This is an amendment to 16.19.20 NMAC, Sections 9, 16, 20, 26, 36, 37, 38, 40, 41, 53, 65, 66, and 69, effective 12/17/2019.

Explanatory paragraph: In 16.19.20.65 NMAC, Subsections A through C and Subsections E through F were not published as there are no changes. In 16.19.20.66 NMAC, Subsections A through C and Subsections E through F were not published as there are no changes.

16.19.20.9 REGISTRATION AND EXPIRATION DATES:

A. Any person who is required to be registered and who is not registered may apply for registration at any time.

B. In December 1982 all registrant renewal dates will be assigned to one of 12 groups which shall correspond to the months of the year. Thereafter, any person who first registers will also be assigned to one of the 12 groups.

C. Expiration date of the registration of all individuals or businesses within any group will be the last day of the month designated for that group. Renewal date will be within 30 days of the date shown on the registration permit and will expire on that date if not renewed by the registrant.

D. Renewal applications will be mailed to the physical, mailing, or electronic address indicated on the application on file or as amended by change of address supplied by the registrant to the board of pharmacy.

[16.19.20.9 NMAC - Rp 16.19.20.9 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.16 PROCEDURE SUMMARY, RESEARCH: A scientific investigator or research applicant shall submit a summary of procedures indicating the nature, extent and duration of such research. The summary shall also include the names of individuals engaged in the project (other than those exempt under the Controlled Substances Act) the name or names of the substances to be used in the research project, the adequacy of safeguards against diversion of the controlled substance(s) to be used, source of supply of controlled substance(s) if applicable, and evidence of FDA and DEA approval and registration if registered by the federal agencies.

[16.19.20.16 NMAC - Rp 16.19.20.16 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.20 INVENTORY RECORDS:

A. All registrants are required to keep inventory and procurement records.

B. All registrants shall comply with the following inventory requirements: schedule I, II, III, IV and V initial, annual [~~inventory~~], newly controlled substances, change in pharmacist in charge, and transfer of pharmacy ownership.

C. All registrants shall conduct an initial inventory of all controlled substances on hand on the date they first engage in controlled substances activity. In the event a registrant commences business with no controlled substances on hand, he/she shall record this fact on the initial inventory.

[~~C~~] **D.** The annual inventory date shall be May 1 [~~for the initial inventory by the registrant~~] or on the registrant's regular general physical inventory date, provided that [~~date does not vary by more than six months before or after May 1~~] the registrant shall notify the board of pharmacy of the [~~date on which the annual inventory will be taken, if different from May 1~~] set alternate annual inventory date. The actual taking of the inventory should not vary more than four days [~~from~~] before or after the annual inventory date (May 1 or set alternate date). [~~The inventory shall document being taken either as of the opening or as of the close of business activity, the inventory date and time, and shall be entered on the inventory record.~~]

[~~D~~] E. [~~Controlled substances added to the Controlled Substances Act after date of enactment~~] On the effective date that a substance is added to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any schedule, every registrant who possesses that substance shall take an inventory of all stock of the substance on hand and file this record with the other inventory records as required.

[~~E~~] F. Upon the change of a pharmacist-in-charge, an inventory of all controlled substances shall be taken within 72 hours, by the new pharmacist-in-charge. [~~The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date, and such time and date taken shall be entered on the inventory record.~~]

[~~F~~] G. Upon transfer of ownership of a pharmacy, an inventory of all controlled substances shall be taken

by the pharmacist-in-charge. [~~The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date, and such time and date taken shall be entered on the inventory record.~~]

H. The inventory shall include:

(1) the date;

(2) time taken (i.e., opening or close of business);

(3) drug name;

(4) the drug strength;

(5) the drug form (e.g., tablet, capsule, etc.);

(6) the number of units or volume;

(7) the total quantity. A commercial container which has been opened shall be the exact count or measure of substances listed in schedule I or schedule II. If the substance is listed in schedule III, IV or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case the count must be exact;

(8) expired or unusable controlled substances shall be documented as such, and inventoried.

(9) The name, address and DEA registration number of the registrant.

(10) The signature of the person or persons responsible for taking the inventory.

[16.19.20.20 NMAC - Rp 16.19.20.20 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.26 PROCUREMENT RECORDS: "Order forms" refer to DEA form 222 or its electronic equivalent required for distribution or procurement of a schedule I or II controlled substance under the federal act. [~~Order forms are issued in books of six forms in triplicate to registrants by requisition from DEA registration branch, Department of Justice, P.O. Box 28083, Central Station, Washington, DC, 20005.~~]

[16.19.20.26 NMAC - Rp 16.19.20.26 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.36 REPORT OF LOSS OR THEFT OF A CONTROLLED SUBSTANCE:

A. The registered supplier shall be responsible for reporting in-transit losses of controlled substances by a common carrier or contract carrier selected by the supplier upon discovery of such loss or theft. Registrant shall complete DEA form 106 as required and furnish a copy to the board of pharmacy.

B. A significant loss or theft of a controlled substance shall be reported in writing to the board of pharmacy and DEA on form 106 as required by federal regulations. "Significant loss" includes suspected diversions, in-transit losses or any other unexplained loss and must be reported to the board of pharmacy within five days of becoming aware of that loss. [~~DEA form 106 may be obtained from the board of pharmacy or DEA.~~]

[16.19.20.36 NMAC - Rp 16.19.20.36 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.37 HOSPITALS, INSTITUTIONS AND CLINICS: Disposal of excess or undesirable controlled substances resulting from extemporaneous amounts of residue or wasted controlled substances. A registrant who needs to dispose of excess or undesirable controlled substances resulting from injections from ampules or less than the full ampule or other such circumstances shall [~~keep a written memorandum report on the hospital narcotic records and periodically file a report on DEA form 41 with DEA pursuant to the requirements of the federal DEA Regulations 1307.21(c)~~] record in accordance with DEA regulations [e.g. 21 CFR 1304.22(c) or successor regulation], and two persons (at least one who is a licensed health care professional) shall witness and record disposal. The registrant will have implemented security controls and procedures that ensure pharmaceutical wastage is not diverted. The disposal method shall render the substance irretrievable.

[16.19.20.37 NMAC - Rp 16.19.20.37 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.38 DISPOSITION OF [~~DAMAGED~~] UNUSABLE, OUTDATED OR UNWANTED CONTROLLED SUBSTANCES: [~~Any registrant in possession of any controlled substances and desiring or required to dispose of such substances(s) may contact the regional director of DEA for authority and instructions to dispose of such substance~~.]

A. Disposition shall be in accordance with DEA regulation 21 CFR Part 1317 (or successor regulation).

B. A registrant, other than a manufacturer, distributor, reverse distributor, importer, exporter, or narcotic treatment program, in possession of any controlled substances and desiring or required to dispose of such substances(s) may contact the Special Agent in Charge of the DEA in the area in which the registrant is located by submitting one copy of the DEA form 41 listing the controlled substance(s) which the registrant desires to dispose for authority and instructions to dispose of such substance (21 CFR 1317.05). The registrant shall keep a written

memorandum report, and use DEA form 41 to record the destruction.

C. Any registrant in possession of any controlled substances and desiring or required to dispose of such substances(s) may:

(1) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;

(2) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: the registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf.

D. Records of disposition shall be maintained in proper form and available for inspection for at least three years.

[16.19.20.38 NMAC -Rp 16.19.20.38 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.40 DISTRIBUTION UPON TRANSFER OR DISCONTINUANCE OF BUSINESS:

A. Upon transfer of a business from one owner to another, the registrant may dispose of the controlled substances in his possession as follows:

(1) On the date of transfer of controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with [~~16.19.20.19~~] 16.19.20.20 NMAC, [~~board of pharmacy regulations to~~] Title 21, Section 1304.11[~~-1304.14~~] of the federal DEA regulations (or successor regulation). This inventory of the registrant-transferee and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with DEA or the board of pharmacy unless requested by either agency. Transfer of schedule I or II substances require the use of [~~order forms (Form DEA 222c)~~] DEA Form 222, and transfer of Schedule III – V substances require the use of invoice.

(2) All records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

(3) All schedule I or II substances must be transferred pursuant to order forms as required by the federal regulations. A copy of the inventory will constitute a record of receipt for the purchaser.

B. Upon discontinuance of business, if there are controlled substances which are not transferred to another registrant, these substances shall be handled as unwanted controlled substances under [~~16.19.20.37~~] 16.19.20.38 NMAC.

[16.19.20.40 NMAC - Rp 16.19.20.40 NMAC, 6/26/2018; A, 12/17/2019]

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).

[~~D.~~ ~~A prescription may not be issued for the dispensing of the narcotic drugs listed in any schedule to a narcotic drug dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.~~]

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

16.19.20.53 DISPENSING WITHOUT PRESCRIPTION:

A. A controlled substance listed in schedule V and a substance listed in schedules II, III, or IV ***which is not a prescription drug*** as determined by FDA and the Drug and Cosmetic Act, may be dispensed by a pharmacist without a prescription provided:

(1) such dispensing is made by a pharmacist or registered pharmacist intern and not by a non-pharmacist employee;

(2) not more than eight ounces of any controlled substance containing opium, nor more than 48-dosage units is dispensed at retail to the same person in any given 48-hour period;

(3) not more than four ounces of any other controlled substance or more than 24-dosage units may be dispensed at retail to the same person in any given 48-hour period;

(4) the purchaser is at least 18 years of age;

(5) the pharmacist requires every purchaser of such substance, not known to him to furnish suitable identification (including proof of age where appropriate);

(6) a bound record book for dispensing such substances is maintained requiring the signature and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance; the book shall contain a statement on each page where purchaser is required to sign, stating no purpose of such substance has been made within the given 48-hour period at another pharmacy and the purchaser shall be made aware of such statement before signing the record.

B. Exempt pseudoephedrine product.

(1) Any pseudoephedrine containing product listed as a schedule V controlled substance in Paragraph (2) of Subsection B of 16.19.20.69 NMAC shall be dispensed, sold or distributed only by a licensed pharmacist, pharmacist intern, or a registered pharmacy technician.

(2) Unless pursuant to a valid prescription, a person purchasing, receiving or otherwise acquiring the compound, mixture or preparation shall:

(a) produce a driver's license or other government-issued photo identification showing the date of birth of the persons;

(b) sign a log after reading the purchaser statement for pseudoephedrine receipt or other program or mechanism indicating the date and time of the transaction, name of the person, address, driver's license number or government issued identification number, name of the pharmacist, pharmacist intern or pharmacy technician conducting the transaction, the product sold and the total quantity, in grams or milligrams, of pseudoephedrine purchased; this log will be only for exempt pseudoephedrine products and shall be kept separate from all other records; the log is to be produced in a way that a customer's personal information is not available to other purchasers;

(c) be limited to no more than three and six-tenths grams per day or more than a total of nine grams of a product, mixture or preparation containing pseudoephedrine within a [~~thirty~~] 30-day period.

(3) Pseudoephedrine purchaser statement must state in addition to any federal requirements: "I have not purchased more than three and six-tenths grams today or more than a total of nine grams of pseudoephedrine as a single entity or in a combination with other medications in the last 30 days. Entering false statements or misrepresentations in this logbook may subject me to criminal penalties."

(4) Prices charged for compounds, mixtures, and preparations that contain pseudoephedrine shall be monitored. The board may adopt rules to prevent unwarranted price increases as a result of compliance with this section.

(5) Pharmacies shall submit the information collected pursuant to Paragraph (2) of Subsection B of 16.19.20.53 NMAC electronically, in a board defined format, to the board or its agents. Pharmacies will submit data every seven days beginning September 15, 2013. Pharmacies may petition the executive director of the board for an alternative method for the submission of the information collected pursuant to this section.

(6) Authority to contract: The board is authorized to contract with another agency of this state or with a private vendor, as necessary, for the collection of the information collected pursuant to Paragraph (2) of Subsection B of 16.19.20.53 NMAC. Any contract shall be bound to comply with the provisions regarding confidentiality of prescription or personal information in 16.19.20.53 NMAC of this regulation and shall be subject to the penalties specified in 16.19.20 NMAC and 16.19.27 NMAC.

[16.19.20.53 NMAC - Rp 16.19.20.53 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.65 SCHEDULE I:

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D. DEPRESSANTS: Unless specifically exempt 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, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Mecloqualone;

(2) Methaqualone;

(3) Benzodiazepines;

(a) Bromazepam;

(b) Camazepam;

(c) Cloxazolam;

(d) Delorazepam;

(e) Ethylloflazepate;

(f) Fudiazepam;

(g) Flunitrazepam;

(h) Haloxazolam;

(i) Ketazolam;

(j) Loprazolam;

(k) Lormetazepam;

(l) Medazepam;

(m) Nimetazepam;

(n) Nitrazepam;

(o) Nordiazepam;

(p) Oxazolam;

(q) Phenazepam

[~~**(q)**~~] **(r)** Pinazepam;

[~~**(r)**~~] **(s)** Tetrazepam;

[~~**(s)**~~] **(t)** Flubromazepan;

[~~(t)~~] (u) Diclazepam

(4) Gamma hydroxybutyric acid and any chemical compound that is metabolically converted to GHB;

(5) Gamma butyrolactone and any chemical compound that is metabolically converted to GHB;

(6) 1-4 butane diol and any chemical compound that is metabolically converted to GHB

(7) GHV or 4-methyl-GHB; γ-hydroxyvaleric acid;

(8) GVL; γ-valerolactone;

(9) MMQ; methylmethaqualone;

(10) MBQ; mebroqualone.

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[16.19.20.65 NMAC - Rp 16.19.20.65 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.66 SCHEDULE II:

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D. DEPRESSANTS: Unless specifically exempt or unless listed in another schedule any material, compound mixture or preparation which contains any quantity of the substance having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers is possible within the specific chemical designation.

(1) Amobarbital;

(2) Secobarbital;

(3) Pentobarbital;

(4) Phencyclidine;

(5) Glutethimide;

(6) 1-phenylcyclohexylamine;

(7) 1-piperidinocyclohexanecarbonitrile.

(8) Dronabinol in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration.

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[16.19.20.66 NMAC - Rp 16.19.20.66 NMAC, 6/26/2018; A, 12/17/2019]

16.19.20.69 SCHEDULE V:

A. Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone.

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than two and five-tenths milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(6) Not more than five-tenths milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

B. Stimulants. 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 stimulant effect on the central nervous system, including its salts, isomers and salts of isomers.

(1) Pyrovalerone.

(2) Pseudoephedrine as a drug that includes any compound, mixture, or preparation that contains any detectable quantity of pseudoephedrine, its salts or its optical isomers, or salts of its optical isomers. Pursuant to 30-31-10.C the following substances are excluded from schedule V controlled substances: pseudoephedrine products in liquid form including liquid filled gel caps and pseudoephedrine products already classified as dangerous drugs.

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]