

**TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY****CHAPTER 1. ADMINISTRATIVE OPERATIONS****SUBCHAPTER 7. INDIVIDUAL PROCEEDINGS****535:1-7-3. Hearings**

(a) **Notice time; continuances.** The time set for a hearing, specified in the notice, shall not be less than ten (10) days after the date of the notice. Written motions for any continuances or extensions of time shall state the time desired and the reasons for the request, and shall be filed with the Board at least five (5) business days before the hearing, and may be denied by the Director of the Board if not filed at least (five) 5 business days before the hearing. The Board hereby authorizes the Director of the Board to rule on said motions. Said application shall be served upon the Director of the Board and be acted upon promptly by the Director; if the motion for continuance or extension is denied; the party may renew the request and make a proper showing for continuance at the hearing.

(b) **Imminent Danger Suspension.** If the Director finds there is imminent danger to the public health or safety, he or she may immediately suspend any registration simultaneously with the scheduling of a Board hearing.

(1) **Method.** The registrant shall be notified of such suspension through an imminent danger letter signed by the Director.

(2) **Notice.** Notice shall be given in the manner described in 535:1-7-2.

(c) **Order of procedure.** The hearing shall be conducted in an orderly manner by the President of the Board, or his designee. The order of procedure will follow that which applies in civil proceedings of Law. However, the rules of evidence shall be those specified by the Oklahoma Administrative Procedures Act.

(d) **Admissibility.** The President of the Board, or his designee, shall rule upon the admissibility of evidence and objections thereto, and shall rule upon other motions or objections arising in the course of the hearing.

**535:1-7-6. Hearing records and record maintenance**

(a) **Recordings.** A record by means of tape recording or shorthand notes will be made of all hearings conducted by the Board of Pharmacy unless the presiding officer designates otherwise.

(1) Oral proceedings during Board hearings shall be electronically recorded.

(A) The record of the hearing and the file containing the pleading will be maintained in the Board Office.

(B) Such record and recordings shall be maintained for such time as to protect the record through judicial review. ~~The tape recordings of the proceedings shall be maintained for a period of one year or for such time as necessary to protect the record through judicial review whichever is more.~~

(2) Copies of the recordings of the proceedings shall be provided by the agency at the request of any party to the proceedings.

(b) **Transcription costs.** The costs of transcription of the recordings shall be borne by the party requesting the transcription. A transcript of the proceedings shall not be made except upon written application and a deposit sufficient in the amount to pay for having the record transcribed.

(c) **Judicial review.** Electronic recordings of an individual proceeding, as certified by the agency, may be submitted to the reviewing court by the agency as part of the record of the proceedings under review. In such case where the reviewing court requires transcription the expense of transcriptions shall be paid by the non-prevailing party.

(d) **Court reporter.** Parties to any Board hearing may have the proceedings transcribed by a court reporter at their own expense.

**535:1-7-7. Final orders**

All final orders in individual proceedings shall be in writing. The final order shall include findings ~~or~~ of fact and conclusions of law, separately stated. A copy of the final order will be mailed forthwith to each party.

**535:1-7-8. Appeal**

A petition for rehearing is not required before an appeal may be perfected. A petition for rehearing, reopening or reconsideration of a final order may be filed with the ~~Director of Board~~ within ten (10) days from the entry of the order. It must be signed by the party or his attorney or representative and must set forth with particularity the statutory grounds upon which it is based. ~~However, a petition for rehearing based upon fraud by any party or procurement of the order by perjured testimony or fictitious evidence may be filed at any time.~~

**SUBCHAPTER 11. FEES****535:1-11-1. Annual licenses, permits and renewals**

Annual license, permit and renewal fees, as set by the Board, shall be as follows:

(1) Pharmacist renewal (active or inactive) - \$ 75

(2) Senior inactive pharmacist renewal (age 65 or over, retired) - \$20

- (3) Pharmacy license
  - (A) (retail, hospital, and non-resident) - \$150
  - (B) Charitable clinic - \$ 75
  - (C) Hospital drug room - \$ 40
  - (D) Long term care pharmacy remote site - \$50
- (4) Parenteral permit - \$ 75
- (5) Drug supplier permit - \$ 20
- (6) Wholesaler permit - \$200
- (7) Packager permit - \$200
- (8) Manufacturer permit - \$200
- (9) Medical gas supplier permit- \$100
- (10) Medical gas distributor permit - \$200
- (11) Pharmacy technician permit - \$40
- (12) Duplicate renewal receipt, permit, or practical experience certificate:
  - (A) Duplicate for lost, destroyed or damaged original - \$10
  - (B) Duplicate or multiple location copy - \$10

### **535:1-11-3. Practical experience licenses and certificates**

Practical experience license and certificate fees, as set by the Board, shall be as follows:

- (1) Intern certificate - ~~\$ 50~~ \$100
- (2) Training area certificate - \$25
- (3) Training area ~~triennial~~-renewal - \$10
- (4) Preceptor certificate - \$25
- (5) Preceptor ~~triennial~~-renewal - \$10

### **535:1-11-4. Other fees ~~Public access, open records~~**

(a) ~~Public access, open record~~ For all records required to be open by the Oklahoma Open Records Act, fees shall be charged for copying as specified in the open records act. ~~Such public records fees, as set by the Board,~~

(b) Other fees shall be as follows:

- (1) Registrant computer address disk or e-mailed file:
    - (A) Facility (wholesaler, packager, manufacturer) - \$50
    - (B) Pharmacy - \$75
    - (C) Technician - \$100
    - (D) Intern - \$100
    - (E) Pharmacist - \$100
  - (2) Photostat copies, per page - \$.25
  - (3) Facsimile (Fax) fee, per page - \$1
  - (4) Annual subscriptions (7/01 – 6/30 each year)
    - (A) Notification of rulemaking intent - \$18
    - (B) OSBP/NABP Quarterly Voluntary Compliance Newsletter for other than Oklahoma registered Pharmacists - \$25
    - (C) Board meeting agenda notice - \$18
  - (5) Research time, when available (per hour)
    - (A) Staff research time - \$20
    - (B) Computer research time - \$100
  - (6) Reproduction of Board meeting recordings, if available;
    - (A) Audio tape copy (per tape), \$15
    - (B) Video tape copy (per tape), \$15
  - (7) Certification of public record, not certification of grades, \$1.00 per page.
  - (8) Certified letters of good standing or licensure verification, \$10
- ~~(b)~~ (c) Open records, available and obtained from our website [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov) - no charge.

### **535:1-11-5. Miscellaneous**

Miscellaneous fees, as set by the Board, shall be as follows:

- (1) Oklahoma State Board of Pharmacy lawbook - \$10
- (2) Duplicate certificate of registration - \$30
- (3) Certification of grades - \$10 - (exempt if ELTP)
- (4) Special inspection fee (each) Not to exceed - ~~\$100~~ \$200
- (5) Pharmacist Reinstatement: Back fees + CE + 15 hours CE penalty + \$100
- (6) Fines (not to exceed on each count) - ~~\$1,000~~ \$3,000
- (7) Duplicate for lost/destroyed license, renewal receipt, permit, or practical experience certificate - \$10.

- (8) Late fee for renewal of registration, licenses and/or permits if not received by the Board office within 15 days after expiration date - \$ fee x 2
- (9) Insufficient check charge - \$25
- (10) Reinstatement of permits or licenses other than pharmacists - \$ fee x 2

**TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY****CHAPTER 10. PHARMACISTS; AND INTERNS, PRECEPTORS AND TRAINING AREAS****SUBCHAPTER 3. PHARMACISTS****535:10-3-1.2. Violations of professional conduct**

Violations of the rules of professional conduct, which may also be called unprofessional conduct, include, but are not limited to, the following:

- (1) The act of violating directly, indirectly, through actions of another, assisting in or abetting the violation of, or conspiring to violate, any provision or term of the Oklahoma State Board of Pharmacy, Title 59, 353 et seq., the Prescription Drug Marketing Act (21 U.S.C., Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C., Sec. 13 et seq.), or federal, state and local laws and rules governing pharmacists or pharmacies.
- (2) Failure to establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.
- (3) Making or filing a report or record which a pharmacist or pharmacy knows or should have known to be false, intentionally or negligently failing to file a report or record required by federal, state or local laws or rules, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the pharmacist or pharmacy is required to make or file in his capacity as a licensed pharmacist or pharmacy.
- (4) Practicing pharmacy without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition.
- (5) Knowingly dispensing a prescription drug after the death of a patient.
- (6) Knowingly billing or charging for quantities greater than delivered, or for a brand when a generic or a compounded product is dispensed.
- (7) Submitting fraudulent billing or reports to a third party payor of prescription drugs.
- (8) Refusing to answer reasonable questions or provide information about prescriptions dispensed by the pharmacy when requested by, or for, the patient and which would aid the patient's health in the professional judgement of the pharmacist.
- (9) Not attempting to resolve a possible prescription error; or situation of potential harm to the patient when apparent or should have been apparent to the pharmacist.
- (10) Not attempting to address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that the patient may be dependent or addicted.
- (11) The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.
- (12) The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.
- (13) Discriminating in any manner between patients or groups of patients for reasons of a particular disease, religion, race, creed, color, sex, age or national origin.
- (14) Violating patient confidentiality. This does not prevent pharmacies from providing drug therapy information to physicians for their patients, nor does it prevent the provision of information as required by law.
- (15) Theft of merchandise (including, but not limited to, legend drugs) while practicing pharmacy.
- (16) Knowingly dispensing prescription drug refills after the death of a physician. (A limited quantity may be allowed for the patient's health and safety.)
- (17) Failure to establish and maintain effective controls to prevent prescription errors or mis-fills.
- (18) The misfilling of a prescription that departs from the standards of care ordinarily exercised by a pharmacist with proof of actual injury not having to be established.
- (19) Providing fictitious information, fraud or misrepresentation in applying for or procuring a pharmacist license, preceptor certificate or other permit, or in connection with applying for or procuring periodic re-registration or renewal of the same.
- (20) Attempting to cheat or subverting the pharmacist licensure examination, ~~Oklahoma~~ law examination, ~~Oklahoma~~ preceptor examination or any other examination required by the Board.
- (21) Allowing a non-pharmacist to perform any of the duties reserved to a pharmacist.
- (22) Use or abuse of an illegal CDS substance or a positive drug screen for such illegal CDS substance or its' metabolite.
- (23) Violation of any voluntary or Board ordered rehabilitation program for the impaired contract, e.g. OPHP contract.
- (24) Failure of pharmacist or pharmacy manager (pharmacist in charge) to fulfill the responsibilities as set out in 535:15.
- (25) Dispensing outdated prescription drugs.
- (26) Failure to cooperate in Board investigations.

(27) Failure by the pharmacist to adequately supervise a pharmacy technician or a pharmacy intern; working or scheduling an intern when there is no supervising pharmacist preceptor present or working or scheduling a technician when there is no pharmacist supervising.

## SUBCHAPTER 5. INTERNS, PRECEPTORS AND TRAINING AREAS

### 535:10-5-3. Intern requirements; licenses

(a) A registered intern shall be defined as a student having completed fifty (50) college hours of credit, with an overall average of not less than "C", currently enrolled and attending classes and in good standing in an accredited college of pharmacy in a PharmD in Pharmacy program, or

(b) a graduate of an accredited college of pharmacy not otherwise eligible for registration as an intern or pharmacist, except as provided in 535:10-7-8.

(1) The Board of Pharmacy shall be notified by the Pharmacy Colleges in Oklahoma

(A) when a student is not continuously enrolled in a college of pharmacy in an accredited Pharmacy program; or,

(B) when a pharmacy student is not in good standing – or when a pharmacy student's ~~for~~ overall grade point average is less than "C";

(C) Then an intern license or registration is automatically void and the intern shall return such license to the Board.

(2) Such intern may apply for a new intern license when the Board is notified by the college of pharmacy that the applicant is in good standing in a PharmD ~~in~~ Pharmacy program and actively attending classes provided the provisions of these regulations have not been violated by the intern.

(3) An intern shall notify the Board when requesting the transfer of intern hours to another state of any intent not to return to Oklahoma; or, within ten (10) days of becoming licensed as a pharmacist in another state.

(4) An intern certificate becomes void five (5) years after date of issuance or at such other date as set by the Board.

### 535:10-5-4. Intern practice requirements

(a) **Supervision requirement.** An intern may practice in an approved training area only under the immediate visual supervision of a preceptor, except as described in 535:10-5-4-(a) (3). See also 535:10-5-2.

(1) A preceptor may supervise only one intern at a time.

(2) A ratio of one (1) faculty preceptor with up to two (2) interns will be allowed in a pro-practice rotation.

(3) Non-dispensing pro-practice rotations are to be supervised by a preceptor, but immediate visual supervision is not required.

(4) An intern may not be on duty in any capacity without a licensed pharmacist preceptor on site and supervising the intern.

(b) **Professional Conduct.** Interns will be held accountable to the rules and violations of professional conduct. The professional conduct rules for interns will be the same as required by 535:10-3-1.1 and 535:10-3-1.2 for pharmacists.

(c) **Employment notification.** All licensed pharmacy interns shall notify the Board of Pharmacy, in writing, of the place of their non-college practice within ten (10) days of going to work and/or termination of this practice location. The pro-practice employment location notification will be the responsibility of the college of pharmacy.

### 535:10-5-8. Preceptor requirements

A person who has been licensed as a registered pharmacist and engaged in the practice of pharmacy for a period of not less than one (1) year and is currently licensed as an Oklahoma pharmacist is eligible to apply for preceptor exam and certificate, as allowed under this section. The preceptor fee for original examination and certification shall be set by the Board.

(1) Any pharmacist desiring approval as a preceptor must make application to the Board on a form supplied by the Board. The Board will consider the requirements and qualifications listed in this section and in 535:25-3 at a minimum. Preceptors will be issued identifying certificates by the Board, which must be conspicuously posted in the training area where they practice.

(A) All preceptors shall successfully complete an examination, prepared by the Board, relating to this Subchapter and pharmacy law and rules. Said examination shall be made a part of the application for certification as a preceptor.

(B) After December 31, 2011 All-all preceptors will have to renew their certification by examination every three years at each renewal date of their doctor of pharmacy license for a fee set by the Board.

~~(C) Preceptor renewal of certification will be effective January 1, 2000 and expire December 31, 2002, 2005 and every three years on a calendar year basis.~~

(2) Preceptors must show themselves to be interested in pharmacy as a profession, and at the same time instruct the intern in all operations of their training area.

(3) Preceptors will supervise only one intern at a time, except as allowed under 535:10-5-4(a).

(4) Preceptor evaluation report(s) shall be submitted by the preceptor at least by the end of each two hundred and forty (240) hours or upon termination of the intern as required under 535:10-5-5(b).

(5) No pharmacist shall be approved or continue as a preceptor, who is under probation or suspension by the Board, or who has been convicted of a felony which was drug related. After practicing two (2) years on probation the pharmacist may request permission from the Board to apply for a new preceptor certificate. A pharmacist will have to apply for a new preceptor certificate after completion of probation and/or suspension by the Board.

#### **535:10-5-9. Training area requirements**

(a) **Pharmacies.** Any pharmacy desiring approval for the training of interns shall make application to the Board of Pharmacy on a form supplied by the Board. The Board will consider the requirements and qualifications listed in 535:25-3 at a minimum. A pharmacy approved as a training area shall conspicuously display its training area certificate in the pharmacy, and be subject to the following provisions:

(1) Such pharmacy shall be subject to inspection by the Board.

(2) Such pharmacy shall agree to furnish the necessary preceptor(s) under whose supervision the intern will be allowed to perform the duties outlined in this Subchapter. The number of interns practicing in a training area is limited to the number of preceptors present and on duty in a training area.

(3) No pharmacy under probation or suspension by the Board shall be approved as a training area. A pharmacy will not be able to continue as a training area under the above conditions. A pharmacy must apply for a new training area certificate and be approved by the Board after completion of probation and/or suspension.

(4) All training areas shall submit reports as required by the Board.

(5) The Board shall set the training area original certification fee.

(6) All training areas shall renew their certification for a fee set by the Board.

(7) ~~Training area renewal certification will be effective January 1, 2000 and expire December 31, 2002, 2005 and every three years thereafter. After December 31, 2011, all training areas will renew their certification when the pharmacy license is renewed.~~

(b) **Unique or specific training areas.** Any Oklahoma college of pharmacy may apply to the Board for approval of a specific or unique training area. This training area shall be subject to Subsection (a) (1), (2), (4) and (5) of this Section.

(c) **Changes.** Changes of pharmacy location, name or ownership shall require a new training area certificate.

### **SUBCHAPTER 7. PHARMACIST LICENSURE**

#### **535:10-7-4. General requirements for pharmacist licensure applicants**

(a) All applicants for Oklahoma pharmacist licensure shall meet the statutory requirements in O.S. 59, Section 353.9, the rules of this Title and subchapter, and the requirements regarding applicants in 535:25.

(b) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with public health and safety.

(c) The Board must approve all applicants for Oklahoma pharmacist licensure as required in Title 59 O.S. 353.9.

(d) All applicants may be required to appear before the Board for interview. If interview is required, the applicant must communicate with the Board in a satisfactory manner.

(e) To be eligible for pharmacist licensure all applicants shall successfully pass ~~the Oklahoma~~ a Board approved jurisprudence examination and/or any licensure examination required by the Board including but not limited to NAPLEX.

(1) Should an applicant fail the pharmacist licensure and/or the ~~Oklahoma Pharmacy Board~~ jurisprudence examination(s) twice the Board may require evidence of additional education before further re-examination.

(2) Providing the applicant fails three times, the Board may deny the applicant further examination.

(f) Applicants shall be forthright and open in the provision of information to the Board in the application process. Applicant shall be candid in regards to providing information related to any academic misconduct, malpractice, legal, or disciplinary action. No license shall be issued to an applicant who does not provide the Board with complete, open and honest responses to all requests for information.

(g) All applicants shall complete the licensure process in a diligent and forthright manner.

(1) An application for licensure may be cancelled by the Board for failure to make a legitimate effort to complete the licensure process within 90 days. An applicant(s) licensure process not completed within one year shall be cancelled.

(2) All cancelled applications are null and void and the applicant must begin the entire licensure process again including, but not limited to any applications, fees, and exams required.

#### **535:10-7-10. Pharmacist reinstatement**

(a) A pharmacist reinstatement applicant shall be an individual who possesses a pharmacist certificate of registration that was cancelled at request or for failure to renew.

(1) A pharmacist who possesses a revoked certificate is not eligible for reinstatement.

- (2) Cancelled pharmacists' records are kept for a limited time. If a pharmacist's record has been destroyed the applicant is not eligible for reinstatement. In this case the applicant shall follow the requirements in 535:10-7 to obtain pharmacist licensure.
- (b) A pharmacist reinstatement applicant shall meet the requirements in the Oklahoma Pharmacy Act, this Title, 535:10-7-4, 535:10-7-9 and this section.
- (c) A pharmacist reinstatement applicant shall send a written request to the Board.
- (d) Reinstatement applicants shall submit a satisfactorily completed Board approved reinstatement application together with the requirements and fees.
- (e) Applicants may be required to appear before the Board for interview as described in 535:10-7-4(c).
- (f) Applicants may be required to take the Oklahoma Board approved law exam as described in 535:10-7-4(d).
- (g) The applicant shall meet any additional requirements that the Board feels are necessary to protect public health.
- (h) Reinstatement will be required when the suspension of a non-current pharmacist's certificate ends or when the suspension is placed on probation.

## SUBCHAPTER 9. PHARMACEUTICAL CARE

### **535:10-9-4. Purpose**

- (a) The purpose of this Subchapter is to identify standards for the provisions of those acts or services that are necessary to provide pharmaceutical care.
- (b) The purpose of this Subchapter shall identify standards and requirement for the provision of collaborative medication therapy, agreements and authorization for an Oklahoma licensed pharmacist by an Oklahoma licensed allopathic or osteopathic physician.
- (c) The rules of this Subchapter are authorized under 353.7 and 353.30 (A).

### **535:10-9-4.1. Definitions**

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

“Collaborative medication therapy management” or “CMTM” means the implementation, management, and adjustment of medication therapy of patients by collaborating licensed pharmacists, as authorized by licensed collaborating physicians, through written protocols established pursuant to collaborative medication therapy management agreements.

“Collaborating pharmacist” or “Collaborating pharmacy” means an individual pharmacist or group of pharmacists, who shall provide the collaborating physician documentation of current competence in the CMTM area(s) covered by the CMTM agreement, employed by a pharmacy holding a current license from the Board who enters into a collaborative medication therapy management agreement with a collaborating licensed physician for collaborative medication therapy management. Documentation of current competence may include disease state certificate programs, Board approved continuing education, pharmacy residency programs, hospital competency assessments, specialized educational programs, and/or other such documentation of current competence as deemed acceptable by the collaborating physician.

“Collaborating physician” means an individual licensed physician or group of licensed physicians holding current unrestricted license(s) from the Oklahoma State Board of Medical Licensure and Supervision or the Oklahoma State Board of Osteopathic Examiners that enter into an agreement with a collaborating pharmacist for collaborative medication therapy management.

“Collaborative medication therapy management agreement” or “CMTM agreement” means the official agreement which is a written document in which collaborating physicians and pharmacists voluntarily agree to participate in collaborative medication therapy management.

“Medication therapy management authorization” means a written order or prescription from the collaborating licensed physician to the collaborating licensed individual patient or patient group.

“Patient authorization” means the patient’s or patient’s authorized representative’s agreement to participate in collaborative medication therapy management.

“Written protocol” means a written document between collaborating licensed physicians and licensed pharmacists establishing directives for decision criteria and outlining functions and procedures for collaborative medication therapy management, e.g. disease or treatment specific protocols.

### **535:10-9-5. Agreements**

- (a) Agreements will be allowed between Oklahoma licensed pharmacists and allopathic and osteopathic physicians licensed by the Oklahoma Board of Medical Licensure or the Oklahoma Board of Osteopathic Examiners.
- (b) A copy of the agreement shall be filed in the pharmacy and be available for review by the Board.
- (c) The agreement shall not violate any state or federal law.

**535:10-9-6. Minimum requirements for collaborative medication therapy management agreement(s)**

The official agreement between collaborating physician(s) or collaborating pharmacist(s) also called the collaborative medication therapy management (CMTM) agreements shall at a minimum include the:

- (1) Names, addresses, telephone numbers, and emergency contact numbers of both the collaborating physician(s) and pharmacist(s);
- (2) Date and signature(s) of the collaborating physician(s) or authorized agent of a physician group and the pharmacist(s), pharmacist-in-charge, or Director of Pharmacy who will directly participate in the collaborative medication therapy management;
- (3) Physician approved written protocol(s) which describes the specific disease state and medication therapy management activities to be performed.
- (4) Procedure for the pharmacist to obtain the patient's or the patient's agent's agreement for collaborative medication therapy management;
- (5) Procedure for documenting and reporting medication therapy management activities by the collaborating pharmacist to the collaborating physician. The collaborating physician must be informed of the status of the patient being managed by the collaborating pharmacist each time patient care is given under the CMTM written protocol;
- (6) Procedure for notification of the physician in the event of an emergent medical situation;
- (7) Provision requiring compliance to the current HIPAA law standard;
- (8) Provision limiting the duration of the agreement for a period of time not to exceed one year, unless the agreement is subject to annual review and mutual continuance, as evidenced by documentation; and,
- (9) Such collaborative medication therapy management agreement only comes into force, or can be acted on when the collaborating physician writes a prescription or order.

**535:10-9-7. Collaborative medication therapy management process**

Collaborative medication therapy management process shall include those acts necessary for pharmaceutical care including, but not limited to:

- (1) Obtaining and assessing relevant patient medical histories;
- (2) Obtaining and/or performing medication related patient measurements and assessments, e.g. vital signs, height, weight, pulse, blood pressure;
- (3) Ordering and evaluating the results of any laboratory test related to medication therapy when performed in accordance with the written protocols;
- (4) Initiating or modifying an individual patient's medication therapy and medication administration as permitted by the collaborating physician in the written protocol;
- (5) Providing education to the patient or patient's authorized representative regarding medication therapy management activities; and,
- (6) Documentation of and communication to the collaborating physician of medication therapy management activities.

**535:10-9-8. Collaborative medication therapy management authorization requirement**

The collaborating licensed physician shall write the official written order or prescription for a pharmacist or group of pharmacists to initiate collaborative medication therapy management services. The physician authorization, order or prescription will, at a minimum, include the following:

- (1) Specification of the individual patient or patient population for which the collaborative medication therapy management agreement applies.
- (2) Acknowledgement and approval of the written protocol verified by the signature of the collaborating physician.

**535:10-9-12. Unauthorized practice**

(a) A collaborating pharmacist shall not practice beyond the scope of the collaborative medication therapy agreement, the written protocol, and the Oklahoma Pharmacy Act.

(b) Unauthorized practice by a collaborating pharmacist will be subject to violations and penalties as defined in the Oklahoma laws governing the practice of pharmacy, the Oklahoma Pharmacy Act, and the rules of the Board of Pharmacy.

(c) Physicians will be subject to violations and penalties as defined in the Oklahoma laws and rules governing the practice of medicine.

**TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY****CHAPTER 15. PHARMACIES****SUBCHAPTER 1. GENERAL PROVISIONS****535:15-1-1. Purpose**

(a) The rules of this Chapter regulate the sale or storage of drugs, medicines, chemicals and poisons and the dispensing of drugs and medicines in all places where drugs and medicines are compounded, dispensed or stored.

(b) The rules of this Chapter concern all places, including premises, equipment, contents and records, where drugs, medicines, chemicals or poisons are sold, stored, vended, given away, compounded, dispensed or manufactured, or the profession of pharmacy is practiced.

(c) The rules of this Chapter further describe the Board's authority and duty to take and copy records and the duty to confiscate all drugs, medicines, chemicals or poisons found to be sold, stored, vended, given away, compounded, dispensed or manufactured contrary to the provisions of Title 59 O.S., Section 353 et seq.

(d) The rules of this Chapter prescribe minimum standards with respect to floor space and other physical characteristics of pharmacies, including retail pharmacies with drug supplier and parenteral permits, and Hospital pharmacies, which are necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public, and which are required to receive new or renewal licenses or to close a pharmacy.

(e) Compliance with the rules of this Chapter is the responsibility of both the pharmacy and pharmacy manager, and in some cases, the pharmacists working in the pharmacy.

**SUBCHAPTER 3. PHARMACIES****535:15-3-2. Pharmacy responsibilities**

(a) **Pharmacy staffing responsibility.** Each pharmacy shall employ an adequate number of pharmacists to perform the practice of pharmacy as defined by the Oklahoma Pharmacy Act with reasonable safety.

(b) **Pharmacy manager.** Each pharmacy, in order to obtain and maintain a pharmacy license, must have a registered pharmacist as the pharmacy manager.

(1) A pharmacy manager (i.e. pharmacist in charge) is designated by his signature on the original pharmacy application or by the appropriate notification to the Board as required in 535:15-3-10(a), and is responsible for all aspects of the operation related to the practice of pharmacy. These responsibilities include, but are not limited to the:

(A) supervision of all employees as they relate to the practice of pharmacy;

(B) establishment of policies and procedures for safekeeping of pharmaceuticals that satisfy Board requirements, including security provisions when the pharmacy is closed;

(C) proper record keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs;

(D) proper display of all licenses;

(E) annual controlled drug inventory; and,

(F) maintenance of prescription files;

(2) Failure of the pharmacy to have a pharmacy manager who fulfills these responsibilities is a violation of this code by both the pharmacy and pharmacy manager (PIC).

~~(2)-(3)~~ No pharmacist may serve as a pharmacy manager in more than one pharmacy at a time.

~~(3)-(4)~~ A pharmacy manager shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager.

(c) **Pharmacy manager's and pharmacy's responsibilities.** The following describe responsibilities of the pharmacy and pharmacy manager.

(1) Where the actual identity of the filler of a prescription is not determinable, the manager of the pharmacy and the pharmacy where the prescription was filled will be the subject of any charges filed by the Board of Pharmacy.

(2) The pharmacy and the pharmacy manager are responsible to establish and maintain effective controls against prescription errors or misfills.

(3) The pharmacy and/or pharmacy manager shall notify the Board immediately by certified mail of the separation of employment of any pharmacist, pharmacy intern, or pharmacy technician for any suspected or confirmed drug or pharmacy related violation. If the pharmacy manager (PIC) is terminated for such reason, the owner or other person in charge of the pharmacy shall notify the Board by certified mail.

(4) Establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.

(5) The pharmacy, pharmacist and pharmacy manager are responsible for supervision of all employees as they relate to the practice of pharmacy.

(d) **Responsibility for automated pharmacy systems.** This subsection describes the responsibilities of the pharmacy and the pharmacy manager for automated pharmacy systems.

(1) Prior written notice must be provided to the Board of the installation or removal of automated pharmacy systems. Such notice must include, but is not limited to the:

- (A) name and address of the pharmacy,
- (B) name of pharmacy manager,
- (C) name of the manufacturer & model of system.

(2) The system being implemented should conform to Board automated pharmacy system guidelines.

(3) The pharmacy shall monitor the automated pharmacy system with a quality assurance program.

(e) **Responsibilities for personnel identification.** The pharmacy manager and the pharmacy are responsible to assure that the public be able to distinguish pharmacy technicians, auxiliary support personnel, and/or interns from any pharmacist in the pharmacy.

(1) All pharmacy technicians, auxiliary support personnel, and/or interns must wear a designation tag and be distinctly identifiable from a practicing pharmacist.

(2) Designation tags must be clear, readable and lettered with "Rx Tech", "Tech", "Clerk", or "Intern".

(3) All pharmacy interns, technicians or clerks must identify themselves as such on any phone calls initiated or received while performing pharmacy functions.

#### 535:15-3-4. Physical requirements for pharmacies

The following are physical requirements for pharmacies:

(1) **Size.** The prescription department shall occupy no less than 125 square feet, and shall be in a commercial location and not a personal dwelling or residence.

(2) **Sanitary facilities.** There shall be installed the proper sanitary facilities which shall include a sink with hot (minimum 104 degrees F) and cold running water separate from the restroom facilities.

(3) **Balances.** There shall be one set of prescription balances with capacity from 1/10 grain to at least one (1) ounce. If the pharmacy proves to the Board that the practice of pharmacy at this particular site does not require weighing of drugs and/or ingredients, an exception may be made by the Executive Director of the Board to the balances requirement.

(4) **Graduates.** There shall be graduates scaled in both metric and apothecary measure sufficient in size and number to assure proper operation of the prescription department.

(5) **Spatulas.** There shall be spatulas of sufficient size and number to assure its proper operation.

(6) **Mortars and pestles.** There shall be mortars and pestles of sufficient size and number to assure its proper operation.

~~(7) Sterilization. There shall be installed sufficient equipment with which to perform all necessary sterilization procedure or heat processes common to the ordinary prescription department.~~

~~(8-7) Library.~~ There shall be the necessary library which has been prescribed and standardized by the Board of Pharmacy in Section 535:15-3-6.

~~(9-8) Refrigeration.~~ There shall be sufficient refrigeration facilities to store all necessary biologicals, injectables, suppositories and other products requiring refrigeration. This refrigerator shall be entirely separate from the storage of any food products in open packages.

~~(10-9) Exempt narcotic book.~~ There shall be a book suitable for the registration of all sales of exempt narcotics, if such are sold or dispensed.

~~(11-10) Poison Book.~~ There shall be a book suitable for the registration of all sales of poisons in accordance with applicable laws, if such are sold or dispensed.

~~(12-11) Filing.~~ There shall be a system of filing for all prescriptions which shall be kept for a period of not less than five (5) years.

~~(13-12) Containers.~~ There shall be sufficient stock of containers suitable for the dispensing of all prescriptions both for internal and external usage.

~~(14-13) Labels.~~ There shall be sufficient stock of labels both for the dispensing of prescriptions and the sale of medicines and chemicals. Label requirements described in Title 59 O.S. Section 353.13A(C)

#### 535:15-3-9. Non-resident pharmacies

(a) **Definitions.** "**Non-resident pharmacy**" means a pharmacy, not located in Oklahoma, ~~which~~ transacts or does business in Oklahoma by soliciting, receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

(b) **Licensing requirements.** A non-resident pharmacy shall:

- (1) make application and receive an annual non-resident pharmacy license at a fee set by the Board;
- (2) maintain in good standing a pharmacy license in its resident state; and,
- (3) comply with the Oklahoma Secretary of State requirements for conducting business in this state.
- (4) be in a commercial location and not a personal dwelling or residence.

(c) **Laws and regulations.** Oklahoma pharmacy laws and regulations shall apply to the practice of pharmacy for the Oklahoma portion of the nonresident pharmacy's practice or operation.

(1) The pharmacist manager (pharmacist in charge (PIC)) and all other pharmacists performing pharmacist-only functions in Oklahoma licensed non-resident pharmacies must be currently licensed in the state in which they are practicing.

(2) The pharmacist manager (PIC) and/or pharmacy owner(s), or partners, or corporate officer(s) shall be responsible for compliance with Oklahoma laws and regulations pertaining to the provisions of receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

(3) The requirement of 535:15-3-9 (c) and (e) shall apply only to the extent that such requirements are consistent with the laws and rules of the pharmacy's resident state.

(d) **Inspections.** Non-resident pharmacies are subject to inspection as follows:

(1) Oklahoma pharmacy inspectors may conduct on-site periodic routine inspections during reasonable business hours; or

(2) The Oklahoma Board may request copies of the resident state Board of Pharmacy's periodic routine inspection reports.

(e) **Records.** Prescription records documenting prescriptions delivered and distributed to Oklahoma residents shall be identifiable, readily retrievable and available for Board review.

(1) Records must be maintained for not less than five years.

(2) Patient records shall comply with 535:15-3-14.

(3) Schedule II, III, and IV prescription records should be sent to the Oklahoma Control Reporting program as set out in Title 63 of the Oklahoma Statutes.

(f) **Counseling services.** Non-resident pharmacies shall provide an accessible toll-free telephone counseling service with a licensed pharmacist for patient drug inquiries during regular working hours. The counseling provided shall comply with the pharmaceutical care requirements listed in OAC 535:10-9.

(g) **Prescription integrity.** A pharmacy shall not increase the quantity of a prescription without the authorization of the prescriber.

#### **SUBCHAPTER 4. REMOTE MEDICATION ORDER PROCESSING (RMOP) and RMOP PHARMACY FOR HOSPITAL PHARMACIES**

##### **535:15-4-1. Purpose**

(a) The rules of this Subchapter, as authorized under Title 59 O.S. 353.7, 353.20, 353.24, and 354, establish the rules for Oklahoma licensed hospitals to employ remote medication order processing (RMOP) and provide for the designation and registration of a remote medication order processing pharmacy.

(b) The rules of this Subchapter do not relieve the licensed hospital pharmacy, the licensed hospital drug room, the pharmacy manager or director of pharmacy from their responsibilities under the Oklahoma laws and rules.

##### **535:15-4-2. Definitions**

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

“Contract employee” means any person who performs services for a hospital, and whose compensation may or may not be reflected on the payroll records of a hospital, hospital pharmacy, or remote medication order processing pharmacy.

“Remote medication order processing” or “RMOP” means the processing of a medication order for a hospital facility by a pharmacist located in a remote medication order processing pharmacy site. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

“Remote medication order processing pharmacy” means a pharmacy which does not stock, own, or dispense any prescription medications, and whose sole business consists of entry and/or review and/or verification of physicians orders and consulting services under contract for hospitals licensed in Oklahoma or any other state; and which provide services under the direction of a pharmacist in charge or PIC, licensed by the Board.

“Remote pharmacist” means any person licensed to practice pharmacy by the Board, either employed or a contract employee of a hospital, hospital pharmacy, or remote medication order processing pharmacy, processing the medication order from a remote site.

“Remote site” means a site located within the continental United States (US) or District of Columbia (DC) that is electronically linked to the hospital via a computer and/or other electronic communications system as defined in the operations, policies and procedures manual of a hospital pharmacy, hospital drug room or remote medication order processing pharmacy for the purposes of remote medication order processing.

**535:15-4-3. Registration**

All remote medication order processing pharmacies shall be licensed with the Board. The fee per year for remote medication order processing pharmacies shall be set by the Board. Licenses shall be issued only to those remote medication order processing pharmacies that satisfy the provisions of this Subchapter.

**535:15-4-4. Staffing requirements**

(a) The pharmacist in charge (PIC) shall be assisted by a sufficient number of additional Oklahoma licensed remote pharmacists to operate such a remote medication order processing pharmacy competently, safely, and adequately to meet the needs of the patients of the hospitals served.

(b) The remote medication order pharmacy, pharmacist manager or pharmacist in charge (PIC) shall notify the Board, in writing, within 10 days of any change of employment of remote pharmacists. This does not remove the requirement that such pharmacist notify within ten days in writing of a change of employment.

**535:15-4-5. Responsibilities and duties of RMOP pharmacies and pharmacy manager [pharmacist in charge (PIC's)]**

Responsibilities of the PIC and the remote medication order processing pharmacy include:

(1) **Written policies and procedures and operation manuals.** The remote medication order processing pharmacy and PIC shall establish a written policy and procedure manual for the RMOP operation, including but not limited to:

(A) Complying with federal and state laws and regulations;

(B) Establish and maintain minimum technical standards and specifications, e.g. RMOP processes, passwords, encryption and firewalls;

(C) Establish and maintain procedures for handling computer system or connectivity downtime;

(D) Establish and maintain confidentiality, privacy, and security to meet HIPAA standards;

(E) Establish and maintain pharmacist training, orientation and competencies;

(F) Establish and maintain workload balancing and staffing levels e.g. when will RMOP be triggered and how will workload or staff balancing be done;

(G) Establish and maintain access to appropriate drug information resources; (H) Establish and maintain hospital staff training and orientation to the remote medication order process;

(I) Establish and maintain a process that documents issues or problems which includes issue escalation and problem resolution to resolve such;

(J) Establish and maintain on-call assistance and communication between the hospital and remote site personnel;

(K) Establish and maintain internal quality assurance and medication error reporting systems;

(L) Clarification of medication orders;

(M) Establish and maintain access to either hard-copy or online references as described in 535:15-5-9 (1) (B) and 535:15-5-9 (1) (C).

(N) Establish and maintain access to Hospital policy resources, policies and procedures;

(O) Establish and maintain records and reports;

(P) Establish and maintain annual review of the remote medication order processing and documentation.

(2) **General responsibility.** The remote medication order processing pharmacy and PIC shall be responsible for the provision of services to the hospital(s), including but not limited to establishing and maintaining:

(A) Establishing and scheduling appropriate RMOP pharmacy staffing levels;

(B) Performance of RMOP duties which include establishing and maintaining:

(i) Review of the patient's profile;

(ii) Clarification of medication orders;

(iii) Reporting of potential drug interactions or allergies;

(iv) Order entry and/or order review;

(v) Monitoring of clinical information, lab values, or dosing issues;

(vi) Provision of drug information to the pharmacist(s) performing remote medication order entry, by establishing and maintaining access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).

(C) Submitting required reports, required by hospital, by procedures manual and by law or rule;

(D) Quality assurance and performance improvement of the RMOP service;

(3) **Confidentiality.** The remote medication order processing pharmacy and PIC shall have responsibility for establishing policies and procedures for the security and integrity of any patient information, confidential and non-confidential and must abide by all applicable state and federal laws and rules. In addition, the following must be met:

(A) Pharmacists performing remote medication order processing entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1-1(6) and 535:10-3-1-2.(14); and,

(B) The hospital shall insure that the remote pharmacist shall have individual pharmacist-specific secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the hospital pharmacy is open.

**(4) Record keeping.**

(A) The remote medication order processing pharmacy shall ensure that records of any and all orders processed for the hospital are maintained for a minimum of two (2) years, and such records shall be readily available for inspection, copying by, or production of upon request by the Board, its designee, or a representative of the Board upon request, including, but not limited to:

(i) Medication orders reviewed or verified by the remote pharmacist;

(ii) Interventions communicated by the remote pharmacist;

(iii) Requests for clinical or other additional information communicated by the remote pharmacist;

(iv) Name or other unique identifier of the remote pharmacist involved in the processing of the RMOP order.

(B) The records required in Section 535:15:5.5-5 (a) (4) (A) above may be kept at either the remote medication order processing pharmacy or the hospital so long as the records are maintained and readily available.

(C) A hospital utilizing a remote pharmacist shall maintain a record of the name and address of such pharmacist(s), evidence of current pharmacist any and all orders processed for the hospital will be maintained.

**535:15-4-6. Governing body**

The pharmacy and pharmacist will recognize the Board as the governing body of the practice of pharmacy and any violations of pharmacy laws or rules that may come to the attention of the pharmacy and/or pharmacist must be reported to the Board.

**535:15-4-7. Unlawful acts and violations**

(a) Unlawful acts and violations are described in the Oklahoma Pharmacy Act and this Title.

(b) Remote medication order processing pharmacy rules for conduct, violations of conduct and rules for applicants are found in 535:25.

(c) Rules for conduct and violations of conduct for pharmacists are found in 535:10-3-1.1, 535:10-3-1.2, 535:15-3-2, 535:15-3-4-2; and rules for applicants are found in 535:25.

(d) Remote medication order processing pharmacies are subject to rules in 535:15-3 unless they clearly do not apply to RMOP pharmacies.

(e) Penalties for violations of this Title, the Oklahoma Pharmacy Act and federal and state laws and rules are listed in Title 59 O.S. Section 353.26.

**SUBCHAPTER 5. HOSPITAL PHARMACIES**

**535:15-5-2. Definitions**

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

**“Automated dispensing systems”** means a mechanical system controlled by a computer that performs operations or activities, relative to the storage, packaging, compounding, labeling, dispensing, administration, or distribution of medications, and which collects, controls, and maintains all transaction information.

**“Auxiliary supportive personnel”** or **“auxiliary supportive person”** means all persons, other than pharmacists, interns and techs, who are regularly paid employees of the hospital pharmacy and who work or perform tasks in the hospital pharmacy that do not require a permit or license (e.g. clerk, typist, delivery, or data entry person, etc.).

**“Certified medication order”** means a filled prescription that has been reviewed and certified by a pharmacist.

**“Certified pharmacy technician”** means a pharmacy technician who has a current Board approved pharmacy technician certification in addition to a current Oklahoma pharmacy technician permit.

**“Director of Pharmacy”** means a pharmacist licensed to engage in the practice of pharmacy in Oklahoma who is thoroughly familiar with the specialized functions of a hospital pharmacy and directs the activities of a hospital pharmacy.

**“Drug room”** means a secured room where drug inventories are maintained for use in a facility licensed and regulated by the Oklahoma Health Department, and which may be inspected by the Board.

**“Hospital employee”** means any individual employed by a hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.

**“Hospital facility”** or **“Hospital”** means any institution licensed as a hospital by this state for the care and treatment of patients.

**“Hospital pharmacy”** means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are stored, controlled and prepared for distribution and administration for the use and/or benefit of patients in a hospital facility. Hospital pharmacy shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or

poisons are compounded and prepared for dispensing to the members of the medical staff, hospital employees, and the members of their immediate families, patients being discharged, and for other persons in emergency situations.

**“Medical staff”** means a medical practitioner who has privileges to practice in the hospital facility.

**“Medication order”** means a prescription as defined in Title 59 O.S. Section 353.1(7).

**“Pharmacist”** means any person licensed to practice pharmacy by the Oklahoma State Board of Pharmacy.

**“Pharmacy technician”, “Tech”, “Technician” or “RxTech”** means a person who has been issued a permit by the Board to assist the pharmacist and performs non-judgmental, technical, manipulative, non-discretionary functions in the prescription department under the pharmacist's immediate supervision.

**“Remote medication order processing” or “RMOP”** means the processing of a medication order for a hospital facility by a pharmacist located in a remote medication order processing pharmacy site. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

**“Remote site”** means a site located within the continental United States (US) or District of Columbia (DC) that is electronically linked to the hospital via a computer and/or other electronic communications system as defined in the operations, policies and procedures manual of a hospital pharmacy for the purposes of remote medication order processing (RMOP) of a remote medication order processing pharmacy.

**“Supportive personnel”** means technicians and auxiliary supportive persons, who are regularly paid employees of the hospital pharmacy and who work or perform tasks in the hospital pharmacy.

### **535:15-5-3. Applicability**

The rules of this Subchapter are applicable to all hospitals and hospital pharmacies, as defined by 535:15-5-2 and may, if specified, apply to drug rooms. Compliance with the rules of this Subchapter is the responsibility of the hospital pharmacy, and the Director of Pharmacy, and may be for the individual pharmacist employed in the hospital pharmacy.

### **535:15-5-4. Registration**

**(a) Registration.** All hospital pharmacies shall register annually with the Board of Pharmacy; hospital pharmacy licenses shall be issued only to those hospital pharmacies that satisfy the provisions of Section 353.18(A) of the Oklahoma Pharmacy Act, and all rules of this Title.

**(b) Minimum hours.** A hospital pharmacy shall be staffed with licensed pharmacist and be open for a minimum of four days a week and for a minimum of at least 32 hours per week to the standards listed in 535:15-5-10 (j).

### **535:15-5-10. Director of Pharmacy responsibilities**

**(a) Written procedures.** The Director of Pharmacy shall establish written procedures for the safe and efficient acquisition, distribution, storage, and utilization of pharmaceutical products with any of the federal legends such as “Rx Only” and medications administered or used in the hospital system. Such procedures shall be annually reviewed and a current copy shall be on hand for Board inspection.

**(b) General responsibilities.** The Director of Pharmacy shall be responsible for the safe and efficient purchasing, acquisition, monitoring, distribution, control, security, and accountability of all drugs including, but not limited to, federal legend drug products used in diagnostic procedures, I.V. fluids, or contained in supply kits. The other professional staff of the hospital facility shall cooperate with the Director in meeting this responsibility. The Director shall be responsible for, at a minimum, the following:

- (1) Preparing and sterilizing parenteral medications prepared within the hospital facility.
- (2) Admixing parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not accomplished within the hospital pharmacy.
- (3) Preparing drug products including unit dose.
- (4) Establishing specifications for procurement of all materials, including drugs, chemicals and biologicals used within pharmacy practice, subject to approval of the appropriate committee of the hospital facility.
- (5) Participating in the development and maintenance of a formulary for use within the hospital facility.
- (6) Filling and dispensing all drugs which are to be administered within the hospital facility.
- (7) Maintaining and making available a sufficient inventory of pharmaceuticals, including antidotes and other emergency drugs, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.
- (8) Maintaining records of all transactions of the hospital pharmacy required by applicable local, state, and federal law, and necessary to maintain accurate control and accountability for all pharmaceutical materials.
- (9) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to pharmaceutical material utilization and effectiveness.
- (10) Cooperating fully with teaching and/or research programs in the hospital facility, if any.

(11) Implementing the policies and decisions of the appropriate committees of the hospital, which deal with drug distribution and drug utilization.

(12) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and the rules and regulations governing the practice of pharmacy within a hospital facility.

(13) Establishing guidelines for the safe and effective distribution of drugs intended for floor stock, and their subsequent administration.

(14) Initial and continuing training of pharmacy technicians.

(c) **Confidentiality.** The Director of Pharmacy shall have direct responsibility for the security and integrity of any patient pharmacy information, confidential and non-confidential, and must comply with all federal and state laws and regulations applicable to the hospital pharmacy.

(1) Rules regarding confidentiality of patient records are described in 535:15-3-14(e); and,

(2) Responsibilities for confidentiality shall be as set forth in 535:10-3-1.1 and 535:10-3-1.2 and the rules of this Title.

(d) **Adverse Drug Events program.** The Director of Pharmacy shall develop and maintain a program to monitor the actual and potential adverse drug events including pharmacist interventions, medication errors, and adverse drug reactions for all medications utilized in the hospital to include system wide programs if an integrated system is involved.

(1) Policies indicating the tracking, review, and outcome of the adverse drug events shall be kept current and available for Board inspection.

(2) ~~Type 1 Deficiencies assessed by the JCAHO for failure to meet standards in Patient Care Medication Use Standards-Sentinel events, direct impact findings, and root cause analyses involving drugs and/or Medication Management Standards of The Joint Commission~~ shall be maintained and be available for Board inspection.

(e) **Investigational drug programs.** The Director of Pharmacy shall maintain a file for review by the Board of all investigational drug protocols open and closed that have been approved by the hospital Investigational Review Board.

(f) **Discontinued drug orders.** The Director of Pharmacy shall develop and implement policies and procedures to insure that discontinued drugs, outdated drugs, and containers with worn, illegible or missing labels are returned to the pharmacy for proper disposition.

(g) **Controlled drug accountability.** The hospital facility shall maintain adequate records regarding the use and accountability of controlled substances and such other drugs as the hospital may designate; and as directed by the Oklahoma State Bureau of Narcotics and the Federal Drug Enforcement Administration. The Director of Pharmacy shall establish effective written procedures to implement this requirement.

(h) **Drug recall procedures.** The Director of Pharmacy shall develop and implement a written recall procedure that can be readily activated which assures that drugs involved, inside or outside of the facility, are returned to the pharmacy for proper disposition. All actions taken in this area are to be properly documented and maintained for 36 months for Board review.

(i) **Records and reports.** The Director of Pharmacy shall maintain and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. These should include the following:

(1) Adverse drug reaction reports.

(2) Floor stock inventories of night cabinets and emergency boxes.

(3) Inventory listing of the pharmacy.

(4) Controlled substance inventory.

(5) Ethyl alcohol inventory.

(6) Pharmacy and therapeutic committee minutes.

(7) Reports and records as required by law and/or rules.

(8) Outpatient prescriptions shall contain all information required by pharmacy law and rule.

(j) **Pharmacist staffing.** The Director of Pharmacy shall maintain adequate staffing levels of pharmacist to insure pharmaceutical patient-focused care support. This staffing shall be a sufficient number of additional registered pharmacists as may be required to operate such a pharmacy competently, safely and adequately to meet the needs of the patients of the hospital facility ~~as to meet requirements described in 535:15-5-4.~~

(k) **Automated dispensing systems.** The Director of Pharmacy shall maintain control to insure that direct pharmacist intervention and responsibility (and certification of medication order) is present and consistent in any cycle of automated dispensing from acquisition of product through the terminal dispensing act prior to administration to the patient of any medication as described in these rules.

(1) The Board must be provided with prior written notice of the installation or removal, or major upgrade that physically changes the operation of automated dispensing systems.

(2) Such notice must include, but is not limited to the:

(A) name and address of the pharmacy;

(B) location of the automated equipment;

(C) identification of the pharmacist-in-charge; and

(D) name of manufacturer and model of system;

(3) Along with such notice, submit a copy of the automated dispensing system quality assurance plan to the Board for review.

(4) The terminal act of automated dispensing must be to a licensed caregiver (nurse or practitioner not intended to include medication technician's or CMA's) in the hospital facility in no more than a 24-hour supply of medication that has been reviewed by a pharmacist.

**535:15-5-19. Remote medication order processing (RMOP)**

(a) Hospitals, the pharmacist manager and the director of pharmacy at the hospital that allow remote medication order processing shall establish and maintain policies and procedures related to remote medication order processing.

(1) Such registrants remain responsible to assure the hospital pharmacy meets requirements under Oklahoma laws and rules.

(2) Such registrants shall be responsible to assure RMOP, if used, is reviewed at least annually and that proper credentialing, review and that oversight is established, maintained and exercised.

(b) Prior to implementation of RMOP services, training shall be provided by the hospital, and the relevant portions of the hospital pharmacy's policy and procedure manual shall be established and maintained on RMOP; and such shall be reviewed by the Pharmacist providing RMOP entry services at least annually.

(c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:

(1) Pharmacists performing RMOP entry must be licensed by the Board.

(2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1-1(6) and 535:10-3-1-2.(14).

(3) The hospital shall ensure the pharmacist performing remote medication order processing has individual, pharmacist-specific access to the hospital pharmacy's patient information system and to other electronic systems that on-site pharmacists have access to during the hours of operation of the hospital pharmacy.

(d) The hospital will make available to the pharmacist(s) performing RMOP entry, access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).

(e) The hospital's computer system shall have the ability to audit the activities of each pharmacist(s) remotely processing the RMOP orders.

(f) A hospital pharmacy may allow RMOP for the patient population served under the hospital's pharmacy license by a pharmacist employed by the same licensed hospital pharmacy. Remote medication order processing performed for patients served under a different hospital pharmacy licensure requires a contractual arrangement fulfilling the responsibilities as outlined in 535:15-4-5.

(g) All Pharmacists who engage in RMOP shall ensure the following minimum information technology standards and specifications are met and maintained at the remote site:

(1) Availability of internet, phone, and scan or fax access to the hospital.

(2) Ability to access the hospital facility via the hospital's information system.

(3) To the extent possible, have redundant systems in place to ensure remote medication order processing service availability (e.g. internet connectivity, other information systems used to facilitate remote medication order processing).

(4) Have secure electronic access to the hospital's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(5) Use of a computer workstation e.g. with passwords, firewalls and encryption.

(h) The record of each patient-specific RMOP drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the review and verification of the order.

(i) Remote medication order processing by a pharmacist shall not relieve the hospital pharmacy from employing or contracting with pharmacist(s) to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed or additional pharmacist assistance is needed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist(s).

(j) Pharmacists performing remote medication order processing shall not be included in the ratio of the pharmacist and technician as outlined in 535:15-5-7.2.(e).

(k) A pharmacist employed by or contracting with a hospital pharmacy for on-site services may also provide remote medication order processing services when the hospital pharmacy is closed or additional pharmacist assistance is needed through a remote medication order processing pharmacy.

**SUBCHAPTER 6. HOSPITAL DRUG ROOM**

**535:15-6-1. Purpose**

The rules of this Subchapter, as authorized under Title 59 O.S. Section 353.7 and 353.18(a) establish the rules for all hospital drug rooms. Compliance with these rules are the responsibility of the hospital drug room, the pharmacist in charge, and may be for pharmacists working in the drug room.

**535:15-6-2. Definitions**

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

“**Adverse Drug Event**” or “**ADE**” means an injury from a medicine or lack of an intended medicine.

“**Authorized licensed independent practitioner**” or “**ALI Practitioner**” or “**Licensed independent practitioner**” means an individual permitted by Oklahoma law and by the hospital to provide care and services, without direct supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. Licensed independent practitioners may include physicians, advanced practice nurses with prescriptive authority, physician assistants, dentists, podiatrists, and optometrists.

“**Contract employee**” means any person who performs services or labor for a hospital, and whose compensation may or may not be reflected on the payroll records of a hospital. Examples of pharmacy contract employees are consultant D.Ph., relief D.Ph. and/or volunteer D.Ph.

“**Drug room**” or “**Hospital drug room**” means a secured room where drug inventories are maintained for use in a hospital, with less than 100 licensed beds including bassinets, licensed and regulated by the Oklahoma Health Department and by the Oklahoma State Board of Pharmacy.

“**Drug room supervisor**” means an Oklahoma registered nurse, licensed practical nurse, or registered pharmacist (D.Ph.) as described in OAC 310:667-21-2 (c).

“**Pharmacist-in-Charge**” or “**PIC**” means an Oklahoma licensed pharmacist director or consultant of the hospital drug room, either employed or a contract employee.

“**Remote medication order processing**” or “**RMOP**” means the processing of a medication order for a hospital facility by a pharmacist located in a remote medication order processing pharmacy site. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

“**Remote site**” means a site located within the continental United States or District of Columbia that is electronically linked to the hospital site via a computer for the purposes of remote medication order processing to a remote medication order processing pharmacy.

**535:15-6-5. Drug room and PIC responsibilities and duties**

(a) **Responsibilities.** Responsibilities of the hospital drug room and PIC include drug purchasing, acquisition, preparation, distribution, monitoring, security, storage and control.

(1) **Written procedures.** The hospital drug room and PIC shall establish written procedures for the safe and efficient acquisition, distribution, and utilization of all medicine products with any of the Federal legends such as “RX only” and medications administered or distributed in the hospital system. A current copy of such procedures shall be available for review by the Board.

(2) **General Responsibility.** The hospital drug room and PIC shall be responsible for the safe and efficient monitoring, distribution, control, purchasing, acquisition and accountability of all drugs including but not limited to Federal legend drug products used in diagnostic procedures, I.V. fluids, or contained in supply kits excluding blood bank products and reagents controlled by the laboratory. The other professional staff of the hospital facility shall cooperate with the pharmacist in meeting this responsibility.

(3) **Confidentiality.** The hospital drug room and PIC shall have responsibility for establishing policies for the security and integrity of any patient information, confidential and non-confidential, and must abide by all relevant State and Federal regulations applicable to the hospital system.

(4) **Adverse Drug Events Program.** The hospital drug room and PIC shall develop and maintain a program to monitor the actual and potential adverse drug events including pharmacist interventions, medication errors, and adverse drug reactions for all medications utilized in the hospital to include system wide programs if an integrated system is involved. Records indicating the tracking, review, and outcome of the Adverse Drug Events shall be kept current and available for Board inspection.

(5) **Investigational drug programs.** The PIC shall establish a policy for investigational drug use.

(6) **Review of medication orders.** The PIC shall cause medication orders to be reviewed by a pharmacist in a timely manner.

(7) **Pharmacists Visits.** The hospital drug room and PIC shall cause and document a minimum of 52 routine in-house visits per year to be made to a hospital with a drug room as required by health department rule OAC 310:667-21-2(a) et seq.

(A) No more than 2 visits in any 7-day period shall be counted towards this minimum.

(B) Visits in any calendar month shall be no less than 2.

(C) The PIC shall submit a report outlining issues encountered and decisions made during visits. A copy of this report shall be available in the hospital drug room for inspection by the Board.

(D) A licensed hospital drug room employing a full-time pharmacist is not required to document the 52 routine in-house visits since daily work is done, interventions are documented, and audit systems are maintained.

(8) **Pharmacy and Therapeutics (P&T) Committee.** The PIC shall be a participating member in the Pharmacy and Therapeutics Committee.

(9) **Effective Controls.** The hospital drug room and PIC shall establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.

(b) **Duties.** The duties of a PIC in a licensed hospital drug room, at a minimum, shall be the following:

(1) The training duties of the PIC are:

(A) Competency training regarding preparation and sterilization of parenteral medications prepared by appropriate hospital staff;

(B) Competency training of personnel concerning medicine incompatibilities and providing incompatibility information; and

(C) Training personnel in confidentiality of protected health and proprietary information and regarding the compliance with all federal and state laws and regulations applicable to the hospital drug room.

(i) Such rules regarding confidentiality of patient records are described in 535:15-3-14(e), the federal HIPAA regulations; and,

(ii) Such responsibilities for confidentiality shall be as set forth in 535:10-3-1.1 (a) (6) and 535:10-3-1.2 (a) (14) and the rules of this Title.

(D) Conducting initial and continuing competency training of all drug room personnel.

(2) Repackaging drug products including unit dose.

(3) Establishing procedures for procurement of all medicines used within the hospital system subject to approval of the medical and professional staff.

(4) Participating in the development and maintenance of a formulary for use within the hospital system.

(5) Maintaining and making available a sufficient inventory of medicines including antidotes and other emergency drugs approved by the medical and professional staff, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.

(6) Maintaining oversight of the records of all transactions of the drug room required by applicable local, state, and federal law, and necessary to maintain accurate control and accountability for all medications.

(7) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to medicine utilization and effectiveness.

(8) Cooperating fully with teaching and/or research programs in the hospital facility, if any.

(9) Implementing the policies and decisions of the appropriate committees of the medical and professional staff that deal with drug distribution.

(10) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and those rules and regulations governing the practice of pharmacy within a hospital facility.

(11) Establishing guidelines for the safe and effective distribution of medicines intended for floor stock, and their subsequent administration.

#### **535:15-6-20. Remote medication order processing**

(a) Hospitals, the pharmacist manager and the director of pharmacy at the hospital that allow remote medication order processing shall establish and maintain policies and procedures related to remote medication order processing. Such registrants remain responsible to assure the hospital drug room meets requirements under Oklahoma laws and rules.

(1) Such registrants remain responsible to assure the hospital drug room meets requirements under Oklahoma laws and rules.

(2) Such registrants shall be responsible to assure RMOP, if used, is reviewed at least annually and that proper credentialing, review and that oversight is established, maintained and exercised.

(b) Prior to implementation of RMOP services, training shall be provided by the hospital drug room and the relevant portions of the hospital drug room's policy and procedure Pharmacist providing RMOP entry services at least annually.

(c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:

(1) Pharmacists performing RMOP entry must be licensed by the Board.

(2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1-1(6) and 535:10-3-1-2.(14).

(3) The hospital shall ensure the pharmacist performing remote medication order processing has individual, pharmacist-specific access to the hospital drug room's patient information system and to other electronic systems that on-site pharmacists have access to during the hours of operation of the hospital drug room.

(d) The hospital will make available to the pharmacist(s) performing RMOP entry, access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).

(e) The hospital's computer system shall have the ability to audit the activities of the pharmacist(s) remotely processing RMOP orders.

(f) A hospital drug room may allow RMOP for the patient population served under the hospital's drug room license by a pharmacist employed by the same licensed hospital drug room. Remote medication order processing performed for patients served under a different hospital drug room licensure requires a contractual arrangement fulfilling the responsibilities as outlined in 535:15-4-5.

(g) All Pharmacists who engage in RMOP shall ensure the following minimum information technology standards and specifications are met and maintained at the remote site:

(1) Availability of internet, phone, and scan or fax access to the hospital.

(2) Ability to access the hospital facility via the hospital's information system.

(3) To the extent possible, have redundant systems in place to ensure remote medication order processing service availability (e.g. internet connectivity, other information systems used to facilitate remote medication order processing).

(4) Have secure electronic access to the hospital's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(5) Use of a computer workstation e.g. with passwords, firewalls, and encryption.

(h) The record of each patient-specific RMOP drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the review and verification of the order.

(i) Remote medication order processing by a pharmacist shall not relieve the hospital drug room from employing or contracting with pharmacist(s) to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital drug room services when the pharmacy is closed or additional pharmacist assistance is needed and are not intended to eliminate the need for an on-site hospital drug room or pharmacist(s).

(j) Pharmacists performing remote medication order processing shall not be included in the ratio of the pharmacist and technician as outlined in 535:15-5-7.2.(e).

(k) A pharmacist employed by or contracting with a hospital drug room for on-site services from also providing remote medication order processing services when the hospital drug room is closed or additional pharmacist assistance is needed through a remote medication order processing pharmacy.

## SUBCHAPTER 9. PARENTERAL PHARMACY PERMITS

### 535:15-9-6. Parenteral pharmacy physical requirements

(a) **Area.** The parenteral pharmacy shall have an area designated for the preparation of sterile therapeutic preparations. This area must be designed to avoid unnecessary traffic and airflow disturbances from activities within the controlled facility. It shall be used only for the preparation of sterile therapeutic preparations. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper access of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security.

(b) **Equipment and supplies.** The parenteral pharmacy shall contain the following equipment and supplies:

(1) Appropriate environmental control devices capable of maintaining at least Class 100 environmental conditions in the work space where critical objects are exposed and critical activities are performed during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal flow of HEPA-filtered air. These products should indicate that they meet Federal Standard 209E et seq.;

(2) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

(3) Appropriate disposal container for used needles, syringes, etc., and if applicable, appropriate disposal containers for cytotoxic waste from the preparation of chemotherapy agents, and infectious wastes from patients' homes;

(4) When cytotoxic products are prepared, appropriate environmental control which includes appropriate biohazard (biological or Class II) safety cabinet. This cabinet should be certified to meet NSF Standard 49;

(5) Refrigerator/freezer with a thermometer;

(6) Appropriate delivery containers suitable to minimize temperature fluctuation;

(7) Infusion devices, if applicable;

(8) Disposable needles, syringes, and other supplies needed for aseptic admixture;

(9) Disinfectant cleaning solutions; and,

(10) Hand-washing agent with bactericidal action.

(c) **Access.** For security purposes, no one may have access to the parenteral pharmacy in the absence of an Oklahoma registered pharmacist.

(d) **Reference materials.**

(1) The parenteral pharmacy shall have, in addition to the library reference material required for retail licensure, one or more reference materials from the following list:

(A) Handbook of Injectable Drugs (ASHP reports)

(B) King's Guide to Parenteral Admixtures

(C) Procedures for Handling Cytotoxic Drugs (ASHP)

(D) MicroMedex

(E) Lexicomp

(2) The following information is for reference purposes only, these standards are not required to be maintained by or in the pharmacy.

(A) The NSF Standard 49 may be obtained from the National Safety Foundation in Ann Arbor, MI (734) 769-8010.

(B) The Federal Standard 209E et seq. may be obtained from General Services Administration or the Institute of Environmental Sciences, Mount Prospect, IL (708) 255-1561.

### SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL

#### 535:15-13-5. Supervision of pharmacy technicians

(a) All tasks performed by pharmacy technicians must be in a licensed pharmacy in Oklahoma and must be accomplished under the immediate and direct supervision of a pharmacist who is currently licensed by the Board. Failure by the licensed pharmacy and pharmacist manager (PIC) to provide adequate supervision; and failure of a pharmacist to adequately supervise a technician is a violation of these rules. An intern cannot supervise a technician.

(b) A pharmacy technician may perform certain non-judgmental functions of dispensing as enumerated in this Subchapter, provided that whenever the pharmacist leaves the prescription department, other than for in-pharmacy counseling of a patient, all dispensing functions listed shall cease.

(c) A ratio of no more than two pharmacy technicians per supervising pharmacist on duty shall be maintained.

(d) A pharmacy intern working in the pharmacy will not affect or change this ratio.

(e) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. An intern cannot certify the completion of a technician filled prescription.

#### 535:15-13-8. Technician annual permit requirement

(a) Each pharmacy technician in Oklahoma shall obtain a permit annually before practicing as such. A pharmacy technician must be employed in a licensed pharmacy to be eligible to renew their pharmacy technician permit.

(1) Upon meeting the qualifications listed in 535:15-13-4 and 535:25, applicants shall apply for a pharmacy technician permit on the form provided by the Board accompanied by such fee authorized by the legislature and in the agency fee schedule.

(2) After the pharmacy technician has completed their portion of the application they must submit it to the pharmacy manager or designated pharmacist who has conducted the technician training for review and signature.

(3) The pharmacy manager or designated pharmacist must first verify the applicant's completion of Phase I of the Board approved pharmacy technician training program. The signature by the pharmacist verifying technician training indicates that there is written training verification in the pharmacy available for Board inspection.

(4) Each pharmacy technician who desires to continue to work as a tech shall annually, on or before the last day of the registrants' birth month, send to the Board of Pharmacy such fee authorized by the legislature and in the agency fee schedule, with a completed Board application signed by the supervising pharmacist and the technician. Renewal notice will be sent to the technician's address on file in the Board office either electronically or by mail.

(b) The Board shall, at a minimum, consider the following factors in reviewing qualifications of persons who apply for a pharmacy technician permit within the state:

(1) any drug or alcohol related convictions arrest, charge, plea of nolo contendere, or conviction, or deferred sentence, for any misdemeanor or felony offense of the applicant under any federal, state, or local laws;

(2) the furnishing of any false or fraudulent material in any application made to the Board;

(3) suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant ~~for the distribution of any drugs, including controlled substances;~~

(4) compliance with permitting requirements under previously granted permits, if any; and,

(5) any use or abuse of an illegal CDS substance or a positive drug screen for such CDS substance or its' metabolite; and,

(6) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(c) The Board shall have the right to deny a permit to an applicant if it determines that the granting of such a permit would not be consistent with the public health and safety.

**TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY****CHAPTER 20. MANUFACTURERS, PACKAGERS AND WHOLESALERS****SUBCHAPTER 3. MANUFACTURERS****535:20-3-6.3. Security**

- (a) Each facilities used for manufacturing shall be secure from unauthorized entry.
- (1) Access from outside the premises shall be kept to a minimum and be well-controlled.
  - (2) The outside perimeter of the premises shall be well-lighted.
  - (3) Entry into areas where drugs are held shall be limited to authorized personnel.
- (b) All facilities shall be equipped with an alarm system to detect entry after hours.
- (c) All manufacturers shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (d) All manufacturers shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:
- (1) The manufacturer must not ship the customer's order if the order is confirmed as suspicious;
  - (2) Each manufacturer shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,
  - (3) Manufacturers shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.

**SUBCHAPTER 5. PACKAGERS****535:20-5-6.3. Security**

- (a) Each facility used for packaging shall be secure from unauthorized entry.
- (1) Access from outside the premises shall be kept to a minimum and be well-controlled.
  - (2) The outside perimeter of the premises shall be well-lighted.
  - (3) Entry into areas where drugs are held shall be limited to authorized personnel.
- (b) All facilities shall be equipped with an alarm system to detect entry after hours.
- (c) All packagers shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (d) All packagers shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:
- (1) The packager must not ship the customer's order if the order is confirmed as
  - (2) Each packager shall notify the Board, within ten (10) days, if an order is confirmed as suspicious.

**SUBCHAPTER 7. WHOLESALERS AND PEDIGREE RULES****535:20-7-7.3. Security and anti-counterfeiting**

- (a) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
- (1) Access from outside the premises shall be kept to a minimum and be well-controlled.
  - (2) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- (b) All facilities shall be equipped with an alarm system to detect entry after hours.
- (c) All facilities shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. All facilities shall be equipped with a security system that will provide suitable protection against theft, counterfeiting, and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (d) All facilities-wholesalers shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:
- (1) The wholesaler must not ship the customer's order if the order is confirmed as suspicious;
  - (2) Each wholesaler shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,
  - (3) Wholesalers shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.
- (e) If a wholesaler has reason to believe, based on the totality of the facts and circumstance, that any drug purchased is counterfeit, suspected of being counterfeit, mis-branded, or adulterated, the purchasing wholesaler must authenticate the pedigree.

**535:20-7-9.1. Prohibited Conduct**

The following shall be considered prohibited conduct and be a violation of these rules:

- (1) Engaging in the wholesale distribution of drugs
  - (A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate pedigree and/or failure to authenticate a pedigree, when required;
  - (B) and destroying, altering, concealing, or failing to maintain complete and accurate pedigree concerning any drug in their possession, when required;
  - (C) and having possession of drug pedigree documents required by the board and failing to authenticate the matters contained in the documents as required, and nevertheless distributing or attempting to further distribute drugs;
  - (D) with intent to defraud or deceive, falsely swearing or certifying that they have authenticated any documents related to the wholesale distribution of drugs;
  - (E) and forging, counterfeiting, or falsely creating any pedigree, falsely representing any factual matter contained on any pedigree, or knowingly omitting to record material information required to be recorded in a pedigree;
  - (F) and knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, in wholesale distribution; or,
  - (G) and selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s) in a wholesale distribution.
- (2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).
- (3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.
- (4) Manufacturing, purchasing, selling, delivering or bringing into the state contraband drug(s), or any one who illegally possesses any amount of contraband drug(s); or,
- (5) Any violation of the rules of registrant conduct in 535:25:9 is prohibited conduct.
- (6) Failing to maintain suspicious order monitoring records in a suspicious order monitoring program; and failing to notify the Board, within ten (10) days, of confirmed suspicious orders.

**SUBCHAPTER 9. MEDICAL GAS SUPPLIERS AND DISTRIBUTORS****535:20-9-3. Medical gas suppliers**

- (a) **Licensing requirement.** Before conducting interstate and/or intrastate transactions in Oklahoma, a medical gas supplier shall register annually with the Board of Pharmacy.
  - (1) A medical gas supplier permit is only valid for the name, ownership and location listed on the permit. Changes of name, ownership or location shall require a new medical gas supplier permit.
  - (2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)
  - (3) Each location shall possess a medical gas supplier permit. A medical gas supplier permit entitles the permit holder to store and supply medical gas (prescription drugs) at the licensed location.
- (b) Permits shall be issued only to those medical gas suppliers who satisfy the provisions of:
  - (1) Title 59, O.S., Section 353.18 (B)(1)(2) et seq.,
  - (2) All medical gas supplier applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.
  - (3) Applicants shall be registered with the federal Food and Drug Administration (FDA) and meet the federal requirements to handle medical gas.
  - (4) The Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or,
  - (5) Any other applicable federal, state, or local laws and regulations.
- (c) **Minimum required information for licensure.** The minimum required information for medical gas supplier licensure shall be as follows, Medical gas supplier applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:
  - (1) The name, full business address, and telephone number;
  - (2) All trade or business names used by the manufacturer applicant;
  - (3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;
  - (4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);
  - (5) The name(s) of the owner and/or operator of the manufacturer applicant; and
  - (6) Any other information the Board deems necessary to protect the public health.
- (d) **Minimum qualifications.** Medical gas suppliers must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(1) Medical gas suppliers must conform to all applicable federal, state or local laws and regulations.

(2) The minimum qualifications shall be the same as those set forth in 535:25 and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in the supplying of medical gases:

(A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;

(B) Any felony convictions of the applicant under federal, state, or local laws;

(C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;

(E) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,

(H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

(e) **Personnel.** Personnel employed by medical gas suppliers shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

(f) **Minimum requirements for storage, handling, and records.** Medical gas suppliers must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

(1) The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.

(A) All medical gas suppliers of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.

(B) All medical gas suppliers shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(C) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(i) Be licensed by the Board;

(ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(iv) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(v) Be maintained in a clean and orderly condition; and,

(vi) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Medical gases housed by a medical gas supplier shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(g) **Prescription requirement.** Medical gas suppliers shall not supply medical gas without a drug order. Drug orders may be issued for institutional or licensed medical practitioner office use as well as to a patient.

(1) An original or copy of a prescription drug order must be kept at the licensed location supplying the medical gas.

(2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.

(h) **Minimum requirements for storage, handling, and records for medical gas.** The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.

(1) **Security.** Each facility used for medical gases shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well-controlled.

(B) The outside perimeter of the premises shall be well-lighted.

(C) Entry into areas where drugs are held shall be limited to authorized personnel.

(D) All medical gas suppliers shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. All facilities shall be equipped with a

~~security system that will provide suitable protection against theft and diversion.~~ When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All medical gas suppliers shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:

(i) The medical gas supplier must not ship the customer's order if the order is confirmed as suspicious;

(ii) Each medical gas supplier shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,

(iii) Medical gas suppliers shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.

(2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(A) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.

(C) The recordkeeping requirement in this Chapter for medical gas suppliers shall be followed for all stored drugs.

(3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.

(4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas supplier shall consider, among other things:

(i) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(B) The recordkeeping requirements for medical gas suppliers in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

(5) **Recordkeeping.** Medical gas suppliers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(C) Each medical gas supplier should maintain an ongoing list of persons with whom they do business.

(6) **Written policies and procedures.** Medical gas suppliers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas suppliers shall include in their written policies and procedures the following:

(i) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(I) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

(II) Voluntary action by the medical gas supplier to remove defective or potentially defective drugs from the market; or

- (II) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.
- (B) A procedure to ensure that medical gas suppliers prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.
- (C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.
- (i) This procedure shall provide for written documentation of the disposition of outdated drugs.
- (ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.
- (7) **Responsible persons.** Medical gas suppliers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
- (8) **Compliance with federal, state and local laws.** Medical gas suppliers shall operate in compliance with applicable federal, state, and local laws and regulations.
- (A) Medical gas suppliers shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.
- (B) Medical gas suppliers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.
- (9) **Salvaging and reprocessing.** Medical gas suppliers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

#### **535:20-9-4. Medical gas distributors**

- (a) **Licensing requirement.** Before conducting interstate and or intrastate transactions in Oklahoma, a medical gas distributor shall register annually with the Board of Pharmacy.
- (1) A medical gas distributor permit is only valid for the name, ownership and location listed on the permit. Changes of name, ownership or location shall require a new medical gas distributor permit.
- (2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)
- (3) Each location shall possess a medical gas distributor permit. Medical gas distributor permit entitles the permit holder to store and distribute medical gas (prescription drugs) at the licensed location.
- (b) **Permits.** Permits shall be issued only to those medical gas distributors who satisfy the provisions of:
- (1) Title 59, O.S., Section 353.18 (B)(1)(2) et seq.,
- (2) All medical gas distributor applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.
- (3) Applicants shall be registered with the federal Food and Drug Administration (FDA) and meet the federal requirements to handle and wholesale medical gas.
- (4) The Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or,
- (5) Any other applicable federal, state, or local laws and regulations.
- (c) **Minimum required information for licensure.** The minimum required information for medical gas distributors licensure shall be as follows, Medical gas distributor applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:
- (1) The name, full business address, and telephone number;
- (2) All trade or business names used by the manufacturer applicant;
- (3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;
- (4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);
- (5) The name(s) of the owner and/or operator of the manufacturer applicant; and
- (6) Any other information the Board deems necessary to protect the public health.
- (d) **Minimum qualifications.** Medical gas distributors must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.
- (1) Medical gas distributors must conform to all applicable federal, state or local laws and regulations.
- (2) The minimum qualifications shall be the same as those set forth in 535:25 and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in medical gas distribution:
- (A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;
- (B) Any felony convictions of the applicant under federal, state, or local laws;
- (C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;

- (D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;
- (E) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;
- (F) Compliance with licensing requirements under previously granted licenses, if any;
- (G) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,
- (H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

(e) **Personnel.** Personnel employed by medical gas distributors shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

(f) **Minimum requirements.** Medical gas distributors must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

(1) The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas distributors and their officers, agents, representatives, and employees.

(A) All medical gas distributors of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.

(B) All medical gas distributors shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(C) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(i) Be licensed by the Board;

(ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space, equipment, and security conditions;

(iv) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(v) Be maintained in a clean and orderly condition; and,

(vi) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Medical gases housed by a medical gas distributor shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(g) **Prescription requirements.** Medical gas distributors shall distribute only to an entity licensed to receive medical gas or upon a practitioner's drug order. A pharmacy, dentist, or licensed practitioner's practice license verifies their authority to receive Rx Only medical gases.

(1) An original or copy of a prescription drug order must be kept at the licensed location distributing the medical gas.

(2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.

(3) Distributors that sell to licensed medical gas suppliers must keep an updated copy of each supplier's license on file.

(h) **Minimum requirements for storage, handling and records for medical gas Rx Only drugs.** The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas distributors and their officers, agents, representatives, and employees.

(1) **Security.** Each facility used for medical gases shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well-controlled.

(B) The outside perimeter of the premises shall be well-lighted.

(C) Entry into areas where drugs are held shall be limited to authorized personnel.

(D) All medical gas distributors shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All medical gas distributors shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:

(i) The medical gas distributor must not ship the customer's order if the order is confirmed as suspicious;

(ii) Each medical gas distributor shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,

(iii) Medical gas distributors shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.

(2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(A) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.

(C) The recordkeeping requirement in this Chapter for medical gas distributors shall be followed for all stored drugs.

(3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.

(4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas distributors shall consider, among other things:

(i) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(B) The recordkeeping requirements for medical gas distributors in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

(5) **Recordkeeping.** Medical gas distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(C) Each medical gas distributor should maintain an ongoing list of persons with whom they do business.

(6) **Written policies and procedures.** Medical gas distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas distributors shall include in their written policies and procedures the following:

(i) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(I) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

(II) Voluntary action by the medical gas distributor to remove defective or potentially defective drugs from the market; or

(III) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(B) A procedure to ensure that medical gas distributors prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

- (C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.
  - (i) This procedure shall provide for written documentation of the disposition of outdated drugs.
  - (ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.
- (7) **Responsible persons.** Medical gas distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
- (8) **Compliance with federal, state and local laws.** Medical gas distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
  - (A) Medical gas distributors shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.
  - (B) Medical gas distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.
- (9) **Salvaging and reprocessing.** Medical gas distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

**TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY****CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS****SUBCHAPTER 3. APPLICANTS, REGISTRANTS, AND APPLICATIONS****535:25-3-3. Qualifications and requirements for registrant applicants**

(a) The Board shall consider at least the following factors in reviewing the qualifications of registrants or applicants; ~~license for licensure~~ e.g.:

- (1) Any charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under any federal, state, or local laws relating to drug samples, drug distribution, or distribution of controlled substances;
- (2) Any felony charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under federal, state, or local laws;
- (3) The applicant's or registrant's past experience with prescription drugs, including controlled substances;
- (4) The furnishing by the applicant or registrant of fictitious, false, misleading, or fraudulent material in any application (original, new or renewal) or failing to provide information relevant to this application;
- (5) The suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant or registrant;
- (6) Compliance with licensing requirements under previously granted licenses, if any;
- (7) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section;
- (8) Abuse of alcohol or habit-forming drugs, or use of illegal CDS drugs or positive drug screen for such illegal substance or its' metabolite;
- (9) Practicing as a registrant without reasonable skill and safety by reason of use and/or abuse of drugs, narcotics, chemicals or any other type of material, or as a result of any mental or physical condition; and,
- (10) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The applicant shall be forthright and open in the provision of information to the Board in the application process. No license, permit or certificate shall be awarded to an applicant who does not provide the Board with complete open and honest responses to all requests for information.

(c) The applicant shall be candid in regards to providing information related to any academic misconduct, malpractice, legal, or disciplinary action.

(d) The applicant shall fully and completely disclose ownership of any pharmacy, wholesaler, manufacturer packager, medical gas supplier or medical gas distributor or any other person licensed under Title 59 O.S. Section 353.18.

(e) The Board shall have the right to deny a license to an applicant or registrant if it determines that the granting of such a license would not be consistent with the public health and safety.

**SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT****535:25-9-8. Failure to establish and maintain effective controls**

(a) Failure to establish and maintain effective controls to prevent prescription errors is a violation of registrant conduct.

(b) Failure to establish and maintain effective controls against the diversion of prescription and/or controlled dangerous drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules is a violation of registrant conduct.

(c) The sale of dangerous drugs to a person or entity not eligible to receive such drugs is a violation of registrant conduct.

(d) The purchase of dangerous drugs from a person or entity not eligible to possess such drugs is a violation of registrant conduct.

(e) Failing to establish and maintain suspicious order monitoring records in a suspicious order monitoring program; and failure to notify the Board of confirmed suspicious orders.

(f) It is a violation to ship orders that are confirmed as suspicious.