TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 20 CONTROLLED SUBSTANCES

16.19.20.1 ISSUING AGENCY: ~~Regulation and Licensing Department~~ - Board of Pharmacy.
[16.19.20.1 NMAC - Rp 16.19.20.1 NMAC, 6/26/2018]

16.19.20.2 SCOPE: All persons or entities that manufacture, distribute, dispense, administer, prescribe, deliver, analyze, or conduct research using controlled substances.
[16.19.20.2 NMAC - Rp 16.19.20.2 NMAC, 6/26/2018]

16.19.20.3 STATUTORY AUTHORITY: Section 30-31-11 of the Controlled Substances Act, 30-31-1 through 30-31-42 NMSA 1978, authorizes the board of pharmacy to promulgate regulations and charge reasonable fees for the registration and control of the manufacture, distribution and dispensing of controlled substances. Paragraph (2) of Subsection B of Section 61-11-6 authorizes the board to provide by regulation for the electronic transmission of prescriptions.
[16.19.20.3 NMAC - Rp 16.19.20.3 NMAC, 6/26/2018]

16.19.20.4 DURATION: Permanent.
[16.19.20.4 NMAC - Rp 16.19.20.4 NMAC, 6/26/2018]

16.19.20.5 EFFECTIVE DATE: June 26, 2018, unless a different date is cited at the end of a section.
[16.19.20.5 NMAC - Rp 16.19.20.5 NMAC, 6/26/2018]

16.19.20.6 OBJECTIVE: The objective of Part 20 of Chapter 19 is to protect the public health and welfare of the citizens of New Mexico by controlling and monitoring access to controlled substances and to give notice of the board's designation of particular substances as controlled substances.
[16.19.20.6 NMAC - Rp 16.19.20.6 NMAC, 6/26/2018]

16.19.20.10 REGISTRATION FEE:

A. The registration fee or renewal fee required by the Controlled Substances Act shall be as listed in 16.19.12 NMAC. ~~$180.00 for registrants per triennium. A locum tenens practitioner may apply for an initial registration which expires no more than one year after date of issuance, and this registration fee shall be $60.00.~~

B. Research applicants registered as a practitioner shall not be required to register as a scientific investigator if he is registered as a practitioner. However, this does not exempt him from the regulations applicable to a scientific investigator.

C. Duplicate license - $10.00
[16.19.20.10 NMAC - Rp 16.19.20.10 NMAC, 6/26/2018]

16.19.20.31 PHARMACY AND HOSPITAL PRESCRIPTION AND DISPENSING RECORDS:

A. Prescriptions for schedule II shall be maintained in a separate file.

B. In pharmacies without computerized prescription information, prescriptions for schedules II, III, IV and V shall have the name of the dispensing pharmacist and the date filled inscribed on the face of the prescription. (Typewritten, printed or rubber stamp are acceptable.)

C. Prescriptions for schedule III, IV and V shall be maintained either in a separate file only, or in such form that they are readily retrievable from other records of the pharmacy. "Readily retrievable" means that at the time of filing, the face of the prescription is stamped in red ink in the lower right hand corner with the letter "C" no less than 1 inch high, or the records comply with 16.19.6.22 NMAC "Computerized Prescription Information".

D. Prescriptions so marked may then be filed with prescriptions for schedule II substances, or in the usual consecutively numbered prescription file for non-controlled drugs.

E. Pharmacies employing automatic data processing systems or other electronic record keeping systems for prescriptions must comply with 16.19.6.22 NMAC "Computerized Prescription Information".

F. Hospital floor stock records. A record of controlled substances administered from floor stock shall contain the following information:

(1) name of patient;

(2) date and time administered;

(3) name of drug;
(4) strength of drug;
(5) amount administered;
(6) name of prescribing physician;
(7) name of person administering the controlled substance.

[16.19.20.31 NMAC - Rp 16.19.20.31 NMAC, 6/26/2018]

16.19.20.41 PRESCRIPTIONS:

A. A prescription for a controlled substance may be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice, and who is registered under the Controlled Substances Act. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

B. A prescription may not be issued in order for a practitioner to obtain controlled substances for supplying the practitioner for the purpose of general dispensing to patients.

C. A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic dependent person for the sole purpose of continuing his dependence upon such drugs, unless all the following conditions are met:

(1) the narcotic controlled drug is in Schedule III, IV, or V and is approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment; and

(2) the prescribing practitioner meets all state and federal requirements to prescribe the narcotic for maintenance or detoxification treatment (e.g. DATA waived practitioner; 21 CFR 1301.28 or successor regulation).

[16.19.20.41 NMAC - Rp 16.19.20.41 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.42 PRESCRIPTION REQUIREMENTS:

A. All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner. Information on the prescription may be added or clarified by the pharmacist after consultation with the practitioner. A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions must be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.

B. Electronic prescriptions shall be created and signed using an application that meets the requirements of Part 1311 of the Code of Federal Regulations. An individual practitioner ~~may~~ will sign and transmit electronic prescriptions for controlled substances in a manner that ~~provided the practitioner~~ meets all of the requirements of Part 1306.08 of the Code of Federal Regulations.

(1) Effective April 1, 2021 all controlled substance prescriptions must be electronically transmitted ("Electronic Prescriptions for Controlled Substances," **EPCS**) except:

a. for patients residing in an intermediate care, skilled nursing or correctional facility;
b. for patients enrolled in hospice;
c. for an animal by a licensed veterinarian;
d. a prescription dispensed by a federal facility not subject to state regulation (e.g. department of veteran affairs, indian health services, military bases);
e. a prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments; or new medications not yet in electronic system;
f. for compounded prescriptions;
g. for prescriptions issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location;
h. for prescriptions issued in an emergency pursuant to federal law and rules of the board;
i. for prescriptions issued in response to a public health emergency where a non-patient specific prescription would be permitted;

j. under extenuating circumstance, not inconsistent with federal law and where the practitioner communicates directly with the pharmacist. The pharmacist, using professional judgment, may accept the non-EPCS and is responsible for ensuring documentation of the circumstance in the prescription record; and that the prescription is otherwise in compliance with state and federal law and rules.

C. Unless otherwise specified, a pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exemption and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription.

D. A prescription that falls under an exception to the EPCS requirement may be transmitted to a pharmacy in one of the following ways:

~~**B(1).**~~ A prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in ~~Subsections~~ Paragraphs 2, 3 and 4~~C and D~~ of this Subsection~~ of 16.19.20.41 NMAC and Subsection E of 16.19.20.42 NMAC~~. The original prescription shall be maintained in accordance with 16.19.20.31 NMAC.

~~**C(2).**~~ A prescription prepared in accordance with Subsection A of 16.19.20.~~41~~ 42 NMAC written for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, or subcutaneous infusion may be transmitted by the practitioner or the practitioner's agent to the parenteral products pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph and it shall be maintained in accordance with 16.19.20.31 NMAC.

~~**D(3).**~~ A prescription prepared in accordance with Subsection A of 16.19.20.~~41~~ 42 NMAC written for a schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this sub-section and it shall be maintained in accordance with 16.19.20.31 NMAC.

~~**E(4).**~~ A prescription prepared in accordance with Subsection A of 16.19.20.~~41~~ 42 NMAC written for a schedule II narcotic substance for a patient enrolled in a hospice program certified by Medicare under title XVIII or licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this sub-section and it shall be maintained in accordance with 16.19.20.31 NMAC.

~~**F(5).**~~ A pharmacist may dispense directly a controlled substance listed in schedule III~~, or~~ IV, or V which is a prescription drug as determined under the New Mexico Drug~~s~~, Device and Cosmetic~~s~~ Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist containing all information required for a prescription except the signature of the practitioner. A telephone order for a new therapy for an opiate listed in schedule III, IV, or V shall not exceed a 10 day supply, based on the directions for use, unless a written prescription is on file at this pharmacy from any practitioner for the same opiate within the past six months. A telephone order for this new opiate therapy may not be refilled.

~~**G**~~**E.** A pharmacy employee shall verify the identity of the patient or the patient's representative who is receiving any prescription for a controlled substance listed in schedule II, III, IV, or V before it is released. Acceptable identification means a current state issued driver's license, including photo, or other current government issued photo identification of the person presenting said identification. The identification type (*e.g.* driver's license, identification card, passport, etc.), number, name imprinted on that identification, and state must be recorded. Exceptions are, a new controlled substance prescription filled for a patient known to the pharmacist or pharmacist intern, whose identification has already been documented in a manner determined by a written policy developed by the pharmacist-in-charge; a controlled substance prescription filled for home delivery; or a controlled substance prescription filled for and delivered to a licensed facility.

[16.19.20.42 NMAC - Rp 16.19.20.42 NMAC, 6/26/2018]

16.19.20.44 REFILL PROCEDURE: Each refilling of a schedule III, IV or V controlled substance prescription shall be entered ~~on the back of the prescription~~in the prescription record, indicating the amount dispensed, if less than the amount called for on the prescription, the date of refill and the initials of the pharmacist dispensing the substance.

[16.19.20.44 NMAC - Rp 16.19.20.44 NMAC, 6/26/2018]

16.19.20.45 PRESCRIPTION FILL AND REFILL REQUIREMENTS:

A. Prescriptions for any controlled substance shall not be filled more than six months after the date of issue.

(1) Controlled substance prescriptions dispensed directly to a patient shall not be refilled before seventy-five percent of the prescription days' supply has passed, unless the practitioner authorizes the early refill, which must be documented by the pharmacist.

(2) Controlled substance prescriptions delivered to a patient indirectly (as mail order) to a patient shall not be refilled before sixty-six percent of a 90 day supply has passed or fifty percent of a 30 day supply has passed, unless the practitioner authorizes the early refill, which must be documented by the pharmacist.

B. Prescriptions for schedule III, IV, or V controlled substances shall not be filled or refilled more than six months after the date of issue or be refilled more than five times unless renewed by the practitioner and a new prescription is placed in the pharmacy files.

[16.19.20.45 NMAC - Rp 16.19.20.45 NMAC, 6/26/2018]

16.19.20.46 PRESCRIPTION - PARTIALLY FILLED:

A. A prescription for a controlled substance in schedule II may be partially filled if:

(1) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;

(2) the partial fill amount is recorded on the written prescription or in the electronic prescription record; and

(3) the remaining portions shall be filled not later than 30 days after the date on which the prescription is ~~written~~issued.

B. A prescription for a controlled substance in schedule II initially filled later than 30 days after the date ~~written~~ issued may be partially filled if;

(1) the pharmacist is unable to dispense the total quantity prescribed;

(2) the partial fill amount is recorded on the written prescription or in the electronic prescription record;

(3) the remaining portion is filled within 72 hours of the partial filling; and

(4) the pharmacist notifies the prescribing physician if the remaining portion cannot be filled within the 72 hour period. No further quantity may be supplied beyond 72 hours without a new prescription.

C. Partial filling of a prescription for schedule III, ~~or~~ IV or V shall be recorded in the same manner as a refill, providing the total quantity of partial filling does not exceed the total quantity prescribed and no dispensing occurs after six months from date of prescription.

D. A prescription for a schedule II controlled substance written for a patient in a long term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities, to include individual dosage units.

(1) If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient".

(2) A prescription that is partially filled and does not contain the notation "terminally ill" or LTCF patient" shall be deemed to have been filled in violation of this regulation. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist.

(3) The total quantity of schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions, for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

[16.19.20.46 NMAC - Rp 16.19.20.46 NMAC, 6/26/2018]

16.19.20.47 EMERGENCY DISPENSING:

A. Emergency dispensing of schedule II controlled substances. "**Emergency situation"** means the

prescribing physician determines:

(1) that immediate administration of a controlled substance is necessary for proper treatment of the intended patient;

(2) that no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II; and

(3) that it is not reasonably possible for the prescribing practitioner to provide an electronically prescribed or written prescription to be presented to the person dispensing the substance prior to the dispensing.

B. A pharmacy may dispense a schedule II controlled substance in the above instance only if he receives oral authorization of a practitioner or authorization via facsimile machine and provided:

(1) the quantity prescribed is limited to the amount needed to treat the patient during the emergency period;

(2) the pharmacist shall reduce the prescription to a written form and it contains all information required of a schedule II controlled substance prescription except the signature of the prescribing practitioner;

(3) the prescribing physician, within seven days after authorization of the emergency dispensing, shall furnish a written, signed prescription to the pharmacist. The signed prescription shall have written on the face "AUTHORIZATION FOR EMERGENCY DISPENSING" and the date of the oral order or facsimile order;

(4) the signed prescription shall be attached to the oral emergency prescription order or the facsimile emergency prescription order and be filed as other schedule II prescriptions.

C. In the event the prescribing physician fails to deliver a signed written prescription to the pharmacist, within the seven days period, the pharmacist shall notify the nearest DEA office, and the board of pharmacy.

[16.19.20.47 NMAC - Rp 16.19.20.47 NMAC, 6/26/2018]

16.19.20.69 SCHEDULE V:

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C. Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Lacosamide [(R)-2acetoamido-N-benzyl-3-methoxy-propionamide]

(2) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid]

(3) Ezogabine [N-[2-amino-4-(4-flurobenzylamino-phenyl]-carbamic acid ethyl ester]

(4) Brivaracetam

~~**(5)** drug product approved for marketing by the U.S. Food and Drug Administration and which contains cannabidiol derived from cannabis and no more than 0.1 percent tetrahydrocannabinols~~.

[16.19.20.69 NMAC - Rp 16.19.20.69 NMAC, 6/26/2018; A, 12/17/2019]