shall have a written agreement with a local pharmacist to be available on any emergency basis. The consultant pharmacist shall be responsible for the proper training and instruction of such local pharmacist. Said local pharmacist shall be known as a "co-consultant". The vendor shall be responsible for the safety and efficacy of back-up pharmaceutical services he provides.

(b) A copy of these agreements must be filed with the board of pharmacy and the facility. Any termination of such agreement shall be reported in writing, within 10 days, of termination to the board and to the administrator.

(c) Should a local pharmacist (co-consultant) not be available, the consultant pharmacist must provide an alternative procedure approved by the board. If the consultant is also the vendor, then such alternative procedure must reasonably assure rapid delivery of drugs; medical supplies and pharmacy service to the facility

C. Consultant pharmacist - clinic facility:

(1) The consultant pharmacist providing services to a clinic shall.

(a) Assume overall responsibility for clinic pharmacy services, for clinic pharmacy supportive personnel, and for procedures as outlined in the procedures manual, including all records of drugs procured, administered, transferred, distributed, repackaged or dispensed from the clinic.

(b) Assume responsibility for the destruction or removal of unwanted or outdated dangerous drugs, including controlled substances, as required by laws and regulations.

(c) Develop the pharmacy services procedures manual for the clinic establishing the system for control and accountability of pharmaceuticals.

(d) Provide in-service education and training to clinic staff, as applicable.

(e) Report in writing to the board within 10 days, any termination of services to the clinic. Report in writing to the board the names and places of employment of any pharmacy technicians under the supervision of the consultant pharmacist.

(f) Comply with all other provisions of Part 10, limited drug clinics, as applicable to the individual clinic facility.

(g) The consultant pharmacist shall personally visit the clinic on the minimum basis described in Items (i) through (iv) of Subparagraphs (a) through (c) to ensure that the clinic is following set policies and procedures. Visitation schedules are as follows.

(i) Class A clinics shall have the on-site services of a consultant pharmacist for the dispensing or distribution of dangerous drugs. The consultant pharmacist shall comply with Paragraphs (4), (5) and (7) of Subsection A of 16.19.4.16 NMAC.

(ii) Class B clinics shall have the services of a consultant pharmacist as listed below: 1. Category 1 clinics shall be visited by the consultant pharmacist at least bi-monthly. 2. Category 2 clinics shall be visited by the consultant pharmacist at least monthly. 3. Category 3 clinics shall be visited by the consultant pharmacist at least bi-weekly.

(iii) Class C clinics shall be visited by the consultant pharmacist at least every three months.

(iv) Class D clinic shall be reviewed at least once yearly during school session.

(v) Class E clinic shall be visited by the consultant pharmacist at least weekly for a clinic with a patient census of 150 or more or with a mobile narcotic treatment program, and at least bi-weekly for a clinic with a patient census of less than 150.

(h) The consultant pharmacist shall review the medical records of not less than five percent of a Class B clinics patients who have received dangerous drugs (as determined by the dispensing or distribution records) since the consultant pharmacist's last visit. Such review shall be for the purpose of promoting therapeutic appropriateness, eliminating unnecessary drugs, and establishing the medical necessity of drug therapy, by identifying over-utilization or under-utilization, therapeutic duplication, drug-disease contraindications, drug-drug contraindications, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, appropriate medication indication, and/or clinical abuse/misuse. Upon recognizing any of the above, the consultant pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

(i) The consultant pharmacist shall maintain a log or record of all visits and activities in the clinic. Such record shall include a log of all medical records reviewed, along with a record of all consultant pharmacist interventions and/or consultations. This log or record shall be available for inspection by state drug inspectors upon request.

(j) Consultant pharmacist serving a Class D school based emergency medicine clinic shall:

(i) review records at least annually; this review shall include a review of the *self-assessment form*, receipt and disposition records, and storage records; this annual review does not require an on-site visit by the consultant pharmacist;

(ii) oversee the removal of expired or unwanted dangerous drugs; removal options are transfer to another licensed location, return to the legitimate source of supply or to a reverse distributor; remaining portions of used dangerous drugs may be destroyed by the consultant pharmacist;

(iii) review dangerous drug administration records within 72 hours of administration; this review shall be documented and available for inspection at the licensed location for three years; review shall include verification of compliance with procedures and protocols, including administration by properly trained personnel.

- (iv) ensure required records are available for inspection at the licensed location for three years, including a log of comments and activities of consultant pharmacist;
- (v) verify a current list of trained staff, in accordance with New Mexico department of health requirements, is maintained at the licensed location and available for inspection;
- (vi) approve a policy and procedures manual outlining procedures for the receipt, storage, record keeping, administration and accountability of all dangerous drugs; this includes policies and procedures for the removal and destruction of unwanted, unused, outdated or recalled dangerous drugs; must verify compliance with all training and protocols required by the New Mexico department of health.

(k) The consultant pharmacist of a Class E clinic shall review dispensing, distribution, and supplying records since the consultant pharmacist's last visit, to ensure records are maintained accurately and in proper form. The consultant pharmacist shall also review the medical records of all clinic patients prior to initiation of take home dosing, and medical records of not less than five percent of clinic patients who have received dangerous drugs (as determined by the dispensing, distribution, or supplying records) since the consultant pharmacist's last visit. Such review shall be for the purpose of promoting therapeutic appropriateness, eliminating unnecessary drugs, and establishing the medical necessity of drug therapy, by identifying over-utilization or under-utilization, therapeutic duplication, drug-disease contraindications, drug-drug contraindications, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, appropriate medication indication, and/or clinical abuse/misuse. Upon recognizing any of the above, the consultant pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. A log or record will be maintained in accordance with Subparagraph (i) of Paragraph (1) of Subsection (C) of 16.19.4.11 NMAC.

(2) A clinic may petition the board for an alternative visitation schedule as set forth in Subsection R of 16.19.10.11 NMAC.

D. Consultant pharmacists serving custodial care facilities:

(1) Custodial care facility as used in this regulation includes: Any facility which provides care and services on a continuing basis, for two or more in-house residents, not related to the operator, and which maintains custody of the residents' drugs.

(2) Any facility which meets the requirements outlined in Paragraph (1) of Subsection D of 16.19.4.11 NMAC shall be licensed by the board of pharmacy, engage a consultant pharmacist, whose duties and responsibilities are indicated in 16.19.4 and 16.19.11 NMAC.

(3) Procurement of drugs or medications for residents will be on the prescription order of a licensed physician - written or by oral communication, which order shall be reduced to writing by the pharmacist as required by law. Refills shall be as authorized by the physician. When refill authorization is indicated on the original prescription, a refill for a resident may be requested by the administrator of the licensed facility or his designee by telephone to the consultant pharmacist, or the providing pharmacy.

(4) The administrator or a designated employee of the facility will sign a receipt for prescription drugs upon delivery.

(5) All prescription drugs will be stored in a locked cabinet or room and the key will be assigned to a designated employee or the administrator as indicated in the procedures manual.

(6) Proper storage as stipulated in the official compendium USP/NF will be the responsibility of the licensed facility.

(7) Records - the consultant pharmacist shall be responsible for the following records:

- (a) incoming medications - including refills;
- (b) record of administration;
- (c) waste or loss; This accountability record shall be maintained on a patient log, on forms provided to the consultant pharmacist by the board of pharmacy.

(8) All prescription containers shall be properly labeled as required in 16.19.11 NMAC. No bulk containers of legend drugs will be kept on the premises, except in a facility with a 24-hour per day and 365 day per year on-site licensed nurse. Only the following stock dangerous drugs may be kept:

- (a) tuberculin testing solution; and
- (b) vaccines as recommended by the centers for disease control (CDC) and prevention's advisory committee on immunization practices and appropriate for the facility population served; and
- (c) naloxone for opioid overdose.

(9) Consultant pharmacist shall include in the procedures manual the name of individual(s) responsible for the assistance with the medication.

(10) It shall be the responsibility of the pharmacist to give proper training/instruction to the person(s) at the facility who have day-to-day responsibility for receipt and administration of medications to resident

when adverse reactions, special diet, or any other information relative to the administration of a drug is needed by the staff.

(11) The consultant pharmacist shall be required to maintain a patient profile on each individual, if applicable to the facility and individual.

(12) The consultant pharmacist shall visit the facility no less than once a quarter or more often, commensurate with patient drug regimen and shall be available in emergencies, when needed. A log shall be maintained indicating all visits to the facility and noting any activities or irregularities to be recorded or reported. This log shall be available for state drug inspectors' review upon request.

(13) The consultant shall be responsible for the preparation of a procedures manual outlining procedures for the receipt, storage, record keeping, maintenance of patient profiles, administration and accountability of all legend drugs and procedures for the removal and destruction of unwanted, unused, outdated or recalled drugs - controlled substances shall be handled pursuant to state and federal regulations.

E. No drug that has been dispensed pursuant to a prescription and has left the physical premises of the facility licensed by the board shall be dispensed or reused again except the re-labeling and reuse of pharmaceuticals may be permitted in the following situations: in a correctional facility, licensed by the board, under the following circumstances dangerous drugs, excluding controlled substances, may be re-used:

- (1) the patients must reside in the same facility;
- (2) the reused medication must have been discontinued from the original patient's drug regimen;
- (3) the drug was never out of the possession of the licensee "keep on person pharmaceuticals may never be reused";
- (4) the drugs were originally dispensed in packaging that is unopened, single-dose or tamper-evident containers;
- (5) the patient receiving the re-labeled medication must have a valid prescription/order for the medication that is to be reused;
- (6) repackaging and re-labeling may only be completed on site by the consultant pharmacist designated for that facility.

F. The consultant pharmacist must maintain records at the facility for three years containing the following information:

- (1) date when the re-labeling occurred;
- (2) the name and ID of the patient for whom the medication was originally intended for and the date in which it was discontinued from his or her drug regimen;
- (3) the name and ID of the patient who will receive the reused medication;
- (4) the name, strength and amount of the medication being reused;
- (5) the name of pharmacist re-labeling the medication;
- (6) pursuant to 16.19.10.11 NMAC the pharmacist must label the reused pharmaceutical and maintain a dispensing log for all such re-issued pharmaceuticals and the expiration date for such re-issued drugs shall be no greater than fifty percent of the time remaining from the date of repackaging until the expiration date indicated on the original dispensing label or container.

[8/27/1990; 16.19.4.11 NMAC - Rn, 16 NMAC 19.4.11, 3/30/2002; A, 6/30/2006; A, 10/24/2014; A, 12/13/2015; A, 11/30/2021; A, 9/13/2022]

16.19.4.12 IMPAIRED PHARMACIST:

A. Definitions; For the purpose of this section:

- (1) Chemical dependence - repeated use of alcohol or drugs culminating in a pattern of chemical need.
- (2) Disciplinary authority - the board which may discipline pharmacists.
- (3) Diversion - illicit dispensing, distribution or administration of a scheduled controlled substance not in the normal course of professional practice.
- (4) Drug - a chemical substance alone or in combination including alcohol.
- (5) Drug abuse - improper or excessive use of a drug to the detriment of the individual and/or society.
- (6) Impaired pharmacist - a pharmacist who is unable to practice pharmacy with reasonable skill, competence or safety to the public because of drug abuse, and/or mental illness, the aging process or loss of motor skills, sight or hearing.
- (7) Licensing authority - authority that licenses/registers pharmacists.

(8) Recovering - a term used to describe an impaired pharmacist who has successfully completed the approved treatment program and is being rehabilitated in accordance with a professionally prescribed aftercare treatment. (Use of "recovering" rather than "recovered" is intended to indicate that recovery is a continuous process with no finite end point).

(9) Reinstatement - the process whereby the recovering impaired pharmacist is permitted to resume the practice of pharmacy.

(10) Treatment - the therapeutic interruption of the disease process by competent and skilled professional resources.

B. Applicability: This regulation is applicable to all licensed/registered externs, interns, pharmacists, and any other board licensee/registrant. For the purpose of this regulation, the word "licensee" shall include all persons licensed/registered by the board of pharmacy.

C. Procedures:

(1) Impaired pharmacist reporting:

(a) If any person knows or suspects that a licensee is impaired, that person shall report any relevant information either to the impaired pharmacist program or to the board of pharmacy ("board").

(b) When the board receives an initial report relating to an alleged impaired board licensee, that authority may:

(i) refer the licensee to the impaired pharmacist program for verification, intervention and subsequent evaluation and/or treatment; or

(ii) verify the information provided on the alleged impaired licensee and assume the responsibility for intervention and referral for evaluation and/or treatment; or

(iii) file a complaint to initiate disciplinary action.

(2) Intervention: board approved intervenors shall:

(a) Respond to information from concerned individuals.

(b) Ascertain validity of the information received.

(c) Perform additional necessary investigations to arrive at an accurate position prior to contacting the alleged impaired licensee; and, if necessary, to perform intervention.

(d) Contact the alleged impaired licensee. After intervention, referral may be made to evaluation/treatment center at licensee's expense. (Contact shall be made as planned intervention).

(e) Reduce all reports in writing and place in permanent file for preservation of the report until the situation is satisfied.

(3) Treatment:

(a) Structured treatment - an approved treatment plan which shall include inpatient and/or outpatient therapy as recommended/required. With the consent of the treatment provider, the plan may include, but is not limited to, individualized inpatient and/or outpatient care. Following either an intensive inpatient or outpatient care, after treatment may be prescribed by the provider with the approval of the board and/or Impaired Pharmacist Committee.

(b) Supervised treatment - treatment which is prescribed by the treatment provider and approved by the board and/or impaired pharmacist program.

(4) Disciplinary sanctions: board authority referral to the impaired pharmacist program - when an impaired licensee who has been reported to the board successfully completes a board/committee approved treatment program, that licensee must appear before the board as a condition of consideration for reinstatement. The licensee must provide documentary evidence from the approved treatment program, stating that the licensee has reached recovery and may be allowed to practice without endangering the public. The board may suspend the registration/license, stay the execution of the suspension and impose a period of probation during which the following conditions shall be met:

(a) the licensee shall strictly adhere to the aftercare program; and

(b) during the probationary period, the licensee shall comply with the general and special conditions of probation imposed by the board, including but not limited to, monitoring and drug screens where applicable.

(5) Confidentiality; The names of voluntary participants in the program and records relating to their referral and treatment are confidential pursuant to Section 61-11A-3 and Section 61-11A-7 NMSA 1978, provided, however, that this information may be disclosed:

(a) in a disciplinary hearing before the board and in court proceedings arising therefrom;

(b) to the board and to the pharmacist's licensing/disciplinary authorities of other jurisdictions in accordance with law;

(c) pursuant to an order of a court of competent jurisdiction;

(d) injunctive proceedings brought by the board; and

(e) as otherwise provided by law.

(6) Civil immunity; No member of the board or the committee or any board-approved intervenor shall be liable for any civil damages because of acts or omissions which may occur while acting in good faith pursuant to the Impaired Pharmacists Act (61-11A-1 to 61-11A-8 NMSA, 1978). [8/27/1990; 16.19.4.12 NMAC - Rn, 16 NMAC 19.4.12, 3/30/2002; A, 9/13/2022]

16.19.4.16 RESPONSIBILITIES OF PHARMACIST AND PHARMACIST INTERN:

A. The following responsibilities require the use of professional ~~judgement~~ judgment and therefore shall be performed only by a pharmacist or pharmacist intern:

(1) receipt of all new verbal prescription orders and reduction to writing;

(2) initial identification, evaluation and interpretation of the prescription order and any necessary clinical clarification prior to dispensing;

(3) professional consultation with a patient or his agent regarding a prescription;

(4) evaluation of available clinical data in patient medication record system;

(5) oral communication with the patient or patient's agent of information, as defined in this section under patient counseling, in order to improve therapy by ensuring proper use of drugs and devices;

(6) professional consultation with the prescriber, the prescriber's agent, or any other health care professional or authorized agent regarding a patient and any medical information pertaining to the prescription;

(7) drug regimen review, as defined in Section 61-11-2L NMSA 1978;

(8) professional consultation, without dispensing, will require that the patient be provided with the identification of the pharmacist or pharmacy intern providing the service.

B. Only a pharmacist shall perform the following duties:

(1) final check on all aspects of the completed prescription including sterile products and cytotoxic preparations, and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container;

(2) evaluation of pharmaceuticals for formulary selection within the facility;

(3) supervision of all supportive personnel activities including preparation, mixing, assembling, packaging, labeling and storage of medications;

(4) ensure that supportive personnel have been properly trained for the duties they may perform;

(5) any verbal communication with a patient or patient's representative regarding a change in drug therapy or performing therapeutic interchanges (i.e. drugs with similar effects in specific therapeutic categories); this does not apply to substitution of generic equivalents;

(6) any other duty required of a pharmacist by any federal or state law.

C. Patient records.

(1) A reasonable effort must be made to obtain, record and maintain at least the following information:

(a) name, address, telephone number, date of birth (or age) and gender of the patient;

(b) individual medical history, if significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices; and

(c) pharmacist's comments relevant to the individual's drug therapy.

(2) Such information contained in the patient record should be considered by the pharmacist or pharmacist intern in the exercise of their professional ~~judgement~~ judgment concerning both the offer to counsel and the content of counseling.

D. Prospective drug review.

(1) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(a) clinical abuse/misuse;

(b) therapeutic duplication;

(c) drug-disease contraindications;

(d) drug-drug interactions;

- (e) incorrect drug dosage;
- (f) incorrect duration of drug treatment;
- (g) drug-allergy interactions;
- (h) appropriate medication indication.

(2) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing a controlled substance prescription monitoring report or another states' reports if applicable and available, and consulting with the prescriber and counseling the patient. The pharmacist shall document steps taken to resolve the potential problem.

E. Prescription monitoring program (PMP) report for opioid prescriptions. When presented with an opioid prescription for a patient, obtaining and reviewing a PMP report for that patient can be an important tool that assists the pharmacist in identifying issues or problems that put his or her patient at risk of prescription drug abuse, overdose, or diversion. A pharmacist shall use professional judgment based on prevailing standards of practice in determining whether to obtain and review a PMP report before dispensing an opioid prescription to that patient, and shall document his or her action regarding such reports.

(1) A pharmacist shall request and review a PMP report covering at least a one year time period and another states' report, where applicable and available if;

(a) a pharmacist becomes aware of a person currently exhibiting potential abuse or misuse of opioids (i.e. over-utilization, early refills, multiple prescribers, appears overly sedated or intoxicated upon presenting a prescription for an opioid or an unfamiliar patient requesting an opioid by specific name, street name, color, or identifying marks, or paying cash when the patient has prescription insurance);

(b) a pharmacist receives an opioid prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area);

(c) a pharmacist receives an opioid prescription for an unfamiliar patient who resides outside the usual pharmacy geographic patient population area;

(d) a pharmacist receives an initial prescription for any long-acting opioid formulations, including oral and transdermal dosage forms (e.g fentanyl or methadone);

(e) a pharmacist becomes aware of a patient receiving an opioid concurrently with a benzodiazepine or carisoprodol;

(2) The pharmacist shall document the review of these PMP reports.

(3) Upon recognizing any of the above conditions described in Paragraph (1) of Subsection E of 16.19.4.16 NMAC, a pharmacist, using professional ~~judgement~~ judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and counseling the patient. The pharmacist shall document steps taken to resolve the potential problem.

(4) After obtaining an initial PMP report on a patient, a pharmacist shall use professional judgment base on prevailing standards of practice, in deciding the frequency of requesting and reviewing further prescription monitoring reports and other states' reports for that patient. Except that PMP reports shall be reviewed a minimum of once every three months during the continuous use of opioids for each established patient. The pharmacist shall document the review of these reports.

(5) In the event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving a report.

(6) A prescription for an opioid written for a patient in a long term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness is exempt from Subsection E of 16.19.4.16 NMAC. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner. The pharmacist shall document whether the patient is "terminally ill" or an "LTCF patient".

F. Counseling.

(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist or pharmacist intern shall personally offer to counsel on matters which will enhance or optimize drug therapy with each patient or the patient's agent. Upon receipt of a refill prescription drug order a pharmacy technician may query the patient or patient's agent regarding counseling by the pharmacist or pharmacist intern concerning drug therapy. Such counseling shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling which may include, in their professional ~~judgement~~ judgment, one or more of the following:

(a) the name and description of the drug;
 (b) the dosage form, dosage, route of administration, and duration of drug therapy;
 (c) intended use of the drug and expected action;
 (d) special directions and precautions for preparation, administration and use by the patient;
 (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur;
 (f) techniques for self-monitoring drug therapy;
 (g) proper storage;
 (h) prescriptions refill information;
 (i) action to be taken in the event of a missed dose;
 (j) the need to check with the pharmacist or practitioner before taking other medication; and
 (k) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) [REPEALED]

(3) Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include, but not limited to, written information leaflets, pictogram labels and video programs.

(4) Patient counseling, as described above and defined in this regulation shall not be required for in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(5) A pharmacist shall in no way attempt to circumvent or willfully discourage a patient or patient's agent from receiving counseling. However, a pharmacist shall not be required to counsel a patient or patients's agent when the patient or patients's agent refuses such consultation.

(6) When the patient or agent is not present when the prescription is dispensed including, but not limited to, a prescription that was shipped by the mail, the pharmacist shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, and: (a) of his or her right to request counseling; and (b) a toll-free telephone number in which the patient or patient's agent may obtain oral counseling from a pharmacist who has ready access to the patient's record. For pharmacies delivering more than fifty percent of their prescriptions by mail or other common carrier, the hours of availability shall be a minimum of 60 hours per week and not less than six days per week. The facility must have sufficient toll-free phone lines and personnel to provide counseling within 15 minutes.

(7) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice concerning available counseling.

G. [REPEALED]

H. Regulatory assessment. Profiles, either electronic or hard copy, shall be available for inspection, and shall provide the capability of storing the described historical information. The profiles must demonstrate that an effort is being made to fulfill the requirements by the completion of the detail required. A patient record shall be maintained for a period of not less than three years from the date of the last entry in the profile record.

[8/27/1990; 16.19.4.16 NMAC - Rn, 16 NMAC 19.4.16, 3/30/2002; 16.19.4.16 NMAC - Rn, 16.19.4.17 NMAC, 12/15/2002; A, 2/1/2004; A, 11/30/2004; A, 1/15/2005; A, 1/31/2007; A, 8/31/2012; A, 10/25/2012; A, 10/19/2019; A, 9/13/2022]

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]- ACCME (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.

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~~ clinician shall review similar reports from adjacent states; the pharmacist ~~clinician~~ 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 [of] 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 ~~judgment~~ judgment 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 enrollment into the opioid treatment program and every three months thereafter while prescribing, ordering, administering, or dispensing opioid treatment medications in schedule II or III 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. [3/14/1998; 16.19.4.17 NMAC - Rn, 16 NMAC 19.4.17, 3/30/2002; 16.19.4.17 NMAC - Rn, 16.19.4.18 NMAC, 12/15/2002; A, 9/30/2003; A, 1/31/2007; A, 5/14/2010; A, 8/16/2010; A, 10/25/2012; A, 3/23/2013; A, 6/29/2013; A, 8/12/2013; A, 10/19/2019; A 9/14/2021; A, 9/13/2022]