This is an amendment to 16.19.10 NMAC, Section 11, effective 6/13/2023.

16.19.10.11 PUBLIC HEALTH CLINICS:

A. Clinic Licensure: All clinics where dangerous drugs are administered, distributed or dispensed shall obtain a limited drug permit as described in Paragraph (7) of Subsection B of Section 61-11-14 NMSA 1978 of the Pharmacy Act which consists of the following types:

(1) Class A clinic drug permit for clinics where:

(a) dangerous drugs are administered to patients of the clinic;

(b) more than 12,500 dispensing units of dangerous drugs are dispensed or distributed annually;

(c) clinics dispensing only one class of dangerous drug or controlled substance, such as oral contraceptives, may be approved by the board as a Class B3 clinic;

(2) Class B clinic drug permit for clinics where dangerous drugs are:

(a) administered to patients of the clinic; and

(b) dispensed or distributed to patients of the clinic. Class B drug permits shall be issued by categories based on the number of dispensing units of dangerous drugs to be dispensed or distributed annually, as follows: 1. CATEGORY 1 up to 2,500 dispensing units; 2. CATEGORY 2 from 2,501 - 7,500 dispensing units; 3. CATEGORY 3 from 7,501 - 12,500 dispensing units;

(3) Class C clinic drug permit for clinics where dangerous drugs are administered to patients of the clinic.

(4) Class D clinic drug permit for school based emergency medicine (SBEM) clinic (which does not include a Class A, B, or C school based health clinic) - any school based facility that chooses to possess a stock supply of emergency dangerous drugs; these emergency dangerous drugs are albuterol aerosol canisters with spacers and epinephrine standard-dose and pediatric-dose auto-injectors; these emergency dangerous drugs are for administration to students of the school; these emergency dangerous drugs shall be the property of the facility; these facilities will not stock of any other dangerous drug.

(5) Class E Narcotic Treatment Program (NTP) clinic drug permit for clinics where opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act [(21 U.S.C. 355)] for use in the treatment of opioid use disorder are used. An NTP shall be licensed and certified as required by state and federal law, including registration under 21 USC 823(g)(1) and certified as an Opioid Treatment Program by the Substance Abuse and Mental Health Services Administration in accordance with 42 CFR 8.11.

B. Formularies:

(1) For all clinic types, drug procurement and storage is limited to the drugs listed in the dispensing formulary for the clinic. The formulary shall be developed by the pharmacy and therapeutics committee of the facility, or if no such committee exists, by the pharmacist and medical director of the clinic. The formulary drugs shall be appropriate for the scope of medical services provided at the clinic facility. A dangerous drug with the same generic name is considered one drug within the formulary (ie) all dosage forms and packages of ampicillin are considered one drug.

(2) For all clinic types, drug procurement and storage is limited to the drugs listed in the administration formulary for on-site administration. The formulary shall be developed by the pharmacy and therapeutics committee of the facility, or if no such committee exists, by the pharmacist and medical director of the clinic. The formulary drugs shall be appropriate for the scope of medical services provided at the clinic facility. A dangerous drug with the same generic name is considered one drug within the formulary (ie) all dosage forms and packages of ampicillin are considered one drug.

(3) For Class D, (SBEM) clinic may only stock the approved dangerous drugs; albuterol aerosol canisters with spacers and epinephrine standard-dose and pediatric-dose auto-injectors.

(4) A clinic may petition the board for an alternative dispensing formulary as set forth in Subsection R of 16.19.10.11 NMAC.

C. Consultant Pharmacist:

(1) Any facility licensed as a clinic by the board which does not employ a staff pharmacist must engage the services of a consultant pharmacist, whose duties and responsibilities are described in Subsection C of 16.19.4.11 NMAC.

(2) The consultant pharmacist shall wear an identification badge listing ~~his~~ name and job title while on duty in the clinic.

D. Pharmacy Technicians and Support Personnel:

(1) Pharmacy technicians, working in a clinic under the supervision of the pharmacist, may perform activities associated with the preparation and distribution of medications, including prepackaging medications and the filling of a prescription or medication order. These activities may include counting, pouring, labeling and reconstituting medications.

(2) The pharmacist shall ensure that the pharmacy technician has completed the initial training required in Subsection A of 16.19.22.9 NMAC.

(3) A written record of the initial training and education will be maintained by the clinic pursuant to requirements of Subsection C of 16.19.22.9 NMAC.

(4) The permissible ratio of pharmacy technicians to pharmacists on duty is to be determined by the pharmacist in charge or consultant pharmacist.

(5) Support personnel may perform clerical duties associated with clinic pharmacy operations, including computer data entry, typing of labels, processing of orders for stock, duties associated with maintenance of inventory and dispensing records.

(6) The pharmacist is responsible for the actions of personnel; allowing actions outside the limits of the regulations shall constitute unprofessional conduct on the part of the pharmacist.

(7) Name tags including job title, shall be required of all personnel while on duty in the clinic.

E. Procurement or Receipt of Dangerous Drugs:

(1) The system of procurement for all drugs shall be the responsibility of the pharmacist.

(2) Records of receipt of dangerous drugs and inventories of controlled substances shall be maintained as required by the Drug, Device and Cosmetic Act 26-1-16 and the Controlled Substances Act 30-31-16 and board of pharmacy regulation 16.19.20 NMAC.

F. Repackaging:

(1) Repackaging from bulk containers to dispensing units for distribution at locations other than the site of repackaging requires FDA registration, whether or not the repackaged drugs enter interstate commerce. (See FDA Regulations Title 21, Sections 207, 210 and 211).

(2) Repackaging of drug from bulk containers into multiple dispensing units for future distribution to clinic patients at the site of repackaging may be done by a physician, dentist, pharmacist, or by a pharmacy technician under the supervision of the pharmacist as defined in Subsection B of 16.19.22.7 NMAC. All drugs repackaged into multiple dispensing units by a pharmacy technician must undergo a final check by the pharmacist.

(3) A record of drugs repackaged must be maintained, to include the following.

- **(a)** Date of repackaging.
- **(b)** Name and strength of drug.
- **(c)** Lot number or control number.
- **(d)** Name of drug manufacturer.
- **(e)** Expiration date (per USP requirements).
- **(f)** Total number of dosage units (tabs, caps) repackaged (for each drug).
- **(g)** Quantity per each repackaged unit container.
- **(h)** Number of dosage units (tabs, caps) wasted.
- **(i)** Initials of repackager.
- **(j)** Initials of person performing final check.

(4) All dispensing units of repackaged medication must be labeled with the following information.

- **(a)** Name, strength, and quantity of the drug.
- **(b)** Lot number or control number.
- **(c)** Name of manufacturer.
- **(d)** Expiration date.
- **(e)** Date drug was repackaged.
- **(f)** Name or initials of repackager.
- **(g)** Federal caution label, if applicable.

(5) Repackaged units must be stored with the manufacturer's package insert until relabeled for dispensing. as specified under Subsection G of 16.19.10.11 NMAC.

G. Clinic Dispensing or Distributing:

(1) Drugs shall be dispensed or distributed only to clinic patients on the order of a licensed practitioner of the clinic.

(2) The clinic practitioner shall record the prescribed drug therapy on the patient medical record indicating the name, strength, quantity and directions for use of the prescribed drug. This information shall be initialed or signed by the practitioner. A separate prescription form in addition to the medical record may be used.

(3) The prescription order may then be prepared by the practitioner, pharmacist or technician under the supervision of the pharmacist and a dispensing label affixed to the dispensing unit of each drug. The following information shall appear on the label affixed to the dispensing unit.

(a) Name of patient.

(b) Name of prescriber.

(c) Date of dispensing.

(d) Directions for use.

(e) Name, strength, and quantity of the drug.

(f) Expiration date.

(g) Name, address and phone number of the clinic.

(h) Prescription number, if applicable.

(4) The pharmacist or practitioner must then provide a final check of the dispensing unit and sign or initial the prescription or dispensing record.

(5) Refill prescription orders must also be entered on the patient's medical record and the dispensing record.

H. Patient Counseling:

(1) Each clinic licensed by the board shall develop and provide to the board policies and procedures addressing patient counseling which are at least equivalent to the requirements of Subsection F of 16.19.4.16 NMAC.

(2) If the consultant pharmacist is absent at the time of dispensing or distribution of a prescription from clinic drug stock to a clinic patient, the patient shall be provided written information when appropriate on side effects, interactions, and precautions concerning the drug or device provided. 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. The clinic shall make the consultant pharmacist's phone number available to patients for consultation on drugs provided by the clinic.

I. Dispensing Records: A record shall be kept of the dangerous drugs dispensed indicating the date the drug was dispensed, name and address of the patient, the name of the prescriber, and the quantity and strength of the drug dispensed. The individual recording the information and the pharmacist or clinic practitioner who is responsible for dispensing the medication shall initial the record.

J. Sample Drugs: Samples of medications which are legend drugs or which have been restricted to the sale on prescription by the New Mexico board of pharmacy are subject to all the record keeping, storage and labeling requirements for prescription drugs as defined by Section 26-1-16 NMSA 1978 and other applicable state and federal laws.

K. Drug Storage:

(1) Space for the storage and dispensing of drugs shall have proper ventilation, lighting, temperature controls, refrigeration and adequate security as defined by the board or its' agent. Minimum space requirements for main drug storage areas are as follows:

(a) for Class A clinics - 240 square foot room;

(b) for Class B clinics;

(i) categories 1, and 2 - 48 square foot room; and

(ii) category 3 - 96 square foot room;

(c) for Class C clinics - an area adequate for the formulary.

(d) for Class D clinics - an area adequate for the formulary:

(i) medication is stored in its original packaging until the time of administration, and secured in a secondary tamper-evident container;

(ii) the dangerous drug is stored in a restricted area, secure but unlocked, and readily accessible to authorized, trained personnel;

(iii) for Class D clinics only, the pre-licensing inspection may be completed by a New Mexico board of pharmacy state drug inspector’s approval of record keeping procedures; the policy and procedure manual; any other required forms or documents; and photographs of the proposed dangerous drug storage

area, secondary tamper-evident container, and drug storage area thermometer; this pre-licensing inspection may not require an onsite inspection.

(e) for Class E clinics – 96 square foot room.

(2) Controlled substances must be stored as defined in 16.19.20.48 NMAC.

(3) All drug containers in the facility shall be clearly and legibly labeled as required under Subsection F of 16.19.10.11 NMAC – (REPACKAGING and Sections 26-1-10 and 26-1-11 of the Drug, Device and Cosmetic Act).

(4) Purchase, storage and control of drugs shall be designed to prevent having outdated, deteriorated, impure or improperly standardized drugs in the facility.

(5) Access to the drug storage area shall be limited to clinic practitioners, the pharmacist, and supportive personnel who are performing pharmacy-related functions.

(6) Clinics licensed by the board prior to adoption of this regulation are exempt from the minimum space requirements set forth in Paragraph (1) of Subsection K of 16.19.10.11 NMAC. When these facilities change ownership, remodel the drug storage area, or relocate after May 15, 1996, the requirements of Paragraph (1) of Subsection K of 16.19.10.11 NMAC shall apply.

L. Dispositon of Unwanted or Outdated Drugs:

(1) The pharmacist shall be responsible for removal of recalled, outdated, unwanted or otherwise unusable drugs from the clinic inventory.

(2) Options for disposal are destruction under the supervision of the pharmacist or return to the legitimate source of supply. Controlled substance disposition shall occur in accordance with 16.19.20.38 NMAC.

M. Reference Material: Adequate reference materials are to be maintained in the clinic. These shall include a current product information reference such as USPDI, facts and comparisons, or American hospital formulary service; a copy of the state drug laws and regulations and a poison treatment chart with the regional poison control center's telephone number.

N. Procedures Manual:

(1) Written policies and procedures shall be developed by the pharmacy and therapeutics committee, or if none, by the pharmacist-in-charge and clinic's executive director, and implemented by the pharmacist-in-charge.

(2) The policy and procedure manual shall include but not be limited to the following:

(a) a current list of the names and addresses of the pharmacist-in-charge, consultant-pharmacist, staff pharmacist(s), supportive personnel designated to provide drugs and devices, and the supportive personnel designated to supervise the day-to-day pharmacy related operations of the clinic in the absence of the pharmacist;

(b) functions of the pharmacist-in-charge, consultant pharmacist, staff pharmacist(s) and supportive personnel;

(c) clinic objectives;

(d) formularies;

(e) a copy of the written agreement, if any, between the pharmacist and the clinic;

(f) date of the last review or revision of policy and procedure manual; and

(g) policies and procedures for

(i) security;

(ii) equipment;

(iii) sanitation;

(iv) licensing;

(v) reference materials;

(vi) drug storage;

(vii) packaging and repackaging;

(viii) dispensing and distributing;

(ix) supervision;

(x) labeling and relabeling;

(xi) samples;

(xii) drug destruction and returns;

(xiii) drug and device procuring;

(xiv) receiving of drugs and devices;

(xv) delivery of drugs and devices;

(xvi) record keeping; and

(xvii) scope of practice.

(3) The procedures manual shall be reviewed on at least an annual basis. A copy of the manual shall be kept at the clinic at all times.

(4) A written agreement defining specific procedures for the transfer, storage, dispensing and record keeping of clinic dangerous drug stock from a licensed New Mexico pharmacy will be included in the procedures manual. The agreement will be signed by a clinic official and pharmacy official and reviewed annually.

O. Patient Record: clinics shall maintain patient records as defined in Subsection C of 16.19.4.16 NMAC.

P. Drug Transfer to a Pharmacy:

(1) Dangerous drug stock unopened containers, except samples, may be transferred physically or electronically to a pharmacy licensed in New Mexico for dispensing to clinic patients.

(a) record of transfer shall be maintained at the clinic and the pharmacy. It will include:

(i) date of transfer or shipment;
(ii) name and strength of drug;
(iii) package size;
(iv) number of packages;
(v) manufacturer or repackager; and
(vi) lot number and expiration date, unless transferred from a clinic supplier to a pharmacy.

(b) A copy of the transfer or shipment record will be provided to the pharmacy at the time of transfer. This record will be compared with the drugs for accuracy and retained by the pharmacy as the receipt document separate from other receiving records of the pharmacy.

(c) Transferred clinic drugs will be stored in the restricted area of the pharmacy and physically separated from all other pharmacy drugs.

(d) Drugs returned to the clinic by the pharmacy will be documented in a transfer record as described in Subparagraph (a) of Paragraph (1) of Subsection P of 16.19.10.11 NMAC. A copy will be maintained by the pharmacy and the clinic.

(2) A clinic may petition the board for an alternative drug transfer system as set forth in Subsection Q of 16.19.10.11 NMAC.

(3) The formulary of transferred drugs for pharmacy dispensing is restricted to the clinic's scope of practice.

Q. Pharmacy Dispensing: Clinic drug stock may be transferred to, and maintained by, a pharmacy for dispensing to clinic patients as provided in this regulation. Clinic drug stock may be dispensed by the pharmacy if:

(1) the drugs are dispensed only to a clinic patient with a valid prescription from a practitioner of that clinic;

(2) clinic prescriptions for clinic drugs are maintained separately from other prescriptions of the pharmacy;

(3) the prescription is dispensed in a container with a label attached which reads "DISPENSED FOR (clinic name and address) BY (pharmacy name and address)";

(4) all packaging and labeling requirements for prescriptions dispensed by a pharmacy have been met; and

(5) patient records and counseling requirements have been maintained separately for all clinic patients whose prescriptions were filled by the pharmacy from clinic drug stock.

R. Petition for Alternative Plan:

(1) A clinic may petition the board for an alternative visitation schedule, dispensing formulary, or drug transfer system (each an "alternative plan") as follows.

(a) Prior to implementation of any alternative plan, the clinic shall provide to the board a written petition that describes the proposed alternative plan and justifies the request. The petition shall include an affidavit that states that the clinic has a current policy and procedures manual on file, has adequate security to prevent diversion of dangerous drugs, and is in compliance with all rules applicable to the clinic. The affidavit shall be signed by the medical director, the consultant pharmacist, and the owner or chief executive officer of the clinic. In addition, a petition for an alternative drug transfer system must include a detailed, written description of the proposed alternative transfer system in the policy and procedures manual describing:

(i) drug ownership;
(ii) drug ordering;

(iii) drug shipping;
(iv) drug receiving;
(v) drug accountability system;
(vi) formulary for transfer; and
(vii) records of transfer.

(b) The board may approve or deny the petition for an alternative plan, at the board's discretion. The board may consider the following:

(i) degree of compliance by the clinic on past compliance inspections;
(ii) size and type of the patient population;
(iii) number and types of drugs contained in the clinic's formulary;
(iv) the clinic's objectives; and
(v) impact on the health and welfare of the clinic's patients.

(2) A copy of the board approved alternative plan shall be maintained at the clinic's license location for review by the board or its agent.

(3) The board may terminate the alternative plan if the board determines that the clinic's status or other circumstances justifying the alternative plan have changed.

S. Class D (SBEM) clinic:

(1) Only trained personnel may administer epinephrine. Trained personnel can be a school employee, agent or volunteer who has completed epinephrine administration training documented by the school nurse, school principal or school leader and approved by the New Mexico department of health and who has been designated by the school principal or school leader to administer epinephrine on a voluntary basis outside of the scope of employment. Epinephrine is administered on the standing order of a health care practitioner employed or authorized by the New Mexico department of health. If administering epinephrine, written policies and procedures must be maintained on the premises. These policies and procedures must follow New Mexico department of health requirements as well as any policy or procedure requirement listed in 16.19.10.11 NMAC. Documentation of New Mexico department of health required training must be maintained on-site for each trained and authorized person.

(2) Only a school nurse may administer albuterol to a student who is perceived to be in respiratory distress. Written policies and procedures must be maintained at the licensed location. Documentation of New Mexico department of health required training must be maintained on-site for each nurse.

(3) The following records must be kept on-site and available for inspection for three years:

(a) receipt records;
(b) destruction or other disposition records;
(c) storage records; storage records include daily (on school days) documented drug storage area temperature; documented verification that medication is sealed in its original packaging until the time of administration, and secured but unlocked in a secondary tamper-evident container; dangerous drugs are stored in a restricted area, unlocked, and readily accessible to trained personnel; policies and procedures must be in place to ensure proper drug storage conditions on non-school days;
(d) usage records; if a dangerous drug is used, a record must be kept; the consultant pharmacist must be notified within a 72-hour period in order to review the record; in addition, all New Mexico department of health guidelines must be followed;
(e) annual self-assessment form; this form will be supplied by the New Mexico board of pharmacy and shall be reviewed by the consultant pharmacist at least annually;
(f) consultant pharmacist record of activities and comments;
(g) a current copy of facility's New Mexico board of pharmacy registration and the consultant pharmacist's current license will be posted in the drug storage area;
(h) policy and procedure manual.

(4) Albuterol and epinephrine must be stored in a secure but unlocked, temper evident, container. This container must be in a restricted area but readily accessible to trained personnel. A list of the contents, including expiration dates, must be posted on the outside of the container.

T. NTP clinic:

(1) Administering, Dispensing, Distributing or Supplying:

(a) Drugs shall be administered, dispensed, distributed, or supplied only to clinic patients on the order of a licensed practitioner of the clinic. This provision does not prohibit guest dosing pursuant to policies and procedures and in compliance with federal law, or supplying an opioid antagonist for rescue use.

(b) The clinic practitioner shall record the prescribed drug therapy on the patient medical record indicating the name, strength, quantity and directions for use of the prescribed drug.

(c) The order may then be prepared by the practitioner, pharmacist, or technician under the supervision of the pharmacist and a dispensing label affixed to the dispensing unit of each drug. The pharmacist or practitioner must then provide a final check of the dispensing unit and sign or initial the prescription or dispensing record.

(d) Methadone for take-home purposes may be supplied to a clinic patient in a properly labeled dispensing unit by a registered nurse or licensed practical nurse employed by the NTP. Supplying of methadone in this manner (pouring and labeling the take home dose) is not considered dispensing.

(e) The following information shall appear on the label affixed to the take home medication unit:

(i) Name of patient;
(ii) Name of prescriber;
(iii) Date of dispensing;
(iv) Directions for use;
(v) Name, strength, and quantity of the drug;
(vi) Expiration date;
(vii) Name, address and phone number of the clinic;
(viii) Prescription number, if applicable; and
(ix) Additional required information, such as federal statement(s)

(2) Records and Reports:

(a) Each NTP clinic, including a mobile NTP, shall maintain records with the following information for each dangerous drug administered, dispensed, distributed or supplied indicating:

(i) Name of substance;
(ii) Strength of substance;
(iii) Dosage form;
(iv) Date dispensed;
(v) Adequate identification of the patient;
(vi) The name of the prescriber
(vii) Amount consumed;
(viii) Amount, units, and dosage form taken home by patient; and
(ix) Initials of personnel who administered, dispensed, distributed or supplied.

(b) These records will be maintained in an administration or dispensing, distributing or supplying log at the NTP site, or in the case of a mobile NTP, at the registered site of the NTP.

(c) As an alternative to maintaining a paper administration or dispensing, distributing of supplying log, an NTP or its mobile component may also use an automated/computerized data processing system for the storage and retrieval of the program's dispensing records, if the following conditions are met:

(i) The automated system maintains the information required in paragraph (a) above;

(ii) The automated system has the capability of producing a hard copy printout of the program's administration or dispensing, distributing or supplying records;

(iii) The NTP or its mobile component prints a hard copy of each day's administration or dispensing, distributing or supplying log, which is then initialed appropriately by each person who administered, dispensed, distributed or supplied medication to the program's patients;

(iv) The automated system is approved by DEA;

(v) The NTP or its mobile component maintains an off-site back-up of all computer generated program information; and

(vi) The automated system is capable of producing accurate summary reports for both the registered site of the NTP and any mobile component, for any time-frame selected by Board personnel during an investigation. If these summary reports are maintained in hard copy form, they must be kept in a systematically organized file located at the registered site of the NTP.

(d) The NTP must retain all records for the NTP as well as any mobile component for three years from the date of execution.

(3) Patient Counseling: Each NTP clinic shall develop and provide to the board policies and procedures addressing patient counseling which are at least equivalent to the requirements of Subsection F of 16.19.4.16 NMAC. When a medication is started, the patient should be provided with patient information to supplement patient counseling. Examples of patient information include, but not are limited to, written information

leaflets, pictogram labels and video programs. The clinic shall maintain a mechanism for the patient to be provided with medication information and counseling as requested.

(4) Policies and Procedures: In addition to requirements of 16.19.10.11(N) NMAC (Procedures Manual), NTPs must maintain procedures to:

(a) ensure appropriate training and qualifications of personnel for competent performance of assigned functions.

(b) ensure appropriate medication administration and supplying,

(c) ensure appropriate supervision consistent with state and federal law.

(d) support prevention of medication errors, including through adequate staffing, training, and supervision.

(5) Controls: Each NTP clinic must maintain effective controls and procedures to ensure maintance of required records in proper form and to identify theft or diversion of NTP clinic controlled substances.

(6) Responsibility: While the consultant pharmacist is responsible for overall clinic pharmacy services, a corresponding responsibility rests with the NTP clinic, the practitioner, and nurses for ensuring proper completion of medication related functions and record maintenance as applicable.

(7) Prescription Monitoring Program (PMP) Utilization: The consultant pharmacist shall request and review a PMP report covering at least a one year time period and another states' report for each program patient receiving an opioid, at least quarterly. The pharmacist will use professional judgement to determine whether more frequent monitoring is appropriate, as in the case of patients who are receiving a benzodiazepine or carisoprodol, or an opioid prescribed outside of the NTP. The pharmacist will use professional judgment in taking steps to avoid or resolve potential isues identified on PMP report review. The pharmacist shall document review of these PMP reports, and his or her action regarding such reports.

(8) Moblie NTP: An NTP may operate one or more mobile NTPs, subject to:

(a) For any NTP intending to operate a mobile NTP, the NTP must notify the Board, in writing, of its intent to do so, and the NTP must receive written approval from the board prior to operating the mobile NTP. The mobile NTP may only operate in New Mexico.

(b) An NTP clinic is not required to obtain a separate clinic license or registration for conveyances (mobile components) utilized by the NTP to transport controlled substances away from registered locations for administration or provision of take home doses at unregistered locations as part of a mobile NTP. Vehicles must possess valid county/city and State information (e.g., a vehicle information number (license plate number) on file at the registered location of the NTP.

(i) A mobile NTP is not permitted to reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location. NTPs with mobile components are not allowed to modify their registrations to authorize their mobile components to act as collectors under 21 CFR 1301.51 and 1317.40. Mobile components of NTPs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and will not transport patients.

(ii) A mobile NTP may operate at any remote location or locations within the state, including correctional facilities, so long as doing so is otherwise consistent with applicable Federal, State, tribal, and local laws and regulations, and so long as the local DEA office, does not otherwise direct.

(c) Physical security controls, mobile NTP; storage areas:

(i) For any conveyance operated as a mobile narcotic treatment program (NTP), a safe must be installed and used to store narcotic drugs in schedules II–V for the purpose of maintenance or detoxification treatment, when not located at the clinic's registered location. The safe must conform to the requirements set forth in 21 CFR 1301.72 (a)(1).

(ii) The mobile component must also be equipped with an alarm system that conforms to the requirements set forth 21 CFR 1301.70 (a)(1)(iii).

(iii) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the NTP shall provide for adequate observation of the area by an employee specifically authorized in writing. The storage area for controlled substances in a mobile component of an NTP must not be accessible from outside of the vehicle. Personnel transporting the controlled substances on behalf of the mobile NTP are required to retain control over all controlled substances when transferring them between the registered location and the conveyance, and when providing medication to patients at remote locations. At all other times during transportation, all controlled substances must be properly secured in the safe. Upon completion of the operation of the mobile NTP on a given day, the conveyance must be immediately returned to the registered location,

and all controlled substances must be removed from the conveyance and secured within the registered location. After the conveyance has returned to the registered location and the controlled substances have been removed, the conveyance may be parked until its next use at the registered location or any secure, fenced-in area, once the local DEA office has been notified of the location of this secure, fenced-in area. All NTPs with mobile components shall be required to establish a standard operating procedure to ensure, if the mobile component becomes inoperable (mechanical failure, accidents, fire, etc.), that all controlled substances on the inoperable conveyance are accounted for, removed from the inoperable conveyance, and secured at the registered location.

(iv) Upon completion of the operation of the mobile NTP on a given day, the conveyance must be immediately returned to the registered location, and all controlled substances must be removed from the conveyance and secured within the registered location. An NTP may apply for an exception to this requirement after receiving an exception from the DEA.

(d) Other security controls: Persons enrolled in any NTP, including those receiving treatment at a mobile NTP, will be required to wait in an area that is physically separated from the narcotic storage and preparation area by a physical entrance such as a door or other entryway. Patients must wait outside of a mobile NTP component if that conveyance does not have seating or a reception area that is separated from the narcotic storage and preparation area. This requirement will be enforced by the program practitioner and NTP employees.

(e) Any controlled substances being transported for disposal from the remote location of a mobile NTP shall be secured and disposed of in compliance with 21 CFR part 1317, and all other applicable Federal, State, tribal, and local laws and regulations.

(f) A conveyance used as part of a mobile NTP may only be supplied with narcotic drugs by the registered NTP that operates such conveyance.

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