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Table of Contents

Agency/Action/Subject Index

Rules Affected Index

[(E) = Emergency action]

Agency/Title Index

[Assigned as of 9-1-21]

An agency may promulgate rules on a permanent basis upon "final adoption," as defined in 75 O.S., Section 250.3(5), of the proposed rules.

Permanent rules are effective ten days after publication in the *Register*, or on a later date specified by the agency in the preamble of the permanent rule document.

Permanent rules are published in the *Oklahoma Administrative Code*, along with a source note entry that cites the *Register* publication of the finally adopted rules in the permanent rule document.

For additional information on the permanent rulemaking process, see 75 O.S., Sections 303, 303.1, 308, 308.1 and 308.3.

TITLE 5. OKLAHOMA ABSTRACTORS BOARD
CHAPTER 2. ADMINISTRATIVE OPERATIONS

[OAR Docket #21-589]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 1. General Provisions
5:2-1-2. Definitions [AMENDED]
AUTHORITY:
Oklahoma Abstractors Board; 1 § 1-22 B. et. seq.
SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:
December 22, 2020
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n/a
INCORPORATIONS BY REFERENCE:
n/a
GIST/ANALYSIS:
The adopted revisions to Chapter 2 address the definition of Electronic Abstracts in support of technological changes in the industry.
CONTACT PERSON:
Katherine Smith, Oklahoma Abstractors Board, 421 NW 13th St., Suite 180, Oklahoma City, OK 73103, or Katherine.Smith@abstract.ok.gov.

PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF NOVEMBER 1, 2021:

SUBCHAPTER 1. GENERAL PROVISIONS

5:2-1-2. Definitions

In addition to the terms defined in the Oklahoma Abstractors Act, the definitions of the following words and terms shall be applied when implementing the Act and rules adopted by the Board:

"Abstractor" means the holder of an abstract license, certificate of authority, or temporary certificate of authority.

"Abstract Plant" shall consist of a set of records in which an entry has been made of all documents or matters which legally impart constructive notice of matters affecting title to real property, any interest therein or encumbrances thereon, which are filed, recorded and currently available for reproduction in the offices of the county clerk and the court clerk in the county for which such abstract plant is maintained including any satellite offices for the county clerk or district court clerk. Such records shall consist of:

(A) a "land index" in which notations of or references to any documents that describe the property affected are included, according to the property described or in which copies or briefs of all such documents that describe the property affected are sorted and filed according to the property described which is compiled from the instruments of record affecting real property in the county and recorded in the county offices and not copied or reproduced from any county index:

(B) a "name index" compiled from the following:

(i) records from the court clerk sorted or filed according to the names of the parties listed in the pending suits which shall include but not be limited to probates, divorces, dissolutions of marriage, guardianships, and civil suits affecting real property; and,

(ii) records from the county clerk sorted or filed according to the names of the parties listed in the documents which shall include but not be limited to liens, tax warrants, statements of judgment, and any other documents which legally impart constructive notice of matters affecting title to real property, any interest therein or encumbrance thereon which are filed, recorded, and currently available for reproduction in the office of the county clerk. The index shall be compiled from instruments of record affecting real property in the office of the county clerk and not copied from any county index.

"Billing Information" means a copy of an invoice reflecting all abstract related charges.

"Compile" means to arrange in an orderly and logical manner all recorded instruments relating to a particular chain of title of real property.

There are no limitations on the factors that the Board may consider in making its decision. If a favorable vote is received, the Board will have the authority to grant parole to the Inmate.

SUBCHAPTER 11. RECONSIDERATION

515:25-11-1. Re-docketing of offenders after denial

(a) **Non-violent.** Inmates convicted of a non-violent offenses shall be reconsidered one year after the date of denial.

(b) **Violent.** Offenders convicted of violent offenses that are denied parole by the Pardon and Parole Board or by the Governor shall be reconsidered in accordance with the following.

(1) Upon the completion of one-third (1/3) of the sentence, unless the one-third date is within twenty-four months of the initial consideration. If the one-third date is within twenty-four months of the initial consideration then the offender will be reconsidered two years from the date of denial; or

(2) Once the offender has passed their one-third date, reconsideration shall be three years from the date of denial, unless the offender is within one year of discharge; or

(3) One year prior to discharge.

(c) **Set off reconsideration.** The members of the Pardon and Parole Board may with a majority vote set off any offender's reconsideration for up to five years.

SUBCHAPTER 13. REVOCATION [RESERVED]

[OAR Docket #21-673; filed 7-7-21]

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 10. PHARMACISTS; AND INTERNS, PRECEPTORS AND TRAINING AREAS

[OAR Docket #21-616]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 3. Pharmacists
535:10-3-1.2. Violations of professional Conduct [AMENDED]
AUTHORITY:
Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.7, 353.9, 353.11, 353.16A, 353.18, 353.20, 353.22, 353.24 - 353.26, 364; Title 59 O.S. Sec. 6002; and Title 63 O.S. Section 2-312.25
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The revision in 535:1-3-1.2 implied (a) (19 and (20) removes "or misfills" and "the misfiling of a" to improve the clarity of the rule. The term "prescription errors" includes misfills.
CONTACT PERSON:
Dr. Marty Hendrick, Executive Director, Oklahoma State Board of Pharmacy, 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212, Phone number 405 521-3815

PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2021:

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 Oklahoma or abetting the violation of, or conspiring to violate, any provision or term of the Pharmacy Act, 59 O.S. Section 353 et seq., the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, 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.), and/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) Failure to have and follow a written drug diversion detection and prevention policy and procedure.

(4) 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 violate this rule. Such reports or records include only those which the pharmacist and/or pharmacy are required to make or file in his capacity as a licensed pharmacist or pharmacy.

(5) 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.
(6) Abuse of alcohol or habit-forming drugs, or use of an illegal CDS drug, or a positive drug screen for such illegal substance or its metabolite.
(7) Knowingly dispensing a prescription drug after the death of a patient.
(8) Knowingly billing or charging for quantities greater than delivered, or for a brand when a generic or a compounded product is dispensed.
(9) Submitting fraudulent billing or reports to a third party payor of prescription drugs.
(10) 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.
(11) 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.
(12) 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.
(13) The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.
(14) The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.
(15) 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.
(16) Violating patient confidentiality. This does not prevent pharmacies from providing drug therapy information to prescribers for their patients, nor does it prevent the provision of information as required by law.
(17) Theft while practicing pharmacy.
(18) Knowingly dispensing prescription drug refills after the death of a prescriber. (A limited quantity may be allowed for the patient's health and safety.)
(19) Failure to establish and maintain effective controls to prevent prescription errors~~or misfills~~.
(20) The ~~misfilling of a~~ prescription error that departs from the standards of care ordinarily exercised by a pharmacist with proof of actual injury not having to be established.
(21) Providing fictitious information, fraud or misrepresentation in applying for or procuring a license, preceptor certificate or permit, or in connection with applying for or procuring periodic re-registration or renewal of the same.
(22) Attempting to cheat or subverting the pharmacist licensure examination, law examination, preceptor examination or any other examination required by the Board.
(23) Allowing a non-pharmacist to perform any of the duties reserved to a pharmacist.
(24) Violation of any voluntary or Board ordered rehabilitation program for the impaired contract, e.g. OPHP contract.
(25) Failure of pharmacist or pharmacy manager (pharmacist in charge) to fulfill the responsibilities as set out in 535:15.
(26) Dispensing outdated prescription drugs.
(27) Failure to cooperate in Board investigations.
(28) Failure by the pharmacist to adequately supervise a pharmacy technician or a pharmacy intern; or 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.
(29) Auto refilling a prescription without the authorization of the patient or the patient's agent.

[OAR Docket #21-616; filed 6-28-21]

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 15. PHARMACIES

[OAR Docket #21-617]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 3. Pharmacies
535:15-3-2. Pharmacy responsibilities [AMENDED]
535:15-3-2.1. Shared services [NEW]
535:15-3-4. Physical requirements for pharmacies [AMENDED]
535:15-3-9. Non-resident pharmacies [AMENDED]
535:15-3-10. Inventory [AMENDED]
535:15-3-11. Prescription drugs [AMENDED]
535:15-3-12. Transfer of prescription refill information [AMENDED]
535:15-3-23. Board of Pharmacy inspections [NEW]
Subchapter 4. Remote medication order processing (RMOP) and RMOP pharmacy for hospital pharmacies
535:15-4-5. Responsibilities and duties of RMOP pharmacies and pharmacy manager [pharmacist in charge (PIC's)] [AMENDED]
Subchapter 5. Hospital Pharmacies
535:15-5-7.2. Supervision of pharmacy technicians [AMENDED]
535:15-5-7.4. Pharmacy technician tasks [AMENDED]
535:15-5-17. Board of Pharmacy inspections [AMENDED]
Subchapter 6. Hospital Drug Room
535:15-6-7. Drug distribution and control [AMENDED]
535:15-6-17. Board of Pharmacy inspections [AMENDED]
Subchapter 7. Drug supplier permits
535:15-7-3. Drug supplier restriction [AMENDED]
Subchapter 9. Sterile compounded preparations pharmacy permits
535:15-9-6. Pharmacy sterile~~Sterile~~ compounding ~~preparation pharmacy~~ physical requirements [AMENDED]
535:15-9-10. Cytotoxic or Hazardous drugs [AMENDED]
535:15-9-11. Quality assurance [AMENDED]
Subchapter 10. Good Compounding Practices
Part 1. Good Compounding Practices for non-sterile preparations
535:15-10-2. Definitions [AMENDED]
535:15-10-3. Pharmacist responsibilities [AMENDED]
535:15-10-8.2. Beyond-use dating [AMENDED]
535:15-10-8-3. Compounding record / log / formula worksheet [NEW]
535:15-10-10. Records and reports [AMENDED]
535:15-10-11. Pharmacy generated products requirements [REVOKED]
535:15-10-16. Violations [AMENDED]
Part 3. Good Compounding Practices for Sterile Preparations
535:15-10-52. Pharmacist responsibilities [AMENDED]
535:15-10-55. Drug compounding facilities [AMENDED]
535:15-10-68. Violations [AMENDED]

Subchapter 11. Charitable clinic pharmacies
535:15-11-1. Charitable clinic pharmacy license [AMENDED]
Subchapter 13. Pharmacy supportive personnel
535:15-13-1. Purpose [AMENDED]
535:15-13-3. Definitions [AMENDED]
535:15-13-5. Supervision of pharmacy technicians [AMENDED]
535:15-13-6. Duties [AMENDED]
Subchapter 19. Automation rules
535:15-19-4. Pharmacist verification [AMENDED]

AUTHORITY:

Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.7, 353.11 - 353.20.1, 353.22, 353.24 - 353.26 - 354, and 367.8

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GIST/ANALYSIS:

The revision in 535:15-3-2 (c) (2) removes the redundant words "or misfills" as errors includes misfills.

Added are the new Shared services rules in 535:15-3-2.1. These rules describe the requirements for pharmacies using and pharmacies providing shared services.

In 535:15-3-4. (a) (4), (5), and (6) regarding graduates, spatulas and mortals and pestles are removed in compliance with the Governors order to remove antiquated rule language. The old 535:15-3-4 (a) (7) - (14) are renumbered to 535:15-3-4 (a) (4) - (11).

The new 535:15-3-9 (j) adds prescription shipping requirements for non-resident pharmacies to maintain integrity of the medication throughout the delivery process.

The rule 535:15-3-10 (b) is changed to remove Inventory "at" renewal and replace with Inventory "for" renewal to improve clarity of the rule.

The new 535:15-3-11 (f) adds prescription shipping requirements for pharmacies to maintain integrity of the medication throughout the delivery process.

The revision in 535:15-3-12 (a) (1) (C) and (D) bring Board rules in compliance with federal DEA requirements by restricting the transfer of Controlled Dangerous Substances (CDS) refill information to between licensed pharmacists. The revision includes a reference to 535:15-3-12 [implied (a)] (1) (C) and (D) in 535:15-3-12 (2).

The new section 535:15-3-23 adds rules regarding Board of Pharmacy inspections.

Rule 535:15-4-5 [implied (a)] (1) (G) and (M) consolidate and removes duplicated language as required by the Governor's order. 535:15-4-5 [implied (a)] (1) (N) - (P) are renumbered to 535:15-4-5 (1) (M) - (O).

The rule revision in 535:15-4-5 (2) (B) (v) adds the word 'and'.

In 535:15-5-7.2 (e) changes the ratio of hospital pharmacy technicians from "shall not exceed two" to "shall not exceed four". In no case may it exceed a ratio that is safe and reasonable by certifying pharmacist.

The revision in 535:15-5-7.4 [implied (a)] removes the word "the" in (3) and adds a new (10) and (11) which describes where technician compounding requirements are located [535:15-10-52 (a) - (h)]. This enables technicians and their supervising pharmacist to locate the requirements for technician compounding. Then 535:15-5-7.4 (10) - (12) are renumbered to 535:15-5-7.4 (12) - (14).

Rule 535:15-5-17 modifies hospital pharmacy board inspections language to improve rule clarity.

The revision in 535:15-6-7 (b) adds a reference to 535:15-6-5 (b) and removes duplicated language in rules as required by Governor's order.

The rule 535:15-6-17 for hospital drug room inspections are changed to improve rule clarity.

Revisions in 535:15-7-3 [implied (a)] remove the PGP reference as PGP's are no longer allowed under FDA law and rules; and it corrects outsourcing 'pharmacy' to 'facility'.

Sterile compounding rules are revised to improve clarity in 535:15-9-6 (a) regarding cytotoxic or hazardous drugs, 535:15-9-10 regarding quality assurance and 535:15-9-11 regarding physical requirements also add references to Board rules and remove references to USP.

Revised 535:15-10-2 the isolator definition is changed to remove "microbially" and change it to 'microbial' to improve clarity. In 535:15-10-2 the PGP or pharmacy generated products definition is removed as Federal FDA law and rules no longer allow PGP's.

Revised 535:15-10-3 (b), (d), and (g) improve rule clarity, correct grammar and add reference to Board rules while removing USP references. The revision in 535:15-10-3 (c) (10) (B) (vi) - (vii) improves the clarity of this rule. The revision in 535:15-10-3 (d) add 'at least annually'. The revision in 535:15-10-3 (d) (2) and (3) more clearly describe reinstruction and reevaluation requirements. The change in 535:15-10-3 (c) (10) (B) (vi) - (vii) improves the clarity of this rule. The revision in 535:15-10-3 (d) add 'at least annually'; and 535:15-10-3 (d) (2) and (3) more clearly describe reinstruction and reevaluation requirements. While 535:15-10-3 (d) (4) is deleted.

The revision in 535:15-10-8.2 changes (c) and removes 535:15-10-8.2 (c) (1) and (c) (1) (A) and (B). It renumbers (c) (2) and (c) (3) to (c) (1) and (c) (2). The revision in 535:15-10-8.2 (d) - (f) more clearly describe BUD requirements for non-aqueous, water-containing oral and water containing formulations.

The new 535:15-10-8.3 describe the compounding record / log / worksheet and requirements regarding it.

The revision in 535:15-10-10 (a) removes the reference to USP and adds "State Board of Pharmacy regulations. 535:15-10-10 (c) revises to require perpetual inventory requirements for all CDS and bulk CDS utilized in compounding.

535:15-10-11 is revoked. Federal FDA law and rules no longer allow PGP's.

The revision in 535:15-10-16 remove violations references to USP and replace it with State Board of pharmacy regulations.

The change in 535:15-10-52 (c) (10) (vi) - (vii) improves rule clarity. The change in 535:15-10-52 (d) and (g) add references to Board rules and remove references to USP and to improve clarity of the rule. The change in 535:15-10-52 (d) (2) - (3) add reinstruction and reevaluation requirements for compounders. Rule 535:15-10-52 (d) (4) is deleted.

The change in 535:15-10-55 (b) sterile rules remove the reference to 535:15-10-3.1 (non-sterile) rules. 535:15-10-55 (g) (9) is deleted and (g) (10), (11) and (12) are moved to (g) (9), (10) and (11).

535:15-10-68 violations remove the USP reference and replaces it with reference to Board rules.

535:15-11-1 (f) adds requirements for charitable pharmacy use of mobile clinics and prohibit CDS from being placed in these charitable pharmacy mobile clinics.

The revision in 535:15-3-1 corrects the pharmacy supportive personnel cite from 59 OS Section '353.29' to '353.18A'.

The revision in 535:15-13-3 adds a new definition for 'Significant compounding'

The revision in 535:15-13-5 (a) (1) and (3) changes to State Board of Pharmacy regulations instead of rules.

535:15-13-5 (d) adds new language regarding significant compounding and technician to pharmacist requirements in compounding. The old 535:15-13-5 (d) and (e) are moved to 535:15-13-5 (e) and (f).

Rule 535:15-13-6 (b) adds new language in (7) - (8) regarding technician participation in non-sterile and sterile compounding respectively; and renumbers 535:15-13-6 (b) (7) - (9) to 535:1-13-6 (b) (9) - (11).

The revision in 535:15-19-4 adds '(a)' to existing rule then adds a new '(b)' which describe pharmacist verification requirements in automation.

CONTACT PERSON:

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED

FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2021:

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) **PIC.** Each pharmacy, in order to obtain and maintain a pharmacy license, must have a licensed pharmacist as the PIC.

(1) A PIC 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 PIC who fulfills these responsibilities is a violation of this code by both the pharmacy and PIC.

(3) No pharmacist may serve as a PIC in more than one pharmacy at a time. This requirement shall not apply to charitable pharmacies or hospital drug rooms.

(4) The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 40 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.

(5) A PIC shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the PIC.

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

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

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

(3) The pharmacy and/or PIC 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 PIC is terminated for such reason, the owner or other person in charge of the pharmacy shall notify the Board by certified mail.

(4) The pharmacy, pharmacist, and/or 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.

(5) The pharmacy, pharmacist and PIC 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 PIC 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 PIC,

(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.

(4) The pharmacy, pharmacist, and/or 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.

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

(e) **Responsibilities for personnel identification.** The PIC and the pharmacy are responsible to assure that the public is 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.

(f) **Written drug diversion detection and prevention.** The pharmacy, pharmacist, and/or PIC shall implement and follow a written drug diversion detection policy. The policy shall be available for Board review.

(g) **Inspections.** Pharmacies are subject to inspection. The Board and/or its authorized representatives may conduct on-site periodic routine inspections and investigations during reasonable business hours.

(h) **Remodel.** The pharmacy and the PIC are responsible to notify the Board in writing in advance of any remodel in

the pharmacy that would result in a change in square footage or additional storage areas. Such pharmacy shall be subject to inspection by the Board and shall be required to pay and inspection fee.

(i) **Closing of a Pharmacy.** The pharmacy and the PIC are responsible to notify the Board in writing within ten (10) days of closing a pharmacy. The notification shall include, but not be limited to:

(1) Date of closing
(2) Copy of final CDS inventory,
(3) Disposition of pharmacy records,
(4) Disposition of prescription drugs, and
(5) Return of pharmacy license.

(j) ~~**Notification of Theft**~~**Reporting.** The pharmacy and the PIC shall report any theft or significant loss of any drugs to the Board within one day of discovery. The pharmacy and the PIC must complete and submit a DEA 106 form for any theft or significant loss of controlled substances to DEA within the required time. A copy shall be sent to the Board within fourteen (14) days of the filing of the DEA form 106.

535:15-3-2.1. Shared services

(a) When used in this section, shared services shall have the following meaning unless the content clearly indicates otherwise: "**Shared services**" means data entry, interpreting the prescription or drug order, performing data entry verification, drug utilization review, or when necessary therapeutic intervention. Shared services, after completion, includes returning the processed order to the requesting pharmacy for order filling, final order verification, and delivery to the patient or patient's care-giver.

(b) Before participating in shared services, a pharmacy shall have a current Board issued resident retail pharmacy license and be located in Oklahoma.

(c) A pharmacy may provide or utilize shared services functions only if the pharmacies involved:

(1) Have the same owner, or
(2) Have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy statutes and rules; and,
(3) Share a common electronic file or technology that allows access to information necessary or required to perform shared services in conformance with the pharmacy act and the State Board of Pharmacy regulations.

(d) A licensed retail pharmacy engaged in shared services shall:

(1) Maintain manual or electronic records that identify, individually for each order processed, the name, initials, or identification code of each pharmacist, intern, and pharmacy technician who took part, as authorized by State Board of Pharmacy regulations, in the data entry, order interpretation, data entry verification, drug utilization review, final order verification, and when necessary therapeutic intervention performed at that pharmacy;
(2) The duties performed by pharmacists, interns and technicians in (d) (1) above shall be those as authorized in Title 59 and OAC 535;
(3) Report to the Board as soon as practical the results of any disciplinary action taken by another state's pharmacy regulatory agency involving shared services;
(4) Provide adequate security to protect the confidentiality and integrity of patient information; and,
(5) Provide access for inspection of any required record or information of any request by the Board or its designee.

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 in 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~~4) **Library.** There shall be the necessary library which has been prescribed and standardized by the Board in Section 535:15-3-6.

(~~8~~5) **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.

(~~9~~6) **Exempt narcotic book.** There shall be a book suitable for the registration of all sales of exempt narcotics if such are sold or dispensed.

(~~10~~7) **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.

(~~11~~8) **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.

(~~12~~9) **Containers.** There shall be sufficient stock of containers suitable for the dispensing of all prescriptions both for internal and external usage.

(~~13~~10) **Labels.** There shall be sufficient stock of labels both for the dispensing of prescriptions and the sale of medicines and chemicals. Label requirements are described in the Act.

(~~14~~11) **E-Prescribing of Controlled Substances (EPCS).** Any pharmacy that dispenses controlled dangerous substances shall have computer software that supports EPCS by January 1, 2019.

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;

(3) Comply with the Oklahoma Secretary of State requirements for conducting business in this state.

(4) Submit on initial licensure and on renewals a written report of an inspection conducted within the previous twenty-four (24) months by the non-resident's state or by any organization approved by the Board;

(5) Be in a commercial location and not a personal dwelling or residence;

(6) Submit on initial licensure the name and license number of an Oklahoma licensed pharmacist in charge (PIC) who is responsible for the non-resident's pharmacy compliance with Oklahoma laws. The name of the Oklahoma licensed PIC shall be reported to the Board, in writing, with each renewal and/or within 10 days of any change of such PIC.

(7) The pharmacy registrant may request, in writing, that the Board allow additional time for a new pharmacist-in-charge to get Oklahoma licensed in emergency or urgent situations. If the Board determines circumstances warrant they may grant up to a 90 day extension

(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 (also called 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. The PIC must also be licensed by the Board.

(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 of prescriptions or prescription medications and devices to Oklahoma residents.

(3) No pharmacist may serve as a PIC in more than one pharmacy at a time.

(d) **Inspections.** Non-resident pharmacies are subject to inspection and investigation. The Board may conduct on-site periodic routine inspections and investigations during reasonable business hours.

(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, IV, and V prescription records. These records shall be sent to the Oklahoma Prescription Drug Monitoring program as set out in Title 63 of the Oklahoma Statutes.

(f) **Counseling services.** Non-resident pharmacies shall provide accessible toll-free telephone counseling by 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 or registrant shall not increase the quantity of a prescription without the authorization of the prescriber. Unless specified otherwise by the prescriber, a pharmacist may exercise his professional judgement to dispense up to a ninety (90) day supply for maintenance non-controlled dangerous drugs, if sufficient quantity has been authorized by the prescriber on the original prescription, including any refills. Increasing controlled dangerous drugs or any medications that require reporting to the controlled substance database are prohibited. See 59 OS 353.20.2

(h) **Written drug diversion detection and prevention.** The pharmacy and the pharmacy manager shall implement and follow a written drug diversion detection and prevention policy and procedure. This policy and procedure shall be available for Board review.

(i) **Pharmacy refrigerator and freezer temperature logs.**

(1) All refrigerators and freezers used to store medications shall have a sensor or thermometer capable of reading internal temperatures.

(2) The internal temperatures maintained in the refrigerators and freezers shall be appropriate for the products stored.

(3) Temperatures in refrigerators and freezers shall be logged twice daily (AM and PM) on days the pharmacy is open for business or shall have continuous temperature monitoring.

(A) Pharmacy name, date, time, temperature and staff person taking reading shall be logged at a minimum for paper logs.

(B) Temperature logs shall be maintained on paper or electronically for two years and be available for inspection.

(4) If there is a temperature reading that falls outside of appropriate ranges, a notation must be made on the temperature log detailing the corrective measures which were taken.

(5) It is the PIC's responsibility to review the temperature readings to ensure compliance with appropriate storage temperatures.

(j) **Prescription shipping.** The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(1) No prescription shipped to a citizen of Oklahoma should have a temperature excursion that exceeds the temperature storage conditions outlined in the package insert or by the manufacturer of the drug product.

(2) A pharmacy or pharmacist shall refuse to deliver by mail or common carrier a prescription drug which, in the professional opinion of the pharmacy or pharmacist, may be therapeutically compromised by delivery by mail or common carrier.

(3) A mail order or non-resident pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy.

535:15-3-10. Inventory

(a) **Change of ownership or pharmacy manager inventory.** When changing the owner or pharmacy manager, a controlled drug inventory must be taken and sent to the Board within ten (10) days. (It is recommended that both the out-going and in-coming managers sign the inventory). The inventory must indicate the new manager's name and registration number. The inventory should indicate the former manager's name, registration number and current employment, if known.

(b) **Inventory for~~at~~ renewal.** An inventory of all controlled dangerous substances (CDS) must be taken between May 1 and July 1 of each year. A copy of this inventory will be included with the pharmacy renewal application.

(c) **Board requested inventory.** In the case of suspected loss, theft, and/or diversion, a pharmacy may be requested by the Board to conduct an inventory (all, or in part), within ten (10) days and submit a copy to the Board.

(d) **Closing Inventory.** A controlled drug inventory must be taken and a copy sent to the Board within ten (10) days of the closing of the pharmacy. No prescription drugs may be maintained in an unlicensed location.

535:15-3-11. Prescription drugs

(a) **Authorization; Original and refill prescriptions.** No prescription for a "dangerous drug" (as defined in 59 O.S., Section 353.1) shall be filled or refilled without the authorization of a prescriber licensed by law to prescribe within the scope of his practice.

(b) **Refill time limit; Non-CDS prescriptions.** Prescriptions may only be refilled as authorized by the prescriber. There shall be a maximum of one year from date of original prescription that the prescription may be refilled. After that time a new prescription shall be required.

(c) **Drug expiration dating.** All outdated prescription drugs shall be removed from the active inventory area upon expiration and cannot be used to fill prescriptions. The removal from the pharmacy of these expired drugs must occur within six months of expiration either by shipping to a reverse distributor for destruction or by being returned to the supplier.

(d) **Prescription integrity.** A pharmacy or registrant shall not increase the quantity of a prescription without the authorization of the prescriber. Unless specified otherwise by the prescriber, a pharmacist may exercise his professional judgment to dispense up to a ninety (90) day supply for a maintenance non-controlled dangerous drug, if sufficient quantity has been authorized by the prescriber on the original prescription, including any refills. Increasing controlled dangerous drugs or any medications that require reporting to the controlled substance database are prohibited. See 59 OS 353.20.2 (A) (B)

(e) **Refills for patient safety.** The following prescription medications and devices are included in an inclusionary formulary of potentially life-saving prescription and devices authorized under 59 OS 353.20.2 (C) (4) which may be refilled by a pharmacist without an authorization in accordance with the requirements in 59 OS Section 353.20.2(C):

(1) Insulin and any devices or supplies necessary for the administration of insulin;

(2) Glucometers and any devices or supplies necessary for the operation of the glucometer;

(3) Rescue inhalers and any devices utilized that are necessary for the administration of a rescue inhaler;

(4) Inhalers for chronic asthma and chronic obstructive pulmonary disease (COPD) and any devices or supplies necessary for administration;

(5) Medication for nebulizers that treat acute and chronic pulmonary conditions and any devices necessary for administration; or

(6) Ophthalmic products for topical treatment of chronic conditions.

(7) No CDS medications can be dispensed pursuant to 353.20.2 (C) (4).

(8) A form will be posted on the Board website for the Pharmacist to complete to document attempts to obtain refill authorization from the prescriber by the patient and by the pharmacist. This completed form shall be maintained in the pharmacy and be available for inspection.

(f) **Prescription shipping.** The pharmacy shall maintain and use adequate storage or shipping containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(1) No prescription shipped to a citizen of Oklahoma should have a temperature excursion that exceeds the temperature storage conditions outlined within the package insert or by the manufacturer of the drug product.

(2) A pharmacy or pharmacist shall refuse to deliver by mail or common carrier a prescription drug which, in the professional opinion of the pharmacy or pharmacist may be therapeutically compromised by delivery by mail or common carrier.

(3) A mail order or non-resident pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy.

535:15-3-12. Transfer of prescription refill information

For the purpose of refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements:

(1) The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies:

(A) For up to the number of originally authorized refills remaining on 'Rx Only' drugs that are not controlled; or

(B) On a **one-time** basis only, for original prescriptions and refills for a controlled dangerous substance (CDS) listed in Schedules III, IV or V for the purpose of refill dispensing. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(C) CDS prescription transfers must be communicated directly between two licensed pharmacists and cannot be done by an intern.

(D) Non controlled prescription transfers must be communicated directly between two licensed pharmacists and /or licensed interns.

(2) The transfer as allowed in 535:15-3-12 (1) (C) and (D) above must be:

(A) Communicated orally directly between two licensed pharmacists and / or licensed interns; or,

(B) The prescription transfer information shall be faxed from one pharmacy to another. Upon receipt of the faxed information, a licensed pharmacist or licensed intern at the receiving pharmacy shall communicate receipt of the prescription transfer information orally directly with a licensed pharmacist or licensed intern at the originating pharmacy; and shall document the communication. The original prescription transfer faxed information shall be printed and stored for:

(i) A non-controlled drug substance prescription in the same manner as a non-controlled drug substance prescription or shall be electronically stored;

(ii) A controlled drug substance prescription in the same manner as a controlled drug substance prescription;

(3) Both the original and the transferred prescription drug order must be maintained for a period of five years from the date of last refill;

(4) The pharmacist transferring the prescription drug order information shall:

(A) Write the word "void" on the face of the invalidated prescription drug order; and,

(B) Record on the reverse of the invalidated prescription drug order the following information:

(i) The name and address of the pharmacy to which such prescription drug order is transferred;

(ii) The last name and registration number of the pharmacist receiving the prescription drug order information;

(iii) The last name and registration number of the pharmacist transferring the prescription drug order information;

(iv) The date of the transfer; and,

(C) As required in federal DEA rules, exchange and document the sending and receiving pharmacy DEA number on a controlled dangerous substance prescription transfer.

(5) The pharmacist receiving the transferred prescription drug order information shall:

(A) write the word "transfer" on the face of the transferred prescription drug order, see 535:15-3-12 (8); and,

(B) Record on the transferred prescription drug order the following information:

(i) The date of the original prescription (refills are allowed only as prescribed for a one year maximum from original prescription date on non-scheduled, as stated in 535:15-3-11 (b) et seq. and up to five refills for no more than six months on Schedule III-V, as stated in 475:30-1-11 (a));

(ii) The original prescription number and the number of refills authorized on the original prescription drug order;

(iii) The number of valid refills remaining and the date of last refill;

(iv) The name and address of the pharmacy from which such prescription information is transferred;

(v) The last name and registration number of the pharmacist transferring the prescription drug order information; and,

(C) As required in federal DEA rules, exchange and document the sending and receiving pharmacy DEA number on a controlled dangerous substance prescription transfer.

(6) Transferring pharmacies with computer systems shall invalidate the prescription drug order in their system for purposes of filling or refilling, but shall maintain the information for refill history purposes;

(7) If the computer system has the capacity to store all of the information required in (4) and (5) of this paragraph, the pharmacist is not required to record this information on the original or transferred prescription drug order.

(8) The computer system used by the pharmacy receiving the transfer must be able to show that a CDS or scheduled prescription is a transferred prescription. (This is to prevent the possible second transfer of a Scheduled prescription in violation of federal law and 535:15-3-12 (1).)

535:15-3-23. Board of Pharmacy inspections

(a) The Board's qualified designee may inspect all aspects of the management and operation of all pharmacies licensed by the state of Oklahoma.

(b) This allows verification of compliance with the law, the State Board of Pharmacy regulations, and such other standards as may be appropriate to insure that the health, safety and welfare of patients serviced by the pharmacy.

(c) Any discrepancies or deficiencies noted at inspection shall be corrected.

SUBCHAPTER 4. REMOTE MEDICATION ORDER PROCESSING (RMOP) AND RMOP PHARMACY FOR HOSPITAL PHARMACIES

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;~~either hard-copy or online references as described in 535:15-5-9 (1) (B) and 535:15-5-9 (1) (C);

(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~~N) Establish and maintain records and reports; and,

(~~P~~O) 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; and

(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 (a) (16); 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 535:15-4-5 (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 licensure in Oklahoma, and the address of each location where records of any and all orders processed for the hospital will be maintained.

SUBCHAPTER 5. HOSPITAL PHARMACIES

535:15-5-7.2. Supervision of pharmacy technicians

(a) All tasks performed by pharmacy technicians in the pharmacy must be accomplished under the immediate supervision of an Oklahoma currently licensed pharmacist.

(b) Non-dispensing and non-compounding tasks performed in the floor stock or "satellite" areas must be under the supervision of the pharmacist.

(c) A pharmacy technician may perform certain non-judgmental tasks of dispensing as enumerated in this Subchapter provided that whenever the pharmacist leaves the pharmacy, all dispensing shall cease. Certified medical orders may be delivered during a pharmacist's absence.

(d) The pharmacist shall include in the Policy and Procedure Manual the specific scope of responsibilities or procedures delegated to pharmacy technicians and the in-service training of pharmacy technicians.

(e) The ratio of pharmacy technicians to supervising pharmacists shall be set by the Director of Pharmacy and should be a ratio that would be considered safe and reasonable by the certifying pharmacist. The ratio shall not exceed four~~two~~ pharmacy technicians to one supervising pharmacist.

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

(g) A licensed pharmacy intern shall not supervise pharmacy technicians.

(h) The pharmacist shall do the final check and certification of the technical tasks performed by technicians. This certification shall be by means of the certifying pharmacist's signature, initial or other identifying mark on a record, the medication order and/or label.

535:15-5-7.4. Pharmacy technician tasks

Pharmacy technicians may perform the following tasks in a licensed hospital pharmacy facility in accordance with 535:15-5-7.2:

(1) ~~any~~Any tasks auxiliary supportive personnel are allowed to perform;

(2) ~~count~~Count and/or pour medications;

(3) ~~affix the~~Affix prescription label to the final container;

(4) ~~affix~~Affix auxiliary labels to the container as directed by the pharmacist;

(5) ~~assist~~Assist the pharmacist in the management of the controlled dangerous substance (CDS) inventory. The pharmacist remains responsible for completeness and accuracy;

(6) ~~fill~~Fill "Modified unit dose distribution systems", "Automated dispensing systems" and/or "Unit dose distributions systems";

(7) ~~prepackage~~ Prepackage and label multi-dose and unit-dose packages of medication as directed by pharmacist-established procedures for such, including selection of containers, labels and lot numbers, with provisions for the pharmacist to check the finished task prior to dispensing to the patient. (While a pharmacy technician may package and label the drug, the certification is the responsibility of the pharmacist.)

(8) ~~perform~~Perform bulk reconstitution of prefabricated non-injectable medication utilizing a pharmacist established procedure for the bulk reconstitution of prefabricated noninjectable medications.

(9) ~~perform~~Perform bulk compounding, including such items as sterile bulk solutions for small-volume injectables, sterile irrigation solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for other departments of the hospital facility. Such intermediate and large scale compounding may be done by a pharmacy technician through the use of a procedural manual and a system of in-process and final checks and controls developed or approved by the pharmacist and which are carefully and systematically enforced.

(10) Technician training and requirements for technician participation in non-sterile compounding is described in 535:15-10-3 (a) - (h).

(11) Technician training and requirements for technician participation in sterile compounding is described in 535:15-10-52 (a) - (h).

(12~~10~~) ~~prepare~~Prepare sterile compounded preparations utilizing a policy and procedure that addresses the verification of the pharmaceutical constituents, the prepared label and the final product by the pharmacist following documented training and demonstrated competency as required in OAC 535:15-10-52 (d).

(13~~11~~) Record ~~record~~ patient or medication information for later validation by the pharmacist pursuant to procedures which prevent the information from being utilized in any way until it is validated by the pharmacist. Exempt from the necessity of pharmacist validation shall

be records, such as financial, inventory control, etc., which can in no way affect the safety and accuracy of medication administration to patients.

(1412) Select ~~select~~ prepackaged and pre-labeled doses of medication from storage areas and place and transport to the patient area such doses in containers bearing a patient's name in a unit dose distribution system or a modified unit dose distribution system if the pharmacist personally checks and verifies by signature or initial all patient medication before it is administered to the patient.

535:15-5-17. Board of Pharmacy inspections

(a) The Board's qualified designee shall inspect all aspects of the management and operation of all hospital pharmacies in the State of Oklahoma. ~~,to verify~~

(b) This allows verification of compliance with the law, the State Board of Pharmacy regulations~~rules of this Title~~, and such other standards as may be appropriate to insure ~~that~~ the health, safety and welfare of patients of the facility serviced by the hospital pharmacy ~~are protected~~.

(c) Any discrepancies or deficiencies noted at inspection shall be corrected.

SUBCHAPTER 6. HOSPITAL DRUG ROOM

535:15-6-7. Drug distribution and control

(a) **General.** The PIC shall establish written procedures for the safe and efficient distribution of medicine products. A copy of such procedures shall be on hand for inspection by the Board.

(b) **Responsibility.** The PIC shall be responsible for the safe and efficient distribution, control, and accountability of drugs, see 535:15-6-5 (b). ~~The other professional staff of the hospital facility shall cooperate with the PIC in meeting this responsibility. The PIC shall be responsible for, at a minimum, the following:~~

~~(1) Competency education and training of nursing personnel concerning admixture of sterile compounded preparations, and incompatibility and provision of proper incompatibility information.~~

~~(2) Prepackaging and/or preparing of drug products including certification of unit dose.~~

~~(3) Establishing of specifications for procurement of all materials, including drugs, chemicals, and biologicals used within the hospital system, subject to approval of the appropriate committee of the hospital system.~~

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

~~(5) Maintaining and making available a sufficient inventory of medicines, 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.~~

~~(6) Reviewing records of all transactions of the hospital drug room required by applicable local, state, and federal law, necessary to maintain accurate control and accountability for all medicine materials.~~

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

~~(8) Developing a mechanism to implement the policies and decisions of the appropriate committees of the hospital that deal with drug distribution and drug utilization.~~

~~(9) Meeting all inspection and other requirements of the Act, and those rules and regulations applying to hospital drug rooms.~~

~~(10) Establishing floor stock guidelines for the safe and effective distribution of drugs intended for floor stock, and their subsequent administration.~~

~~(11) Fully cooperating with teaching and/or research programs in the hospital facility, if any.~~

~~(12) Prepackaging medications included in the hospital drug room formulary in 535:15-6-9.~~

(c) **Labeling.** Hospital drug room labeling requirements shall be as follows:

(1) **Labeling for use inside the hospital facility.** All drugs outside of the drug room intended for use within the facility shall be adequately labeled by the pharmacist or in their original container.

(2) **Labeling for use outside the hospital facility.** All drugs labeled by the pharmacist or licensed practitioner for after-hours dispensing to discharge or emergency room patients shall be labeled with the following:

(A) Name and address of the hospital facility,

(B) Date and identifying number,

(C) Name of the patient,

(D) Directions for use to the patient,

(E) Name of the prescriber,

(F) Initials of the dispenser,

(G) Required precautionary information regarding controlled substances,

(H) Such other accessory or cautionary information as may be required or desirable for proper use and safety to the patient, and,

(I) the name of the drug, its strength, and the number of units dispensed.

(3) **Sterile compounded admixtures.** When any drugs are added to sterile solutions or suspensions, such admixtures shall be labeled whether within or outside the direct personal supervision of a pharmacist. This label shall indicate the name and amount of the drug added, date and time of such addition, expiration date and time of admixture, and the initials of the persons (preparer and the verifier) responsible for the admixture.

(d) **Discontinued and outdated drugs.** The PIC shall develop and implement policies and procedures to insure that discontinued and outdated drugs, and containers with worn, illegible or missing labels are returned to the drug room for proper disposition.

(e) **Prescriber's orders.** Hospital drug room requirement regarding prescriber's orders shall be as follows:

(1) Drugs may be dispensed to specific patients only upon the written or verbal order of an authorized prescriber. A pharmacist or other authorized individual in a patient care area of the hospital facility must commit verbal prescriber's orders to writing.

(A) **Authorization.** The appropriate hospital committee shall designate those prescriber's authorized to issue and accept orders for hospital patients.

(B) **Requirements.** Orders for drugs for use by inpatients of the facility shall, at a minimum, contain the patient name and room number, drug name, strength, directions for use, any relevant stop date or time, order date and time, and prescriber's signature. A copy of the order is to be provided to the drug room from which the order is to be processed.

(2) Orders for drugs for outpatients shall be considered prescriptions and must fulfill all of the requirements of a prescription identified within the Pharmacy Practice Act; and state and federal law and rules.

(f) **Controlled drug accountability.** The hospital facility shall establish effective written procedures and maintain adequate records as required by law and rule regarding the use and accountability of controlled substances and such other drugs as the hospital may designate.

(g) **Drug recall procedures.** The PIC shall develop and implement a written recall procedure that can be readily activated which assures that drugs involved, inside or outside the facility, are returned to the hospital drug room for proper disposition. All actions taken in this area are to be properly documented.

(h) **Records and reports.** The PIC shall develop a mechanism for maintaining and submitting 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) Drug list or formulary of the hospital drug room as required by state health department rules,

(4) Controlled substance inventory,

(5) Ethyl alcohol inventory,

(6) Pharmacy and therapeutics committee minutes; and

(7) Reports and records as may be required by law, and the rules of this chapter.

535:15-6-17. Board of Pharmacy inspections

(a) The Board's qualified designee shall inspect all aspects of the management and operation of all hospital drug rooms in the State of Oklahoma~~., to verify~~

(b) This allows verification of compliance with the law, the State Board of Pharmacy regulations~~the rules of this Title~~, and such other standards as may be appropriate to insure ~~that~~ the health, safety and welfare of patients of the facility serviced by the hospital drug room~~ are protected~~.

(~~b~~ c) Any discrepancies or deficiencies noted at inspection shall be corrected.

SUBCHAPTER 7. DRUG SUPPLIER PERMITS

535:15-7-3. Drug supplier restriction

(a) Retail pharmacies shall not sell or otherwise supply or provide dangerous substances, prescription drugs, ~~or~~ controlled dangerous substances, ~~PGP~~ or a compounded preparation to a wholesaler, manufacturer or repackager, outsourcing facility~~pharmacy~~ or logistics provider. Return of a drug to the wholesaler from whom it was purchased is allowed.

(b) This restriction does not apply to packaging services provided to a pharmacy where the ownership of the pharmacy's drug does not change hands.

SUBCHAPTER 9. STERILE COMPOUNDED PREPARATIONS PHARMACY PERMITS

535:15-9-6. Pharmacy sterile ~~Sterile~~ compounding ~~preparation pharmacy~~ physical requirements

(a) Pharmacies and personnel who engage in ~~non-sterile or~~ sterile compounding are responsible for complying with ~~all aspects of USP Compounding Standards~~State Board of Pharmacy regulations~~ and these rules~~.

(b) Reference materials.

(1) The sterile compounding preparation 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

(B) King's Guide to Parenteral Admixtures

(C) Micromedex

(D) Lexicomp

(E) Applicable USP standards

(2) Electronic versions are acceptable.

535:15-9-10. Cytotoxic or Hazardous drugs

Pharmacies and personnel who engage in ~~non-sterile or~~ sterile compounding are responsible for complying with ~~all aspects of USP Compounding Standards~~State Board of Pharmacy regulations~~ and these rules~~.

535:15-9-11. Quality assurance

Pharmacies and personnel who engage in ~~non-sterile or~~ sterile compounding are responsible for complying with ~~all aspects of USP Compounding Standards~~State Board of Pharmacy regulations~~ and these rules~~.

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PREPARATIONS

535:15-10-2. Definitions

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

"**Beyond-Use Date (BUD)**" means the date and time, as appropriate, after which administration is not to begin of a compounded preparation; and such date is determined from the date the preparation is compounded.

"**Biological Safety Cabinet (BSC)**" means a ventilated cabinet for hazardous drugs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection meeting USP standards.

"**Compounder**" means a compounder is a pharmacist or anyone compounding under the direct supervision of a pharmacist pursuant to a prescription order by a licensed prescriber.

"**Compounding**" means compounding as defined in 59 O.S. Section 353.1 et seq.

"**Component**" means any ingredient used in the compounding of a drug preparation, including those that may not appear on the labeling of such a preparation.

"**Inordinate Amount**" means an amount of compounded drug that exceeds the amount a pharmacy anticipates may be used or dispensed before the BUD of the compounded drug and/or is unreasonable considering the intended use of the compounded drug.

"**Isolator**" means a device that is sealed or is supplied with air through a microbial~~microbially~~ retentive filtration system (HEPA minimum) and may be reproducibly decontaminated.

"**Labeling**" means all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term 'label' designates that part of the labeling on the immediate container.

"**Manufacturing**" means manufacturing as defined in 59 O.S. Section 353.1 et seq.

"**Personal Protective Equipment (PP**E)" means items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

~~"**Pharmacy Generated Preparations**" or "**(PGP)**" means a medical preparation that is prepared, packaged and labeled in a pharmacy that can be sold by the pharmacy without a prescription.~~

"**Preparation**" means an article compounded in a licensed pharmacy pursuant to the order of a licensed prescriber.

"**Product**" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

"**USP**" means "United States Pharmacopeia".

535:15-10-3. Pharmacist responsibilities

(a) All Pharmacists who engage in drug compounding, shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

(b) All pharmacists and personnel~~Every pharmacist~~ engaging in drug compounding shall be familiar with ~~all details of USP Compounding Standards~~State Board of Pharmacy regulations and should be familiar with patent regulations.

(c) The pharmacist has the responsibility to:

(1) Ensure the validity of all prescriptions

(2) Certify all prescriptions.

(3) Approve or reject all components, drug product containers, closures, in-process materials, and labeling.

(4) Ensure preparations are of acceptable strength, quality, and purity.

(5) Verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation.

(6) Prepare and review all compounding records to ensure that no errors have occurred in the compounding process.

(7) Ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.

(8) Ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and,

(9) Ensure only authorized personnel shall be in the immediate vicinity of the drug compounding operation.

(10) Perform final check of preparations prior to their release from the pharmacy.

(A) A check for compounding accuracy must ensure accuracy of the label and volumes or quantities of all drugs and solutions

(B) A visual examination procedure must ensure:

(i) Comparison with original order for initial dispensing;

(ii) Accuracy of calculations;

(iii) Use of proper solutions, additives and equipment;

(iv) Labels are complete;

(v) Proper assignment of beyond use date and time;

(vi) The integrity~~Integrity~~ of the container, including checking for visual defects;

(vii) Proper storage; and,

(viii) Absence of particulate matter, precipitates, turbidity, discoloration, evidence of contamination or other signs that the preparation should not be used.

(C) The pharmacist shall reject and destroy all preparations that do not pass the final examination.

(D) Pharmacists shall document final preparation examinations prior to releasing the Compounded Preparations from the pharmacy.

(d) The pharmacist-in-charge has the responsibility to ensure that all compounders who compound pharmaceuticals meet all requirements for training, testing and education set forth in Board~~these~~ regulations ~~and contained in the regulations set forth in USP standards~~at least annually.

(1) Competency shall be demonstrated prior to preparing any products for patient use, and

(2) Whenever the quality assurance program yields unacceptable results the compounder shall be immediately reinstructed and reevaluated, and

(3) Whenever unacceptable or questionable techniques are observed the compounder shall be immediately reinstructed and reevaluated.~~, and~~

~~(4) Evaluated at least annually.~~

(e) Pharmacist requirements. Any pharmacist in charge who performs or supervises the preparation of compounded medications shall:

(1) Have available written policies and procedures for all steps in the compounding of preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, quality assurance, expiration dating, and other procedures as needed.

(2) Certify that all participating pharmacists, interns and technicians have completed training and testing program in product preparation. Documentation of training and testing shall be available for review.

(3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians.

(f) Staff will be trained and evaluated accordingly as follows:

(1) Training is required for any individual who prepares compounded preparations. This training must be completed before such individual is allowed to compound preparations.

(2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards.

(3) A written test shall be administered and passed based on the material referenced above upon initial hire or prior to assignment to compound preparations.

(4) Testing will be conducted annually for every individual involved in compounding preparations. Compounding personnel who fail written tests shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all practice deficiencies.

(5) An 'Individual Training Record' shall be maintained for every individual involved in non-sterile product preparation.

(6) Nothing in these regulations shall prohibit a licensed intern engaged in experiential classes from assisting a properly qualified pharmacist in compounding non-sterile preparations under that pharmacist's direct supervision.

(7) Complete documentation by a pharmacist of training and testing shall be available for inspection.

(g) All pharmacists and personnel who engage in non-sterile compounding are responsible for complying with ~~all aspects of USP-Compounding Standards~~State Board of Pharmacy regulations~~and these rules~~.

(h) Technicians and interns participating in the compounding of preparations shall have completed a pharmacist supervised training and testing program in compounding preparations. Completed documentation by a pharmacist of training and testing shall be available for inspection.

535:15-10-8.2. Beyond-use dating

(a) Pharmacies engaging in compounding shall assign every compounded preparation an appropriate beyond-use date (BUD).

(b) BUD may be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(c) BUD are to be assigned conservatively, and should be based on the following USP-NF standards in (d) through (f) below:

~~(1) For Non-aqueous liquids and solid formulations~~

~~(A) Where the manufactured drug product is the source of active Ingredient The BUD is not later than 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.~~

~~(B) Where a USP of NF substance is the source of active ingredient the BUD is not later than 6 months for~~

~~(i) Water containing oral formulations (prepared from ingredients in solid form) the BUD is not later than 14 days for liquid preparations when stored at cold temperatures between 2°and 8°C (36° and 46° F).~~

~~(ii) All other formulations The BUD is not later than the intended duration of therapy or 30 days, whichever is earlier.~~

(1~~2~~) The USP-NF standards listed above may be exceeded when there is supporting scientific stability information that is directly applicable to the specific preparation (e.g., the same drug concentration range, pH, excipients, vehicle, water content, etc.)

(2~~3~~) Information to be considered when assigning a BUD includes chemical, physical and microbiological stability; nature of the drug, its chemical degradation mechanism, the container in which it is packaged, expected storage conditions, and the intended duration of therapy.

(d) Non-aqueous Formulations. The BUD for non-aqueous formulations is not later than the time remaining until the earliest expiration date of any ingredient utilized or 6 months, whichever is earlier.

(e) Water-Containing Oral Formulations. The BUD for water-containing oral formulations is not later than 14 days when stored at controlled cold temperatures.

(f) Water-Containing Topical / Dermal and Mucosal Liquid and Semisolid formulations. The BUD for water-containing topical / Dermal and Mucosal Liquid and semisolid formulations is not later than 30 days.

(g) If water is not added to a topical compounded preparation itself then the compound could be considered anhydrous with a BUD of 6 months or the earliest expiration of products used, whichever is less.

535:15-10-8.3. Compounding record/ log/ formula worksheet

(a) Every pharmacy shall document the drug compounding controls required in 535:15-10-8. Each pharmacy shall complete a compounding record/ log/ formula worksheet for each preparation which will include, but not be limited to, the following:

(1) The assigned name of the preparation.

(2) The name and actual measured quantity of each ingredient used.

(3) The lot number, expiration date and manufacturer of each ingredient used.

(4) The total quantity compounded.

(5) The name/initials of the employee that compounded the preparation and the name/initials of the supervising pharmacist that approved the preparation.

(6) The date the compound is prepared.

(7) The lot/batch number assigned to the preparation.

(8) The assigned beyond use date (BUD).

(b) If an assigned BUD exceeds the allowable BUD according to 535:15-10-8.2, then you must include documentation of the source of the assigned BUD.

(c) The assigned BUD cannot exceed the expiration date of any ingredient utilized to compound the preparation.

(d) Compounding record/ log/ formula worksheet(s) shall be maintained in the pharmacy as required in 535:15-10-10.

535:15-10-10. Records and reports

(a) Any procedures or other records required to comply with State Board of Pharmacy regulations~~USP Compounding Standards~~ shall be retained for the same period of time as required for retention of prescription records; and copies of such records, shall be readily available for authorized inspection.

(b) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.

(c) ~~Adequate records must be kept of controlled dangerous substances (Scheduled drugs) used in compounding.~~Perpetual inventory is required for all controlled dangerous substances (CDS) and all bulk CDS's utilized for compounding.

535:15-10-11. Pharmacy generated product requirements [REVOKED]

~~(a) A Pharmacy Generated Preparations (PGP) if prepared from RX Only drugs, may not exceed recommended OTC strengths and doses.~~

~~(b) PGP will be labeled properly and will be sold with the public's health and welfare in mind.~~

~~(c) Compounded PGP's are to be sold directly to the consumer after professional interaction or consultation with the health care provider and the consumer.~~

~~(d) A PGP cannot be bulk compounded to sell to a second entity for resale. This would require a manufacturer's license.~~

~~(e) Compounded PGPs must be labeled in compliance with FDA OTC labeling regulations.~~

535:15-10-16. Violations

It shall be a violation to fail to comply with ~~all aspects of USP compounding standards and these rules~~State Board of Pharmacy regulations.

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PREPARATIONS

535:15-10-52. Pharmacist responsibilities

(a) All Pharmacists who engage in drug compounding, shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

(b) Every pharmacist engaging in drug compounding must be familiar with all details of USP Compounding Standards.

(c) The pharmacist has the responsibility to:

(1) Ensure the validity of all prescriptions

(2) Certify all prescriptions.

(3) Approve or reject all components, drug product containers, closures, in-process materials, and labeling.

(4) Ensure preparations are of acceptable strength, quality, and purity.

(5) Verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation.

(6) Prepare and review all compounding records to ensure that no errors have occurred in the compounding process.

(7) Ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.

(8) Ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and,

(9) Ensure only authorized personnel shall be in the immediate vicinity of the drug compounding operation.

(10) Perform final check of preparations prior to their release from the pharmacy.

(A) A check for compounding accuracy must ensure accuracy of the label and volumes or quantities of all drugs and solutions

(B) A visual examination procedure must ensure:

(i) Comparison with original order for initial dispensing;

(ii) Accuracy of calculations;

(iii) Use of proper solutions, additives and equipment;

(iv) Labels are complete;

(v) Proper assignment of beyond use date and time;

(vi) The integrity~~Integrity~~ of the container, including checking for visual defects;

(vii) Proper storage; and,

(viii) Absence of particulate matter, precipitates, turbidity, discoloration, evidence of contamination or other signs that the preparation should not be used.

(C) The pharmacist shall reject and destroy all preparations that do not pass the final examination.

(D) Pharmacists shall document final preparation examinations prior to releasing the Compounded Sterile Preparations from the pharmacy.

(d) The pharmacist-in-charge has the responsibility to ensure that all compounders who compound sterile pharmaceuticals meet all requirements for training, testing and education set forth in Boardthese regulations and contained in the regulations set forth in USP standardsat least annually.

(1) Competency shall be demonstrated prior to preparing any sterile products for patient use, and

(2) Whenever the quality assurance program yields unacceptable results the compounder shall be immediately reinstructed and reevaluated, and

(3) Whenever unacceptable or questionable techniques are observed the compounder shall be immediately reinstructed and reevaluated.and

(4) Evaluated at least annually.

(e) Pharmacist requirements. Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:

(1) Have available written policies and procedures for all steps in the compounding of preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.

(2) Certify that all participating pharmacists, interns and technicians have completed training and testing program in sterile product preparation. Documentation of training and testing shall be available for review.

(3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.

(f) Staff will be trained and evaluated as follows:

(1) Training is required for any individual who compounds sterile preparations. This training must be completed before the individual is allowed to compound sterile preparations.

(2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards,

(3) A written test shall be administered and passed based on the material referenced above upon initial hire or prior to assignment to compound sterile preparations.

(4) Media-fill challenge tests will be used to evaluate sterile technique.

(5) Results of the media challenge tests shall be documented and logged.

(6) End product testing that results in a failure, will result in a review of the aseptic technique of the individual involved.

(7) Testing involving media challenge tests will be conducted annually for every individual involved in sterile preparation compounding. Semiannual testing will be conducted for personnel involved in high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

(8) Glove fingertip sampling using processes compliant with the most current USP standards required procedures shall be used to evaluate competency of personnel in performing hand hygiene and garbing procedures initially and at least annually. Such test shall be repeated until the required number of consecutive negative culture results are obtained.

(9) An 'Individual Training Record' shall be maintained for every individual involved in sterile preparation compounding.

(10) Nothing in these regulations shall prohibit a licensed student pharmacy intern engaged in experiential classes from assisting a properly qualified pharmacist in compounding sterile preparations under that pharmacist's direct supervision.

(11) Complete documentation by a pharmacist of training and testing shall be available for inspection.

(g) All pharmacists who engage in sterile compounding are responsible for complying with all aspects of USP Compounding Standards and these rulesState Board of Pharmacy regulations.

(h) Pharmacy technicians and interns participating in the compounding of sterile preparations shall have completed a pharmacist supervised training and testing program in sterile compound preparation. Completed documentation by a pharmacist of training and testing shall be available for inspection

535:15-10-55. Drug compounding facilities

(a) Pharmacies engaging in compounding shall have a specifically designated and adequate space for the orderly compounding of prescriptions, including the placement and storage of equipment and materials.

(b) The aseptic processing for sterile preparations shall be in an area separate and distinct from the area used for the compounding of non-sterile drug preparations. If sterile compounded preparations are being compounded, the rules in OAC 535:15-10-3.1 should be met. A primary engineering control (PEC), (laminar airflow workbench (LAFW), biological safety cabinet (BSC), compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)) will be used to prepare all sterile preparations, except those compounded for Immediate Use.

(c) The area(s) used for the compounding of drugs shall be maintained in a good state of repair. These area(s) shall also be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided and sewage, trash and other refuse in the compounding area is to be disposed of in a safe, sanitary, and timely manner.

(d) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers.) Bulk drugs shall also be stored such that they are protected from contamination.
(e) Adequate lighting and ventilation shall be provided in all compounding areas.
(f) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug preparation.
(g) Work area and equipment. Any pharmacy dispensing compounded sterile preparations shall meet or exceed the following requirements:

(1) A transition area from the general pharmacy (also called ante area or ante room) shall have a certified and inspected ISO Class 8 or better area which may contain a sink. All personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed in the ante area. Drugs and other materials, taken into the transition area shall be removed from corrugated cardboard and other particle-generating materials before being taken into the area.

(2) A separate controlled limited access area (also called a buffer area or buffer room) shall have a certified and inspected ISO Class 7 or better environment for compounding sterile solutions. The buffer room shall be of adequate space. Cleanliness of the area is of critical importance.

(3) A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have controlled temperature. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.

(4) The controlled limited access area shall have a certified and inspected ISO Class 5 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting ISO Class 5 requirements) used for the preparation of all compounded sterile products. The ISO Class 5 environment device or area is to be inspected and certified semiannually. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.

(5) A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the clean room and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.

(6) Hazardous drugs shall be prepared within a certified Class II, Type A (exhaust may be discharged to the outdoors) or Class II, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. Hazardous drug compounding shall have negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas, thus providing inward airflow to contain any airborne drug. All vented cabinets shall be vented through HEPA filtration, preferably to outside air or through use of suitable technology or equipment. Ventilation exhaust shall be placed as not to reenter the facility at any point.

(7) The area shall be designed to avoid excessive traffic and airflow disturbances.

(8) The area shall be ventilated in a manner not interfering with laminar flow hood conditions.

(9) ~~Daily procedures must be established for cleaning the compounding area.~~

~~(10)~~ PECs should be left on continuously. If a PEC has been turned off, allow the blowers to run continuously for at least 30 minutes before using.

(10~~11~~) Daily procedures must be established for cleaning the compounding area. The pharmacy must keep cleaning logs consistent with the minimum cleaning frequency as outlined in USP 797 standards:

(11~~12~~) Minimum frequency of cleaning and disinfecting compounding areas (USP 797), site and minimum frequency are listed below:

(A) ISO Class 5 [Primary Engineering Control (e.g. LAFW, BSC, CAI, CACI)] shall be cleaned and disinfected at the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities occur, after spills, and when surface contamination is known or suspected.

(B) Counters and easily cleanable work surfaces shall be cleaned and disinfected daily.

(C) Floors shall be cleaned and disinfected daily.

(D) Walls shall be cleaned and disinfected monthly.

(E) Ceilings shall be cleaned and disinfected monthly.

(F) Storage shelving shall be cleaned and disinfected monthly.

535:15-10-68. Violations

It shall be a violation to fail to comply with ~~all aspects of USP compounding standards rules~~State Board of Pharmacy regulations.

SUBCHAPTER 11. CHARITABLE CLINIC PHARMACIES

535:15-11-1. Charitable clinic pharmacy license

(a) A charitable clinic pharmacy license may be issued by the Board to clinics operating on a non-profit basis to furnish medical care to poor and underprivileged persons and in which drugs are dispensed or administered without charge to such persons on orders or prescriptions of prescribers authorized by law to prescribe or administer said drugs.

(b) Charitable clinic pharmacies must assure that the pharmacy area be secured during the pharmacist's absence.

(c) The minimum of (40) hours for a lock out pharmacy shall not apply to charitable clinic pharmacies.

(d) All dangerous drugs for patients shall be on an individual prescription basis, and the pharmacist shall dispense drugs properly labeled, and adhere to the requirements for proper storage, safeguarding, preparation and recordkeeping for prescription drugs.

(e) Before a charitable clinic pharmacy license is issued, all pharmacy policies and procedures must first be approved by the Board.

(f) A charitable clinic pharmacy can be part of a medical clinic that utilizes a mobile clinic to provide medical services to indigent patients provided that;

(1) The charitable clinic pharmacy has a permanent location where all dangerous drugs and records are stored,

(2) All dangerous drugs are returned to the permanent location each day and stored there, (3) The permanent location is the address of record for the pharmacy, and

(4) A charitable clinic that utilizes mobile clinics shall not have controlled dangerous substances (CDS). No CDS are allowed in mobile clinics.

SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL

535:15-13-1. Purpose

In an effort to assist the pharmacist with regular, routine, non-judgmental, mechanical and nondiscretionary tasks so that the pharmacist may counsel patients and improve pharmaceutical care and therapeutic outcomes, this Subchapter allows certain tasks to be performed by and describes the role of pharmacy supportive personnel as authorized at 59 O.S., Section ~~353.29~~ 353.18A.

535:15-13-3. Definitions

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

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

"Certify a prescription" means the confirmation by the supervising pharmacist of the accuracy and completeness of the acts, tasks or functions undertaken by supportive personnel to assist the pharmacist in the practice of pharmacy. This process shall be completed before the prescription is given to the patient.

"Pharmacy technician", **"Technician"**, or **"Rx Tech"** means a person who has been issued a permit by the Board to assist the pharmacist and perform nonjudgmental, technical, manipulative, non-discretionary functions in the prescription department under the pharmacist's immediate and direct supervision.

"Significant compounding" means compounding activity which equals at least ten percent (10%) of the prescription volume of the pharmacy.

"Supportive personnel" means supportive personnel as defined in 59 O.S. Section 353.1 et seq.

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

(a) All tasks performed by pharmacy technicians must be in a licensed pharmacy located in Oklahoma and must be accomplished under the immediate and direct supervision of a pharmacist who is currently licensed by the Board.

(1) Failure by the licensed pharmacy and pharmacist manager (PIC) to provide adequate supervision; and/or failure of a pharmacist to adequately supervise a technician is a violation of these State Board of Pharmacy regulations~~rules~~.

(2) An intern cannot supervise a technician.

(3) Failure to adequately supervise a pharmacy technician is a violation of these State Board of Pharmacy regulations~~rules~~ by the pharmacist, pharmacy and pharmacist manager.

(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 licensed pharmacy that conducts significant compounding may utilize up to two pharmacy technicians specifically trained in compounding who shall, only while performing compounding duties, not be counted for the purposes of the pharmacy technician to pharmacist ratio of two pharmacy technicians to one supervising pharmacist.

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

(~~e~~f) 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.

535:15-13-6. Duties

(a) The following tasks may be performed by auxiliary supportive personnel:

(1) Retrieval tasks such as retrieving prescriptions or files as necessary;
(2) Clerical tasks such as typing labels and maintaining patient profiles;
(3) Secretarial tasks such as telephoning, filing, and typing;
(4) Accounting tasks such as record keeping, maintaining accounts receivables, third party billing and posting;
(5) Inventory control tasks including monitoring, pricing, dating, invoicing, stocking pharmacy, and preparation of purchase orders; and
(6) Help maintain a clean and orderly pharmacy.

(b) The following tasks may be performed by pharmacy technicians:
(1) Count and/or pour medications;
(2) Repackage (e.g. unit dose) and properly label medications;
(3) Affix the prescription label to the proper container;
(4) Affix auxiliary labels to the container as directed by the pharmacist;
(5) Reconstitution of medications (i.e. liquid antibiotics);
(6) Bulk compounding, including such items as non-sterile topical compounds, sterile bulk solutions for small volume injectables, sterile irrigation solutions and products prepared in relatively large volume for internal or external use. Documentation of a system of in-process and final checks and controls must be developed or approved by the certifying pharmacist and carefully and systematically enforced;
(7) Technician training and requirements for technician participation in non-sterile compounding is described in 535:15-10-3 (a) - (h).
(8) Technician training and requirements for technician participation in sterile compounding is described in 535:15-10-52 (a) - (h).
(~~7~~9) Any duties auxiliary personnel are allowed to perform;
(~~8~~10) Assist the pharmacist in the annual CDS inventory. The pharmacist remains responsible for completeness and accuracy; and,
(~~9~~11) Take verbal authorizations from licensed prescriber or licensed prescriber's authorized agent (when allowed) for refill of non-controlled prescriptions with no changes to strength or directions.

SUBCHAPTER 19. AUTOMATION RULES

535:15-19-4. Pharmacist verification

(a) A licensed pharmacist shall inspect and verify the accuracy of the contents of any final dispensing container filled or packaged by an automated dispensing system, and any label affixed thereto, prior to dispensing.
(b) The pharmacist verification requirements of Subsection (a) shall be deemed satisfied if:
(1) Individual unit-dose, bar-coded medications are employed by the automated system, and
(2) The process of filling / loading the system includes bar-code verification to prevent errors, and
(3) The process includes a pharmacist verification step either prior to or after loading the automated system.

[OAR Docket #21-617; filed 6-28-21]

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 20. MANUFACTURERS, REPACKAGERS, OUTSOURCING FACILITIES, WHOLESALERS, THIRD-PARTY LOGISTICS PROVIDERS, AND MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

[OAR Docket #21-618]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 6. Outsourcing Facilities
535:20-6-6. Personnel
Subchapter 7. Wholesale Distribution Rules
535:20-7-7.10. Compliance with federal, state and local laws
AUTHORITY:
Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.7, 353.11 - 353.20.1, 353.22, 353.24 - 354, and 367.8; Title 51 OS 24A et seq.; Title 75 OS, Sec 2-201, 2-208, and 2-210.
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GIST/ANALYSIS:
The new 535:20-6-6 (e) and (f) add Pharmacist in charge (PIC) requirements to 'Personnel' for Outsourcing facilities.
In 535:10-7-7.10 (c) shipping only allowed to the address on the license.
CONTACT PERSON:
Dr. Marty Hendrick, Executive Director, Oklahoma State Board of Pharmacy, 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212, Phone number 405 521-3815

PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2021:

SUBCHAPTER 6. OUTSOURCING FACILITIES

535:20-6-6. Personnel

(a) Outsourcing facilities shall establish and maintain for Board inspection a list of each partner, limited liability company member or corporate officer and corporate director, as well as designated representatives and facility managers, including a description of their duties and a summary of their qualifications.

(b) Each outsourcing facility shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the outsourcing facility for each location licensed.

(c) Each outsourcing facility shall designate, in writing on a Board-approved form, a person to serve as the PIC who is a pharmacist licensed by the Board. No pharmacist may serve as the PIC for more than one outsourcing facility and/or pharmacy at a time unless they are located at the same physical address and are dually licensed with the Board.

(d) No outsourcing facility shall have as an owner, designated representative, facility manager, or pharmacist-in-charge anyone convicted of any felony for conduct relating to compounding prescription drugs, any felony for violation of 21 U.S.C. § 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering. No outsourcing facility shall have as an owner, designated representative, facility manager or pharmacist-in-charge anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

(e) The PIC shall be present and practicing at the outsourcing facility for which he holds the PIC position no less than 20 hours per week during the outsourcing facility's ordinary course of business. In the event the outsourcing facility's normal hours of business are less than 40 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.

(f) A PIC shall work sufficient hours in the outsourcing facility to exercise control and meet the responsibilities of the PIC.

SUBCHAPTER 7. WHOLESALE DISTRIBUTOR RULES

535:20-7-7.10. Compliance with federal, state and local laws

(a) A wholesale distributor shall operate in compliance with applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Supply Chain Security Act of 2013 and the rules promulgated thereunder and the Act, 59 O.S. Section 353 et seq., and the Board rules, OAC 535. A wholesale distributor shall comply with 21 C.F.R. Part 205, e.g. facilities, security, storage and written policies and procedures.

(b) A wholesale distributor shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate records to the extent authorized by law or rules.

(c) A wholesaler distributor shall ship only to the address listed on the ~~licensee's~~ license.

[OAR Docket #21-618; filed 6-28-21]

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

[OAR Docket #21-619]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 3. Applicants, Registrants, and Applications
535:25-3-7. Change requirements and notification [AMENDED]
Subchapter 6. ~~Post-Military~~Post and Active Duty Military Service and their Spouse Applicants
535:25-6-1. Purpose [NEW]
535:25-6-2. Active duty military and their spouse requirements [NEW]
Subchapter 9. Violations of the Rules of Registrant Conduct
535:25-9-9. Prescription~~Misfill or incorrect fill of a prescription~~ or drug order error
AUTHORITY:
Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.7, 353.11 - 353.20.1, 353.22, 353.24 - 353.26 - 354, and 367.8; Title 51 OS 24A et seq.; Title 75 OS, Sec 2-201, 2-208, and 2-210
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The changes in rule 535:25-3-7 (b) (2) - (3) makes the change and notifications requirements clear. 535:25-6-1 describes Subchapter 6's purpose, of implementing 59 OS Section 4100.5 - 4100.8. 535:25-6.2 (a) - (d) describe active duty military and their spouses requirements. Changed 535:25-9-9 corrects the word "misfill" to "errors" to fully more describe occurrences, and removes "The incorrect fill or misfill of a" and replaces it with an "A".
CONTACT PERSON:
Dr. Marty Hendrick, Executive Director, Oklahoma State Board of Pharmacy, 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212, Phone number 405 521-3815

PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S.,

SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2021:

SUBCHAPTER 3. APPLICANTS, REGISTRANTS, AND APPLICATIONS

535:25-3-7. Change requirements and notification

(a) Change of name, ownership, and/or location shall require a new license for all business permits, certificates or licenses (e.g. pharmacy, wholesale distributor, repackager, manufacturer, outsourcing facility, third-party logistics provider, medical gas supplier and distributor, training areas, sterile compounding, drug supplier, etc.)

(1) A change of ownership occurs when:

(A) A change of 20% or more of the ownership of the entity owning the license, permit or certificate occurs (for example, when the corporation owning the license, permit or certificate sells 20% or more of the stock); or

(B) A change of ownership form occurs (for example, from a sole proprietor ownership to a partnership, limited liability company or corporation).

(2) Any ownership change not reported as a change of ownership because it involves a transfer of less than 20% of the ownership of the entity owning the license, permit or certificate must be reported at the next renewal of the entity license, permit or certificate.

(3) For publicly traded corporations, a routine sale of stock is not a change of ownership. (Note: a publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.)

(b) Changes:

(1) Changes of ownership, name, and/or location require a new license, special inspection and special inspection fee.

(2) The following ~~All~~ changes in ~~any~~ information ~~required for licensure~~ must be reported to the Board within ten (10) days: manager, representative~~(e.g. for businesses the address, manager,~~ contact person, officer(s), phone number, email address, ~~etc.~~and hours of operation. ~~and/or for individuals name, address, etc.)~~

(3) Address change requires a new license prior to drugs being moved or stored at the new address, see (1) above.

(c) Every applicant for change or renewal of license, permit or certificate shall meet the requirements in 535:25 at a minimum.

SUBCHAPTER 6. ~~POST-MILITARY~~POST AND ACTIVE DUTY MILITARY SERVICE AND THEIR SPOUSE APPLICANTS

535:25-6-1. Purpose

The purpose of this subchapter is to implement 59 O.S. Section 4100.5 -4100.8 regarding active duty military personnel who receive notice or orders for military transfer or honorable discharge to this state, and their spouse.

535:25-6-2. Active duty military and their spouse requirements

(a) Active duty military personnel and their spouse licensed as a pharmacist or permitted as a pharmacy technician in another state, upon receiving notice or orders for military transfer or honorable discharge to Oklahoma are eligible for expedited pharmacist reciprocity license or initial technician permit.

(b) Active duty military personnel and their spouse shall provide copies of military notice or orders as indicated in (a) and complete the required application. Such applicant shall present satisfactory evidence of education, training and experience of such valid license or certificate from another state.

(c) Not required for active duty military personnel who are performing their duties only on the premises of an assigned military base pursuant to federal or military law or rule.

(d) Upon receipt of the completed application and when the required documentation from the other state is found to be in good standing and reasonably equivalent to the requirements in this state, the Board shall issue such licenses or permits within 30 days.

(e) The Board shall waive the fee for active duty military and their spouse described in (a) above for the first period of issuance for such pharmacist reciprocity license or technician permit.

SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT

535:25-9-9. Prescription ~~Misfill or incorrect fill of a prescription~~ or drug order error

~~The incorrect fill or misfill of a~~ A prescription or drug order error which departs from the standards of care ordinarily exercised by a registrant with proof of actual injury not having to be established is a violation of registrant conduct.

[OAR Docket #21-619; filed 6-28-21]

TITLE 590. OKLAHOMA PUBLIC EMPLOYEES RETIREMENT SYSTEM

CHAPTER 10. PUBLIC EMPLOYEES RETIREMENT SYSTEM

[OAR Docket #21-620]

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RULES:

Subchapter 1. General Provisions

590:10-1-15. Hazardous Duty Members [REVOKED]

590:10-1-23. Transferred employees-board of trustees for the Quartz Mountain Arts and Conference Center [NEW]