# 16.19.6.27 REMOTE PHARMACY TECHNICIAN DATA ENTRY SITES:

## A. General requirements.

- (1) A New Mexico licensed pharmacy located in New Mexico may employ one or more certified pharmacy techs for the purpose of data input in remote practice sites provided that all security requirements are met.
- (2) All Pharmacy Technicians employed to work at a remote data entry practice site must be registered for at least 2 years as a certified pharmacy technician with the Board.
- (3) All remote pharmacy technician data entry sites will operate under a New Mexico licensed pharmacy located in New Mexico under the authority of its pharmacist-in-charge.
- (4) No drug inventory shall be kept at any remote pharmacy technician data entry site and no dispensing shall take place from a remote pharmacy technician data entry site.
- (5) The remote pharmacy technician will not be considered in the computation of the technician to pharmacist ration.
- (6) All remote pharmacy technician data entry sites will have a procedure for identifying the pharmacy technician and the pharmacist responsible for each aspect of the prescription preparations.
- (7) All remote pharmacy technician data entry sites will have quality monitoring and improvement programs in place

## B. Personnel.

- (1) The pharmacist-in-charge:
- (a) shall provide a written policy and procedure document outlining the operation and security of each remote pharmacy technician data entry sites location; the document shall be available at each practice site;
- (b) shall keep a continuously updated list of all remote pharmacy technician data entry sites to include address, phone number and hours of operation for each site; the record shall be retained as part of the records of the licensed pharmacy;
- (c) is responsible for ensuring that the New Mexico licensed pharmacy and each remote data entry pharmacy technician has entered into a written agreement outlining all conditions and policies governing the operation of the remote site;
- (d) shall ensure that all computer equipment used at the remote site is in good working order, provides data protection and complies with all security and HIPAA requirements.
  - (2) data entry pharmacy technician:
    - (a) shall be a certified pharmacy technician registered with the board;
- (b) Shall have a minimum of 2 years' experience performing data entry functions as a certified pharmacy tech.
- (c) shall be trained in the use of all equipment necessary for secure operation of the remote site.

## C. Operations.

- (1) If the remote pharmacy technician data entry sites is located within a home there must be a designated area in which all of the pharmacy technicians work will be performed.
- (2) All computer equipment used at the remote pharmacy technician data entry sites must be able to establish a secure connection which the site is operating. Remote equipment must be configured so that patient information is not stored at the remote site electronically or in printed form.
- (3) Computer equipment may only be used for remote pharmacy technician data entry. No other use of equipment will be allowed.
- (4) Computer equipment must be locked or shut down whenever the pharmacy technician is absent.
- (5) All remote pharmacy technician data entry sites are subject to unannounced inspection by representatives of the New Mexico board of pharmacy during established hours of operation.

# D. Security.

- (1) Remote pharmacist pharmacy technician data entry sites shall have adequate security to maintain patient confidentiality.
- (2) Must utilize equipment that prevents unauthorized storage or transfer of patient information.
- (3) If the remote site is in a home, the equipment must be located in a designated area where patient information cannot be viewed by anyone other than the remote pharmacy technician.

# **REQUEST:**

Mr. McAlister is inquiring as to how pharmacy technicians can operate from remote locations (from home) in accordance with our statutes and regulations. We have been asked to review the statutes and the rules and make rule changes that would allow remote technicians.

### **AGENDA**

- 1. Statutory Authority: hinges around interpretation of definition of supervision
- 2. In this scenario is the pharmacist observing and directing the pharmacy technician as required in the statute?
- 3. Remote-telepharmacy rule required video surveillance to satisfy the supervision requirement. Is that necessary here? Or required by statute?
- 5. Security requirements?
- 6. What language changes need to be considered?
- 7. How does this improve the BOP mission to protect the safety and welfare of the public?

# 1.) SUPERVISION

# **STATUTES:**

61-11-11.1. Pharmacy technician; qualifications; duties.

- C. The supervising pharmacist shall observe and direct the pharmacy technician to a sufficient degree to assure the accurate completion of the activities of the pharmacy technician and shall provide a final check of all aspects of the prepared product and document the final check before dispensing.
- D. The supervising pharmacist shall be responsible for the tasks performed by the pharmacist technician and subject to discipline for failure to appropriately supervise the performance of the pharmacist technician.

#### REGULATIONS

### **16.19.22.7 DEFINITIONS:**

- **A.** "Direct supervision" means that the pharmacist onsite shall observe and direct to a degree sufficient to assure the accurate completion of the activities of the pharmacy technicians and must provide a final check of all aspects of the prepared product and document the final check before dispensing.
- **B.** "Indirect supervision" means that the pharmacist offsite shall observe via live surveillance cameras and direct pharmacy activity remotely via remote tele-pharmacy communication technology to a degree sufficient to assure the accurate completion of the activities of the pharmacy technicians and must provide a final check of all aspects of the prepared product and document the final check before dispensing.
- C. "Pharmacy technician" means a person who, under the supervision of a licensed pharmacist, performs repetitive tasks not requiring the professional judgment of a pharmacist. This includes assisting in various technical activities associated with the preparation and distribution of medications.

  16.19.33.7 DEFINITIONS:
- **K.** "Remote tele-pharmacy technician" means a New Mexico registered pharmacy technician employed by the hub pharmacy, with a minimum of two-thousand hours of experience working as a certified registered pharmacy technician who under the computer aided supervision of an off-site pharmacist, handles the day to day operation of a remote tele-pharmacy, including the preparation and dispensing of prescription drugs.

# 2.) SECURITY

# **16.19.6.26 REMOTE PHARMACIST DUR SITES:**

## A. General requirements.

- (1) A New Mexico licensed pharmacy may employ one or more pharmacists for the purpose of conducting drug utilization reviews in remote practice sites provided that all security requirements are met.
- (2) All pharmacists employed to work at a remote DUR practice site must be New Mexico licensed pharmacists.
- (3) All remote pharmacist DUR sites will operate under a New Mexico licensed pharmacy and under the authority of its pharmacist-in-charge.
- (4) No drug inventory shall be kept at any remote pharmacist DUR site and no dispensing shall take place from a remote DUR site.
- (5) The remote pharmacists will not be considered in the computation of the technician to pharmacist ration.
- (6) Procedure identifying the pharmacist responsible for each aspect of the prescription preparations.

#### B. Personnel.

- (1) The pharmacist-in-charge:
- (a) shall provide a written policy and procedure document outlining the operation and security of each remote pharmacist DUR location; the document shall be available at each practice site;
- (b) shall keep a continuously updated list of all remote DUR sites to include address, phone number and hours of operation for each site; the record shall be retained as part of the records of the licensed pharmacy;
- (c) is responsible for ensuring that the New Mexico licensed pharmacy and each remote pharmacist has entered into a written agreement outlining all conditions and policies governing the operation of the remote site;
- (d) shall ensure that all computer equipment used at the remote site is in good working order and complies with all security requirements.
  - (2) Remote pharmacist:
    - (a) shall be a New Mexico licensed pharmacist;
    - (b) shall be trained in the use of all equipment necessary for secure operation of the

remote site.

# C. Operations.

- (1) If the remote DUR site is located within a home there must be a designated area in which all of the pharmacist's work will be performed.
- (2) All computer equipment used at the remote DUR sites must be able to establish a secure connection which the site is operating. Remote equipment must be configured so that patient information is not stored at the remote site electronically or in printed form.
- (3) Computer equipment may only be used for remote DUR. No other use of equipment will be allowed.
  - (4) Computer equipment must be locked or shut down whenever the pharmacist is absent.
- (5) All remote DUR sites are subject to unannounced inspection by representatives of the New Mexico board of pharmacy during established hours of operation.

## D. Security.

- (1) Remote pharmacist DUR sites shall have adequate security to maintain patient confidentiality.
- (2) Must utilize equipment that prevents unauthorized storage or transfer of patient information.
- (3) If the remote site is in a home, the equipment must be located in a designated area where patient information can not be viewed by anyone other that the remote pharmacist

# ARIZONA LANGUAGE:

- 1. The tech will work for and be a responsibility of a pharmacy licensed in Arizona.
- 2. The PIC of that pharmacy retains full authority and responsibility for that tech.
- 3. Data protection and HIPAA compliance is maintained.
- 4. There is quality monitoring and improvement programs in place.

## Here is the rule from R4-423-621:

**F.** Nothing in this Section shall prohibit an individual pharmacist licensed in Arizona, who is an employee of or under contract with a pharmacy, or an Arizona-licensed graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:

1. The pharmacy establishes controls to protect the confidentiality and integrity of patient information; and

2. None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

#### Statutes:

- 61-11-11.1. Pharmacy technician; qualifications; duties. (Repealed effective July 1, 2016.)
- A. The classification of pharmacy technician is established. An applicant for registration as a pharmacy technician shall:
- (1) be at least eighteen years of age and not addicted to drugs or alcohol;
- (2) complete initial training as required by regulations of the board that includes on-the-job and related education commensurate with the tasks to be performed by the pharmacy technician; and
- (3) if the potential duties of the pharmacy technician will include the preparation of sterile products, complete an additional one hundred hours of experiential training as required by regulations of the board.
- B. Permissible activities for pharmacy technicians under the supervision of a pharmacist include:
- (1) the preparation, mixing, assembling, packaging and labeling of medications;
- (2) processing routine orders of stock supplies;
- (3) preparation of sterile products;
- (4) filling of a prescription or medication order that entails counting, pouring, labeling or reconstituting medications; and
- (5) tasks assigned by the supervising pharmacist that do not require his professional judgment.
- C. The supervising pharmacist shall observe and direct the pharmacy technician to a sufficient degree to assure the accurate completion of the activities of the pharmacy technician and shall provide a final check of all aspects of the prepared product and document the final check before dispensing.
- D. The supervising pharmacist shall be responsible for the tasks performed by the pharmacist technician and subject to discipline for failure to appropriately supervise the performance of the pharmacist technician.

**RULE:** 

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING

CHAPTER 19 PHARMACISTS

PART 22 SUPPORT PERSONNEL AND PHARMACY TECHNICIANS

**16.19.22.1 ISSUING AGENCY:** Regulation and Licensing Department-Board of Pharmacy, (505) 222-9835.

[16.19.22.1 NMAC - Rp, 16 NMAC 19.22.1, 06-27-01; A, 11-15-10]

**16.19.22.2 SCOPE:** All Pharmacy technicians and non-technicians supportive personnel, supervising pharmacists and pharmacists in charge of entities that utilize supportive personnel. [16.19.22.2 NMAC - Rp, 16. NMAC 19.22.2, 06-27-01]

**16.19.22.3 STATUTORY AUTHORITY:** Section 61-11-6-(A) NMSA 1978 authorizes the Board of pharmacy to register and regulate qualifications, training and permissible activities of pharmacy technicians. [16.19.22.3 NMAC - Rp, 16 NMAC 19.22.3, 06-27-01]

**16.19.22.4 DURATION:** Permanent.

[16.19.22.4 NMAC - Rp, 16 NMAC 19.22.4, 06-27-01]

- **16.19.22.5 EFFECTIVE DATE:** June 27, 2001, unless a later date is cited at the end of a section. [16.19.22.5 NMAC Rp, 16 NMAC 19.22.5, 06-27-01]
- **16.19.22.6 OBJECTIVE:** The objective of Part 22 of Chapter 19 is to promote responsive delivery of pharmaceutical products and services to the public by establishing standards for training and supervision of support personnel and limitations on their use.

[16.19.22.6 NMAC - Rp, 16 NMAC 19.22.6, 06-27-01]

### **16.19.22.7 DEFINITIONS:**

- **A.** "Direct supervision" means that the pharmacist onsite shall observe and direct to a degree sufficient to assure the accurate completion of the activities of the pharmacy technicians and must provide a final check of all aspects of the prepared product and document the final check before dispensing.
- **B.** "Indirect supervision" means that the pharmacist offsite shall observe via live surveillance cameras and direct pharmacy activity remotely via remote tele-pharmacy communication technology to a degree sufficient to assure the accurate completion of the activities of the pharmacy technicians and must provide a final check of all aspects of the prepared product and document the final check before dispensing.
- **C. "Pharmacy technician"** means a person who, under the supervision of a licensed pharmacist, performs repetitive tasks not requiring the professional judgment of a pharmacist. This includes assisting in various technical activities associated with the preparation and distribution of medications.
- (1) "Certified pharmacy technician" means a pharmacy technician who has completed the training and certification outlined in 16.19.22.9 NMAC, completed a board approved certification exam, is registered by the board of pharmacy and maintains current board approved certification.
- (2) "Non-certified pharmacy technician" means a pharmacy technician who is in the process of completing the training and education outlined in 16.19.22.9 NMAC and is registered by the board of pharmacy.
- (3) "Remote pharmacy technician" means a certified pharmacy technician who meets the special requirements for indirect supervision at a remote dispensing site as specified in the board of pharmacy telepharmacy regulations.
- **D.** "Prescription drug" means and human drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act.
- **E.** "Professional judgment" means a cognitive process, by a licensed professional, that takes education, experience, current primary literature and current standards of practice into consideration when drawing conclusions and reaching decisions.
- **F.** "Stocking" means placing prescription drugs on pharmacy shelf, in bin or dispensing technology system.
- **G.** "Supervision" means that the pharmacist shall observe and direct to a sufficient degree to assure the accurate completion of the activities of the pharmacy technicians and must provide a final check of all aspects of the prepared product and document the final check before dispensing.
- **H.** "Support personnel" means pharmacy personnel other than pharmacy technicians, which may include clerks, secretary's and delivery personnel, who under the supervision of a pharmacist, may perform duties associated with the practice of pharmacy, excluding the direct processing and filling of prescriptions, stocking prescription drugs, in sites that do not utilize a barcode verification, electronic verification or similar verification process to ensure correct selection of medication or duties restricted to only a pharmacist, pharmacist intern, or pharmacy technician.
- **I.** "**Technician training sponsor**" means pharmacist-in-charge, pharmacist or designated administrator at a pharmacy technician training program who assumes responsibility for training and duties performed by a non-certified technician.

[16.19.22.7 NMAC - Rp, 16 NMAC 19.22.7, 06-27-01; A, 11-15-10; A, 11-27-11; A, 06-29-13]

**16.19.22.8 PERMISSIBLE ACTIVITIES:** Pharmacy technician activities under the direct supervision of a pharmacist shall be limited to tasks enumerated in policies and procedures implemented by the pharmacist-in-charge that do not require professional judgment.

[16.19.22.8 NMAC - Rp, 16 NMAC 19.22.8, 06-27-01; A, 11-15-10]

## 16.19.22.9 TRAINING AND EDUCATION:

- **A.** The pharmacist-in-charge shall ensure that the pharmacy technician has completed initial training which includes:
- (1) federal and state laws and regulations that affect pharmacy practice; specific regulations which address the use of supportive personnel and technicians;
  - (2) ethical and professional standards of practice;
- (3) medical and pharmaceutical terminology, symbols and abbreviations used in the practice of pharmacy and components of a prescription;
  - (4) pharmaceutical calculations necessary for the preparation and dispensing of drug products;
  - (5) manufacturing, preparation, packaging, labeling and proper storage of drug products;
  - (6) dosage forms and routes of administration; and
  - (7) trade and generic names for medications frequently dispensed by the pharmacy;
  - (8) basic comprehension of pharmacology;
  - (9) basic knowledge of appropriate pharmacy references.
- **B.** If the duties of the technician will include the preparation of sterile products then, in addition to the training and education requirements listed in this section, the technician will complete training outlined in Paragraph (2) of Subsection C of 16.19.6.11 NMAC.
- **C.** A written record of training and education will be maintained by the pharmacy technician and contain the following:
  - (1) name of person receiving the training;
  - (2) date(s) of the training;
  - (3) description of the topics covered;
  - (4) names of the person(s) who provided the training; and
  - (5) signature of the technician and the technician training sponsor.
- **D.** A written record of training and education must be submitted to the board with certification exam documentation to obtain certified pharmacy technician registration.
- **E.** All technicians are required to obtain board approved certification within one year of registration with the board as a technician. Extensions will no longer be granted to pharmacy technicians registered on or after November 15, 2010.
- **F.** The pharmacist-in-charge shall be responsible for the implementation of policies and procedures for additional training appropriate to duties and responsibilities performed by a pharmacy technician as well as an ongoing quality assurance plan to assure competency.

[16.19.22.9 NMAC - Rp, 16 NMAC 19.22.9, 06-27-01; A, 11-15-10; A, 11-27-11]

# 16.19.22.10 RATIO OF TECHNICIANS TO PHARMACISTS:

- **A.** The permissible ratio of pharmacy technicians to pharmacists on duty is to be determined by the pharmacist in charge.
- **B.** The board reserves the right to impose a ratio of pharmacy technicians to pharmacists if circumstances so dictate.

[16.19.22.10 NMAC - Rp, 16 NMAC 19.22.10, 06-27-01; A, 06-29-13]

# 16.19.22.11 IMPROPER ACTIVITIES OF PHARMACY TECHNICIANS:

- **A.** The supervising pharmacist and the pharmacist-in-charge are responsible for the actions of pharmacy technicians. Performance of tasks by the pharmacy technician and support personnel outside the limits of the regulations that are authorized by the supervising pharmacist shall constitute unprofessional conduct on the part of the pharmacist and the pharmacist-in-charge.
- (1) The following responsibilities require the use of professional judgment and therefore shall be performed only by a pharmacist or pharmacist intern:
  - (a) receipt of all new verbal prescription orders and reduction to writing;
- (b) evaluation and interpretation of the prescription order and any necessary clinical clarification prior to dispensing;
- (c) clinical consultation with a patient or his agent regarding a prescription or over-the-counter drug;
  - (d) evaluation of available clinical data in patient medication record system;
- (e) oral communication with the patient or patient's agent of information, as defined in the section under patient counseling, in order to improve therapy by ensuring proper use of drugs and devices;

- (f) professional consultation with the prescriber, the prescriber's agent, or any other health care professional or authorized agent regarding a patient and any medical information pertaining to the prescription.
  - (2) ONLY A PHARMACIST SHALL PERFORM THE FOLLOWING DUTIES:
- (a) final check on all aspects of the completed prescription including sterile products and cytotoxic preparations, and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container;
  - (b) evaluation of pharmaceuticals for formulary selection within the facility;
- (c) supervision of all pharmacy technicians and support personnel activities including preparations, mixing, assembling, packaging, labeling and storage of medication;
- (d) ensure the pharmacy technicians and support personnel have been properly trained for the duties they may perform;
- (e) any verbal communication with a patient or patient's representative regarding a change in drug therapy or performing therapeutic interchanges (i.e. drugs with similar effects in specific therapeutic categories); this does not apply to substitution of generic equivalents;
  - (f) any other duty required of a pharmacist by any federal or state law.
- **B.** In accordance with section 61-11-20 NMSA 1978 a pharmacy technicians registration may be revoked, denied, or suspended for grounds stated in section 61-11-20(A). [16.19.22.11 NMAC Rp, 16 NMAC 19.22.11, 06-27-01; A, 11-15-10]
- **16.19.22.12 IDENTIFICATION OF PHARMACY PERSONNEL:** All personnel in pharmacy restricted area shall wear an identification badge which must include name and job title. [16.19.22.12 NMAC Rp, 16 NMAC 19.22.12, 06-27-01]

### 16.19.22.13 (RESERVED)

[16.19.22.13 NMAC - Rp, 16 NMAC 19.22.13, 06-27-01]

### 16.19.22.14 REGISTRATION OF PHARMACY TECHNICIANS:

- **A.** Application (and required registration fee) shall be submitted to the board prior to performing any technician duties. Non-certified pharmacy technicians must:
- (1) Complete requirements for certified pharmacy technician within (1) one year of original application.
- (2) Not re-apply with the board of pharmacy as a non-certified pharmacy technician unless enrolled in a board recognized technician training program.
- (3) Provide the name of the technician training sponsor responsible for training and education with application.
- (4) Provide documentation of training and completion of certification exam to be registered as a certified pharmacy technician.
- **B.** Registration for certified pharmacy technicians will expire biennially on the last day of their birth month and must be renewed prior to expiration. Registration renewal applications must include documentation of current national certification.

[16.19.22.14 NMAC - Rp, 16 NMAC 19.22.14, 06-27-01; A, 11-15-10; A, 06-29-13]

**16.19.22.15 CHANGE OF ADDRESS:** Pharmacy technicians shall report in writing or through the online process available on the board's website of any change of address or employment to the board within ten (10) days. [16.19.22.15 NMAC - Rp, 16 NMAC 19.22.15, 06-27-01; A, 11-15-10]

## **HISTORY of 16.19.22 NMAC:**

## **Pre-NMAC History:**

Regulation 22, Supportive Personnel, filed 01/29/93.

## **History of Repealed Material:**

16 NMAC 19.22, Supportive Personnel, filed 02/02/96.