This is an amendment to 16.19.11 NMAC, Section 1, 3, 8, and adding new section 9 effective 11/17/2026.

16.19.11.1 ISSUING AGENCY:[~~Regulation and Licensing Department~~] Board of Pharmacy [~~, Albuquerque, NM, (505) 841-9102.~~]
[16.19.11.1 NMAC - Rp 16 NMAC 19.11.1, 12-15-02; A, 11/17/2026]

16.19.11.3 STATUTORY AUTHORITY: Paragraph (6) of Subsection A of Section 61-11-6 [~~A(6)~~] NMSA 1978 authorizes the board of pharmacy to license nursing home drug facilities and all places where dangerous drugs are dispensed or administered and to provide for the inspection of their facilities and activities. Paragraph (9) of Subsection B of Section 61-11-14 [~~B(9)~~] NMSA 1978 directs the board to issue drug custodial licenses for licensed nursing homes and to adopt regulations that define and limit those licenses. Section 61-11-31 NMSA 1978 allows custodial care facilities authorized to provide withdrawal management to acquire and possess dangerous drugs and controlled substances in accordance with board rules.
[16.19.11.3 NMAC - Rp 16 NMAC 19.11.3, 12-15-02; A, 11/17/2026]

16.19.11.8 MINIMUM STANDARDS:

A. Minimum standards for the distribution, storage, handling and record keeping of drugs:

(1) The pharmaceutical service shall be organized and maintained primarily for the benefit and safety of the patient.

(2) All medications administered to patients shall be by direct order of a physician, or other licensed practitioner, as defined in the Pharmacy Act, Subsection P of Section 61-11-2 [~~P~~] NMSA 1978.

(3) The pharmaceutical service shall be under the direction of a registered pharmacist, who may be on a part-time or consultant basis.

(4) [~~Policies relating to the control, distribution and administration of medications shall be developed by the pharmacist. Preparation of a written procedures manual shall be the responsibility of the pharmacist.~~] The pharmacist is responsible for developing policies for medication control, distribution and administration and preparing a written procedures manual.

(5) An automatic stop-order policy shall be adopted to provide guidance in these instances where medications ordered are not specifically limited as to time or number of doses.

(6) Adequate facilities to be provided for storage of medications. Proper labeling is required on each patient's medication container.

(7) Complete records - In addition to those records specifically required by federal and state laws, records shall be maintained of the receipt, use, or disposition of medications. The receipt and destruction journal shall show:

(a) date;
(b) patient's name;
(c) pharmacy's name;
(d) name of drug;
(e) strength and dosage form;
(f) prescription number;
(g) quantity;
(h) initials of person accepting delivery; and
(i) inventory of drugs to be destroyed.

(8) Appropriate current drug reference sources shall be provided at the facility, in printed or electronic form.

(9) [~~In licensed nursing homes an emergency drug supply shall be maintained to be used in a medical emergency situation, contents and quantity to be determined by a physician, nursing director and the pharmacist of each institution. In licensed custodial care facilities an emergency drug supply may be used. This emergency drug supply shall be accessed only when licensed personnel are on duty. In licensed custodial care facilities without a 24-hour/365 day per year on-site nurse, the emergency drug tray shall not contain any controlled substances. Licensed custodial care facilities, with a 24-hour/365 day per year on-site nurse may use an emergency drug tray containing controlled substances. A list of the contents of the emergency drug supply shall be attached to the outside of the tray.~~] In licensed nursing homes, an emergency drug supply must be maintained for medical

emergencies, with its contents and quantity determined by a physician, nursing director, and the pharmacist of each institution. In licensed custodial care facilities, the emergency drug supply can be used only when licensed personnel are on duty. Facilities without a 24/7 on-site nurse cannot include controlled substances in the emergency drug supply, while those with a 24/7 nurse can. A list of the emergency drug supply's contents must be attached to the tray.

(10) Medication errors and adverse drug reactions [~~should~~] will be documented and a method of reporting shall be addressed in the pharmacy procedure manual.

B. Policy and procedures manual:

(1) The pharmacist shall be responsible for the preparation of a written procedures manual, the aim of which shall be:

(a) To improve communications with the facility;

(b) to improve patient care;

(c) to aid in personnel training;

(d) to increase legal protection;

(e) to aid in evaluating performance;

(f) to promote consistency and continuity.

(2) [~~There shall be a copy of the policy and procedure manual at each facility location. This copy must be read and initialed by all personnel responsible for the procurement, administration or control of the patient's medication.~~] Each facility must have a copy of the policy and procedure manual, which must be read and initialed by all personnel responsible for procuring, administering, or controlling patient medication. The manual may be maintained in paper or electronic form.

(3) [~~The consultant pharmacist shall make an annual review of the procedures manual. Findings of which shall be reported to the facility administration.~~] The consultant pharmacist must annually review the procedures manual and report findings to the facility administration.

(4) Guidelines for developing a pharmaceutical procedures manual;

(a) Drug policy: A written policy [~~concerning~~]detailing the methods and procedures for [~~the~~]pharmaceutical services, [~~stating the appropriate methods and procedures for~~] including obtaining, dispensing and administering drugs and biologicals.

(b) Prescription drug orders: The designated agent of the licensed facility may transcribe prescription drug orders from a licensed practitioner and transmit those orders via telephone or facsimile to the pharmacy.

(c) Licensed practitioners will identify the designated agents of a facility by written authorization according to the facility's policy and procedures manual.

(d) The facility shall have a medication administration record (MAR) documenting medications administered to residents, including over-the-counter medications. This documentation shall include:

(i) Name of resident;

(ii) date given;

(iii) drug product name;

(iv) dosage and form;

(v) strength of drug;

(vi) route of administration;

(vii) how often medication is to be taken;

(viii) time taken and staff initials;

(ix) dates when the medication is discontinued or changed;

(x) the name and initials of all staff administering medications.

(e) Any medications removed from the pharmacy container or blister pack must be given immediately and documented by the person assisting.

(f) All PRN medications shall have complete detailed instructions regarding the administering of the medication. This shall include:

(i) Symptoms that indicate the use of the medication;

(ii) exact dosage to be used;

(iii) the exact amount to be used in a 24 hour period.

(g) Describe medication storage, procedures, and function at the nursing stations.

(h) Describe the medication administration system used with means of verifying accuracy of delivered dosage. Describe the procedure for recording missed or refused doses and the procedure followed for missed or refused doses.

(i) State that medications prescribed for one patient shall not be administered to any other patient.

(j) Describe policy concerning self-administration of medications by patients. A physician's order shall be required before any resident is allowed to self-administer medications.

(k) State procedures for documenting medication errors and adverse drug reactions:

(i) Should a staff member of the facility notice an error, possible overdose, or any discrepancy in any of the prescriptions filled by the pharmacy, they will immediately contact the pharmacy. If necessary, the pharmacy will contact the physician.

(ii) In the event of an adverse drug reaction the facility will immediately contact the physician.

(l) List labeling and storage requirements of medications in conformity with the official compendium (USP/NF).

(5) O**ther information:**

(a) Emergency drug tray - use, inventory control, replacement of drugs, security when licensed staff is not on duty.

(b) Location of emergency drug tray.

(c) 24-hour emergency pharmaceutical services.

(d) Part-time or consultant pharmacist hours on premises.

(e) In-service training.

(f) Drug information service.

(g) Automatic stop orders.

(h) Controlled substances - inventory, security and control.

(i) Renewal of physician's orders.

(j) A policy concerning "PASS" medications.

(k) Discontinued medication.

(l) Records and standards of storage of over-the-counter drugs.

(m) Drug receipt and disposition records.

(6) **Drug distribution:**

(a) All dangerous drugs shall be obtained from a properly licensed facility. Stock dangerous drugs acquired, maintained and administered by or at the nursing home shall be listed in the nursing home policy and procedure manual. The stock dangerous drugs shall be used when a licensed nurse (LPN or RN) is on duty. The following is the approved list of stock dangerous drugs:

(i) Sterile normal saline and water - injectable;

(ii) sterile normal saline and water - irrigation;

(iii) tuberculin testing solution;

(iv) 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;

(v) any additional nursing home stock dangerous drugs must be defined and listed in the policy and procedure manual and must be approved by the board of pharmacy or board's agent prior to obtaining or using.

(b) No drugs will be compounded by other than a pharmacist unless done in accordance with that exemption in the State Pharmacy Act - Section 61-11-22 NMSA 1978.

(c) The pharmacist shall be responsible for the proper removal and destruction of unused, discontinued, outdated or recalled drugs. The pharmacist shall be responsible for proper transfer and documentation of eligible drugs donated in accordance with 16.19.34 NMAC.

(d) The pharmacist shall require the person receiving a patient's drugs from the pharmacist or his agent to sign a drug receipt record listing those prescriptions received from the pharmacy.

(e) The pharmacist shall provide the staff with a receipt listing those prescriptions removed from the facility.

(f) Medications will be released to patients on discharge from the facility only upon the authorization of the physician.

(7) **Drug control:**

(a) All state and federal laws relating to storage, administration and disposal of controlled substances and dangerous drugs shall be complied with.

(b) Separate sheets shall be maintained for controlled substances records indicating the following information for each type and strength of controlled substances: date, time administered, name of

patient, dose, physician's name, signature of person administering dose, and balance of controlled substance in the container.

(c) All drugs shall be stored in locked cabinets, locked drug rooms, or state of the art locked medication carts.

(d) Medication requiring refrigeration shall be kept in a secure locked area of the refrigerator or in the locked drug room.

(e) All refrigerated medications will be kept in separate refrigerator or compartment from food items.

(f) Medications for each patient shall be kept and stored in their originally received containers, and stored in separate compartments. Transfer between containers is forbidden, waiver shall be allowed for oversize containers and controlled substances at the discretion of the drug inspector.

(g) Prescription medications for external use shall be kept in a locked cabinet separate from other medications.

(h) No drug samples shall be stocked in the licensed facility.

(i) All drugs shall be properly labeled with the following information:

(i) Patient's full name;

(ii) physician's name;

(iii) name, address and phone number of pharmacy;

(iv) prescription number;

(v) name of the drug and quantity;

(vi) strength of drug and quantity;

(vii) directions for use, route of administration;

(viii) date of prescription (date of refill in case of a prescription renewal);

(ix) expiration date where applicable: The dispenser shall place on the label a suitable beyond-use date to limit the patient's use of the medication. Such beyond-use date shall be not later than (a) the expiration date on the manufacturer's container, or (b) one year from the date the drug is dispensed, whichever is earlier;

(x) auxiliary labels where applicable;

(xi) the manufacturer's name;

(xii) state of the art drug delivery systems using unit of use packaging require items i and ii above, provided that any additional information is readily available at the nursing station.

[~~**(j)** 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 caregiver, 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.~~

~~**(k)** 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.~~

~~**(l)** Return of Patient Medication Package Drugs: Patient medication packages with more than one drug within a container may not under any circumstances be returned to a pharmacy stock.~~

~~**(m)** Patient Medication Packages with only one drug within a container:~~

~~**(i)** 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;~~

~~**(ii)** 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 is to remain sealed and labeled until dispensed; (2) the expiration date of drug shall become 50% of the time left of the expiration for the drug; (3) no Schedule II drugs may be returned to inventory; and (4) proper record keeping for the addition of other scheduled drugs into inventory must be done.~~]

(8) Drug information:

(a) The pharmacist shall be accessible for providing drug information.

(b) A current drug reference [~~books~~] shall be located in each nursing station, and may be in paper or electronic form.

(c) Each nursing station shall have poison control information and phone number and a conversion chart for pharmaceutical weights and measures, and as a part of the drug procedures manual.

(9) Emergency drug supply

(a) There shall be an accountability record indicating the following:

(i) Name of drug, strength, and amount of medication used;

(ii) date used;

(iii) time;

(iv) patient's name;

(v) physician's name;

(vi) nurse administering drug;

(vii) nature of emergency.

(b) Pharmacist shall make notation of date and time medication replacement is made on the line following that line containing withdrawal information and sign his name, unless the pharmacy chooses to change out the complete emergency box each time it is used. The pharmacy shall keep a record of each time the box is changed and a list of all drugs that were replaced in the box.

(10) Destruction of dispensed drugs for patients in health care facilities or institutions:

(a) The drugs are inventoried and such inventory is verified by the consultant pharmacist. The following information shall be included on this inventory:

(i) name and address of the facility or institution;

(ii) name and pharmacist license number of the consultant pharmacist;

(iii) date of drug destruction;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name of dispensing pharmacy;

(vii) name, strength, and quantity of drug;

(viii) signature of consultant pharmacist destroying drugs;

(ix) signature of witness(es); and

(x) method of destruction.

(b) The drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

(c) The actual destruction of the drug is witnessed by the consultant pharmacist and one of the following:

(i) An agent of the New Mexico board of pharmacy;

(ii) facility administrator;

(iii) the director of nursing.

(11) A consultant pharmacist may utilize a waste disposal service or reverse distributor to destroy dangerous drugs and controlled substances in health care facilities, boarding homes or institutions provided the following conditions are met:

(a) The inventory of drugs is verified by the consultant pharmacist. The following information must be included on this inventory:

(i) Name and address of the facility or institution;

(ii) name and pharmacist license number of the consultant pharmacist;

(iii) date of packaging and sealing of the container;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name of dispensing pharmacy;

(vii) name, strength and quantity of drug;

(viii) signature of consultant pharmacist packaging and sealing container; and

(ix) signature of the witness.

(b) The consultant pharmacist seals the container or drugs in the presence of the facility administrator, the director of nurses or an agent of the board of pharmacy.

(c) The sealed container is maintained in a secure area at the facility or pharmacy until transferred to the waste disposal service or the reverse distributor by the consultant pharmacist, facility administrator, director of nursing or agent of the board of pharmacy.

(d) A record of the transfer to the waste disposal service or reverse distributor is maintained and attached to the inventory of drugs. Such records shall contain the following information:

(i) Date of the transfer;

(ii) signature of the person who transferred the drugs to the waste disposal service or reverse distributor;

(iii) name and address of the waste disposal service or reverse distributor;

(iv) signature of the employee of the waste disposal service or the reverse distributor who receives the container; and

(v) the waste disposal service or reverse distributor shall provide the facility with proof of destruction of the sealed container.

(12) Record retention: All records required above shall be maintained by the consultant pharmacist and the health care facility or institution for three years from the date of destruction.

[16.19.11.8 NMAC - Rp 16.19.11.8, 12/15/2002; A, 10/24/2014; A, 12/13/2015; A, 11/17/2026]

16.19.11.9 CUSTODIAL CARE FACILITY – WITHDRAWAL MANAGEMENT:

A. A licensed custodial care facility that is authorized to provide medically monitored withdrawal management that is under the supervision of a consultant pharmacist and has nursing staff on-site 24 hours per day, 365 days per year, may acquire, stock, maintain and have in the facility's possession dangerous drugs, including controlled substances only in Schedules III–V as limited in Paragraph (4) of Subsection D of this section, for administration for withdrawal management purposes, in accordance with board rules.

B. Definitions as used in this section:

(1) "**administer**" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means as a result of an order of a licensed practitioner.

(2) "**authorized personnel**" means licensed healthcare professionals acting within their scope of practice who:

(a) are specifically authorized by facility policy to access, handle, or administer dangerous drugs or controlled substances;

(b) are listed on the current authorized access roster with date granted and terminated; and

(c) have documented completion of initial training required by Paragraph (2) of Subsection H of this section prior to being granted access or administration authority.

(3) "**downtime**" means any period during which the primary electronic access or record system is unavailable.

(4) "**emergency override**" means any access to controlled substances outside normal access controls as permitted by facility policy during downtime or urgent care.

(5) "**facility stock**" means dangerous drugs, including controlled substances, maintained by the facility under its board and DEA registrations for administration to facility patients and not dispensed to a specific patient.

(6) "**MAR reconciliation**" means the documented comparison of MAR entries to the perpetual inventory, wastage, and access logs to confirm agreement.

(7) "**medically monitored withdrawal management**" means withdrawal management services provided under medical supervision, including the use of dangerous drugs authorized under this section, consistent with patient assessment, monitoring, documentation, and staffing requirements in Subsections G and H of this section and other applicable state and federal regulations.

(8) "**perpetual inventory**" means a continuously maintained record that reflects the on-hand quantity after each receipt, administration, wastage, transfer, or destruction entry, with running balance.

(9) "**significant loss**" has the meaning provided in 16.19.20 NMAC and applicable DEA regulations.

(10) "**variance**" means any difference between the physically counted quantity and the documented perpetual inventory balance; "variance greater than zero" means any non-zero difference, positive or negative.

(11) "**wastage**" means the irreversible disposal of a remaining portion of a dose not administered to a patient.

C. Licensure: Before acquiring or possessing stock dangerous drugs, including controlled substances, the facility must:

(1) be licensed by the board to operate as a custodial facility providing withdrawal management;

(2) be licensed by the board to operate as a limited drug clinic as described in Paragraph (3) of Subsection A of 16.19.10.11 NMAC, or successor provision; and

(3) hold current board and DEA controlled substance registrations issued for, and listing, the facility's physical street address.

D. Minimum Standards:

(1) Custodial care withdrawal management facilities shall comply with 16.19.11.8 NMAC of this part and 16.19.10 NMAC, as applicable. For facility stock this section governs and controls over conflicting provisions in 16.19.11.8 NMAC of this part and 16.19.10 NMAC. The requirements in Paragraphs (10) through (12) of Subsection B of 16.19.11.8 NMAC of this part apply only to dispensed, patient-specific drugs; destruction or reverse distribution of facility stock controlled substances shall comply with 16.19.20.38 NMAC and 21 CFR Part 1317. Nothing in this section alters labeling and MAR documentation requirements applicable to patient-specific medications under 16.19.11.8 NMAC of this part.

(2) Consultant pharmacist: All custodial care withdrawal management facilities shall engage the services of a pharmacist whose duties and responsibilities are described in 16.19.4.11 NMAC, pertaining to custodial facilities and clinics. The pharmacist shall review one hundred percent of active patient charts at least quarterly and shall perform a drug regimen review for each newly admitted patient within 72 hours of admission or by the next business day if the 72-hour period includes a state or federal holiday. The pharmacist shall reconcile all controlled substances and gabapentin (and any additional dangerous drugs designated by facility policy) at each quarterly visit, review all required perpetual inventories, reconciliation records, emergency par levels, and analyze variances and wastage for issues or patterns. As part of reconciliation, the pharmacist shall obtain, from the contracted pharmacy, all records of facility stock procured during the quarterly reconciliation period. Discrepancies identified during quarterly reconciliation must be documented and addressed under Subsection I of this section. The pharmacist quarterly report shall document completion of required activities and a quarterly reconciliation report summarizing counts, variances, wastage analysis, access log review, procurement vs. usage reconciliation, discrepancies identified, investigations initiated under Subsection I of this section, and corrective actions.

(3) Medical director: The facility shall be under the supervision of a medical director responsible for prescribing for facility patients. Controlled substances may be prescribed only by an appropriately registered individual practitioner acting in the usual course of professional practice for a legitimate medical purpose.

(4) Stock eligibility: Facility stock controlled substances are limited to Schedules III–V and may be administered for clinically appropriate withdrawal management or directly related supportive care indications documented in the medical record. If the controlled substance is an opioid, it must be FDA-approved for maintenance or detoxification and used consistent with state and federal law. Schedule II controlled substances may not be maintained, stocked, or administered as facility stock under this Section.

(5) No separate emergency drug supply. A facility operating under this Section shall not acquire, stock, or maintain a separate emergency drug supply, emergency drug tray, or emergency kit of facility-stock controlled substances under Paragraph (9) of Subsection B of 16.19.11.8 NMAC of this part. Surge and emergency access needs shall be met through facility stock maintained within the perpetual inventory, including the emergency par level authorized under Subsection F of this section. Nothing in this paragraph limits a patient-specific medication order or the administration of facility stock for withdrawal management or directly related supportive care under Paragraph (4) of this subsection.

E. Patient-specific medications: Self-administration requires a prescriber order and must conform to facility policy and applicable law. The facility shall not take possession of patient-specific controlled substances unless possession and custody are authorized by applicable state and federal law. When authorized, patient-specific dangerous drugs and controlled substances shall be:

(1) logged upon receipt with patient name, drug, strength, quantity, and source;

(2) stored separately from facility stock in a securely locked manner preventing contamination and diversion;

(3) administered only pursuant to a valid order and documented on the MAR;

(4) tracked on separate controlled substance count sheets or electronic equivalent capturing all elements in Subparagraph (b) of Paragraph (7) of Subsection B of 16.19.11.8 NMAC of this part or successor

provision. Patient-specific controlled substances in facility custody shall be included in the shift-change joint physical count and reconciliation required by Paragraph (5) of Subsection G of this section; and

(5) returned, transferred, or destroyed in accordance with applicable law when therapy is discontinued or upon discharge.

F. Contracted pharmacy; unit-dose stock: Facilities may obtain manufacturer or pharmacy-prepared unit dose stock dangerous drugs and controlled substances from a contracted pharmacy. Solid oral dosage forms must be in unit-dose packaging; bulk bottles are not allowed. Quantities procured and maintained shall not exceed the documented average 30-day utilization by drug and strength, calculated using at least the prior three months (or all available months if fewer than three) of facility administration data, plus an emergency par level. Initial quantities obtained upon facility licensure shall be documented in a written utilization projection prepared by the facility and approved by the consultant pharmacist, including anticipated census, acuity, and formulary rationale. For new formulary items, the facility shall prepare a written utilization projection approved by the consultant pharmacist. The policy and procedure manual shall designate a primary and one back-up contracted pharmacy. Changes in the primary or back-up contracted pharmacy shall be reported to the board within 15 days in the manner prescribed by the board. For purposes of this Section, 'emergency par level' means an additional on-hand quantity not to exceed twenty-five percent of the calculated 30-day average. The consultant pharmacist may approve higher temporary par levels with written justification based on census volatility, acuity, or formulary changes; such approvals shall be documented and reviewed at least quarterly. Emergency par levels must be documented and approved by the pharmacist at least quarterly.

G. Storage; access; records; reconciliation; retention; security:

(1) Facilities must comply with all applicable state and federal regulations regarding the handling and storage of dangerous drugs including controlled substances. Access to the drug storage area will be limited to authorized personnel. Patients may not enter the drug storage area under any circumstance. The Inspector will evaluate for adequate security of facility and controls as part of prelicensing.

(2) Controlled substances shall be stored in a securely locked, substantially constructed cabinet or safe meeting applicable state and federal physical security requirements, with access limited to authorized personnel. Access shall be controlled by documented key or code management with a current authorized access list; if physical keys are used, they shall be maintained under the control of authorized personnel and never left unattended. Any spare key shall be maintained sealed with a numbered, tamper-evident seal with seal number logged and verified at each shift change when the duty key is passed to the incoming authorized personnel. Upon discovery of an unexplained broken or mismatched spare key seal, the outgoing and incoming authorized personnel shall immediately secure the spare key with a new numbered, tamper-evident seal, document the new seal number before completing handoff, initiate an internal discrepancy review under Subsection I of this section, and notify the consultant pharmacist and medical director within 24 hours. Electronic access systems shall maintain an auditable access log. Facilities utilizing electronic access systems shall implement a secondary contingency access protocol that maintains auditable controls during downtime. Emergency override access shall require dual authorization whenever two authorized personnel are on duty, regardless of system functionality; where only one authorized person is on duty, real-time supervisory notification and post-event supervisory attestation are required. Downtime and override access events shall be contemporaneously logged, including the reason for the override and the identity of the authorizing supervisory personnel, and retained with the perpetual inventory records, with corresponding perpetual inventory entries cross-referencing the downtime or override access. The authorized access list shall be reviewed at least quarterly and updated immediately upon any personnel change affecting access. Temporary or agency staff may be authorized only if listed on the current access list. Temporary or agency staff shall not be granted access until license verification is completed and initial training under Paragraph (2) of Subsection H of this section is documented. Non-licensed personnel shall not be granted access.

(3) Records: Facilities shall maintain accurate, contemporaneous records of all dangerous drugs and controlled substances received, administered, transferred, wasted, or destroyed, consistent with the Drug, Device and Cosmetic Act, the Controlled Substances Act, 16.19.20 NMAC, and federal regulations. All transactions affecting on-hand quantities shall be reflected in the perpetual inventory. Late entries or corrections shall be dated, timed, and signed or electronically authenticated by the individual making the entry, shall not obliterate the original entry, and shall state the reason for the correction. Backdating, overwriting, or alteration of original balances is prohibited; corrections shall be made as additive, attributed entries with cross-reference to the original entry. Electronic records shall maintain unique user identification and an immutable audit log of entries, corrections, and access. All records required by this section, including access logs, downtime/override logs, perpetual inventory, MAR reconciliation logs, wastage documentation, and quarterly reconciliation reports, shall be maintained in a centralized, indexed record system (electronic or paper) and be readily available for inspection.

(4) Administration records: The perpetual inventory record of facility stock administered shall be updated at the time of administration and include the name of patient; date and time administered; name of drug; strength of drug; amount administered; balance remaining; name of prescribing practitioner and name of person administering the drug. For controlled substances, any partial dose wastage must be co-witnessed and co-signed by a second authorized personnel as defined in Paragraph (2) of Subsection G of this section, present at the time of wastage, who positively identifies the drug to be destroyed, and the running balance updated immediately. If only one authorized person is on duty, secure temporary sequestration must use a single-use, tamper-evident container placed within the controlled substance cabinet or safe; the seal number shall be documented on the perpetual inventory and MAR, and the co-witness wastage shall occur at the next shift change. Facilities may adopt the co-witness standard for gabapentin by policy. Administration shall also be documented on the MAR consistent with Paragraph (4) of Subsection B of 16.19.11.8 NMAC of this part. Each shift shall verify completion of MAR entries for doses administered during that shift; any omissions shall be corrected with attributed late entries consistent with Paragraph (3) of Subsection G of this section. Facilities shall reconcile, at least weekly, all controlled substances and gabapentin by comparing MAR entries, perpetual inventory entries, documented wastage, and downtime/override logs; discrepancies shall be treated as internal discrepancies under Subsection I of this section. Reconciliation shall be documented.

(5) Inventory and reconciliation: A perpetual inventory system shall be maintained for facility stock controlled substances and gabapentin (and any additional dangerous drugs designated by facility policy) and updated at the time of receipt, administration, wastage or destruction. At each shift change, outgoing and incoming licensed personnel shall jointly perform a physical count of all controlled substances, including any patient-specific controlled substances, and reconcile to the perpetual inventory or controlled substance count sheet at handoff. The facility may adopt the same shift change standard for gabapentin; regardless, weekly reconciliation under Paragraph (4) of Subsection G of this section remains required. Any variance greater than zero identified at shift handoff shall be jointly reviewed contemporaneously; if not resolved by corrective documentation before the end of the handoff process, it shall be treated as an internal discrepancy under Subsection I of this section. External reporting to the board and DEA shall follow the 'theft or significant loss' standards in Paragraph (1) of Subsection I of this section.

(6) Diversion controls: The facility shall provide effective controls and procedures to guard against theft and diversion of dangerous drugs and controlled substances.

(7) Restricted area room requirements. Facility stock, including controlled substances, shall be stored in a restricted area that is a dedicated, enclosed room of adequate size to permit orderly storage, accurate counting, and reconciliation of all drugs maintained. The restricted area shall be: (a) of substantial construction, with walls, ceiling, floor, and door sufficient to resist unauthorized entry; (b) secured by controlled-access locking consistent with Paragraph (2) of Subsection G of this section, with access limited to authorized personnel and with patients prohibited from entry under any circumstance, consistent with Paragraph (1) of Subsection G of this section; (c) equipped with climate control adequate to maintain drugs within the storage conditions required by Paragraph (8) of this subsection; and (d) evaluated by the inspector for adequate size, construction, and security as part of prelicensing and inspection under Paragraph (1) of Subsection G of this section.

(8) Temperature monitoring. The facility shall monitor and maintain the temperature (and, where applicable, humidity) of each drug storage area, including any refrigerated storage, within the manufacturer's recommended range and applicable United States Pharmacopeia standards. Monitoring shall be documented on a contemporaneous log, excursions shall be recorded and acted upon under facility policy, and monitoring records shall be maintained and available for inspection consistent with Paragraph (3) of Subsection G of this section.

(9) Video surveillance. The facility shall maintain a functioning video camera providing continuous coverage of the restricted area. Recorded footage shall not be altered, edited, or deleted by facility staff, shall be secured against tampering, and shall be retained for at least ninety (90) days and made available to the board or its agent upon request.

H. Administration authority; training:

(1) Only authorized personnel may administer dangerous drugs, including controlled substances.

(2) All personnel involved in handling, storage, reconciliation, administration, or documentation of controlled substances must complete initial and at least annual refresher training (in person or virtual) on applicable state and federal regulations and facility policies, including designated agent identification and order transmission consistent with Subparagraphs (b) and (c) of Paragraph (4) of Subsection B of 16.19.11.8 NMAC of this part, storage and access controls (Paragraph (2) of Subsection G of this section), recordkeeping and perpetual inventory (Paragraph (3) of Subsection G of this section), wastage (Paragraph (4) of Subsection G of this section),

reconciliation (Paragraph (5) of Subsection G of this section), and requirements under Subsection I of this section. Initial training shall occur prior to independent access or administration authority. Training documentation shall be maintained in personnel files or a centralized record and be readily available for inspection.

I. Reporting discrepancies, theft, or loss; written policy:

(1) Any theft or significant loss of controlled substances must be reported to the board in accordance with 16.19.20 NMAC and to DEA in accordance with federal requirements, within required time frames. The facility shall contemporaneously document the assessment of significance, including quantity lost, specific controlled substance involved, pattern or aggregate loss over time, and potential diversion risk, and whether the loss can be associated with known, documented cause, and reporting determinations. Internal investigation timelines do not delay external reporting.

(2) For this section, 'discrepancy' includes unresolved count variances, suspected diversion, or unexplained losses identified during reconciliation. Facilities must maintain a written policy establishing:

(i) internal reporting shall occur no later than the end of the shift in which a discrepancy is discovered, notice shall also be provided to the consultant pharmacist and medical director in writing within 24 hours;

(ii) an investigation shall be initiated within 24 hours and, absent extenuating circumstances documented in the file, completed within five business days, with interim controls implemented as indicated (e.g. enhanced counts, restricted access); and

(iii) corrective actions and reconciliation updates shall be documented within 24 hours of final determination of root cause, and the perpetual inventory updated to reflect final resolution.

(3) All investigation and corrective action records shall be retained for three years from the date of final determination and be readily available for inspection.

J. Procurement, ordering authority, and transport of facility stock:

(1) Designated ordering authority. The facility's policy and procedure manual shall name one designated licensed person, approved by the consultant pharmacist, as the sole individual authorized to order facility-stock dangerous drugs, including controlled substances, from the contracted pharmacy. The facility shall name a designated back-up only as provided in the policy and procedure manual and approved by the consultant pharmacist.

(2) Notice to pharmacies. The consultant pharmacist shall notify the primary contracted pharmacy and the one back-up contracted pharmacy designated under Subsection F of this section of the identity of the authorized designated licensed person, and shall notify both pharmacies of any change without delay.

(3) Authorized pickup roster. The facility shall perpetually maintain a current list of its licensed staff and shall provide that list, and any update to it, to each contracted pharmacy. Only an individual appearing on the current list, and only while on duty, may pick up medication from a contracted pharmacy.

(4) Direct transit. Transport of medication shall proceed directly from the facility to the contracted pharmacy and directly back to the facility, with no intervening stops.

(5) Transit log. The facility shall maintain a log of all medication transits sufficient to permit reconciliation, recording at minimum the time of departure, the time of return, the identity of the individual transporting the medication, and receipt information adequate to reconcile the drugs received against the perpetual inventory under Paragraph (5) of Subsection G of this section.

K. Temporary closure: If a facility temporarily closes, all dangerous drugs including controlled substances shall be removed from the facility no later than the time of closure and properly dispositioned by the consultant pharmacist in accordance with applicable state and federal law. Disposition shall be documented, and the perpetual inventory reconciled to zero on-hand for facility stock as of closure.

L. Emergency relocation: A facility may not resume acquiring, stocking, or maintaining facility-stock dangerous drugs or controlled substances at a relocated site until the facility has notified the board of the relocation, the relocated site has been inspected, and the board has approved drug storage operations at the new location. Board and DEA controlled-substance registrations must list the facility's current physical street address consistent with Paragraph (3) of Subsection C of this section before facility stock is maintained at the new site.

[16.19.11.9 NMAC – N, 11/17/2026]