TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY

CHAPTER 1. ADMINISTRATIVE OPERATIONS

[**Authority:** 51 O.S., §§ 24A et seq.; 51 O.S. § 24A.5(3); 59 O.S., §§ 353.3, 353.5 through 353.7, 353.9, 353.11 through 353.20.1, 353.22, 353.24 through 354; 63 O.S., §§ 2-201, 2-208, and 210; 75 O.S., §§ 302, 305, 307, and 309]
[**Source:** Codified 12-31-91]

SUBCHAPTER 1. GENERAL PROVISIONS

535:1-1-1. Purpose

(a) The rules of this Chapter describe the organization and the administrative operation of the Board, the procedures and practices at individual proceedings, the practices at rulemaking hearings, the procedures for requests for rule changes and the procedures for the filing and prompt disposition of petitions for declaratory rulings as to the applicability of any rule or order of the Board as required under the Administrative Procedures Act.
(b) The fee schedule of this Chapter provides the public and registrants access to records, information and fees as required or suggested by the Open Records Act.

[**Source:** Amended at 9 Ok Reg 2133, eff 6-11-92; Amended at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 3. DESCRIPTION OF ORGANIZATION

535:1-3-1. Creation of Board

(a) The State Board of Pharmacy is created by virtue of Article 5, Section 39 of the Constitution of Oklahoma. Statutes relating thereto are found in the Oklahoma Pharmacy Act, 59 Section 353 et seq. of the Oklahoma Statutes.
(b) Unless otherwise stated, as used herein, Board means Board of Pharmacy.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-3-2. Board members

The Board shall consist of six (6) members who are qualified and appointed in accordance with the provisions of 59 O.S. Section 353.3.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-3-3. Powers and duties of Board

The powers and duties of the Board are set forth in the Oklahoma Pharmacy Act (the "Act"), 59 O.S.Section 353 et seq.

[**Source:** Amended at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 5. BOARD ADMINISTRATIVE OPERATIONS

535:1-5-1. Board office

The office of the Board is in the Bryan H. Potter Oklahoma State Board of Pharmacy Building, 2920 North Lincoln Boulevard, Oklahoma City, Oklahoma.

[**Source:** Added at 32 Ok Reg 1222, eff 8-27-15]

535:1-5-2. Office hours

General office hours are from 8:00 a.m. to 4:30 p.m. each day except Saturday and Sunday and any legal holiday established by statute or proclamation of the Governor.

535:1-5-3. Communication in writing

Every communication in writing to the Board shall be addressed to the Director at the Board's principal office, unless the Board directs otherwise.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-5-4. Board meetings

(a) The Board shall hold at least one regular meeting in each calendar year.
(b) The Board shall hold other meetings as it deems necessary at the Office of the Board in Oklahoma City, Oklahoma, or such other location as the Board desires.
(c) Special meetings may be called by the President and Director, or a majority of the Board.
(d) Four (4) members of the Board constitute the quorum and may transact any business or hold any hearing by simple majority vote of the quorum.
(e) The Board president shall vote only in the case of tie.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 12 Ok Reg 2587, eff 6-26-95; Amended at 32 Ok Reg 1222, eff 8-27-15; Amended at 35 Ok Reg 1916, eff 9-14-18]

535:1-5-5. Appearance before the Board

All persons desiring to appear before the Board for any purpose must first furnish the Board with a copy of information, and/or explanation of the purpose in writing ten (10) days prior to the next regularly scheduled Board meeting in order that they may be placed on the agenda and a time allocated for discussion.

[**Source:** Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-5-5.1. Complaint confidentiality

(a) In order to encourage the public and affected individuals to come forward with complaints regarding registrants and fully share the particulars, the Board will hold all informant or complainant names, addresses or other personal information as confidential and shall not release this information.
(b) The Board shall use all complainant and informant information provided in conducting its investigations;and may use this information in cases filed against registrants.
(c) Information obtained during an investigation into violations of the Oklahoma Pharmacy Act is not a record as that term is defined in the Oklahoma Open Records Act nor shall such information be subject to subpoena or discovery in any civil or criminal proceeding.
(d) The respondent may acquire information obtained during an investigation, unless the disclosure of such information is otherwise prohibited, except for the investigation report, if the respondent signs a protective order whereby the respondent agrees to use the information solely for the purposes of defense in the Board proceeding and in any appeal there from and agrees not to otherwise disclose the information.

[**Source:** Added at 19 Ok Reg 1791, eff 7-1-02; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 25 Ok Reg 1974, eff 7-1-08; Amended at 26 Ok Reg 2270, eff 7-1-09; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-5-6. Availability of records

(a) **Document location.** All rules and other written statements of policy or interpretations formulated, adopted or used by the Board in the discharge of its functions and all final orders, decisions and opinions will be made available for public inspection at the principal office during regular office hours.
(b) **Official records.** Copies of official records of the Board may be madeand certified by the Director or his designee according to the fee schedule enacted by the Board. Any Board records or material in the Board's offices protected from disclosure by state law shall not be released.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 7. INDIVIDUAL PROCEEDINGS

535:1-7-1. Complaints

(a) **Sworn complaint.** In every individual proceedinga sworn complaint shall be filed naming the person against whom relief is sought and containing a brief statement of the factual allegations and alleged violations.
(b) **Notice of hearing.** The Director shall issue a notice of hearing thereby notifying the person named in the complaint of said filing and the date, time and the place for the hearing. The notice should comply with the requirements of 75 O.S. Section 309 or its successor.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-7-2. Serving of notices

(a) All notices or other papers requiring service in an individual proceeding shall be served in one of the following manners:

(1) personally by any person appointed to make service by the Director and in any manner authorized by the law of this State for the personal service of summonses in proceedings in a state court; or,

(2) by certified mail to the respondent at the last address provided to the Board by respondent or to respondent's attorney.

(b) **Service of notice.** Such service shall constitute proper service upon the personal service or certified mailing of the notice or other paper.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 14 Ok Reg 3019, eff 7-11-97; Amended at 26 Ok Reg 2270, eff 7-1-09; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-7-3. Hearings

(a) **Notice time; continuances.** The time set for a hearing, specified in the notice, shall not be less than ten (10) days after the date of the notice. Written motions for any continuances or extensions of time shall state the time desired and the reasons for the request, and shall be filed with the Board at least five (5) business days before the hearing, and may be denied by the Director if not filed at least (five) 5 business days before the hearing. The Director is authorized to rule on said motions. If the motion is denied; the party may renew the request for continuance at the hearing.
(b) **Imminent Danger Suspension.** If the Director finds that there is imminent danger to the public health or safety, he may immediately suspend any registration simultaneously with the scheduling of a Board hearing.

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

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

(c) **Order of procedure.** Hearings shall be conducted in an orderly manner by the President of the Board, or his designee. The order of procedure and rules of evidence shall be those specified by the Oklahoma Administrative Procedures Act.
(d) **Admissibility.** The President of the Board, or his designee, shall rule upon the admissibility of evidence and objections thereto, and shall rule upon other motions or objections arising in the course of the hearing.

[**Source:** Amended at 9 Ok Reg 2133, eff 6-11-92; Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 13 Ok Reg 2803, eff 6-27-96; Amended at 14 Ok Reg 3019, eff 7-11-97; Amended at 27 Ok Reg 2244, eff 7-11-10; Amended at 32 Ok Reg 1222, eff 8-27-15; Amended at 34 Ok Reg 1880, eff 9-11-17]

535:1-7-3.1. Standard of proof

The standard of proof in an individual proceeding before the Board is that of clear and convincing evidence.

[**Source:** Added at 19 Ok Reg 1791, eff 7-1-02; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-7-4. Failure to appear or failure to comply

(a) Any respondent who fails to appear as directed may be determined to have waived his right to present a defense to the charges alleged in the complaint. If the Board finds, after having reviewed the evidence, that the violation alleged did in fact occur, and suspension, revocation or other disciplinary action may be ordered by the Board.
(b) Failure to comply with the Board's order(s) may result in additional sanctions by the Board.

[**Source:** Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 26 Ok Reg 2270, eff 7-1-09; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-7-5. Subpoenas

(a) **Issuance; serving.** Subpoenas for the attendance of witnesses, and/or for the furnishing of information required by the Board, and/or for the production of evidence or records of any kind shall be issued by the Director or his designee. Subpoenas shall be served and a return made in any manner prescribed by Oklahoma Administrative Procedures Act
(b) **Order to compel.** Upon the failure of any person to obey a subpoena, upon the refusal of any witness to be sworn, or to make an affirmation or to answer a question put to him in the course of a hearing, appropriate judicial proceedings may be instituted under the laws of the State for an order to compel compliance with the subpoena or the giving of testimony. Any scheduled hearing shall proceed, so far as it is possible, but the Board, in its discretion, at any time, may continue the proceeding for such time as may be necessary to secure a final ruling in the judicial proceedings.

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 22 Ok Reg 2166, eff 7-1-05; Amended at 26 Ok Reg 2270, eff 7-1-09; Amended at 32 Ok Reg 1222, eff 8-27-15]

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

(a) **Recordings.** The Board's hearings shall be electronically recorded.

(1) The recording of the hearing and the file containing the pleading will be maintained in the Board Office. Such record shall be maintained for such time as to protect the record through judicial review.
(2) A copy of the recording of the hearing shall be provided by the Board at the request of any party to the hearing.

(b) **Transcription costs.** The costs of transcription of the recording of a hearing shall be borne by the party requesting the transcription. A transcript of the hearing shall not be made by the Board except upon written application and a deposit sufficient to pay for having the recording transcribed.
(c) **Judicial review.** Electronic recordings of an individual proceeding, as certified by the Director, may be submitted to the reviewing court by the agency as part of the record of the proceedings under review. In such case where the reviewing court requires transcription, the expense of transcription shall be paid by the non-prevailing party.
(d) **Court reporter.** Parties to any Board hearing may have the proceedings transcribed by a court reporter at their own expense.

[**Source:** Amended at 9 Ok Reg 2133, eff 6-11-92; Amended at 13 Ok Reg 2803, eff 6-27-96; Amended at 19 Ok Reg 1791, eff 7-1-02; Amended at 27 Ok Reg 2244, eff 7-11-10; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-7-7. Final orders

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

[**Source:** Amended at 26 Ok Reg 2270, eff 7-1-09; Amended at 27 Ok Reg 2244, eff 7-11-10]

535:1-7-8. Appeal

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

[**Source:** Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 27 Ok Reg 2244, eff 7-11-10]

SUBCHAPTER 8. REQUESTS FOR RULE CHANGES

535:1-8-1. Requests for rule changes

(a) All interested persons may request the Board to promulgate, amend or repeal a rule. Requests are to be made in writing and filed with the Director. Each request shall set forth fully the reasons for its submission; the alleged need or necessity therefor; whether or not the proposal conflicts with any existing rule, and what, if any, statutory provisions are involved.
(b) Each request to the Board to promulgate, amend or repeal a rule, shall be considered by the Board.
(c) After consideration of a request to promulgate, amend or repeal a rule the Board may:

(1) approve the proposed change in compliance with the Oklahoma Administrative Procedures Act; or,
(2) determine that the proposal or request is not a necessary rule, amendment or repeal; refuse the same and reflect the decision in the regular minutes of the Board.

[**Source:** Added at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 9. RULEMAKING HEARINGS

535:1-9-1. Reasonable opportunity for public input on proposed rulemaking

Prior to the adoption, amendment, or repeal of any rule, the Board shall afford any interested person a reasonable opportunity to submit data, views, or arguments, orally or in writing, to the Board concerning the proposed action on the rule.

[**Source:** Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-9-2. Administrative Procedures Act (APA) rulemaking requirements

In any rule-making action, the Board shall comply with the then current requirements in the Oklahoma Administrative Procedures Act.

[**Source:** Amended at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 11. FEES

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

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

(1) Pharmacist renewal (active or inactive) - $100
(2) Senior inactive pharmacist renewal (age 65 or over, retired) - $20
(3) Pharmacy license
    (A) Retail, hospital, non-resident, and remote medication order processing - $150
    (B) Charitable clinic - $ 75
    (C) Hospital drug room - $ 40
(4) Oklahoma licensed pharmacy emergency medication kit placed in an Oklahoma Facility [59 O.S. 367.8 (C)] remote site - $50
(5) Sterile compounding permit - $ 75
(6) Drug supplier permit - $ 20
(7) Wholesale distributor license - $200
(8) Repackager license - $200
(9) Manufacturer license - $200
(10) Medical gas supplier license - $100
(11) Medical gas distributor license - $200
(12) Outsourcing facility license - $200
(13) Third-party logistics provider license - $200
(14) Pharmacy technician permit - $40
(15) Duplicate renewal receipt, permit, or practical experience certificate:
    (A) Duplicate for lost, destroyed or damaged original-$10
    (B) Duplicate or multiple location copy - $10

[**Source:** Amended at 10 Ok Reg 3165, eff 6-25-93; Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 12 Ok Reg 2587, eff 6-26-95; Amended at 13 Ok Reg 2803, eff 6-27-96; Amended at 15 Ok Reg 3270, eff 7-13-98; Amended at 18 Ok Reg 2730, eff 8-15-01; Amended at 22 Ok Reg 2166, eff 7-1-05; Amended at 27 Ok Reg 2244, eff 7-11-10; Amended at 28 Ok Reg 1760, eff 7-1-11; Amended at 29 Ok Reg 1640, eff 7-12-12; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-11-2. Pharmacist initial registration and other fees

(a) Pharmacist initial registration fees, as set by the Board, shall be as follows:
    (1) Registration by reciprocity - $200
    (2) Registration by examination - $125 + the examination cost
    (3) Registration by score transfer - $200
(b) Other fees
    (1) Duplicate certificate of registration - $30

(2) Pharmacist Reinstatement: Back fees + CE + 15 hours CE penalty + $100

[**Source:** Added at 13 Ok Reg 2803, eff 6-27-96; Amended at 18 Ok Reg 2730, eff 8-15-01; Amended at 32 Ok Reg 1222, eff 8-27-15]

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

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

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

[**Source:** Added at 13 Ok Reg 2803, eff 6-27-96; Amended at 14 Ok Reg 3019, eff 7-11-97; Amended at 18 Ok Reg 2730, eff 8-15-01; Amended at 27 Ok Reg 2244, eff 7-11-10]

535:1-11-4. Other fees

(a) For all records required to be open by the Oklahoma Open Records Act, fees shall be charged for copying as specified in the open records act.
(b) Other fees shall be as follows:

(1) Registrant computer address disk or e-mailed file:
    (A) Facility (wholesaler, packager, manufacturer) - $50
    (B) Pharmacy - $75
    (C) Technician - $100
    (D) Intern - $100
    (E) Pharmacist - $100
(2) Photostat copies, per page - $.25
(3) Facsimile (Fax) fee, per page - $1
(4) Annual subscriptions (7/01 - 6/30 each year)
    (A) Notification of rulemaking intent - $18
    (B) OSBP/NABP Quarterly Voluntary Compliance Newsletter for other than Oklahoma licensed Pharmacists - $25
    (C) Board meeting agenda notice - $18
(5) Research time, when available (per hour)
    (A) Staff research time - $20
    (B) Computer research time - $100
(6) Reproduction of Board meeting recordings, if available;
    (A) Audio recording, each, $15
    (B) Video recording, each, $15
(7) Certification of open public record, not certification of grades, $1.00 per page.
(8) Certified letters of good standing or licensure verification, $10

(c) Board records, which are available and may be obtained from the Board's website www.pharmacy.ok.gov at no charge.

[**Source:** Added at 13 Ok Reg 2803, eff 6-27-96; Amended at 14 Ok Reg 3019, eff 7-11-97; Amended at 17 Ok Reg 2617, eff 7-1-00; Amended at 18 Ok Reg 2730, eff 8-15-01; Amended at 22 Ok Reg 2166, eff 7-1-05; Amended at 27 Ok Reg 2244, eff 7-11-10; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-11-5. Miscellaneous

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

(1) Oklahoma Board lawbook - $10

(2) Certification of grades - $10 - (exempt if ELTP)
(3) Special inspection fee (each) Not to exceed - $200
(4) Fines - Not to exceed on each count - $3,000
(5) Duplicate for lost/destroyed license, renewal receipt, permit, or practical experience certificate - $10.
(6) Late fee for renewal of registration, licenses and/or permits if not received by the Board office within 15 days after expiration date - $ fee x 2
(7) Insufficient check charge - $25
(8) Reinstatement of permits or licenses other than pharmacists - $ fee x 2

[**Source:** Added at 13 Ok Reg 2803, eff 6-27-96; Amended at 14 Ok Reg 3019, eff 7-11-97; Amended at 17 Ok Reg 2617, eff 7-1-00; Amended at 18 Ok Reg 2730, eff 8-15-01; Amended at 27 Ok Reg 2244, eff 7-11-10; Amended at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 13. REQUESTS FOR RULE CHANGES [REVOKED]

535:1-13-1. Requests for rule changes [REVOKED]

[**Source:** Added at 9 Ok Reg 2133, eff 6-11-92; Amended at 11 Ok Reg 3423, eff 6-27-94; Revoked at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 14. SCHEDULED OR CONTROLLED DANGEROUS SUBSTANCES CLASSIFICATIONS OR EXCLUSIONS

535:1-14-1. Purpose

The rules of this chapter implement Title 63 O.S. Section 2-201, 2-208 and 2-210 regarding Board's responsibilities and actions to schedule and exclude non-prescription and prescription drugs from Oklahoma controlled dangerous substance schedules.

[**Source:** Added at 19 Ok Reg 1791, eff 7-1-02]

535:1-14-2. Definitions

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

"**Controlled dangerous substance**" or "**CDS**" or "**Scheduled drug**" or "**SCH**" means a drug, substance or immediate precursor in Schedules I through V of the Oklahoma Uniform Controlled Dangerous Substance Act, Title 63, Section 2-101 et seq.

[**Source:** Added at 19 Ok Reg 1791, eff 7-1-02]

535:1-14-3. Procedure

The procedure for interested persons to request the consideration of scheduling or exclusion from scheduling of any Rx Only drug shall be the same as that defined in 535:1-13-1 for rule revision requests.

[**Source:** Added at 19 Ok Reg 1791, eff 7-1-02]

535:1-14-4. Exclusion of Rx Only products not federally scheduled from Oklahoma Controlled dangerous substances scheduling

"RX Only" products listed in this section shall be excluded from Oklahoma scheduling of controlled dangerous substances as long as they maintain, under the Federal Food Drug and Cosmetic Act and the Drug Enforcement Administration Act, an exemption from federal scheduling.

[**Source:** Added at 19 Ok Reg 1791, eff 7-1-02; Amended at 30 Ok Reg 2009, eff 7-25-13]

SUBCHAPTER 15. DECLARATORY RULINGS

535:1-15-1. Definitions

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

"Declaratory ruling" means an interpretation of a Board's rule by the Board.

[**Source:** Added at 9 Ok Reg 2133, eff 6-11-92; Amended at 32 Ok Reg 1222, eff 8-27-15]

535:1-15-2. Declaratory rulings

(a) Any person affected by any of the rules or orders of the Board may request in writing an interpretation or ruling regarding the application of such rules or orders.
(b) Such request shall state fully the facts to which the rule or order may apply, and the particular rule or order about which the question exists.
(c) The request or inquiry will be added to the agenda for the next scheduled Board meeting but may, if necessary, be continued for further consideration to a subsequent meeting.
(d) The Board's interpretation of the rule or order will be furnished in writing to the person making the request within a reasonable time after Board consideration.

[**Source:** Added at 9 Ok Reg 2133, eff 6-11-92; Amended at 10 Ok Reg 3165, eff 6-25-93; Amended at 12 Ok Reg 2587, eff 6-26-95; Amended at 32 Ok Reg 1222, eff 8-27-15]

SUBCHAPTER 17. PILOT PROJECTS

535:1-17-1. Purpose

The Board may approve pilot projects designed to utilize new or expanded technology or processes and designed to provide patients with better pharmacy products or provide pharmacy services in a more safe and efficient manner.

[**Source:** Added at 34 Ok Reg 1880, eff 9-11-17]

535:1-17-2. General requirements

(a) These pilot project rules become effective upon the pilot project statute effective date.
(b) A petitioner who wishes the Board to consider a pilot project for approval shall submit to the Board a petition that contains all of the following information:

(1) The name, address, telephone number, electronic mail address and Oklahoma license number of the pharmacist responsible for overseeing the proposed pilot project.
(2) The specific location where the proposed pilot project will be conducted. The petitioner shall include the Oklahoma license number of the pharmacy and a statement that the Oklahoma license of the pharmacy and any pharmacist involved with the pilot project is current and is not subject to sanction for violation of federal or state statutes or rules.
(3) A detailed summary of the proposed pilot project that includes all of the following:

(A) The goals and objectives, as applicable, of the proposed pilot project.

(B) A full explanation of the proposed pilot project and how the project will be conducted.

(C) The initial time frame for the pilot project, including the proposed start date and length of the project, which initial time frame shall not exceed twelve (12) months.

(D) All background information and literature review, as applicable, to support the proposed pilot project.

(E) If applicable, identification of the rules from which the petitioner is requesting an exception as provided in subsection (c) in order to complete the proposed pilot project and a request for that exception.

(F) If applicable, procedures the petitioner will use during the proposed pilot project to ensure that the public's health and safety are not compromised as a result of an exception to a rule being granted under subsection (c).

(c) The Board shall not approve a pilot project that does any of the following:

(1) Expands the definition of the practice of pharmacy.

(2) Provides for the therapeutic substitution or substitution of medical devices used in patient care.

(3) Allows a pharmacy or pharmacist to be involved with a pilot project if the pharmacy's or pharmacist's license is not current or is subject to a sanction for a violation of the Pharmacy Act and/or federal or state laws.

(d) The Board may grant to a petitioner conducting an approved pilot project under this section an exception to a rule promulgated by the Board. The Board may grant an exception under this section for a specified period of time, which period shall not exceed twelve (12) months, unless the pilot project is extended under subsection (h) and/or (i).

(e) Upon approval of a petition for a pilot project, the Board shall specify a time period for the operation of that pilot project, which period shall not exceed twelve (12) months. This time period may later be extended under subsections (h) and/or (i). The Board may include appropriate conditions or qualifications on approval of a pilot project. The Board may suspend the operation of a pilot project if it determines that the petitioner or any person involved with the pilot project has deviated the operation of the pilot project from the plan of operation that was approved. The Board may terminate a pilot project at any time if it determines that the health and safety of the public have become endangered by the pilot project.

(f) If determined appropriate for the pilot project approved under this section, the Board may require the petitioner to notify patients that pharmacy services are being provided as part of a pilot project. If required under this subsection, the petitioner shall notify patients in the manner required by the Board.

(g) The petitioner shall allow the Board to inspect and review pilot project documentation and the pilot project site at any time during the review process and after the pilot project is approved.

(h) The pharmacist responsible for overseeing an approved pilot project shall forward all of the following to the Board:

(1) Progress reports at intervals specified by the Board.

(2) A summary of the results of the project and conclusions drawn from the results of the project within three (3) months after completion of the pilot project.

(3) Documentation required by these rules shall be maintained by the petitioner and be available for review for a minimum of two (2) years.

(i) If determined appropriate by the Board, the specified period of time for conducting a pilot project may be extended for an additional two periods of up to twelve (12) months each. The Board shall not grant an extension that would result in the specified period of time for conducting a pilot project under this section to exceed thirty-six (36) months.
(j) If the Board determines that a pilot project for which an exception to a rule has been granted under subsection (c) should be extended so that rules may be promulgated in order to allow the pilot project to be conducted on a permanent basis, the Board may extend the thirty-six (36) months period of time for conducting a pilot project under subsection (i) for an additional period of up to twelve (12) months in order to promulgate such rules.

[**Source:** Added at 34 Ok Reg 1880, eff 9-11-17]

CHAPTER 10. PHARMACISTS; AND INTERNS, PRECEPTORS AND TRAINING AREAS

[**Authority:** 59 O.S., §§ 353.7, 353.9, 353.10, 353.11, 353.11a, 353.12, 353.16A, 353.17, 353.17A, 353.18, 353.20, 353.22, 353.24 through 353.26, 353.30, 364, 6002; 63 O.S., § 2–312.25]
[**Source:** Codified 12-31-91]

SUBCHAPTER 1. GENERAL PROVISIONS

535:10-1-1. Purpose

(a) The rules of this Chapter regulate the practice of pharmacy by adopting and establishing rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.
(b) The rules of this Chapter assure that all applicants for examination and licensure as pharmacists are of good moral character, graduates of an accredited School or College of Pharmacy approved by the Board, and experienced in the practice of pharmacy. These rules further describe the place and manner in which an applicant may receive experience in the practice of pharmacy prior to registration.
(c) The rules of this Chapter include requirements for examination for issuance and renewal of appropriate certificates of registration to all applicants qualified under the provision of 59 O.S. Section 353 et seq.

[**Source:** Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 33 Ok Reg 1774, eff 9-11-16]

SUBCHAPTER 3. PHARMACISTS

535:10-3-1. Rules and violations of professional conduct [AMENDED AND RENUMBERED TO 535:10-3-1.1]

[**Source:** Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 10 Ok Reg 3167, eff 6-25-93; Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 14 Ok Reg 3020, eff 7-11-97; Amended and renumbered to 530:10-3-1.1 at 17 Ok Reg 2618, eff 7-1-00]

535:10-3-1.1. Rules of professional conduct

The rules of professional conduct are as follows:
(1) **Compliance with laws.** Business conducted as a pharmacist will at all times be in conformity with all federal, state and municipal laws.
(2) **Substitution.** At no time will a pharmacist substitute or cause to be substituted any drug, medicine, chemical or pharmaceutical preparation

without the authority of the prescriber or purchaser.
(3) **Conduct.** A pharmacist shall conduct himself at all times in a manner which will entitle him to the respect and confidence of the community in which he practices. Evidence of willful untruthfulness in the course of a pharmacist's professional capacity shall presumptively constitute a failure to comply with this standard of professional conduct required of a pharmacist.
(4) **Unprofessional promotion.** A pharmacist will not lend his support or his name to the promotion or exploitation of objectionable or unworthy products, nor will he participate in any advertising or promotional program which would tend to lower the honor and dignity of his profession.
(5) **Professional fee.** A pharmacist's fee for professional services will be fair and equitable, and commensurate with his knowledge and skill in the compounding and dispensing of prescriptions, and the rendering of other professional services.
(6) **Patient Health and Safety and Confidentiality.** The health and safety of patients shall be a pharmacist's first consideration and the nature of their problems or ailments or any confidence entrusted to him in his professional capacity will not be divulged by the pharmacist except in response to legal requirements or in the best interest of the patron.
(7) **Practice of medicine.** A pharmacist will refrain from any attempt at diagnosis or treatment that might infringe upon the legally constituted right or obligation of any licensed practitioner or mid-level practitioner.
(8) **Arrangements.** Licensees shall oppose any arrangement inimical to public health. Such an arrangement could include, but is not limited to, an arrangement between a licensee and a prescriber whereby fees are divided or in which private formulas are concerned.
(9) **Promote profession.** A pharmacist will seek to attract people of good moral character, good habits and high intellect to the profession and share freely of his knowledge and experiences as a further aid to their instruction.
(10) **Professional services.** A pharmacist will at all times make his professional services available to the allied professions, state and local government agencies and to the office of civilian defense in any project beneficial to public health and the welfare or defense of our country.
(11) **Governing body.** A pharmacist will recognize the Board as the governing body of the practice of pharmacy in the State of Oklahoma and report to it any violation of pharmacy laws or regulations that may come to his attention.

[**Source:** Amended and renumbered from 530:10-3-1 at 17 Ok Reg 2618, eff 7-1-00; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 33 Ok Reg 1774, eff 9-11-16]

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.

(20) The 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.

[**Source:** Added at 17 Ok Reg 2618, eff 7-1-00; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 20 Ok Reg 2473, eff 7-11-03; Amended at 21 Ok Reg 2450, eff 7-1-04; Amended at 25 Ok Reg 1974, eff 7-1-08; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 Ok Reg 1774, eff 9-11-16; Amended at 38 Ok Reg 2439, eff 9-11-21]

535:10-3-2. Consultant pharmacist

(a) A practicing pharmacist may serve as a consultant.
(b) Consultant pharmacist services may be provided for but not limited to hospitals, hospices, home care agencies, and long-term care facilities.

[**Source:** Amended at 12 Ok Reg 2589, eff 6-26-95]

535:10-3-3. Reciprocity applicants [AMENDED AND RENUMBERED TO 535:10-7-6]

[**Source:** Amended at 10 Ok Reg 3167, eff 6-25-93; Amended at 11 Ok Reg 3425, eff 6-27-94; Amended and renumbered to 535:10-7-6 at 12 Ok Reg 2589, eff 6-26-95]

535:10-3-4. Uniform pharmacy continuing education

(a) **Certification.** At the time of annual renewal of registration each pharmacist must certify that he has obtained at least 15 clock hours of continuing education credits through satisfactory completion of an accredited program during the previous calendar year (January 1 -December 31).
(b) **Verification forms.** Verification forms of attendance and/or completion of continuing education programs shall be obtained and maintained by the pharmacist.
(c) **Records.** Proof of continuing education will be maintained by the individual pharmacist for a period of two (2) years from renewal date and submitted to the Board only on request.
(d) **Graduate school.** Pharmacists in pharmacy graduate school will be allowed credit for the required fifteen (15) hours continuing education.

(e) **Military personnel.** Military personnel will not be exempt from the continuing education requirement because of the availability of correspondence courses, etc.
(f) **Job credit.** No credit for continuing education will be granted for anything directly connected with a pharmacist's job.
(g) **Journals.** No credit will be allowed for reading, subscribing to or writing articles for various professional and trade journals.
(h) **Meetings.** Requests for approval of credit for individual meetings will be submitted to the Committee on Continuing Education by the individual pharmacist for review and decision.
(i) **Prior approval.** Prior approval of programs of continuing education shall be obtained by the program sponsor. Each program must be submitted in its entirety, including all materials, in order to be evaluated by the Continuing Education Committee. Continuing education programs sponsored by various drug companies may be acceptable, if the programs are continuing education oriented and not promotional or product oriented.
(j) **Approved programs notice.** Programs approved for credit by the Continuing Education Committee and the Board will be published on the Board's webpage as these programs are approved.
(k) **Colleges of pharmacy.** The two State colleges of pharmacy may review the various continuing education programs and make recommendations to the Continuing Education Committee.
(l) **American Council on Pharmaceutical Education (ACPE).** The Board accepts ACPE approved continuing education (CE) for CE credit.
(m) **Continuing Education Committee.** The Continuing Education Committee will consist of up to six (6) pharmacist members appointed by the Board for a three (3) year minimum term. The committee will meet quarterly or as needed.
(n) **Live Continuing education recommended.** Pharmacists are encouraged to attain three (3) hours or more of live continuing education (CE) each year as part of the fifteen (15) hours required. Live CE is attained in the presence of other pharmacists with a presenter and the possibility of interaction with a peer group. Webinars are considered live CE if the pharmacist can ask questions and get answers from the presenter(s) or the moderator during the webinar.
(o) **Specific Continuing Education requirement.** The Board may, at its discretion, require up to three (3) hours of continuing education on a specific topic. Adequate notice shall be provided to registrants of any specific continuing education when required by the Board.

[**Source:** Amended at 10 Ok Reg 3167, eff 6-25-93; Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 14 Ok Reg 3020, eff 7-11-97; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 20 Ok Reg 2473, eff 7-11-03; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 Ok Reg 1774, eff 9-11-16 [1]; Amended at 33 Ok Reg 1782, eff 9-11-16 [1]; Amended at 39 Ok Reg 2055, eff 9-11-22]

EDITOR'S NOTE: *[1]In 2016, the agency promulgated two permanent versions of this Section (535:10-3-4) with the same effective date (9-11-16). Both versions were published in the 2016 and 2021 Editions of the OAC. In 2022, the agency reconciled the two versions through permanent rulemaking, effective 9-11-22.*

535:10-3-5. Drug Screening [REVOKED]

[**Source:** Amended at 13 Ok Reg 2805, eff 6-27-96; Revoked at 17 Ok Reg 2618, eff 7-1-00]

535:10-3-6. Revoked pharmacists [REVOKED]

[**Source:** Revoked at 17 Ok Reg 2618, eff 7-1-00]

535:10-3-7. Pharmacist responsibility for identification of auxiliary personnel [REVOKED]

[**Source:** Added at 9 Ok Reg 2135, eff 6-11-92; Amended at 11 Ok Reg 3425, eff 6-27-94; Revoked at 17 Ok Reg 2618, eff 7-1-00]

535:10-3-8. Foreign pharmacy graduates licensure requirements [AMENDED AND RENUMBERED TO 535:10-7-8]

[**Source:** Added at 11 Ok Reg 3425, eff 6-27-94; Amended and renumbered to 535:10-7-8 at 12 Ok Reg 2589, eff 6-26-95]

SUBCHAPTER 5. INTERNS, PRECEPTORS AND TRAINING AREAS

535:10-5-1. Licensure applicants experience requirements [AMENDED AND RENUMBERED TO 535:10-5-1.3]

[**Source:** Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 10 Ok Reg 3167, eff 6-25-93; Amended and renumbered to 530:10-5-1.3 at 17 Ok Reg 2618, eff 7-1-00]

535:10-5-1.1. Purpose

(a) The rules of this subchapter define how pharmacy college students or graduates can obtain the experience required of them under the Oklahoma Pharmacy Act, 59 O.S. Section 353 et seq. in order to be eligible for licensure as a pharmacist.
(b) These rules allow individuals to work as an intern when they are continuously actively enrolled and participating in a Doctor of Pharmacy program to earn the practical experience required for licensure as a pharmacist.
(c) The purpose of an intern license is to allow a registrant to gain the required practical experience, under supervision, to become licensed as a pharmacist.

[**Source:** Added at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-5-1.2. Definitions

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

"Currently enrolled" means a student currently enrolled in a college of pharmacy in a Doctor of Pharmacy program and attending classes or experiential rotations.

"Experiential rotations" or **"college experiential rotations"** means a structured advance practice experiential rotation administered by the faculty of a college of pharmacy.

"Faculty preceptor" means an Oklahoma licensed pharmacist who is an Oklahoma licensed preceptor employed by a college of pharmacy to conduct a experiential rotations.

"Foreign pharmacy graduate intern" means a graduate of a foreign college of pharmacy who has verified NABP FPGEC certification and has received an Oklahoma intern certificate from the Board.

"Intern" means a student having completed fifty (50) college hours of credit, with an overall average of not less than "C"; currently enrolled and in good standing attending classes in an accredited college of pharmacy Doctor of in Pharmacy program currently approved by the Board; or a graduate of an accredited college of pharmacy currently approved by the Board not otherwise eligible for registration as an intern or pharmacist, except as provided in 535:10-7-8 who has

received an Oklahoma Intern certificate from the Board.

"Intern duties" means those duties that may be performed by a licensed Intern while working in a licensed training area under the supervision of a preceptor. The licensed Intern may do any of the functions of a Pharmacist for which they have been trained with the exception of supervising technicians or any other exceptions noted in Title 535. All intern duties must be performed in compliance with the rules of 535:10-5 and this Title.

"Intern hours" means the hours a licensed intern must acquire in order to be eligible for licensure as a pharmacist.

[**Source:** Added at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-5-1.3. Intern experience requirements

Each applicant, before sitting for licensure examination for registration as a pharmacist, shall furnish the Board with documentary evidence that said applicant has completed at least fifteen hundred (1500) hours of pharmacy practice training, under the supervision of a preceptor, in a licensed pharmacy or other professional practice site that has been approved as a training area by a Board. Credit will not be granted for practice experience gained in out-of-state sites not subject to the regulations of a State Board of Pharmacy.

(1) No credit shall be allowed for experience obtained in Oklahoma unless such experience was obtained in accordance with the regulations governing Pharmacy Interns, Preceptors and Training Areas.

(2) To obtain credit in Oklahoma for experience obtained in another state, applicant must arrange with the Board of Pharmacy in the state where the hours were worked to furnish this Board with a letter certifying the hours and dates worked; place of employment and preceptor; and certification that the hours in question are approved by and acceptable to that Board.

(3) In the case where another state Board of Pharmacy does not track or certify hours earned while attending that state's ACPE approved school or college of pharmacy, the applicant may submit the following for review and consideration by the Board:

(A) Certification from the ACPE approved school or college of pharmacy of hours earned while attending such school or college.

(B) Upon request, a letter from the state Board of Pharmacy confirming that they do not certify intern hours earned while attending that state's ACPE approved school or college of pharmacy.

(4) The Oklahoma Board will not accept hours that are refused or denied by another State Board of Pharmacy.

[**Source:** Amended and renumbered from 530:10-5-1 at 17 Ok Reg 2618, eff 7-1-00; Amended at 33 Ok Reg 1774, eff 9-11-16 [1]; Amended at 33 Ok Reg 1782, eff 9-11-16 [1]; Amended at 35 Ok Reg 1916, eff 9-14-18]

EDITOR'S NOTE: *[1]In 2016, the agency promulgated two permanent versions of this Section (535:10-5-1.3) with the same effective date (9-11-16). Both versions were published in the 2016 Edition of the OAC. In 2018, the agency reconciled the two versions through permanent rulemaking, effective 9-14-18.*

535:10-5-2. Intern registration

Interns shall license with the Board on an application form supplied by the Board. The intern certificate fee shall be set by the Board.

(1) Interns shall conspicuously display in their training area the intern license provided by the Board. The intern shall be assumed to be presently practicing as such in the training area, by the Board or its agents, where such certificate is posted.
(2) An intern, to be practicing as such, must abide by the regulations governing same, whether logging hours for credit or not.

[**Source:** Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 20 Ok Reg 2473, eff 7-11-03; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-5-2.1. Multiple locations of employment, duplicate

An intern working in multiple locations regularly or on an emergency relief basis may be issued a duplicate certificate on request. A written request indicating the need for such duplicate shall be sent to the Board by the intern.

[**Source:** Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 33 Ok Reg 1774, eff 9-11-16]

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

(a) A licensed intern shall be defined as a student having completed fifty (50) college hours of credit, with an overall average of not less than "C", currently enrolled and attending classes and in good standing in an accredited college of pharmacy in a Doctor of Pharmacy program, or a graduate of an accredited college of pharmacy not otherwise eligible for licensure as an intern or pharmacist, except as provided in 535:10-7-8.

(1) The Board shall be notified by the Pharmacy Colleges in Oklahoma
(A) when a student is not continuously enrolled in a college of pharmacy in an accredited Pharmacy program; or,
(B) when a pharmacy student is not in good standing - or when a pharmacy student's overall grade point average is less than "C";
(C) Then an intern license or registration is automatically void and the intern shall return such license to the Board.

(2) Such intern may apply for a new intern license when the Board is notified by the college of pharmacy that the applicant is in good standing in a Doctor of Pharmacy program and actively attending classes provided the provisions of these regulations have not been violated by the intern.
(3) An intern shall notify the Board when requesting the transfer of intern hours to another state of any intent not to return to Oklahoma; or, within ten (10) days of becoming licensed as a pharmacist in another state.
(4) An intern certificate becomes void five (5) years after date of issuance or at such other date as set by the Board.

[**Source:** Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-5-4. Intern practice requirements

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

(1) A preceptor may supervise only one intern at a time.
(2) A ratio of one (1) faculty preceptor with up to two (2) interns will be allowed in a experiential rotations.
(3) Non-dispensing experiential rotations are to be supervised by a preceptor, but immediate visual supervision is not required.

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

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

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

[**Source:** Amended at 11 Ok Reg 543, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-5-4.1. Intern identification requirements.

(a) The public must be able to distinguish an intern from any practicing pharmacists or technicians in the pharmacy. Pharmacy interns shall wear a designation tag and be distinctly identifiable from a practicing pharmacist.

(b) All interns shall identify themselves as interns on any phone calls initiated or received while performing pharmacy functions.

(c) No person(s) shall wear or use an intern designation unless currently licensed as an intern by the Board.

[**Source:** Added at 18 Ok Reg 2732, eff 7-1-01]

535:10-5-5. Intern credit hours; computation

(a) **Intern experiential rotations hours.** A pharmacy intern pursuing a Doctor of Pharmacy degree in an accredited college of pharmacy may obtain up to 1,500 intern hours while completing the degree.

(1) Experiential hours will be obtained through a board approved college of pharmacy professional practice program.

(2) Documentation of experiential hours shall be provided to the Board by the college of pharmacy on a Board approved form.

(b) **Intern non-experiential or non-college practice hours.** Non-experiential employment hours will be a learning experience, earned in a pharmacy that is licensed as a training area, under the supervision of licensed preceptor. The preceptor will send a "Preceptor's Intern Progress Report" to the Board (on a form furnished by the Board) every 240 hours or upon termination of the intern.

(c) **Computation of hours.** Computation of hours for credit for an intern shall be on the basis of forty (40) hours for one (1) calendar week's work. Hours gained in excess of forty (40) hours in one calendar week shall not be credited.

[**Source:** Amended at 11 Ok Reg 543, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-5-6. Intern non-current hours [REVOKED]

[**Source:** Amended at 11 Ok Reg 543, eff 11-3-93 (emergency); Revoked at 11 Ok Reg 3425, eff 6-27-94]

535:10-5-7. Intern concurrent hours [REVOKED]

[**Source:** Revoked at 11 Ok Reg 543, eff 11-3-93 (emergency); Revoked at 11 Ok Reg 3425, eff 6-27-94]

535:10-5-8. Preceptor requirements

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

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

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

(B) Preceptors are subject to renewal at each renewal date of their doctor of pharmacy license for a fee set by the Board.

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

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

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

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

[**Source:** Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 15 Ok Reg 3271, eff 7-13-98; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-5-9. Training area requirements

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

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

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

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

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

(5) The Board shall set the training area original certification fee.
(6) All training areas shall renew their certification for a fee set by the Board.
(7) Training Areas are subject to renewal when their pharmacy license is renewed.

(b) **Unique or specific training areas.** Any Oklahoma college of pharmacy may apply to the Board for approval of a specific or unique training area. This training area shall be subject to Subsection (a) (1), (2), (4) (5) and (6) of this Section.

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

[**Source:** Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 10 Ok Reg 3167, eff 6-25-93; Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 Ok Reg 1774, eff 9-11-16; Amended at 35 Ok Reg 1916, eff 9-14-18]

535:10-5-10. Director of Internship [REVOKED]

[**Source:** Amended at 11 Ok Reg 3425, eff 6-27-94; Revoked at 17 Ok Reg 2618, eff 7-1-00]

535:10-5-11. Violations

(a) Interns will report to the Executive Director of the Board any laxity of supervision shown by their preceptors, and likewise the preceptor should report to the Executive Director of the Board, in writing, any acts of the intern which are found to be contrary to the ethics of his profession, or any conduct which might bring discredit to his place of practice or to his preceptor.

(b) Violations of the regulations of this Title may result in citation of the intern, preceptor and training area involved before the Board.

[**Source:** Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 11 Ok Reg 3425, eff 6-27-94]

535:10-5-12. Internship Training Guide [REVOKED]

[**Source:** Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 11 Ok Reg 543, eff 11-3-93 (emergency); Revoked at 11 Ok Reg 3425, eff 6-27-94]

535:10-5-13. Intern file destruction

(a) An intern file may be destroyed if an intern:
(1) is dropped from a college of pharmacy;
(2) becomes a licensed pharmacist in any state; or transfers by reciprocity or score transfer to another state; or,
(3) license expires.

[**Source:** Added at 12 Ok Reg 2589, eff 6-26-95; Amended at 14 Ok Reg 3020, eff 7-11-97; Amended at 15 Ok Reg 3271, eff 7-13-98; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 26 Ok Reg 2271, eff 7-1-09]

SUBCHAPTER 7. PHARMACIST LICENSURE

535:10-7-1. Purpose

The rules of this Chapter describe the process to receive and maintain an Oklahoma pharmacist license as authorized under the Oklahoma Pharmacy Act.

[**Source:** Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 18 Ok Reg 2732, eff 7-1-01]

535:10-7-2. Definitions

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

"**FPGEC Certificate"** means the NABP Foreign Pharmacy Graduate Examination Committee Certificate indicating the foreign pharmacy graduate has passed the Foreign Pharmacy Graduate Equivalency Examination and the Test of English as a Foreign Language at a minimum.

"**Foreign Pharmacy Graduate**" means a pharmacist whose undergraduate pharmacy degree was conferred by a school or college of pharmacy not approved by the Board.

"**Foreign Pharmacy Graduate Applicant**" means a foreign pharmacy graduate who has received a FPGEC Certificate from NABP.

"NABP" means the National Association of Boards of Pharmacy.

"NAPLEX" means the North American Pharmacist Licensure Examination.

"Reciprocity" means the process through NABP by which a registered pharmacist can obtain licensure in Oklahoma (after graduation from an accredited school or college of pharmacy approved by the Board) based on his pharmacist license in a participating state with like requirements.

"Score Transfer" means the process by which applicants can sit for the NAPLEX in one state (after graduation from an accredited school or college of pharmacy approved by the Board) and transfer their score to another participating state through NABP.

[**Source:** Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 14 Ok Reg 3020, eff 7-11-97; Amended at 18 Ok Reg 2732, eff 7-1-01]

535:10-7-3. Application, fee, requirements and registration [AMENDED AND RENUMBERED TO 535:10-7-7]

[**Source:** Amended at 11 Ok Reg 3425, eff 6-27-94; Amended and renumbered to 535:10-7-7 at 12 Ok Reg 2589, eff 6-26-95]

535:10-7-3.1. Standard of proof [EXPIRED]

[**Source:** Added at 17 Ok Reg 3223, eff 7-7-00 through 7-14-01 (emergency)[1]]

EDITOR'S NOTE: *[1]This emergency action expired without being superseded by a permanent action. Upon expiration of an emergency action enacting a new section, the text is no longer effective. Therefore, on 7-15-01 (after the expiration of the emergency action), the text of 535:10-7-3.1 was no longer effective. For the official text of the emergency rule as it existed from 7-7-00 through 7-14-01, see 17 Ok Reg 3223.*

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

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

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

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

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

(e) To be eligible for pharmacist licensure all applicants shall successfully pass a Board approved jurisprudence examination and/or any licensure examination

required by theBoard including but not limited to NAPLEX.

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

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

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

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

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

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

[**Source:** Added at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-7-5. NAPLEX, licensure examination applicants

(a) Graduates of an accredited school or college of pharmacy approved by the Board applying for licensure by NAPLEX examination, shall meet the experience requirements set forth in 535:10-5 and the requirements of this Subchapter and Title.

(b) Foreign pharmacy graduates who have completed the requirements in 535:10-7-8 shall meet the requirements in this Subchapter and Title.

(c) NAPLEX applicants shall submit the required fees and applications by the deadline set by the Executive Director.

(d) All NAPLEX applicants shall meet the requirement for pharmacist licensure in 535:10-7-4, in this Subchapter and Title.

[**Source:** Added at 12 Ok Reg 2589, eff 6-26-95; Amended at 14 Ok Reg 3020, eff 7-11-97; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01]

535:10-7-6. Reciprocity licensure applicants

(a) Reciprocity applicants, as defined in 535:10-7-2, shall meet the requirements set forth in 535:10-5, 535:10-7-4, 535:25 and this Subchapter and Title.

(b) Reciprocity applicants shall have a minimum of one year's experience obtained as an intern and/or as a pharmacist.

(c) Reciprocity applicants shall submit to the Board a completed "NABP Official Application for Transfer of Pharmaceutical licensure" and the required Oklahoma fee by the deadline set by the Executive Director.

(d) Oklahoma requires reciprocity applicants to reciprocate from an active original license by examination.

[**Source:** Amended and renumbered from 535:10-3-3 at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 33 Ok Reg 1782, eff 9-11-16]

535:10-7-7. Score transfer licensure applicants

(a) Score transfer applicants shall meet the requirements set forth in 535:10-5, 535:10-7-4, 535:25 and this Subchapter and Title.

(b) Score transfer applicants must have met the NABP requirements for Score Transfer including completing the official NAPLEX Score Transfer form requesting that NABP transfer their score to the Oklahoma Board.

(c) After the Board has received the applicant's passing NAPLEX score, the applicant shall submit a completed Oklahoma "Application for Registered Pharmacist Certificate" with the required Oklahoma fee by the deadline set by the Executive Director.

(d) Score transfer applicants shall complete the score transfer process within one year of passing the NAPLEX.(e)The license issued to a score transfer applicant shall be an original license by examination.

[**Source:** Amended and renumbered from 535:10-7-3 at 12 Ok Reg 2589, eff 6-26-95; Amended at 14 Ok Reg 3020, eff 7-11-97; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01]

535:10-7-8. Foreign pharmacy graduate licensure applicants

(a) Foreign pharmacy graduate applicants shall meet the requirements set forth in 535:10-7-4, 535:25 and this Subchapter and Title.

(b) Foreign pharmacy graduate applicants, as defined in 535:10-7-2 shall:

(1) First, submit a copy of applicant's valid NABP FPGEC Certificate to the Board;

(2) second, apply and be approved for an Oklahoma intern certificate as required by 535:10-5-2; and,

(3) third, complete 1000 hours of internship in Oklahoma within 12 months of licensure as an Oklahoma intern.

(A) The foreign pharmacy graduate intern and the preceptor shall satisfactorily report these hours on forms supplied by the Board.

(B) The foreign pharmacy graduate intern is subject to all Board rules.

(c) Upon satisfactorily completing the requirements of this section, a foreign pharmacy graduate may make application for the NAPLEX (licensure by examination) as set forth in 535:10-7-5.

(d) Foreign pharmacy graduates applicants may apply for licensure by reciprocity once they have met the following:

(1) Successfully complete the NABP FPGEC certificate, and submit a copy to the Board;

(2) Have passed the NAPLEX Examination; and,

(3) Have met the requirements in 535:10-7-6.

[**Source:** Amended and renumbered from 535:10-3-8 at 12 Ok Reg 2589, eff 6-26-95; Amended at 13 Ok Reg 2805, eff 6-27-96; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 25 Ok Reg 1974, eff 7-1-08; Amended at 26 Ok Reg 417, eff 12-11-08 (emergency); Amended at 26 Ok Reg 2271, eff 7-1-09]

535:10-7-9. Pharmacist renewal

(a) Pharmacist renewal applicants shall meet and maintain the requirements listed in the Oklahoma Pharmacy Act and the rules of this Title.

(b) The qualifications and requirements for pharmacist renewal applicants shall be the same as those listed in 535:25 and as follows:

(1) Pharmacist renewal applicants shall possess an Oklahoma pharmacist license.

(2) Pharmacist renewal applicants shall maintain compliance with the rules of professional conduct and not be involved in violations of the rules of professional conduct.

(c) Any person who shall make any false representations in procuring or attempting to procure a renewal for himself or for another pharmacist may be deemed ineligible by the Board for any registration or renewal of license, certificate or permit with the Board.

(d) Any willfully false representations for the same purpose(s) may subject the applicant to felony charges of perjury see 59 O.S. Section 353.25 (B).

(e) Applicants for pharmacist renewal shall satisfactorily complete and submit a renewal application on a form supplied by the Board together with the fee by the due date.

(1) Renewal applications received after due date established by the Board shall be subject to the late fee as established in the Board's fee schedule.

(2) Renewal applications received after cancellation by the Board shall be subject to reinstatement fees and requirements.

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

[**Source:** Added at 18 Ok Reg 2732, eff 7-1-01; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-7-10. Pharmacist reinstatement

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

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

(2) Cancelled pharmacists' records are kept for a limited time. If a pharmacist's record has been destroyed the applicant is not eligible for reinstatement. In this case the applicant shall follow the requirements in 535:10-7 to obtain pharmacist licensure.

(b) A pharmacist reinstatement applicant shall meet the requirements in the Oklahoma Pharmacy Act, this Title, 535:10-7-4, 535:10-7-9 and this section.

(c) A pharmacist reinstatement applicant shall send a written request to the Board.

(d) Reinstatement applicants shall submit a satisfactorily completed Board approved reinstatement application together with the requirements and fees.

(e) Applicants may be required to appear before the Board for interview as described in535:10-7-4(d).

(f) Applicants may be required to take the Board approved law exam as described in535:10-7-4(e).

(g) The applicant shall meet any additional requirements that the Board feels are necessary to protect public health.

(h) Reinstatement will be required when the suspension of a non-current pharmacist's certificate ends or when the suspension is placed on probation.

[**Source:** Added at 18 Ok Reg 2732, eff 7-1-01; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 Ok Reg 1774, eff 9-11-16]

SUBCHAPTER 9. PHARMACEUTICAL CARE

535:10-9-1. Prospective drug review [REVOKED]

[**Source:** Added at 10 Ok Reg 991, eff 1-27-93 (emergency); Added at 10 Ok Reg 3167, eff 6-25-93; Revoked at 33 Ok Reg 1774, eff 9-11-16]

535:10-9-1.1. Purpose

The purpose of this Subchapter is to identify standards for the provisions of those acts or services that are necessary to provide pharmaceutical care.

[**Source:** Added at 33 Ok Reg 1774, eff 9-11-16]

535:10-9-1.2. Prospective drug review

Prospective drug review shall be performed by the pharmacist in all pharmacies when deemed appropriate in the pharmacist's professional judgement or when required by applicable federal or state laws or rules.

(1) A pharmacist shall review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying the following:

(A) overutilization or underutilization;
(B) therapeutic duplication;
(C) drug-disease contraindications, if disease is known;
(D) drug-drug contraindications;
(E) incorrect drug dosage or duration of drug treatment;
(F) drug-allergy interactions;
(G) clinical abuse/misuse.

(2) Upon recognizing any of (1) (A)-(G) of this section, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with or notification of the prescriber.

[**Source:** Added at 33 Ok Reg 1774, eff 9-11-16]

535:10-9-2. Counseling

Counseling shall be performed by the pharmacist when deemed appropriate in the pharmacist's professional judgement or when required by applicable federal or state laws or rules.

(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall assure that an offer is made to each patient or caregiver of such patient to discuss matters which will enhance or optimize drug therapy. Such discussion shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling. Such elements may include the following:

(A) the name and description of the drug;
(B) the dosage form, dose, route of administration, and duration of drug therapy;
(C) intended use of the drug, if known, and expected action;
(D) special directions and precautions for preparation, administration, and use by the patient;
(E) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(F) techniques for self-monitoring drug therapy;
(G) proper storage;
(H) prescription refill information;
(I) action to be taken in the event of a missed dose; and

(J) pharmacist comments on patient's drug therapy.

(2) The pharmacist shall be responsible to assure that a reasonable effort is made to obtain, record, and maintain patient information generated at the individual pharmacy.

(A) This information shall include:

(i) name, address, telephone number, date of birth or age, and gender;

(ii) individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(iii) any additional comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.

(B) The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that such offer was accepted and that such counseling was provided;

(C) Such information may be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records.

(3) Alternative forms of information may be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(4) Patient counseling is not required on prescription refill requests, unless deemed appropriate in the pharmacist's professional judgement.

(5) Patient counseling, as described and defined in this section, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s). Outpatient pharmacies in hospitals are not exempt and counseling will be required for discharged patients exiting the hospital with prescription medication.

(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

(7) If a pharmacy is routinely filling prescriptions that are being shipped or delivered to patients in another state or if a pharmacy in another state is routinely filling and shipping prescriptions to patients in Oklahoma, the pharmacy will make a reasonable effort to call the patient and counsel by phone. A toll free phone number shall be provided for patients to call and interact with a pharmacist for drug information.

[**Source:** Added at 10 Ok Reg 991, eff 1-27-93 (emergency); Added at 10 Ok Reg 3167, eff 6-25-93]

535:10-9-3. Intern role in pharmaceutical care

(a) Nothing shall restrict licensed interns from performing any and all of the functions in this Subchapter under the supervision of a licensed pharmacist unless otherwise stated in the laws and rules (e.g.: 535:15-5-7.2(g) and 535:10-5-1.2).

(b) An intern shall not certify a prescription.

(c) An intern shall not supervise a technician.

[**Source:** Added at 10 Ok Reg 991, eff 1-27-93 (emergency); Added at 10 Ok Reg 3167, eff 6-25-93; Amended at 22 Ok Reg 2168, eff 7-1-05; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-9-4. Purpose [REVOKED]

[**Source:** Added at 14 Ok Reg 3020, eff 7-11-97; Revoked at 33 Ok Reg 1774, eff 9-11-16]

535:10-9-5. Agreements

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

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97; Added at 20 Ok Reg 2476, eff 7-11-03]

535:10-9-6. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97]

535:10-9-7. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97]

535:10-9-8. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97]

535:10-9-9. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97]

535:10-9-10. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97]

535:10-9-11. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97]

535:10-9-12. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3020, eff 7-11-97]

535:10-9-13. Administer

(a) A pharmacist may administer drugs that have been dispensed on orders from a prescriber.
(b) A pharmacist should inform or teach the patient or the patient's caregiver how to administer their drugs.

[**Source:** Added at 14 Ok Reg 3020, eff 7-11-97; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-9-14. Epinephrine

(a) **Purpose.** The rules in this section implement Title 59 Section 6002 provisions for pharmacists.
(b) **Definitions.** The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

(1) **"Authorized Entity"**means any entity or organization at or in connection with allergens capable of causing anaphylaxis may be present, including but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, and sports areas.

(2) **"Emergency public access station"**or**"EPAS"**means a locked, secure container for the storage of epinephrine auto-injectors under the general oversight of a physician, which allows lay rescuer to consult with a physician in real time by audio, televideo or other similar means of electronic communication and upon authorization of the consulting physician, may be unlocked to make available the auto-injector.
(3) **"Epinephrine auto-injector"**means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

(c) A pharmacist may fill a prescription authorized by a prescriber for epinephrine auto-injectors to any authorized entity or organization for storage in an Emergency Public Access Station (EPAS) in accordance with protocols established by the practitioner.
(d) The epinephrine must be dispensed, stored, and administered per Section 6002 of Title 59.

[**Source:** Added at 35 Ok Reg 1916, eff 9-14-18]

535:10-9-15. Naloxone

(a) The purpose of this subsection is to implement Title 63 O.S. 2-312.2 provisions for pharmacists.
(b) Definitions. [RESERVED]
(c) A Pharmacist may prescribe and dispense Naloxone without a protocol or prescription to any person at risk of experiencing an opioid-related drug overdose, family or friend of an at-risk person, or first responder. Naloxone may only be dispensed by, or under the supervision of, a licensed pharmacist.

[**Source:** Added at 35 Ok Reg 1916, eff 9-14-18; Amended at 37 Ok Reg 2041, eff 9-11-20]

SUBCHAPTER 11. PHARMACIST ADMINISTRATION OF IMMUNIZATIONS

535:10-11-1. Purpose

(a) The purpose of this Subchapter is to identify standards for the provisions of those acts or services that are necessary for pharmacists to administer immunizations.
(b) The rules in this Subchapter implement a portion of the requirements authorized in 59 O.S. Section 353.30.

[**Source:** Added at 20 Ok Reg 19, eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 33 Ok Reg 1774, eff 9-11-16; Amended at 39 Ok Reg 2055, eff 9-11-22]

535:10-11-2. Definitions

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

"Controlled dangerous drug" or **"CDS drugs"** means those drugs, substances or immediate precursors that require a prescription and are scheduled under federal or state law.

"Healthcare provider" means an individual, licensed as a Doctor of Pharmacy by the Board, who provides healthcare.

[**Source:** Added at 20 Ok Reg 19, eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-11-3. D.Ph. administering of immunization requirements

(a) A D.Ph. must have completed an approved training course and received registration for immunizations with the Board as stated in 535:10-11-4 prior to administering immunizations.

(b) The Board will maintain a register of those pharmacists who have been approved to administer immunizations.

(c) A D.Ph. with immunization registration must maintain ongoing competency through required training, including at a minimum current CPR certification and current continuing education.

[**Source:** Added at 20 Ok Reg 19, eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 Ok Reg 1774, eff 9-11-16; Amended at 39 Ok Reg 2055, eff 9-11-22]

535:10-11-4. Immunization registration

(a) In order to obtain and maintain eligibility to administer immunizations an applicant must be licensed as a pharmacist in Oklahoma and have successfully completed an approved training described in 535:10-11-5.

(b) Each D.Ph. immunization applicant is subject to the rules regarding applicants in Subchapter 535:25-3.

(c) Prior to administering immunizations, each D.Ph. shall obtain an immunization permit with the Board.

(1) Such D.Ph. shall apply obtain an immunization permit by completing an application form furnished by the Board and paying the $25 fee.

(2) The immunization permit must be displayed in the pharmacy where the D.Ph. is performing immunizations.

(3) Duplicate immunization permits are available with duplicate application and fee.

(d) An Oklahoma licensed intern who has successfully completed an approved immunization training program described in 535:10-11-5, while working under an Oklahoma licensed pharmacist preceptor with an immunization registration, shall be exempt from immunization registration. Such intern shall provide proof of such successfully completed immunization training program upon request of the Board.

[**Source:** Added at 20 Ok Reg 19, eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 33 Ok Reg 1774, eff 9-11-16]

535:10-11-5. D.Ph. training requirements for administration of immunizations

(a) The following is a list of approved pharmacist training programs for administration of immunizations:

(1) Programs that include training in immunizations offered by the two state colleges of pharmacy:

(A) Southwestern Oklahoma State University (SWOSU) College of Pharmacy

(B) University of Oklahoma (OU) College of Pharmacy

(2) Immunization programs approved by the Accreditation Council for Pharmacy Education (ACPE).

(3) Immunization programs offered by the American Pharmaceutical Association (APHA).

(4) Immunization programs offered by the National Community Pharmacy Association (NCPA).

(5) Immunization programs offered by the American Society of Health System Pharmacists (ASHP).

(b) Each D.Ph must have successfully completed one of these training courses in immunization prior to registering with the Board or administering immunizations prescribed by an Oklahoma licensed prescribing practitioner.

[**Source:** Added at 20 Ok Reg 19, eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 26 Ok Reg 2271, eff 7-1-09]

535:10-11-6. Records

(a) Records of these immunizations will be kept on file by the pharmacy. The files will include, but not be limited to, the following:

(1) Patient name (Parent name, if patient is a minor)
(2) Address of patient
(3) Prescribing licensed practitioner or pharmacist
(4) Immunization order
(5) Name, Manufacturer, Lot no., Expiration Date
(6) Date for continued dose regimen if required

(b) Such records must be readily available for inspection in the pharmacy.
(c) Records or reports will be sent to the State Health Department, if required.
(d) Report of immunization to prescribing licensed practitioner, if requested.

[**Source:** Added at 20 Ok Reg 19, eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 33 Ok Reg 1774, eff 9-11-16; Amended at 39 Ok Reg 2055, eff 9-11-22]

APPENDIX A. INTERNSHIP TRAINING GUIDE [REVOKED]

[**Source:** Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 10 Ok Reg 3167, eff 6-25-93; Revoked at 11 Ok Reg 3425, eff 6-27-94]

CHAPTER 12. UNUSED PRESCRIPTION DRUG PROGRAM FOR OKLAHOMA'S MEDICALLY INDIGENT

[**Authority:** 59 O.S.,§§ 367.1 through 367.8]
[**Source:** Codified 7-1-05]

535:12-1-1. Purpose

(a) The rules of this Chapter describe a statewide program to take unused prescription drugs from nursing homes, assisted living centers; and donated drugs from pharmaceutical manufacturers and utilize them for dispensing to medically indigent Oklahoma residents as authorized under Title 59 O.S. Section 367.1 through 367.7, et seq., the Utilization of Unused Prescription Medication Act.
(b) The rules of this Chapter describe the eligibility to donate. They describe the eligible prescription drug formulary, the eligible recipients, and the protections for participants. They describe pharmacies eligible to accept and dispense such drugs, the requirements for eligible pharmacies, and the responsibilities for pharmacist managers.
(c) The rules of this Chapter describe safe handling of medications to protect drug integrity, tracking, sanitation, security and dispensing requirements for these unused prescription drugs. The rules of this Subchapter describe confidentiality requirements as well as violations.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-2. Definitions

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

"Assisted living center" means assisted living center as defined in Title 59 O.S. Section 367.2.

"Cancer drugs" means cancer drugs as defined in Title 59 O.S. Section 367.2.

"Charitable Clinic" means charitable clinic as defined in Title 59 O.S. Section 367.2.

"Eligible Pharmacy" means a pharmacy eligible to participate in the unused prescription drug program and includes those pharmacies operated by the following:

(A) A County in Oklahoma;
(B) A City-County Health Department in Oklahoma;
(C) A firm under contract with a City County Health Department in Oklahoma;
(D) A Charitable Clinic; or
(E) The Oklahoma Department of Mental Health and Substance Abuse Services.

"Health care professional" means health care professional as defined in Title 59 O.S. Section 367.2.

"**Manifest**" means an invoice used to list drugs being transferred or destroyed.

"Medically indigent" means medically indigent as defined in Title 59 O.S. Section 367.2

"Prescription drug" means prescription drug as defined in Title 59 O.S. Section 367.2.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-3. Eligibility to donate prescription drugs

(a) Oklahoma licensed Nursing homes, and approved Oklahoma licensed Assisted Living Centers (ALC) may donate eligible unused prescription drugs.

(1) Oklahoma Nursing Homes are eligible to participate if they are licensed and in good standing with the Oklahoma State Department of Health (OSDH) and are meeting OSDH drug handling standards:

(A) The OSDH will be consulted regarding rules for Nursing Homes' participation in this program;
(B) The OSDH sets requirements under which nursing homes shall maintain prescription drugs. Such rules establish security, sanitation and control;
(C) Licensed healthcare personnel shall have kept control of such unused prescription drugs in sanitary and secure conditions as required under OSDH rules for Nursing Homes; and
(D) Such unused prescription drugs kept to these standards shall be eligible for donation.

(2) Approved licensed ALC eligibility requirements for participating in donation of unused prescription drugs under the provisions of this Subchapter:

(A) An application for participation shall be completed by the consultant pharmacist of the ALC and submitted to the Board.
(B) Only those ALC's that maintain prescription drugs under the control of licensed healthcare professionals in sanitary and secure

conditions in a manner similar to the OSDH rules for nursing home drug control may be approved.

(C) Such application must show adequate controls exist in ordering, storage, security, etc.

(D) Application must be reviewed and approved by OSBP with the advice of the Oklahoma State Health Department.

(b) A licensed prescription drug manufacturer may donate samples or eligible prescription drugs to eligible pharmacies in this program.

(1) Manufacturer's patient assistance program (PAP) prescriptions that are not claimed in a reasonable length of time or abandoned by the patient may be used for another medically indigent patient.

(2) A patient specific stock bottle sent by a drug manufacturer and not claimed in a reasonable length of time or abandoned by the patient may be used for another medically indigent patient.

(c) A prescription is the property of the patient for whom it is prescribed regardless of who paid for the prescription as described in 59 O.S. Section 354. The patient or agent of the patient must authorize the donation of the unused prescription drugs, unless the:

(1) Patient has died; or,

(2) Drug has been discontinued as described in OSDH nursing home rules.

(d) Prescription medications donated under this Subchapter shall only be transferred to eligible pharmacies.

(e) Prescription medications donated under this Subchapter shall not be sold, resold, offered for sale nor traded, except the transfer as allowed in 535:12-1-9 (d) between eligible pharmacies.

(f) Violations of the unused prescription drug program are described in 535:12-1-12.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-4. Consultant pharmacist responsibilities in eligible nursing homes or approved assisted living centers (ALC) participating in the program

(a) All donating nursing homes or approved ALC's must have a consultant pharmacist.

(b) Consultant pharmacists for the nursing home or the ALC eligible to donate unused prescription drugs shall be responsible to:

(1) Determine quality and suitability of the unused prescription drugs for reuse by assuring;

(A) Drugs have been kept under control of a health care professional

(B) Drugs have been stored properly (e.g. heat, cold, moisture),

(C) Drugs can be identified, and

(D) Drugs are not adulterated, mutilated, etc.

(2) Determine that the expiration date exceeds 45 days to allow time for re-distribution;

(3) Determine if it is cost effective to transfer such drugs to an eligible pharmacy;

(4) Assure manifest is properly filled out with the following;

(A) Names of Consultant Pharmacist and Director of Nursing (D.O.N.) or designee, the nursing home and the name of the receiving pharmacy;

(B) Name and strength of the eligible prescription drug (EPD);

(C) Expiration date of the EPD;
(D) Number of tablets or capsules or volume if liquid or injectable; and

(5) A copy of this manifest shall be provided to the pharmacy and a copy shall be maintained by the nursing home or ALC for two years;
(6) Assure controlled dangerous substances (CDS), also known as Scheduled drugs, are not transferred but handled as required under state and federal law;
(7) Assure that the selected pharmacy is eligible to receive unused prescription medications under these rules; and,
(8) Notify the eligible pharmacy when the drugs are ready to be picked up. The transportation of the unused drugs shall be the responsibility of the eligible receiving pharmacy. Such eligible pharmacy shall pick up donated drugs in an expedient manner.

(c) The consultant pharmacist and Director of Nursing [D.O.N.] (or designee) of the Nursing Home will initiate a manifest of the unused prescription drugs to be sent to the eligible pharmacy as described in (b)(4) and (5) above. They will be responsible for determining that the patient has authorized the donation of the drugs.
(d) The consultant pharmacist and the D.O.N. shall assure the name of the patient, name of the pharmacy, and directions on the label will be redacted with black ink or removed before sending to the eligible receiving pharmacy to protect confidentiality.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-5. Eligible prescription drugs, formulary

(a) All FDA approved prescription drugs excluding any controlled dangerous substances (e.g. Prescription drugs found in Schedule I, II, III, IV, or V) subject to the following:

(1) Only eligible prescription drugs in original sealed unit dose or unused injectables;
(2) Packaging must be unopened;
(3) No expired drugs;
(4) No lost identity or unknown drugs;
(5) No adulterated drugs; and,
(6) No drugs held outside of licensed healthcare person's control where sanitation and security can not be assured.

(b) Compounded drugs shall not be eligible for transfer.
(c) Cancer Drugs as approved by the Board and American Cancer Society representatives.

(1) Such cancer drugs shall be in manufacturer's unit dose packaging.
(2) Receiving pharmacy must have the capacity to safely handle cancer drugs.

(d) Licensed prescription drug manufacturers may donate eligible prescription drugs.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-6. Eligible recipients of unused prescription drugs

(a) Oklahoma medically indigent residents are entitled to receive dispensed unused prescription drugs as described in this subchapter.

(b) This program is to provide medications to needy Oklahomans. OAC 535:12-1-12 discusses possible action for abuse and violations.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-7. Protection for participants in the unused prescription drug program

Title 59 O.S. Section 367.6 describes protection for donors and participants in the unused prescription drug program under this act.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-8. Pharmacies eligible to accept and dispense unused prescription medications

(a) The following Oklahoma licensed pharmacies may accept unused prescription drugs as described in 535:12-1-4 for dispensing under this act, when operated by:

(1) a County in Oklahoma;
(2) a City-County Health Department in Oklahoma;
(3) a firm under contract with a City County Health Department in Oklahoma;
(4) a Charitable Clinic; or
(5) The Oklahoma Department of Mental Health and Substance Abuse Services

(b) All eligible pharmacies prior to beginning or terminating participation shall send written notice to the Board. A list of these eligible pharmacies will be posted on the Board web-site.
(c) The Board will request input and consult with the Oklahoma State Health Department regarding rules for City-County Health Department pharmacies.
(d) The Board will request input and consult with the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS) regarding rules for ODMHSAS pharmacies.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-9. Requirements for Pharmacies dispensing unused prescription drugs

(a) The following are requirements for eligible Oklahoma licensed pharmacies dispensing unused prescription drugs;

(1) Maintain a current drug identification book, or may have a current computer program or online service for the same;
(2) Dispense unused prescription drugs only upon the valid prescription of an Oklahoma licensed health care prescribers;
(3) Properly label all dispensed unused prescription drugs;
(4) Comply with all federal and state law and rules regarding storage and distribution of prescription drugs;
(5) Inspect all prescription drugs prior to dispensing to determine that the donated drugs shall meet all federal and state requirements for product integrity;
(6) Unused prescription drugs, prescription drug manufacturer's drug samples and donated manufacturers drug stock obtained or donated under this Subchapter shall not be resold, except transfers as allowed in 535:12-1-9 (d) between licensed eligible pharmacies.

(b) If it is determined by the pharmacist's professional judgment that it would be best for the patient, the drugs can be removed from bingo cards (unit dose packaging [UDP]) and placed in a proper vial for dispensing. If the bingo card is relabeled and used the pharmacist must ensure that the patient is made aware that the medication is not in a child resistant container.

(1) See expiration dating requirements in labeling 535:12-1-11.

(2) The removal of the medication from the bingo card (UDP) may only be done by the dispensing pharmacy's licensed pharmacist or permitted pharmacy technician.

(3) Samples must remain in original package as required under federal law, and cannot be removed from original packaging for dispensing.

(c) Eligible Oklahoma licensed charitable pharmacies may establish the following policy and procedures for dispensing of unused prescription drugs to the medically indigent.

(1) May limit the number of prescriptions per patient per visit or per month, to allow a greater number of individuals access to such prescription drugs.

(2) When established, this should be a written policy that is enforced equally to prevent discrimination.

(d) Eligible Pharmacies (EP) may transfer unused prescription drugs to another pharmacy in the program when one EP has the need for a drug and another EP has it available.

(1) A manifest will be prepared by the transferring pharmacy and kept on file for two (2) years.

(2) A copy of the manifest will be sent with the transferred drugs and kept on file in the receiving pharmacy for two (2) years.

(e) The Board will request input from the Oklahoma Department of Mental Health andSubstance Abuse Services regarding rules for their eligible pharmacies.

(f) The Board will request input from the Oklahoma Department of Health regarding rules for their eligible pharmacies.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05; Amended at 32 Ok Reg 1227, eff 8-27-15]

535:12-1-10. Responsibilities of pharmacist manager of eligible licensed pharmacies

(a) The pharmacist manager of eligible licensed pharmacies shall be responsible for the following:

(1) Coordinate retrieval of donated unused prescription drugs from nursing homes and eligible ALC. Such retrieval shall be in an expedient manner;

(2) Check unused prescription drugs (UPD) against the manifest and resolve any discrepancy;

(3) Store and secure these UPD as required under state and federal law and rules;

(4) Check the unused prescription drugs for adulteration;

(5) Assure expired, adulterated, lost identity drugs are not dispensed;

(6) Assure such unacceptable drugs are not put in dispensing stock. Destroy such unacceptable drugs within 14 days as described in 535:12-1-10 (a) (8).

(7) Assure safety in drug recalls. If a drug is recalled and the eligible pharmacy does not have the lot number on the label to differentiate between the recall and non-recalled, all such donated recalled drug shall be destroyed.

(8) Assure destruction of expired, adulterated, and/or recalled unused prescription medications.

(A) A manifest shall be made of unused prescription drugs expired, adulterated and/or recalled to be destroyed.

(B) Following destruction such manifest shall be signed by the pharmacist manager and witness verifying such destruction.

(C) Drug destruction manifest shall be kept in the files of the pharmacy for two (2) years.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-11. Labeling

(a) All previous patient or pharmacy labeling on an unused prescription drug will be redacted or removed by dispensing eligible pharmacy.

(b) Dispensed prescription for a medically indigent patient will clearly indicate the final dispensing pharmacy and the current patient information to assure clarity for receiving patient and shall be properly labeled.

(c) Expiration date is required on all unused prescription drugs dispensed.

(1) The expiration date is brought forward to the filled prescription if only one expiration date is used in the filling of the prescription.

(2) If multiple packages of unused prescription drugs are used to fill a single prescription with varied expiration dates, the shortest expiration date is used for the dispensed prescription.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

535:12-1-12. Violations

(a) Theft or diversion of any of the unused prescription drugs is a violation of these rules. This includes any expired, lost identity drug, recalled drug, or other drug found to be unusable under the requirements of this Subchapter.

(1) Such violation by a licensed nursing home or licensed Assisted Living Center of these rules will be referred to the Oklahoma State Health Department and/or other proper authorities for possible action.

(2) Such violation by the Oklahoma Department of Mental Health and Substance Abuse Services facility of these rules will be reported to the Oklahoma Department of Mental Health and Substance Abuse Services and/or other proper authorities for possible action.

(3) Such violation by a registrant of the Board may result in action under Title 59 O.S. Section 353.26.

(b) Dispensing of expired unused prescription drugs is a violation of these rules.

(c) Sale, trade, offer for sale or trade (except transfer as allowed in 535:12-1-9 (d) between licensed eligible pharmacies) any of the drugs obtained pursuant to this Subchapter and shall include any expired, lost identity, recalled or other such drug unacceptable for dispensing that comes into the program shall be a violation of these rules.

(d) Violation of this section by a registrant may result in loss of the ability to participate in this program; and may include Board action against the registrant as described in Title 59 O.S. Section 353.26.

(e) Abuse of this program shall be reported to the legislature and may result in the loss of this program.

[**Source:** Added at 22 Ok Reg 345, eff 1-1-05 (emergency); Added at 22 Ok Reg 2168, eff 7-1-05]

CHAPTER 13. EMERGENCY / DISASTER PRESCRIPTION DRUG RULES

[**Authority:** 51 O.S., §§ 24A.5(3) et seq.; 59 O.S., §§ 353.7, 353.13, 353.16A, 353.17, 353.18, 353.20, 353.22, 353.24 through 353.26, and 353.29 through 354; 63 O.S., §§ 2-201, 2-208, and 210; 75 O.S., §§ 302, 305, 307, and 309]
[**Source:** Codified 7-1-07]

535:13-1-1. Purpose

(a) The rules of this chapter define what procedures pharmacies, pharmacists, medical gas suppliers, and medical gas distributors may use to accommodate patient medication needs in the event of an emergency / disaster situation that disrupts the normal prescription drug distribution channels.
(b) The rules of this chapter will maintain controls to protect public health while allowing emergency actions to accommodate patient medication needs during such emergencies or disasters.

[**Source:** Added at 24 Ok Reg 2256, eff 7-1-07; Amended at 30 Ok Reg 2009, eff 7-25-13]

535:13-1-2. [RESERVED]

[**Source:** Reserved at 24 Ok Reg 2256, eff 7-1-07]

535:13-1-3. Declaration of emergency

Emergency / disaster prescription drug rules may be used when the governor of Oklahoma makes a disaster or emergency declaration and the Board finds this disaster or emergency disrupts the normal prescription drug distribution channels in the state of Oklahoma.

[**Source:** Added at 24 Ok Reg 2256, eff 7-1-07; Amended at 30 Ok Reg 2009, eff 7-25-13]

535:13-1-4. Prescription Drug Emergency / Disaster Response

(a) If a patient from the area affected by the emergency / disaster declaration requests a refill of a non-controlled maintenance medication, the pharmacist, medical gas supplier, or medical gas distributor should make an attempt to contact the original prescriber for authorization to dispense refills.

(1) If the prescriber cannot be contacted; and if in the pharmacist's professional judgment, or in the medical gas supplier's or medical gas distributor's sound judgment, the dispensing of the medication is essential to the patient's health and safety, the pharmacist, or in the case of a medical gas supplier or medical gas distributor may dispense a one-time emergency supply up to a 30-day supply of such medication.

(2) Only prescription medical gases may be dispensed by medical gas suppliers and medical gas distributors under these rules.

(3) The prescription should be marked as an "Emergency" prescription for a person displaced or affected by such disaster.

(b) If a patient from the area affected by the emergency / disaster requests refills of controlled dangerous substance (CDS), the pharmacist should make an attempt to contact the original prescriber for authorization to dispense refills.
(c) If the pharmacist is unable to contact the prescriber regarding a CDS prescription, then they must check with the federal Drug Enforcement Agency (DEA) and Oklahoma Bureau of Narcotics (OBN) to see if they have approved an emergency dispensing of CDS for patients affected by the emergency / disaster.

(1) If the federal DEA and OBN approve dispensing CDS in an emergency or disaster situation; and, if in the pharmacist's professional judgment the

dispensing of the medication is essential to the patient's health and safety, the pharmacist may dispense up to the allowed limit set by DEA and OBN not to exceed a ten (10) day supply of CDS medication.

(A) The patient should provide identification and a prescription vial or some means of determining the person has been prescribed such medication.

(B) The prescription should be marked as an "Emergency" prescription for a person displaced or affected by the disaster.

(2) If emergency CDS dispensing is NOT approved by the federal DEA and OBN the patients will have to be referred to a healthcare professional.

[**Source:** Added at 24 Ok Reg 2256, eff 7-1-07; Amended at 30 Ok Reg 2009, eff 7-25-13; Amended at 32 Ok Reg 1228, eff 8-27-15]

CHAPTER 15. PHARMACIES

[**Authority:** 59 O.S., §§ 353.7, 353.9, 353.11 through 353.20.2, 353.22, 353.24 through 353.26, 353.30, 354, 356 through 356.5, 357 through 360, and 367.1 through 376.8]
[**Source:** Codified 12-31-91]

SUBCHAPTER 1. GENERAL PROVISIONS

535:15-1-1. Purpose

(a) The rules of this Chapter regulate the sale or storage of drugs, medicines, chemicals and poisons and the dispensing of drugs and medicines in all places where drugs and medicines are compounded, dispensed or stored.
(b) The rules of this Chapter concern all places, including premises, equipment, contents and records, where drugs, medicines, chemicals or poisons are sold, stored, vended, given away, compounded, dispensed or manufactured, or the profession of pharmacy is practiced.
(c) The rules of this Chapter further describe the Board's authority and duty to take and copy records and the duty to confiscate all drugs, medicines, chemicals or poisons found to be sold, stored, vended, given away, compounded, dispensed or manufactured contrary to the provisions of 59 O.S. Section 353 et seq.
(d) The rules of this Chapter prescribe minimum standards with respect to floor space and other physical characteristics of pharmacies, including retail pharmacies with drug supplier and sterile compounding permits, and hospital pharmacies, which are necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public, and which are required to receive new or renewal licenses or to close a pharmacy.
(e) Compliance with the rules of this Chapter is the responsibility of both the pharmacy and pharmacy manager, and in some cases, the pharmacist working in the pharmacy.

[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

SUBCHAPTER 3. PHARMACIES

535:15-3-1. Requirements in pharmacy [REVOKED]

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 10 Ok Reg 923, eff 1-27-93 (emergency); Amended at 10 Ok Reg 3171, eff 6-25-93; Amended at 11 Ok Reg 3431, eff 6-27-94; Revoked at 12 Ok Reg 2593, eff 6-26-95]

535:15-3-1.1. Definitions

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

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

"Controlled dangerous substance" or **"CDS"** or **"Scheduled drug"** or **"Sch"** means a drug, substance or immediate precursor in Schedules I through V of the Oklahoma Uniform Controlled Dangerous Substance Act, 63 O.S. Section 2-101 et seq.

"Pharmacist in charge" or "(PIC)" means a pharmacist manager. This is the pharmacist manager required for pharmacy licensure in 59 O.S. Section 353.18 (A)(2).

[**Source:** Added at 17 Ok Reg 2626, eff 7-1-00; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 19 Ok Reg 1796, eff 7-1-02; Amended at 32 Ok Reg 1229, eff 8-27-15]

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.

(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) **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.

[**Source:** Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 14 Ok Reg 3024, eff 7-1-97; Amended at 15 Ok Reg 3272, eff 7-13-98; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1882, eff 9-11-17; Amended at 35 Ok Reg 1918, eff 9-14-18; Amended at 37 Ok Reg 2041, eff 9-11-20; Amended at 38 Ok Reg 2440, eff 9-11-21]

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.

[**Source:** Added at 38 Ok Reg 2440, eff 9-11-21]

535:15-3-3. Requirements for pharmacies employing assistant pharmacists

All regularly licensed pharmacies employing registered assistant pharmacists must have a fully registered pharmacist actively engaged in the operation of said pharmacy for a period of not less than twenty-eight (28) hours per week.

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) **Library.** There shall be the necessary library which has been prescribed and standardized by the Board in Section 535:15-3-6.
(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.
(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.
(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.
(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.
(9) **Containers.** There shall be sufficient stock of containers suitable for the dispensing of all prescriptions both for internal and external usage.
(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.

(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.

[**Source:** Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 35 Ok Reg 1918, eff 9-14-18; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-3-4.1. Pharmacy licensing requirement

(a) Every pharmacy conducting intrastate transactions in Oklahoma shall be licensed as required under 59, O.S. Section 353.18(A). Every pharmacy shall also be licensed as required by 59 O.S. Section 353.18(A) if Oklahoma is the state from which or into which it delivers, distributes, or dispenses or offers to sell, sale, deliver, distribute, or dispense dangerous drugs, medicines, chemicals or poisons for the treatment or prevention of diseases, excluding agricultural chemicals and drugs.
(b) Every applicant for pharmacy license issued under 59 O.S. Section 353.18 shall fully and completely disclose ownership as required by the Board on his new and/or renewal application.

[**Source:** Added at 17 Ok Reg 2626, eff 7-1-00; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 29 Ok Reg 1641, eff 7-12-12; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-3-4.2. Minimum required information for licensure

(a) Minimum required information for licensure shall be that information required by 59 O.S. Section 353.18(A) and the rules in 535:25-3.
(b) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g.: manager, contact person, phone, etc.)
(c) Changes of location, name, or ownership shall require a new license.
(d) Each location and/or pharmacy shall require a license.

[**Source:** Added at 17 Ok Reg 2626, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-3-5. Lock out pharmacy or prescription department

(a) **"Lock out Pharmacy or Prescription Department"** means a prescription department that is to be operated for a period less than the regular business hours of the entire store. The following shall apply to lock out pharmacies or prescription departments:

(1) **Separate area.** The prescription room shall be separated from other departments of the store by a floor to ceiling partition which shall be a secure partition, secured by lock from other departments of the store.
(2) **Space.** No prescription department shall occupy less than 125 square feet of space, all of which must be contiguous and on the same floor level.
(3) **Responsibility.** The prescription department or pharmacy will be under the direction and in the charge of a registered pharmacist or assistant pharmacist at all times the department is open for business.
(4) **Minimum hours.** The hours of said department shall be a minimum of forty (40) hours per week five (5) days per week, excluding holidays.
(5) **Posting of hours.** The business hours of the prescription department shall be plainly posted on all entrances to such department and no unregistered personnel will have access to this department either before or after these hours.
(6) **Equipment.** The equipment of such pharmacy departments shall be the same as specified in the regular application for pharmacy license contained in 535:15-3-4.

[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00]

535:15-3-6. Required library reference books or computer sources

A pharmacy library shall contain the following current reference books or computer sources:

(1) **Oklahoma law books.** The latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy; and, a recent copy of Oklahoma State Bureau of Narcotics & Dangerous Drugs Control Rules.

(2) **Library menu.** A recent copy of any two of the following:

(A) USP/NF (3 years or latest edition);
(B) Merck Manual (3 years or latest edition);
(C) Remington (6 years):
(D) A toxicology reference (3 years);
(E) Mosby's Drug Consult (2 years);
(F) Facts and Comparisons (2 years);
(G) ASHP, American Hospital Formulary Service (AHFS) Drug Information (2 years);
(H) Monthly Prescribing Reference (MPR) (2 years);
(I) Drug Information Handbook (2 years);
(J) Thomson Micromedex, USP-DI (2 years); and/or,
(K) Current computer professional pharmacy reference program, approved by the Board (not duplicating a hard copy reference) e.g. one or two of the following:

(i) Thomson Micromedex, USP-DI
(ii) Clinical Pharmacology
(iii) Facts and Comparisons
(iv) Natural Medicines Comprehensive Database
(v) Trissel's 2 Clinical Pharmaceutical Database
(vi) Unlimited internet access to internet professional pharmacy reference program, e.g. WEB MD

[**Source:** Amended at 10 Ok Reg 3171, eff 6-25-93; Amended at 13 Ok Reg 2807, eff 6-27-96; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 22 Ok Reg 2172, eff 7-1-05; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-3-7. Condemnation authority for open packages of drugs taken in thefts / burglaries

The Board or its authorized representatives may condemn any packages of drugs taken in a criminal action and order their destruction if these drugs would be unfit for consumption.

[**Source:** Amended at 22 Ok Reg 2172, eff 7-1-05; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-3-8. Closing a drug store; violation notice

In the event it becomes necessary for the Board to close a drug store for a direct violation of the Oklahoma State Pharmacy law, the following notice shall be placed on the front door where it will be plainly visible to the public. This sign should not be less than 10" by 12". This sign should have letters not less than one-half inch in height. "This drug store closed by order of the Oklahoma State Board of Pharmacy for (violation
stated) . . . . . ., which is a direct violation of . . . . . (pharmacy law
section) . . . . . ."

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

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 the non-resident pharmacy is located. The PIC must also be licensed by the Oklahoma 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.

(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.

(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 O.S.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.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 13 Ok Reg 2807, eff 6-27-96; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1231, eff 8-27-15; Amended at 35 Ok Reg 1918, eff 9-14-18; Amended at 37 Ok Reg 2041, eff 9-11-20; Amended at 38 Ok Reg 2440, eff 9-11-21; Amended at 39 Ok Reg 2057, eff 9-11-22]

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 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.

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 35 Ok Reg 1918, eff 9-14-18; Amended at 38 Ok Reg 2440, eff 9-11-21]

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.

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 35 Ok Reg 1918, eff 9-14-18; Amended at 37 Ok Reg 2041, eff 9-11-20; Amended at 38 Ok Reg 2440, eff 9-11-21]

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).)

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 14 Ok Reg 3024, eff 7-1-97; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 19 Ok Reg 1796, eff 7-1-02; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 30 Ok Reg 2010, eff 7-25-13; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-3-12.1. Electronic transfer of prescription refill information

(a) Two or more pharmacies that have established and use a common electronic file tomaintain required prescription information may transfer the refill information electronically as described in Subsection (b), except as restricted in 535:15-3-12(1).

(b) Electronic transfer of prescription refill information shall be completed by a licensed pharmacist as follows:

(1) Prior to the transfer or dispensing the pharmacist accessing the file of the original pharmacy shall review the profile of the patient.

(2) In the electronic transfer file system the pharmacist shall be able to void the original prescription and identify the pharmacy and pharmacist taking the prescription refill information.

(3) The original pharmacy shall be notified electronically of the transfer.

(4) The rules in 535:15-3-12 (1), (3) and (5) (B),(i),(ii), (iii) apply to electronic transfers.

[**Source:** Added at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-3-13. Pharmacist's responsibility in a pharmacy

(a) **Access to drugs.** Only a pharmacist shall be responsible for control and distribution of all drugs.

(1) Only the pharmacist shall be permitted to unlock the pharmacy area or any additional storage areas for dangerous drugs, except in extreme emergency.
(2) An extreme emergency shall be in case of fire, water leak, electrical failure, public disaster or other catastrophe whereby the public is better served by overlooking the safety/security restrictions on drugs.
(3) Prescription medications shall not be left outside the prescription area when the pharmacist is not in attendance.

(b) **Professional judgement.** A pharmacist is required to exercise sound professional judgement with respect to the legitimacy of a prescription. The law does not require a pharmacist to dispense a prescription if the pharmacist doubts its origin or if he believes that the prescription may not have been issued for a legitimate medical purpose.

(c) **Legitimate purpose.** The pharmacy and pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized prescriber acting in the usual course of the prescriber's professional practice. The pharmacist maintains the right not to fill the valid prescription.

(d) **Valid patient prescriber relationship.** The pharmacy and pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued without a valid preexisting patient-prescriber relationship.

(e) **Valid prescription drugs.** Only those prescription drugs legal to sell in the United States shall be dispensed. (e.g. FDA approved prescription drugs, or legally compounded prescription drugs, or drugs in a drug-testing protocol, or other legal prescription drugs.)

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 22 Ok Reg 2172, eff 7-1-05; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-3-14. Patient records

(a) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed.

(b) The patient record system shall provide for the immediate retrieval of the following information:

(1) full name of the patient for whom the drug is intended;
(2) address and telephone number of the patient;
(3) patient's age or date of birth;
(4) a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the previous six months showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
(5) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) The pharmacist shall assure that a reasonable effort is made to obtain and record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs or devices currently being used by the patient, which may relate to prospective drug review.

(d) A patient record shall be maintained for a period of not less than two years. This record may be a hard copy or a computerized form.

(e) This information shall be deemed privileged and released only to the patient or to persons designated by the patient; to those prescribers and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being; and to such other persons or governmental agencies authorized by law to receive such confidential information. Rules regarding a pharmacist's confidentiality responsibility can be found in 535:10-3-1.1 (6) and 535:10-3-1.2 (a) (16).

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-3-15. Identifying auxiliary personnel [REVOKED]

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Revoked at 17 Ok Reg 2626, eff 7-1-00]

535:15-3-15.1. Transmission of prescription orders other than verbal

(a) All transmitted prescription drug orders, other than verbal, shall be transmitted:
- (1) to a pharmacy of the patient's choice with no intervening person or persons altering the prescription order or breeching patient confidentiality;
- (2) by an authorized practitioner; or his designated agent when
  - (A) designated agents are allowed by the practitioner's practice act, and
  - (B) if transmitting designated agent's identity is included in the order.

(b) Transmitted prescription drug orders shall include the transmitter's phone number for verbal confirmation, and the time and date of transmission.
(c) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of a prescription drug order transmitted consistent with federal, state and local laws and rules.
(d) All equipment for receipt of prescription drug orders shall be maintained so as to ensure against unauthorized access.
(e) Prescriptions may be transferred if all requirements of federal, state and local laws and rules are met.
(f) No agreement between a prescribing practitioner and a pharmacy or device and medical equipment holder shall require that prescription orders be transmitted from the prescribing practitioner to only that pharmacy or device or medical equipment permit holder.

[**Source:** Added at 22 Ok Reg 2172, eff 7-1-05; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 33 Ok Reg 1784, eff 9-11-16]

535:15-3-16. Adequate staffing rules for pharmacists and pharmacies

(a) Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an unsafe manner, each shall take action to correct the problem.
(b) In order to ensure adequate staffing levels a staffing form shall be available in each pharmacy. A copy of this form, when executed, will be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection.
- (1) Such form shall include, but not be limited to the following:
  - (A) Date and time the inadequate staffing occurred;
  - (B) Number of prescriptions filled during this time frame;
  - (C) Summary of events; and
  - (D) Any comments or suggestions.

(2) Such forms are not to be sent to the Board.

(c) A pharmacist shall complete the staffing report form when:

(1) A pharmacist is concerned regarding staffing due to:

(A) inadequate number of support persons (cashiers, technicians, auxiliary supportive personnel, etc.); or,

(B) excessive workload;

(2) Filling out the form may enable management to make a better decision concerning staffing.

(d) If the pharmacy manager feels that the situation warrants earlier Board review, the pharmacy manager shall inform the Board.

(e) Each pharmacy shall review completed staffing reports and address any issues listed as well as document any corrective action taken or justification for inaction to assure continual self-improvement. If the issue is not staffing related, measures taken to address the issue should be described.

(f) Each pharmacy shall retain completed staffing reports until reviewed and released by the Board. Such reports requiring further review may be held by the Board and may become part of an investigation file.

(g) A registrant, including a pharmacy, a pharmacy manager, or a pharmacist, shall not be subject to discipline by the employing pharmacy for completing a staffing report in good faith.

[**Source:** Reserved at 14 Ok Reg 3024, eff 7-1-97; Added at 22 Ok Reg 2172, eff 7-1-05; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-3-17. Pharmacy prescription records

(a) The original prescription [as defined in 353.1] shall be maintained and readily retrievable for five years.

(b) Faxed prescriptions received in electronic format (which have not been printed) or electronically transmitted prescriptions may be electronically stored and maintained in a readily retrievable format for five years.

(c) Prescriptions for controlled dangerous substances (CDS) must additionally meet the requirements of the federal Drug Enforcement Administration (DEA) and the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD).

[**Source:** Added at 14 Ok Reg 3024, eff 7-1-97; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 29 Ok Reg 1641, eff 7-12-12; Amended at 34 Ok Reg 1882, eff 9-11-17]

535:15-3-18. Pharmacy prescription drug purchase records

(a) All prescription purchases (e.g. invoices, etc.) and inventory records shall be maintained and be readily retrievable for a period of at least 2 years. Invoices for non-controlled drugs may be maintained electronically.

(b) A pharmacist and/or pharmacy shall exercise careful professional judgment regarding where they purchase the pharmacy's drugs to assure a safe and sanitary drug supply is maintained. Prescription drug purchases may only be made from entities licensed to sell such drugs.

[**Source:** Reserved at 14 Ok Reg 3024, eff 7-1-97; Added at 24 Ok Reg 2257, eff 7-1-07; Amended at 33 Ok Reg 1784, eff 9-11-16]

535:15-3-19. Three prescription files

Three prescriptions files will be kept as follows:

(1) Dangerous Drugs file,

(2) Controlled Dangerous Substances (CDS) - Schedule II's file, and

(3) Controlled Dangerous Substances (CDS) - Schedule Ill's, IV's, V's file.

[**Source:** Added at 14 Ok Reg 3024, eff 7-1-97]

535:15-3-20. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3024, eff 7-1-97]

535:15-3-21. Prescription fill, refill and partial fill records and reports

(a) **Dangerous drugs.**

(1) Refills may be entered on the back of each original prescription.

(2) Refill records may be kept by using an automated data processing system to maintain the refill information.

(b) **Controlled dangerous Substances (CDS) - Schedule II.** No refills are allowed on Schedule II CDS.

(c) **Controlled dangerous Substances (CDS) - Schedule III, IV and V Hard copy method.** The refills are entered on the back of the original (hard copy) prescription according to Oklahoma Bureau of Narcotics and Dangerous Drugs' rules in OAC 475:30-1-11 et seq.

(d) **CDS automated data processing method.** A pharmacy may elect to use an automated data processing system to maintain the prescription files including the original information and the refill information. **Caution:** The pharmacy must maintain complete and retrievable prescription records for five years whether logbooks, nightly reports, or a manual system are used. If the pharmacy elects the automated system certain compliance reports are required.

(1) **Nightly reports.** Nightly reports are required for Schedule II and for Schedule III, IV and V. These reports will include but are not limited to:

(A) Schedule II reports will include the information in ASAP/NABP Committee on Standardization's Computerized Compliance Reports (e.g. run date, run by, Rx #, drug name, dose form, quantity, date written, date dispensed; pharmacist, patient and prescriber names, DEA number, and patient and prescriber addresses.)

(B) Schedule III, IV and V reports will include the same information as in (A) above, except patient and prescriber addresses are not required. These reports may be mixed or be Schedule III, IV or V specific.

(C) These nightly reports shall be verified, signed and dated by the pharmacist as required. (See CFR 1306.22, et seq.)

(D) These reports must be kept for five years.

(2) **Logbook or file alternate procedure.** In lieu of the nightly reports procedure for Schedule II, III, IV & V provided in 535:15-3-21, the pharmacy may choose to use the following method:

(A) The pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such refill dispensing shall sign a statement (in the manner described in CFR 1306.22) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by them and is correct as shown.

(B) Such a book or file must be maintained at the pharmacy employing such a system for a period of five years after the date of dispensing the appropriately authorized refill.

(3) **Refill reports.** Any pharmacy using an automated data processing system to track refills shall be able to print such reports as required in CFR

1306.22 et seq.

(4) **Audit reports.** If an automated data processing system is used to maintain refill information, the ability to print upon request the following Controlled Dangerous Substance (CDS) audit reports is required. The following required audit reports must include the information in ASAP/NABP Committee on Standardization's Computerized Compliance Reports:

(A) CDS Audit Report by Drug
(B) CDS Audit Report by Prescriber
(C) CDS Audit Report by Pharmacist
(D) Patient Profile Report

[**Source:** Added at 14 Ok Reg 3024, eff 7-1-97; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 37 Ok Reg 2041, eff 9-11-20]

535:15-3-22. Pharmacy refrigerator and freezer temperature logs

(a) All refrigerators and freezers used to store medications shall have a sensor or thermometer capable of reading internal temperatures.
(b) The internal temperatures maintained in the refrigerators and freezers shall be appropriate for the products stored.
(c) 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.

(1) Pharmacy name, date, time, temperature and staff person taking reading shall be logged at a minimum for paper logs.
(2) Temperature logs shall be maintained on paper or electronically for two years and be available for inspection.

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

[**Source:** Added at 37 Ok Reg 2041, eff 9-11-20]

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.

[**Source:** Added at 38 Ok Reg 2440, eff 9-11-21]

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

535:15-4-1. Purpose

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

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

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-4-2. Definitions

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

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

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

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

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

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

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10]

535:15-4-3. Registration

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

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10]

535:15-4-4. Staffing requirements

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

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

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

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

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

(A) Complying with federal and state laws and regulations;
(B) Establish and maintain minimum technical standards and specifications, e.g. RMOP processes, passwords, encryption and firewalls;
(C) Establish and maintain procedures for handling computer system or connectivity downtime;
(D) Establish and maintain confidentiality, privacy, and security to meet HIPAA standards;
(E) Establish and maintain pharmacist training, orientation and competencies;
(F) Establish and maintain workload balancing and staffing levels e.g. when will RMOP be triggered and how will workload or staff balancing be done;
(G) Establish and maintain access to 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 Hospital policy resources, policies and procedures;
(N) Establish and maintain records and reports; and,
(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.

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-4-6. Governing body

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

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10]

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

(a) Unlawful acts and violations are described in the Oklahoma Pharmacy Act and this Title.
(b) Remote medication order processing pharmacy rules for conduct, violations of conduct and rules for applicants are found in 535:25.
(c) Rules for conduct and violations of conduct for pharmacists are found in 535:10-3-1.1, 535:10-3-1.2, 535:15-3-2, 535:15-3-4.2; and rules for applicants are found in 535:25.
(d) Remote medication order processing pharmacies are subject to rules in 535:15-3 unless they clearly do not apply to RMOP pharmacies.
(e) Penalties for violations of this Title, the Oklahoma Pharmacy Act and federal and state laws and rules are listed in 59 O.S. Section 353.26.

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

SUBCHAPTER 5. HOSPITAL PHARMACIES

535:15-5-1. Purpose

The rules of this Subchapter are to accomplish the purposes of the Oklahoma Pharmacy Act, as specified in 59 O.S., Section 353.18(A), by implementing the rules and regulations of a licensed hospital pharmacy and a drug room, and as specified in 59 O.S., Section 353.29 by implementing rules regarding supportive personnel.

[**Source:** Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 20 Ok Reg 2479, eff 1-1-04; Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-5-2. Definitions

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

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

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

entry person, etc.).

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

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

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

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

"Hospital" or **"Hospital facility"** or means hospital as defined in 59 O.S. Section 353 et seq.

"Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are stored, controlled and prepared for distribution and administration for the use and/or benefit of patients in a hospital facility. Hospital pharmacy shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded and prepared for dispensing to the members of the medical staff, hospital employees, and the members of their immediate families, patients being discharged, and for other persons in emergency situations.

"Medical staff" means a prescriber who has privileges to practice in the hospital facility.

"Medication order" means a prescription as defined in Title 59 O.S. Section 353.1.

"Pharmacist" means any person licensed to practice pharmacy by the Oklahoma Board.

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

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

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

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

[**Source:** Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 20 Ok Reg 2479, eff 1-1-04; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff

8-27-15; Amended at 34 Ok Reg 1882, eff 9-11-17; Amended at 37 Ok Reg 2041, eff 9-11-20]

535:15-5-3. Applicability

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

[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 27 Ok Reg 2249, eff 7-11-10]

535:15-5-4. Registration

(a) **Registration.** All hospital pharmacies shall register annually with the Board of Pharmacy; hospital pharmacy licenses shall be issued only to those hospital pharmacies that satisfy the provisions of Section 353.18(A) of the Oklahoma Pharmacy Act, and all rules of this Title.
(b) **Minimum hours.** A hospital pharmacy shall be staffed with licensed pharmacist and be open for a minimum of four days a week and for a minimum of at least 32 hours per week to the standards listed in 535:15-5-10 (j).

[**Source:** Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 27 Ok Reg 2249, eff 7-11-10]

535:15-5-5. Director and pharmacy manager

(a) Each hospital pharmacy shall be directed by a pharmacist, hereinafter referred to as the Director of Pharmacy. The Director of Pharmacy shall be responsible for all activities of the hospital pharmacy, and for meeting the requirements of the Oklahoma Pharmacy Act and the rules of this Title.
(b) A hospital pharmacy manager's responsibilities are the same as those set out in Section 535:15-3-2 and the rules of this Subchapter.
(c) When the Director of Pharmacy and the pharmacy manager are separate individuals and the pharmacy manager is under the direction of the Director of Pharmacy, both individuals will be cited when action is taken against the pharmacy and/or the pharmacy manager.

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 14 Ok Reg 3024, eff 7-1-97; Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-6. Staff pharmacists [REVOKED]

[**Source:** Revoked at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7. Supportive personnel

The rules from 535:15-5-7.1 through 535:15-5-7.12, et seq. describe the rules for pharmacy supportive personnel in a licensed hospital pharmacy facility and may include references to the rules in 535:15-13, and other rules of this Title.

[**Source:** Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-5-7.1. Pharmacy technician qualifications and training

(a) A pharmacy technician must have completed a high school education or G.E.D. equivalence, be of good moral character, be non-impaired (e.g. alcohol or drugs) and have adequate education to perform assigned duties.

(b) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job training (OJT) program as described in 535:15-13-13.
(c) The Director of Pharmacy must demonstrate that the pharmacy technician has been given additional training before being allowed to prepare sterile products and that the training given is at a level consistent with the scope of pharmaceutical product being prepared.
(d) A pharmacy technician, to be eligible for a technician permit, must comply with the requirements in this Title and 535:25.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01]

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 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.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-5-7.3. Auxiliary supportive personnel tasks

Auxiliary supportive personnel may perform the following tasks:
(1) Retrieve prescriptions or files as necessary;
(2) Clerical tasks such as data entry, 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.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

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 tasks auxiliary supportive personnel are allowed to perform;

(2) Count and/or pour medications;

(3) Affix prescription label to the final container;

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

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

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

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

(9) 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) 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) 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.

(14) 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.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 35 Ok Reg 1918, eff 9-14-18; Amended at 37 Ok Reg 2041, eff 9-11-20; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-5-7.5. Prohibited duties

These prohibited duties shall be performed by a pharmacist and shall not be performed by supportive personnel:

(1) Final interpretation of the prescriber's original order.

(2) Performance of the prospective drug utilization review and determination of action to be taken when there is an indication of a drug interaction.

(3) Receipt of new phone-in prescriptions from prescribers or their agents.

(4) Determination of product selection if substitution is requested or approved.

(5) Certification of the completed prescription or medication order for accuracy and completeness before dispensing from the pharmacy department.

(6) Provision of patient counseling or drug information as necessary.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-5-7.6. Pharmacy technician annual permit requirement

(a) Annual permit requirements for pharmacy technicians are set forth in this Title, in 535:15-13-8 and in 535:25.

(b) No pharmacy technician permit shall be issued or continued for an applicant or permit holder who fails to meet and maintain the requirements in 535:25-3 and 535:25-7 or who violates the rules in 535:25-9.

(c) A pharmacy technician must be employed in a licensed pharmacy located in Oklahoma to be eligible to renew their pharmacy technician permit.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-5-7.7. Permit display

Each pharmacy technician permit issued by the Board shall be displayed as set forth in 535:15-13-9.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.8. Change of address and employment location notification

A pharmacy technician must notify the Board of change of address or employment location as set forth in 535:15-13-10.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.9. Multiple employment locations

A pharmacy technician may work in more than one pharmacy location provided the tech has been "trained" for each location and the training is documented in each pharmacy.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.10. Work schedule display

A pharmacy shall display a work schedule as required by 535:15-13-12.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.11. Technician training

Pharmacy technicians shall meet the training requirements as set forth in 535:15-13-13.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.12. Identification of Pharmacy technicians

Pharmacy technicians practicing in a hospital shall be distinctly identifiable from practicing pharmacists.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-8. Absence of pharmacist

During such times as a hospital pharmacy may be unattended by a registered pharmacist, arrangements shall be made in advance by the Director of Pharmacy for provision of drugs to the medical staff and other authorized personnel of the hospital facility by use of night cabinets and in emergency circumstances, by access to the pharmacy. A pharmacist must be "on call" during all absences. Written policies and procedures shall be established to implement the requirements of this section and shall be available for Board review.

(1) **Night cabinets.** IF NIGHT CABINETS ARE USED THE FOLLOWING SHOULD PREVAIL: In the absence of a registered pharmacist, controlled drugs shall be kept in locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized person by force or otherwise. The Director shall, in conjunction with the appropriate committee of the hospital facility, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(A) such drugs available therein are properly labeled;

(B) only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(C) whenever access to such cabinet(s) shall have been gained, written physician's orders and proofs of use, if applicable, are provided; and,

(D) proper inventories and a complete review of all activity concerning such cabinet(s) are conducted no less than once per month.

(2) **Access to pharmacy.** Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this paragraph. One supervisory nurse and only one in any given shift is responsible for removing drugs therefrom. The responsible nurse may, in time of emergency, delegate this duty to another nurse. The responsible nurse shall be designated by position in writing by the appropriate committee of the hospital facility, and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures

required. Such education and training shall be conducted by the Director of Pharmacy, or a pharmacist designee. Access to the pharmacy as described above shall require, at a minimum, the following records and procedures:

(A) a record of the removal of any drug from the pharmacy by an authorized nurse on a suitable form showing patient name, room number, name of drug, strength, amount, date, time and signature of nurse; and,

(B) such form shall be left with the container from which the drug was removed, both placed conspicuously so that it will be found by a pharmacist and checked properly and promptly.

[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-9. Hospital pharmacy physical requirements

A hospital pharmacy shall have sufficient facilities to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this Chapter. The following are in addition to the equipment and library requirements listed in 535:15-3-4 and 535:15-3-6.

(1) **Equipment and materials.** Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing and storage of drugs.

(A) For sterile compounded preparations a hospital must comply with 535:15-10 Part 3.

(B) A library shall be maintained which includes four of the following current references (not more than 2 years old or most recent). Current electronic sources may be substituted for hard copy information sources:

(i) Drug interactions;
(ii) Drug compatibility;
(iii) Poison and antidote information;
(iv) Toxicology;
(v) Pharmacology;
(vi) Bacteriology;
(vii) Patient counseling;
(viii) Rational therapy;
(ix) Dispensing information; and,
(x) Applicable USP standards.

(C) The library shall include the latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy and a recent copy of Oklahoma State Bureau of Narcoti cs & Danger ous Drugs Contro l Rules.

(2) **Storage.** All pharmaceuticals bearing a federal legend such as "RX Only" and medications administered in the hospital shall be stored in designated areas within the hospital which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation and security. The storage shall be as directed by the Director of Pharmacy and shall remain under the direct supervision of a pharmacist.

(3) **Alcohol and flammables.** Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or regulations as may apply.

(4) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked and inspected on a regular schedule of at least monthly as directed by the Director of Pharmacy.
(5) **Security.** All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 10 Ok Reg 3171, eff 6-25-93; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 22 Ok Reg 2172, eff 7-1-05; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

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

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

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

(10) Cooperating fully with teaching and/or research programs in the hospital facility, if any.
(11) Implementing the policies and decisions of the appropriate committees of the hospital, which deal with drug distribution and drug utilization.
(12) Meeting all inspection and other requirements of the Act, and the rules and regulations governing the practice of pharmacy within a hospital facility.
(13) Establishing guidelines for the safe and effective distribution of drugs intended for floor stock, and their subsequent administration.
(14) Initial and continuing training of pharmacy technicians.

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

(1) Rules regarding confidentiality of patient records are described in 535:15-3-14(e); and,
(2) Responsibilities for confidentiality shall be as set forth in 535:10-3-1.1(6) and 535:10-3-1.2 (a) (16) and the rules of this Title.

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

(1) Policies indicating the tracking, review, and outcome of the adverse drug events shall be kept current and available for Board inspection.
(2) Sentinel events, direct impact findings, and root cause analyses involving drugs and/or Medication Management Standards of The Joint Commission shall be maintained and be available for Board inspection.

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

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

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

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

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

(1) Adverse drug reaction reports.
(2) Floor stock inventories of night cabinets and emergency boxes.

(3) Inventory listing of the pharmacy.
(4) Controlled substance inventory.
(5) Ethyl alcohol inventory.
(6) Pharmacy and therapeutic committee minutes.
(7) Reports and records as required by law and/or rules.
(8) Outpatient prescriptions shall contain all information required by pharmacy law and rule.

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

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

(1) The Board must be provided with prior written notice of the installation or removal, or major upgrade that physically changes the operation of automated dispensing systems.
(2) Such notice must include, but is not limited to the:
(A) name and address of the pharmacy;
(B) location of the automated equipment;
(C) identification of the pharmacist-in-charge; and
(D) name of manufacturer and model of system;
(3) Along with such notice, submit a copy of the automated dispensing system quality assurance plan to the Board for review.
(4) The terminal act of automated dispensing must be to a licensed caregiver (nurse, prescriber, or person authorized by law to administer the drug not intended to include medication technicians or CMAs) in the hospital facility in no more than a 24-hour supply of medication that has been reviewed by a pharmacist.

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 10 Ok Reg 3171, eff 6-25-93; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-5-10.1. Labeling

Hospital pharmacies shall label drugs in the following manner:

(1) **For use inside the hospital facility.** All drugs dispensed by a hospital pharmacy to any department of the hospital system, intended for use within the facility, shall be adequately labeled.

(2) **For use outside the hospital facility.** All drugs dispensed by a hospital pharmacy whose patients are about to be discharged, or patients that receive emergency treatment, or to whom it is certain will take the drug dispensed outside of the facility, shall be labeled with the following information:

(A) Name and address of the hospital pharmacy,
(B) Date and identifying serial number,
(C) Name of the patient,
(D) Directions for use to the patient,

(E) Name of the prescriber,
(F) Initials of the dispensing pharmacist,
(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 with a distinctive supplementary label whether added within or outside the direct and personal supervision of a licensed pharmacist. This label shall indicate the name and amount of the drug added, date and time of such addition, expiration date and time of the admixture, and the initials of the persons (preparer and verifier) responsible for the admixture.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-5-10.2. Medication orders

The following rules apply to hospital pharmacies regarding prescriber medication orders:

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

(A) **Authorization.** The appropriate hospital committee shall designate the prescribers authorized to issue 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 the physician's signature. A direct copy or facsimile of the order is to be provided to the pharmacy 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 of the State of Oklahoma and the rules of this Title.

[**Source:** Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-5-11. Non-distributive roles of pharmacists

(a) Written policies and procedures of the Department of Pharmacy shall reflect the scope of non-distributive roles carried out by the pharmacists of the institution and be readily available for inspection by the Board.
(b) These policies shall include a description of the credentials and certifications required of pharmacists by the appropriate hospital committees.
(c) These policies shall include the process for pharmacist credentialing and/or certifying and must comply with state and federal regulation.

[**Source:** Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-12. Administration of drugs to patients

(a) **General provisions.** Drugs shall be administered at a hospital facility in accordance with the policies and procedures of that facility.
(b) **Self-administration.** Self-administration of drugs by patients shall be permitted only when specifically authorized by the prescribing physician, provided a pharmacist or physician has identified the drugs.

[**Source:** Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-13. Medications from other sources

(a) **Drugs from outside pharmacies.** Whenever drugs or pharmaceutical services are obtained from outside of a hospital facility, arrangements shall be made to insure that such outside pharmacies provide their services in a manner which assures the safety of the patients and properly serves the need of the hospital facility. Such arrangements shall be made in writing and shall at a minimum specify that:

(1) A pharmacist shall act in the capacity of a Director of Pharmacy, and therefore, shall be subject to these rules and regulations.
(2) A pharmacist shall provide on-call services at all times.
(3) The hospital will provide adequate storage facilities for these drugs.
(4) All drugs supplied shall be labeled so as to insure that recalls can be effected and that proper control and supervision of such drugs may be exercised. (Unit dose packaging is recommended).

(b) **Emergency sources of medications.** Procedures shall be made, in writing, for the hospital facility to obtain emergency items from a neighboring facility, retail pharmacy, or other source of pharmaceuticals. (Unit dose packaging is recommended).
(c) **Medications from home.** Whenever patients bring drugs into a hospital facility, such drugs shall not be administered unless they can be precisely identified and the physician has specifically indicated on the patient chart that the patient is to take their own medication.

[**Source:** Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-14. Performance improvement

(a) **Purpose.** As a part of the hospital or health system's performance improvement program, the quality and appropriateness of patient care services provided by the Department of Pharmacy shall be monitored and evaluated through a planned and systematic approach to improving performance.
(b) **Responsibility.** The Director of Pharmacy is responsible for assuring that the process described in this Section is implemented to assure safe use of drugs for good patient outcomes.

(1) The Board recommends the Director of Pharmacy serve as a voting member of the hospital wide Performance Improvement Committee.
(2) The Board recommends the Director of Pharmacy assume a leadership role within the hospital or health system for the medication-use process performance improvement (including dispensing, administration, monitoring, prescribing, and education) across the continuum of care.
(3) The Director of Pharmacy shall work in collaboration with patients, prescribers, nurses, and other health care providers in improving the medication use process.

(c) **Measurement.** The pharmacy department shall have a systematic process in place to collect data and measure performance related to the medication-use process.

(d) **Assessment.** The Pharmacy Department shall assess data to identify ways to improve the medication-use process.
(e) **Performance improvement.** The Pharmacy Department shall monitor, achieve and sustain improved performance in the medication-use process towards safe drug use with good patient medication-use outcomes.
(f) **Documentation.** The process described in (a) through (e) of this Section is recorded and documented in a manner consistent with the facility's overall performance improvement program.

[**Source:** Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-5-15. Investigational drugs

(a) **Use within hospital.** Policies and procedures of the Department of Pharmacy shall reflect the use of investigational drugs within the hospital facility. The Director of Pharmacy shall maintain a list of investigational drug protocols and agents being used in the hospital readily available for review by the Board.
(b) **Approval for use.** The appropriate committee of the hospital shall approve all investigational drugs for use within a hospital.
(c) **Labeling and administration.** All investigational drugs shall be labeled in accordance with this Chapter with the drug's investigational status identified on the label. In addition, the individual responsible for the administration of the drug must be provided with complete information regarding its use.
(d) **Storage.** Investigational drugs shall be stored in an area separated from approved pharmaceuticals and shall have the capacity to be locked and secured.

[**Source:** Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-16. Monthly inspections

The Director of Pharmacy, or his appropriate designee, shall conduct an inspection of all areas of the hospital on at least a monthly basis. This inspection shall include, but not be limited to, the following (see 535:15-5-10 for additional requirements):

(1) Drugs for internal use are stored separately from drugs and disinfectants for external use.
(2) Drugs requiring special storage conditions to insure their stability are properly stored.
(3) No outdated drugs are stocked in the facility.
(4) Distribution, administration, and wastage of controlled substances are properly and adequately documented and reported.
(5) Emergency drugs, designated pursuant to 535:15-5-8, are adequate and in proper supply.
(6) All necessary and required security and storage standards are met.
(7) Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
(8) Policies and procedures of the Department of Pharmacy of the hospital facility are followed.

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 18 Ok Reg 2738, eff 7-1-01]

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.

(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 the health, safety and welfare of patients of the facility serviced by the hospital pharmacy.
(c) Any discrepancies or deficiencies noted at inspection shall be corrected.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-5-18. Drug rooms

(a) A drug room, as defined in 535:15-5-2, shall comply with all federal, state and local rules for drug rooms.
(b) At a minimum there shall be a consultant pharmacist on duty as required by the rules of the Oklahoma State Department of Health.
(c) The drugs dispensed from a drug room shall be for administration only to patients in the facility hospital.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2479, eff 1-1-04]

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

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

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

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

(b) Prior to implementation of RMOP services, training shall be provided by the hospital, and the relevant portions of the hospital pharmacy's policy and procedure manual shall be established and maintained on RMOP; and such shall be reviewed by the Pharmacist providing RMOP entry services at least annually.
(c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:

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

(2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1.1 (6) and 535:10-3-1.2 (a) (16).

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

(d) The hospital will make available to the pharmacist(s) performing RMOP entry, access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).
(e) The hospital's computer system shall have the ability to audit the activities of each pharmacist(s) remotely processing the RMOP orders.
(f) A hospital pharmacy may allow RMOP for the patient population served under the hospital's pharmacy license by a pharmacist employed by the same licensed hospital pharmacy. Remote medication order processing performed for patients served under a different hospital pharmacy licensure requires a contractual

arrangement fulfilling the responsibilities as outlined in 535:15-4-5.
(g) All Pharmacists who engage in RMOP shall ensure the following minimum information technology standards and specifications are met and maintained at the remote site:

(1) Availability of internet, phone, and scan or fax access to the hospital.
(2) Ability to access the hospital facility via the hospital's information system.
(3) To the extent possible, have redundant systems in place to ensure remote medication order processing service availability (e.g. internet connectivity, other information systems used to facilitate remote medication order processing).
(4) Have secure electronic access to the hospital's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open.
(5) Use of a computer workstation e.g. with passwords, firewalls and encryption.

(h) The record of each patient-specific RMOP drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the review and verification of the order.
(i) Remote medication order processing by a pharmacist shall not relieve the hospital pharmacy from employing or contracting with pharmacist(s) to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed or additional pharmacist assistance is needed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist(s).
(j) Pharmacists performing remote medication order processing shall not be included in the ratio of the pharmacist and technician as outlined in 535:15-5-7.2. (e).
(k) A pharmacist employed by or contracting with a hospital pharmacy for on-site services may also provide remote medication order processing services when the hospital pharmacy is closed or additional pharmacist assistance is needed through a remote medication order processing pharmacy.

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

SUBCHAPTER 6. HOSPITAL DRUG ROOM

535:15-6-1. Purpose

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

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-2. Definitions

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

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

"Contract employee" means any person who performs services or labor for a hospital, and whose compensation may or may not be reflected on the payroll

records of a hospital. Examples of pharmacy contract employees are consultant D.Ph., relief D.Ph. and/or volunteer D.Ph.

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

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

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

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

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

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-3. Registration

(a) All Oklahoma hospital drug rooms shall be licensed annually with the Board of Pharmacy at a fee set by the Board.

(b) A hospital drug room license shall be issued only to those drug rooms that satisfy and maintain compliance with the provisions of Title 59 O.S. Section 353.18 (a), OAC Title 535, 535:25 for rules regarding registrants, and the rules of this Subchapter.

(c) Each drug room, in order to obtain and maintain a hospital drug room license shall have an Oklahoma D.Ph. as the PIC.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-4. Staffing requirements

(a) The PIC shall be assisted by a sufficient number of additional pharmacists (D.Ph.s) to operate such a drug room competently, safely and adequately to meet the needs of the patients of the hospital facility.

(b) Each hospital drug room shall have oversight by a PIC who shall be responsible for certifying that the drug room meets the requirements of the Oklahoma Pharmacy Act and the rules of this Title. The PIC shall notify the Board, in writing, within 10 days of any change of employment.

(c) A drug room supervisor must be assigned as designated in the rules of the Oklahoma Department of Health under OAC 310:667-21-2(c) et seq.

(1) Designation of the drug room supervisor must be reported to the Board, in writing, on the Hospital Drug Room initial application and on each

subsequent renewal application.
(2) Written notice of change of drug room supervisor must be provided to the Board within 10 days of the change.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

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

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

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

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

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

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

(6) **Review of medication orders.** The PIC shall cause medication orders to be reviewed by a 100 pharmacist in a timely manner.

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

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

(B) No more than 5 visits in any one month count toward the 52 visit total for the year.

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

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

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

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

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

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

(1) The training duties of the PIC are:

(A) Competency training regarding preparation and sterilization of sterile compounded preparations prepared by appropriate hospital staff;

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

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

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

(ii) Such responsibilities for confidentiality shall be as set forth in 535:10-3-1.1(6) and 535:10-3-1.2 (a) (16) and the rules of this Title.

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

(2) Repackaging drug products including unit dose.

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

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

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

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

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

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

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

(10) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and those rules and regulations governing the practice of pharmacy within a hospital facility.
(11) Establishing guidelines for the safe and effective distribution of medicines intended for floor stock, and their subsequent administration.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 37 Ok Reg 2041, eff 9-11-20]

535:15-6-6. Physical and library requirements

A hospital drug room shall have sufficient facilities to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this Chapter.

(1) **Equipment and materials.** Each hospital drug room shall have sufficient equipment and physical facilities for proper compounding, dispensing and storage of drugs.

(A) For compounded sterile preparations:

(i) If a laminar hood is used, a hospital drug room shall comply with 535:15-9-6 and 535:15-9-10, 1 through 5.

(ii) If a laminar hood is not used, a closed system for parenteral admixtures should be utilized. If sterile compounding must be done, an area must be designated for that activity. This area must be at least a counter used for only this purpose and be away from patient care areas. Acceptable aseptic techniques shall be used.

(B) A library shall be maintained which includes four of the following current references (not more than 2 years old or most recent). Current electronic sources may be substituted for two hard copy information sources:

(i) Drug interactions;
(ii) Drug compatibility;
(iii) Poison and antidote information;
(iv) Toxicology;
(v) Pharmacology;
(vi) Microbiology;
(vii) Patient counseling;
(viii) Rational therapy;
(ix) Dispensing information; and,
(x) Applicable USP standards

(C) The library shall include the latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy and a recent copy of Oklahoma State Bureau of Narcotics & Dangerous Drugs Control Rules.

(2) **Storage.** All drugs bearing a federal legend such as "RX Only" and medications administered in the hospital shall be stored in designated areas within the hospital which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation and security. The storage shall be as directed by the PIC and shall remain under the supervision of such pharmacist.

(3) **Alcohol and flammables.** Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or regulations as

may apply.

(4) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked.

(5) **Security.** All areas occupied by a hospital drug room shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 22 Ok Reg 2172, eff 7-1-05; Amended at 32 Ok Reg 1229, eff 8-27-15]

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).

(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.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-6-8. Emergency dispensing and pre-packaged medications

(a) **Emergency dispensing.** A pharmacist or licensed practitioner on duty may label and dispense an appropriate supply of a medication from the hospital drug room when ordered by a prescriber for a patient of the hospital to take with them when dismissed. An appropriate supply would include only sufficient doses required from the time of dismissal until resumption of normal business hours of local pharmacies.

(b) **Pre-packaged medications.** A pharmacist may pre-package medications in sufficient amounts to meet the immediate needs of patients of the hospital. The pre-dispensed medications must be labeled and packaged properly as required under sub-section 535:15-6-7 (c) Labeling, excepting items B, C, D, and E, and adding the medication expiration date and lot number. Such pre-packaged medications shall be securely stored, and an accurate accounting of their use shall be kept.

(1) When such medications are ordered by prescriber, to be used after dismissal from the hospital, the prescriber [with dispensing privileges] shall complete the medication label with the appropriate information including

the patient's name, the prescriber's name, appropriate directions for use, the date the medication is distributed to the patient, and an identifying number.
(2) The prescriber who orders the medication shall be responsible for appropriate patient counseling and drug information dissemination.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1882, eff 9-11-17]

535:15-6-9. Emergency room pre-packaged medications formulary

(a) Each hospital drug room may choose the medicines to be included in their emergency room (ER) pre-packaged medications formulary within the requirements and limits listed below. This formulary shall be included within the policies and procedures of the hospital drug room. These pre-packaged medications shall be administered only as allowed in 535:15-6-8 for a maximum of a 72-hour supply.

(b) Type of Medication defined or parameters for choice **[**Limits**]**

(1) Controlled Dangerous Substances (CDS):
- (A) Codeine/acetaminophen combination [one]
- (B) Tramadol [one]
- (C) Codeine containing antitussive preparation [one]

(2) ACE inhibitor: per ER formulary [two]
(3) Anti-nausea: per ER formulary [two]
(4) Anti-viral: per ER formulary [two]
(5) Anti-coagulant: per ER formulary [two]
(6) Antihistamine: per ER formulary [two]
(7) Anti-hypertensive: per ER formulary [three]
(8) Antimicrobial: per ER formulary [unlimited]
(9) Asthma: per ER formulary [one]
(10) Beta blocker: per ER formulary [two]
(11) Diuretic: per ER formulary [two]
(12) Ear: antibiotic/steroid or antibiotic/ steroid/pain combination
(13) Eye: antibiotic or antibiotic/steroid combination
(14) Miscellaneous:
- (A) terbutaline
- (B) oral contrast media

(15) Muscle relaxant: per ER formulary [two non-CDS]
(16) Pain: per ER formulary [two non-CDS]
(17) Proton pump inhibitor per ER formulary [one]
(18) Steroid: per ER formulary [three]

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 29 Ok Reg 1641, eff 7-12-12; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-10. Access to drugs in absence of PIC or drug room supervisor

(a) **Absence of the PIC or the drug room supervisor.** Advance arrangements shall be made for provision of drugs to the medical staff and other authorized personnel of the hospital facility by use of night cabinets and in emergency circumstances, by access to the drug room by authorized personnel during such times as the drug room may be unattended.

(b) **Night cabinets.** IF NIGHT CABINETS ARE USED THE FOLLOWING SHOULD PREVAIL:

(1) In the absence of a pharmacist (D.Ph.), a supply of controlled dangerous substances may be kept in locked cabinet(s) or other enclosure(s)

constructed and located outside of the hospital drug room area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to an unauthorized person by force or otherwise.

(2) The PIC shall, in conjunction with the appropriate committee of the hospital facility, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(A) Such drugs, available therein, are properly labeled;

(B) Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(C) Whenever access to such cabinet(s) shall have been gained, written ALI practitioner's orders and proofs of use, if applicable, are provided;

(D) A method of documenting responsibility for the key(s) at all times, and their transfer from one authorized person to another, is established;

(E) All drugs therein are monitored weekly, and discrepancies are reported in the PIC's report.

(F) A complete review of all activity concerning such cabinet(s) is conducted no less than once per month; and,

(G) Written policies and procedures are established to implement the requirements of this paragraph.

(c) **Access to drug room.** Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the drug room in accordance with the requirements of this paragraph.

(1) One supervisory registered professional nurse and only one in any given shift is responsible for removing drugs from the hospital drug room. The responsible nurse may, in time of emergency, delegate this duty to another nurse.

(2) The responsible nurse shall, prior to being permitted to obtain access to the drug room, be designated by position in writing by the appropriate committee of the hospital facility; and shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required from the PIC.

(3) Such education and training shall be given by the PIC.

(4) The PIC shall require, at a minimum, the following records and procedures:

(A) The removal of any drug from the hospital drug room by an authorized licensed nurse must be recorded on a suitable record showing patient name, room number, name of drug, strength, amount, date, time and signature of nurse; and

(B) The drug room supervisor or the pharmacist shall properly and promptly check such record.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-11. Administration of drugs to patients

(a) **General provisions.** Drugs shall be administered at a hospital facility in accordance with the policies and procedures of that facility.

(b) **Self-Administration.** Self-administration of drugs by patients shall be permitted per hospital policy only when specifically authorized by the prescriber

per hospital policy, provided the drugs to be self-administered have been identified by a licensed pharmacist or prescriber.
(c) **Administration only.** The drugs supplied or provided from a drug room shall be for administration only to patients of the hospital. No drugs may be provided to employees nor to individuals who are not patients of the hospital.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-12. Medication from other sources

(a) **Drugs from outside sources.** Whenever drugs or pharmaceutical services are obtained from outside of the hospital facility on a regular basis, arrangements shall be made to insure that such outside pharmacists provide their services in a manner that assures the safety of the patients and properly serves the need of the hospital drug room. Such arrangements shall be made in writing and shall at a minimum specify that:

(1) A pharmacist shall act in the capacity of a PIC, and therefore, shall be subject to these rules and regulations.
(2) A pharmacist shall provide on-call services at all times.
(3) The hospital drug room shall provide adequate storage facilities for such drugs.
(4) All drugs supplied shall be labeled so as to insure that recalls can be affected and that proper control and supervision of such drugs may be exercised. (Unit dose packaging is recommended.)

(b) **Emergency sources of medications.** Procedures shall be made, in writing, for the hospital facility to obtain emergency medications from a neighboring facility, retail pharmacy, or other source of drugs. (Unit dose packaging is recommended.)
(c) **Medications from home.** Whenever patients bring drugs into a hospital facility, such drugs shall not be administered unless they can be precisely identified and the prescriber has specifically indicated on the patient chart that the patient is to receive their own medications.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-13. Investigational drugs

(a) **Use within hospital.** Policies and procedures of the drug room shall reflect the use of investigational drugs within the hospital facility.
(b) **Approval for use.** The appropriate committee of the hospital shall approve all investigational drugs for use within a hospital.
(c) **Labeling and administration information.** All investigational drugs shall be labeled in accordance with this Subchapter with the drug's investigational status identified on the label. In addition, the individual responsible for the administration of the drug must be provided with complete information regarding its use.
(d) **Storage.** Investigational drugs shall be stored in an area separated from approved pharmaceuticals and shall be secured.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-14. Drug storage stock inspections

(a) The PIC or his appropriate designee shall conduct an inspection of all drug storage areas within the hospital on at least a monthly basis.
(b) This monthly drug storage area stock inspection shall verify at least the following (see 535:15-6-5 (a) for additional requirements):

(1) Drugs for internal use are stored separately from drugs and disinfectants for external use.
(2) Drugs requiring special storage conditions to insure their stability are properly stored.
(3) No outdated drugs are stocked in the facility and are removed from the facility not more than 6 months after the expiration date.
(4) Distribution and administration of controlled substances are properly and adequately documented and reported.
(5) Emergency drugs are adequate and in proper supply.
(6) All necessary and required security and storage standards are met.
(7) Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
(8) Policies and procedures of the hospital drug room are followed.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-15. Non-distributive roles of pharmacists

The policies and procedures of the hospital drug room shall reflect the scope of non-distributive roles carried out by the pharmacist of the hospital system.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-16. Performance improvement

(a) **Purpose.** As a part of the hospital or health system's performance improvement program, the quality and appropriateness of patient care services provided by the drug room shall be monitored and evaluated through a planned and systematic approach to improving performance.
(b) **Responsibility.** The PIC is responsible for assuring that the process described in this section is implemented to assure safe use of drugs for good patient outcomes.
(1) The Board recommends the PIC serve as a voting member of the hospital wide Performance Improvement Committee.
(2) The Board recommends the PIC assume a leadership role within the hospital or health system for the medication-use process performance improvement (including dispensing, administration, monitoring, prescribing, and education) across the continuum of care.
(3) The PIC shall work in collaboration with patients, prescribers, nurses, and other health care providers in improving the medication use process.
(c) **Measurement.** The drug room shall have a systematic process in place to collect data and measure performance related to the medication-use process.
(d) **Assessment.** The drug room shall assess data to identify ways to improve the medication-use process.
(e) **Performance improvement.** The drug room shall achieve and sustain improved performance in the medication-use process.
(f) **Documentation.** The process described in (a) through (e) of this Section is recorded and documented in a manner consistent with the facility's overall performance improvement plan.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

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.

(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 the health, safety and welfare of patients of the facility serviced by the hospital drug room.
(c) Any discrepancies or deficiencies noted at inspection shall be corrected.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-6-18. Drug room training area

(a) A licensed hospital drug room may apply for a training area certificate after meeting the requirement in 535:10-5 and 535:25.
(b) If approved by the Board, such training area certificate enables the drug room to serve as a licensed training area so long as a qualified pharmacist preceptor is present and supervising each intern working in the drug room, as required in 535:10-5.
(c) Each drug room training area, pharmacist preceptor and intern shall meet requirements in 535:10-5.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-19. Violations

(a) Unlawful acts are described in the Oklahoma Pharmacy Act.
(b) Hospital drug room rules of conduct, violations of rules of conduct, and rules for all applicants are found in 535:25.
(c) Rules of conduct and violations of rules of conduct for PIC are found in 535:10-3.
(d) Penalties for violations of this Title, the Oklahoma Pharmacy Act and federal and state laws and rules are listed in Title 59 O.S. Section 353.26.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04]

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

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

(1) Such registrants remain responsible to assure the hospital drug room meets requirements under Oklahoma laws and rules.
(2) Such registrants shall be responsible to assure RMOP, if used, is reviewed at least annually and that proper credentialing, review and that oversight is established, maintained and exercised.

(b) Prior to implementation of RMOP services, training shall be provided by the hospital drug room and the relevant portions of the hospital drug room's policy and procedure manual on RMOP entry shall be established and maintained; and reviewed by the Pharmacist providing RMOP entry services at least annually.
(c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:

(1) Pharmacists performing RMOP entry must be licensed by the Board.
(2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1.1 (6) and 535:10-3-1.2 (a) (16).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

SUBCHAPTER 7. DRUG SUPPLIER PERMITS

535:15-7-1. Definitions

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

"Drug supplier" means a licensed retail pharmacy which supplies legend drugs to licensed prescribers for their office administration and/or which supplies legend drugs to hospitals and other licensed pharmacies for their dispensing.

"Legend drugs" means including, but not limited to, drugs, medicines, poisons, and/or chemicals (as defined in 59 O.S. Section 353 et seq.) which bear the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "RX Only", or any other label FDA may require which restricts drugs to dispensing with a practitioner's prescription.

[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-7-2. Drug supplier requirements

(a) **Permit eligibility.** In order to obtain and maintain a drug supplier permit, the applicant must have a valid retail pharmacy license.
(b) **Total annual sales.** The total annual sales of the drug supplier shall not exceed five percent (5%) of the total annual sales of the pharmacy.
(c) **Records.** Separate records of sales will be kept on file by the pharmacy. The files will include, but not be limited to, invoices of sales with name and address of purchaser, quantity sold, drug description, price, and date of transaction. These files must be readily available for inspection.
(d) **Controlled Dangerous Substances.** Sales of controlled dangerous substances must conform with statutes and regulations of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, the Federal Drug Enforcement Administration and/or any other federal, state or municipal laws, ordinances or regulations.

535:15-7-3. Drug supplier restriction

(a) Retail pharmacies shall not sell or otherwise supply or provide dangerous substances, prescription drugs, controlled dangerous substances, or a compounded preparation to a wholesaler, manufacturer or repackager, outsourcing facility 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.

[**Source:** Added at 32 Ok Reg 1229, eff 8-27-15; Amended at 33 Ok Reg 1784, eff 9-11-16; Amended at 38 Ok Reg 2440, eff 9-11-21]

SUBCHAPTER 9. STERILE COMPOUNDED PREPARATIONS PHARMACY PERMITS

535:15-9-1. Scope and purpose

The rules of this Subchapter provide standards for the preparation, labeling, and distribution of sterile compounded preparations by licensed retail pharmacies, pursuant to an order or prescription. These standards are intended to apply to all sterile compounded preparations, notwithstanding the location of the patient.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-2. Definitions

The definitions for this Subchapter shall be the same as those defined in 535:15-10-51, as well as the following words or terms, when used in this Subchapter, shall

have the following meaning, unless the context clearly indicates otherwise:

"Sterile preparation pharmacy" means a licensed retail pharmacy with an additional specialized board-approved sterile preparation permit to allow the compounding and dispensing of sterile preparations by an Oklahoma licensed pharmacist pursuant to a prescription order.

"Sterile preparations" means sterile compounded preparations and may include nutrition and/or hazardous or antineoplastic agents and/or sterile irrigation solutions and/or sterile solutions for nebulization and/or sterile eye drops, which are free from living micro-organisms (aseptic) and for parenteral preparations pyrogen and endotoxin free as well.

[**Source:** Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-3. Sterile compounding preparation permit requirements

The following are required to obtain and maintain a sterile compounding preparation pharmacy permit:

(1) **Valid retail license.** The applicant must have a valid retail or non-resident pharmacy license.

(2) **Equipment and supplies.** The pharmacy must have the required equipment and supplies pursuant to the rules and regulations of the Oklahoma Board regarding sterile compounding preparation pharmacy permits.

(3) **Manager.** The pharmacy manager of sterile compounding preparation pharmacy will have sufficient knowledge, education and/or experience in the practice of sterile compounding preparation pharmacy.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-4. Permit issuance

(a) **Required permit.** A sterile compounding preparation pharmacy permit will be required of all pharmacies compounding sterile preparations.
(b) **Fee.** The sterile compounding preparation permit fee will be set by the Board.
(c) **Renewal.** The sterile compounding preparation pharmacy permit will be renewed annually with the retail or non-resident pharmacy license.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-5. Policy and procedure manual

(a) **Availability.** To obtain a sterile compounding preparation pharmacy permit, a policy and procedure manual as it relates to sterile preparations and services that are provided shall be available for inspection at the pharmacy location.
(b) **Review.** The policy and procedure manual shall be reviewed and/or revised on an annual basis. A copy of the policy and procedure manual shall be available for inspection and submitted to the Board upon request by the Board.
(c) **Pre-approval by Board.** The Board may choose to pre-approve all policy and procedure manuals prior to inspection of the sterile preparation pharmacy area.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-6. Pharmacy sterile compounding physical requirements

(a) Pharmacies and personnel who engage in sterile compounding are responsible for complying with State Board of Pharmacy regulations.
(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.

[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 14 Ok Reg 3024, eff 7-1-97; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-9-7. Manager

Each sterile compounding preparations pharmacy shall be managed by a pharmacist who is licensed to practice pharmacy in the State of Oklahoma, and who is knowledgeable in the specialized functions of compounding, preparing and dispensing sterile preparations, including the principles of aseptic technique and quality assurance. This knowledge may be obtained through residency training programs, continuing education programs and/or experience in an infusion admixture facility.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-8. Pharmacist accessibility

Each sterile compounding pharmacy and pharmacy manager shall assure that a qualified pharmacist is accessible and available to respond to patients and healthcare professional questions and needs at all times. A 24-hour telephone number shall be provided.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-9. Drug distribution and control

(a) **Labeling.** Each preparation dispensed to patients by a sterile compounding preparation pharmacy shall be labeled with the following information with a permanent label:

(1) Name, address, and telephone number of the pharmacy;
(2) Date and prescription number;
(3) Patient's name;
(4) Name, strength, and amount of each drug;
(5) Directions for use, including infusion rate where applicable;
(6) Prescriber's name;
(7) Required controlled substance transfer warnings, where applicable;
(8) Date of compounding;
(9) Expiration date and time;
(10) Identity of pharmacist compounding and dispensing;
(11) Storage requirements;
(12) Auxiliary labels, where applicable;
(13) Hazardous drug auxiliary labels, where applicable.

(b) **Delivery service.** The pharmacy manager shall assure the environmental control of all products shipped. Therefore, any compounded sterile preparation or pharmaceutical must be shipped in appropriate containers to insure minimal temperature fluctuation (as defined by USP standards), and stored appropriately in

the patient's home. Chain of possession for the delivery of Schedule II controlled substances via courier must be documented.
(c) **Disposal of infectious waste.** The pharmacy manager is responsible for assuring that there is a system for the disposal of infectious waste in a manner so as not to endanger the public health.

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

Pharmacies and personnel who engage in sterile compounding are responsible for complying with State Board of Pharmacy regulations.

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-9-11. Quality assurance

Pharmacies and personnel who engage in sterile compounding are responsible for complying with State Board of Pharmacy regulations.

[**Source:** Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-9-12. Pharmacist manager responsibility

The pharmacist manager of the pharmacy dispensing sterile compounded preparations shall provide the following or assure that they are provided prior to providing medications.

(1) **Training.** The pharmacist must assure that the patient is properly trained, if self-administering.

(2) **Nurses.** In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacy manager must:

(A) Employ a registered nurse.

(B) Assure that proper records are maintained and are in compliance with laws and regulations.

(C) Make these records available to inspectors from appropriate agencies.

(3) **Twenty-four hour service.** Twenty-four (24) hour service shall be assured by the pharmacy.

(4) **Laboratory data.** Pharmacists shall recommend and monitor clinical laboratory data as needed.

(5) **Side effects and potential drug interactions.** Side effects and potential drug interactions should be documented and reported to the physician.

(6) **Patient histories.** Patient histories and therapy plans should be maintained.

[**Source:** Amended at 32 Ok Reg 1229, eff 8-27-15]

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PREPARATIONS

535:15-10-1. Purpose

The rules of this subchapter describe the requirements of minimum current good compounding practices for the compounding of drug preparations by

Oklahoma licensed pharmacies for dispensing and/or administration to humans or animals.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15]

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 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.

"**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".

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

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 engaging in drug compounding shall be familiar with 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 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 regulations 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.

(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 State Board of Pharmacy regulations.

(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.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 30 Ok Reg 2010, eff 7-25-13; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-10-4. 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 area used for the compounding of non-sterile compounded preparations shall be in an area separate and distinct from the area used for the compounding and aseptic processing of sterile preparations.

(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) Hazardous drugs shall be prepared within a certified Biological Safety Cabinet (Powder Containment hood). Hazardous drug compounding shall be prepared in compliance with applicable USP standards. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. Do not use a ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatize while they are being handled or after they are captured by the HEPA filter.
(e) 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.
(f) Adequate lighting and ventilation shall be provided in all compounding areas.
(g) 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.
(h) Purified water must be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-5. Compounding equipment

(a) Equipment used in the compounding of drug preparations shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning and maintenance.
(b) Compounding equipment shall be of suitable composition so the surfaces that contact components shall neither be reactive, additive nor absorptive therefore not affecting or altering the purity of the compounded preparation.
(c) Equipment and utensils used for compounding shall be thoroughly cleaned promptly after every use to prevent contamination and must be stored in a manner to protect them from contamination. A cleaning log is recommended.
(d) Defective equipment shall be clearly labeled as such.
(e) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated as necessary or checked to ensure proper performance. An equipment calibration log must be maintained.
(f) When drug products with special precautions (antibiotics and hazardous materials) are involved appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs. A cleaning log must be maintained. Equipment dedicated for specific use (i.e. penicillin) shall be clearly designated as such.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-6. Component selection requirements

(a) The pharmacist shall first attempt to use USP-NF drug substances and inactive components that have been made in an FDA registered facility.
(b) If components are not obtainable from an FDA registered facility or if the FDA and/or the company cannot document FDA registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing or using drug components that meet official compendia requirements or another high quality source.
(c) If components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, American Chemical Society-certified, or Food Chemicals Codex grade may be used.
(d) Components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-7. Control of drug product containers

(a) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.
(b) Containers and closures shall be of suitable material as to not alter the compounded drug as to quality, strength or purity of the compounded preparation.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-8. Drug compounding controls

(a) There shall be written procedures for the compounding of drug preparations to assure that the finished products have the identity, strength, quality and purity they purport to have. These procedures should be available in either written form or electronically stored with printable documentation.
(b) The objective of the documentation is to allow another compounder to reproduce an equivalent prescription at a future date.
(c) Documentation shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process (e.g. log, formula worksheet, original prescription, etc.) In addition, all equipment and utensils and the container/closure system, relevant to the compounding procedure shall be listed.
(d) These written procedures shall be followed in the execution of the compounding procedure and are designed to enable a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.
(e) Components shall be accurately weighed, measured, and subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist, at each stage of the process, to ensure that each weight and measure is correct as stated in the written compounding procedures.
(f) Written procedures shall be established and followed that describe the tests or examinations to be conducted on the preparation compounded (e.g., degree of weight variation among capsules) to assure reasonable uniformity and integrity of compounded drug preparations. Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall

contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation.

(1) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug preparation. These procedures shall include, but are not limited to, the following (where appropriate):

(A) Capsule weight variation to ensure that each unit shall be not less than 90% and not more than 110% of the theoretically calculated weight for each unit;

(B) Adequacy of mixing to assure uniformity and homogeneity;

(C) Clarity, completeness or pH of solutions.

(2) The compounder shall label any excess compounded preparation so as to reference them to the formula used, the assigned batch number, and beyond use date based on the compounder's appropriate testing, published data, or USP-NF standard.

(g) Material safety data sheet (MSDS) files should be easily accessible.

(h) **General requirements:**

(1) Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product is generally prohibited unless patient therapy is compromised.

(2) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is different from an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient's specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available.

(A) The unavailability of such drug product must be documented prior to compounding.

(B) This or similar documentation must be available when requested by the Board.

(3) Except for those preparations where stability prohibits advanced compounding, all preparations dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

(4) Compounding may be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(5) Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(6) Reconstitution of commercial products is not considered compounding for the purposes of this subchapter.

(7) Manipulation of commercial available products according to or beyond the manufacturer's instructions or copying commercial products for the reason of non-availability or component specifications would be considered compounding as pertaining to a practitioner / patient / compounder relationship.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-8.1. Transfer of compounded prescriptions

(a) If a patient requests a transfer of their prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist.
(b) The information included in the transfer of the prescription shall include:

(1) Active ingredient(s),
(2) Concentration,
(3) Dosage Form e.g. capsule, cream, suspension, injectable, etc.
(4) Route of delivery e.g. oral, injectable, topical, vaginal, etc.
(5) Delivery mechanism e.g. topical, transdermal, immediate release, sublingual, etc.
(6) Dosing Duration e.g. Q12H, Q24H, Q72H, etc.
(7) Details about the compounding procedure must be reasonably available from the transferring pharmacy.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09]

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) 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) 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.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

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.

[**Source:** Added at 38 Ok Reg 2440, eff 9-11-21]

535:15-10-9. Labeling

(a) If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in, and stored in another container) the new container shall be identified with the:

(1) Component name,

(2) Lot and BUD if available,

(3) Strength and/or concentration, and;

(4) Weight or measure

(b) Preparations prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.

(1) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.

(2) These preparations shall be labeled or documentation referenced with the:

(A) Complete list of ingredients or preparation name and reference,

(B) Preparation date,

(C) Assigned BUD:

(i) Based on published data, or;

(ii) Appropriate testing, or;

(iii) USP-NF standards.

(D) Specific storage conditions dictated by composition and stability shall be specified (refrigerator, freezer etc), except where clean dry area is dictated, and;

(E) Batch or lot number.

(c) Upon the completion of the drug compounding operation, the pharmacist shall examine the preparation for correct labeling.

(d) The containers and closures shall be of suitable material so as not to alter the quality, strength, or purity of the compounded drug.

(e) The outpatient prescription label shall contain the following:

(1) Patient name,

(2) Prescriber's name,

(3) Name & address of pharmacy,
(4) Directions for use,
(5) Date filled,
(6) BUD & storage (may be auxiliary labels), and;
(7) An appropriate designation that this is a compounded prescription, such as "Compounded Rx"unless the product is a radiopharmaceutical prepared from an FDA approved commercially manufactured radiopharmaceutical drug. In such case labeling requirements can be found in 535:15-17.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-10. Records and reports

(a) Any procedures or other records required to comply with State Board of Pharmacy regulations 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) Perpetual inventory is required for all controlled dangerous substances (CDS) and all bulk CDS's utilized for compounding.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 38 Ok Reg 2440, eff 9-11-21]

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

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1882, eff 9-11-17; Revoked at 38 Ok Reg 2440, eff 9-11-21]

535:15-10-12. Compounding for a prescriber's office use [REVOKED]

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Revoked at 34 Ok Reg 1882, eff 9-11-17]

535:15-10-13. Compounding veterinarian preparations

(a) Prescriptions for animals may be compounded based on an order or prescription from a licensed prescriber.
(b) Compounded preparations must comply with federal statutes, rules and FDA guidances.
(c) Caution should be taken as to not violate federal patent laws by duplicating an available product in inordinate quantities.
(d) Compounding with bulk chemicals for food-producing animals is not permitted.
(e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.
(f) Veterinarians may not transfer compounded medications to any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.

[**Source:** Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1882, eff 9-11-17; Amended at 35 Ok Reg 1918, eff 9-14-18]

535:15-10-14. Compounding of non-sterile hazardous drugs

Pharmacies engaging in compounding of hazardous drugs shall be responsible for meeting the following criteria:

(1) Non-sterile hazardous drugs shall include the NIOSH list of hazardous drugs as well as any individual products named per each individual pharmacy by referencing MSDS sheets or any other reference relating to above definition.
(2) Exposure control shall begin when hazardous drugs enter the facility. The PIC shall be responsible to confirm that medical products have labeling on the outer container that can be understood by all workers who will be separating hazardous from nonhazardous drugs.
(3) All individuals must wear PPE when opening containers to unpack hazardous drugs. Individuals must also wear chemotherapy gloves to prevent contamination when transporting the drug to the work area.
(4) Hazardous drugs must be stored separately from other drugs, as recommended by current ASHP guidelines on handling hazardous drugs. Hazardous drugs must be stored and transported in closed containers that minimize the risk of breakage.
(5) Pharmacies and pharmacist shall make sure the storage area has sufficient general exhaust ventilation to dilute and remove any airborne contaminants. Use a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. Do not use a ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatize while they are being handled or after they are captured by the HEPA filter.
(6) Staff should be fully trained and procedures established for their particular equipment and unique workplace setting.
(7) All staff shall wear PPE while working with hazardous drugs.
(8) Mix, prepare, and otherwise manipulate, count, crush, compound powders, or pour liquid hazardous drugs inside a ventilated cabinet designed to prevent hazardous drugs from being released into the work environment.
(9) Do not use supplemental engineering or process controls (such as needleless systems, glove bags and closed-system drug transfer devices) as a substitution for ventilated cabinets, even though such controls may reduce the potential for exposure when preparing and administering hazardous drugs.
(10) Use a high-efficiency particulate air filter (HEPA filter) for the exhaust from these controls.
(11) When drug preparation is complete, seal the final product in a plastic bag or other sealable container for transport before taking it out of the ventilated cabinet.
(12) Wash hands with soap and water immediately before donning and after removing gloves.
(13) Develop a written safety plan for all routine maintenance activities performed on equipment that could be contaminated with hazardous drugs.
(14) Manage hazardous drug spills according to policies and procedures for each workplace according to size of spill, possible spreading etc. Locate spill kits and other cleanup materials in the immediate area where exposures may occur.
(15) Consider a medical surveillance program or allow workers to have routine medical care.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-15. Compounding of non-sterile radiopharmaceuticals

(a) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.
(b) Radiopharmaceuticals prepared for oral administration shall be designated as, and conform to, the standards for non-sterile preparations. Any variation in certain chapter standards may be required to meet radiation safety concerns to operators and shall be documented with supporting evidence upon request.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-16. Violations

It shall be a violation to fail to comply with State Board of Pharmacy regulations.

[**Source:** Added at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PREPARATIONS

535:15-10-50. Purpose

(a) The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (non-sterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins they are potentially most hazardous to patients when administered into the central nervous system.
(b) To achieve the above five conditions and practices, this part 3 of subchapter 10 provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this part 3 of subchapter 10 is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this part 3 of subchapter 10 do not pertain to the clinical administration of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. For the purposes of this chapter, CSPs include, but are not limited to the following:

(1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues,

injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

(2) Manufactured sterile products prepared according to the instructions in manufacturers' approved labeling. Product package inserts usually refer to aseptic technique, but do not usually describe environmental quality controls, storage, or BUD and times for radiopharmaceuticals.

(c) All personnel who prepare CSPs shall be responsible for understanding these fundamental practices and precautions, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-51. Definitions

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

"ACPH" means "air changes per hour".

"ALARA" means "as low as reasonably achievable".

"Ante-Area" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

"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 CSPs, 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.

"Buffer Area" means an ISO Class 7 or better area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the staging of components and supplies used when compounding CSPs.

"Clean Room" means an ISO Class 5 or better room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

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

"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

"Compounding Aseptic Containment Isolator (CACI)" means a compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding

sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

"Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).

"Critical Site" means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.

"CSP" means "Compounded Sterile Preparation".

"CSTD" means "Closed-System Vial-Transfer Device".

"FDA" means the federal "Food and Drug Administration".

"Hazardous drug" means any drug listed as such by NIOSH and/or any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity.

"HEPA" means "High Efficiency Particulate Air".

"Immediate Use" means "administration begins not later than 1 hour following the start of the compounding procedure".

"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 is unreasonable considering the intended use of the compounded drug.

"ISO" means "International Organization for Standardization"

"ISO 5" means air containing no more than 100 P/ft of air of a size at least 0.5 micron or larger in diameter (3520 P/m^3), formerly FS209e Class 100.

"ISO 7" means air containing no more than 10,000 P/ft of air of a size at least 0.5 micron or larger in diameter (352,000 P/m^3), formerly FS209e Class 10,000.

"ISO 8" means air containing no more than 100,000 P/ft of air of a size at least 0.5 micron or larger in diameter (3,520,000 P/m^3), formerly FS209e Class 100,000.

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

"Labeling" means a term that designates 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.

"LAFW" means "Laminar Airflow Workbench".

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

"MDV" means 'Multiple Dose Vial'.

"Media-Fill Test" means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

"Multiple-Dose Container" means a multiple-unit container for articles or preparations intended for sterile compounded preparations administration only and usually containing antimicrobial preservatives.

"Negative Pressure Room" means a room that is at a lower pressure than the adjacent spaces and therefore, the net flow of air is into the room.

"National Safety Foundation" or **"NSF"** means the foundation that certifies that Biological or Class II safety cabinets meet NSF Standard 49.

"NIOSH" means "National Institute for Occupational Safety and Health"

"PEC" means "Primary Engineering Control".

"PET" means "Positron Emission Tomography".

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

"Primary Engineering Control (PEC)" means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

"Preparation" means an article compounded in a licensed pharmacy pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

"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.

"Positive Pressure Room" means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

"Single-dose container" means a single-dose, or a single-unit, container for articles or preparations intended for sterile compounded preparations administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

"Segregated Compounding Area" means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

"Terminal Sterilization" means the application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of

achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a non-sterile unit.

"Unidirectional Flow" means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

"USP" means "United States Pharmacopeia".

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

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 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 Board regulations at 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.

(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 State 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

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-10-53. General requirements

(a) Compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product is generally prohibited unless patient therapy is compromised.

(b) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is different from an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available.

(1) The unavailability of such drug product must be documented prior to compounding.

(2) This or similar documentation must be available when requested by the Board.

(c) Except for those preparations where stability prohibits advanced compounding, all preparations dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

(d) Compounding may be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(e) Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(f) Reconstitution of commercial products is not considered compounding for the purposes of this subchapter.

(g) Manipulation of commercial available products beyond the manufacturer's instructions or copying commercial products for the reason of non-availability or component specifications would be considered compounding as pertaining to a practitioner / patient / compounder relationship.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-54. CSP microbial contamination risk levels

(a) **Sterile preparations.** Pharmacies and pharmacists dispensing sterile preparations shall comply with all applicable federal, state, and local law and regulation concerning pharmacy. If the PEC (primary engineering control) is a compounding aseptic isolator that does not meet the environmental requirements

described in USP or is a laminar air-flow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous CSPs pursuant to a physician's order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. Low-risk level CSPs with a 12-hour or less BUD shall meet all of the following criteria:

(1) PECs (LAFWs, BSCs, CAIs, CACIs,) shall be certified and maintain ISO Class 5 as described in USP for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.

(2) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction. Sinks should not be located adjacent to the ISO Class 5 PEC. Sinks should be separated from the immediate area of the ISO Class 5 PEC device.

(3) Personnel shall follow proper procedures for personnel cleansing and garbing prior to compounding and maintain proper competency of aseptic work practices.

(4) Personnel will follow proper procedures in ensure cleaning and disinfection of sterile compounding areas. Additionally, viable and non-viable environmental air sampling must be performed according to facility written procedures.

(b) **Risk level.** Requirements for compounding of sterile preparations will be based on the distinction of sterile products as either low-risk, medium-risk or high-risk preparations. These risk levels apply to the quality of CSPs immediately after the final aseptic mixing or filling or immediately after the final sterilization, unless precluded by the specific characteristics of the preparation.

(1) **Low-Risk Level CSPs.** Sterile preparations compounded under all of the following conditions are at a low risk of contamination:

(A) The CSPs are compounded with aseptic manipulations entirely within an ISO Class 5 environment or better air quality using only sterile ingredients, products, components, and devices.

(B) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.

(C) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and package containers of other sterile products, and containers for storage and dispensing.

(2) **Medium-Risk Level CSPs.** When CSPs compounded aseptically under low-risk conditions, and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 132

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile product that will be administered either to multiple patients or to one patient on multiple occasions.

(B) The compounding process includes complex aseptic manipulations other than the single volume transfer.

(C) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogeneous mixing.

(3) **High-risk Level CSPs.** CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.

(A) Non-sterile ingredients are incorporated, or a non-sterile device is employed before terminal sterilization

(B) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour

(i) Sterile contents of commercially manufactured products,

(ii) CSPs that lack effective antimicrobial preservatives, and

(iii) Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

(C) Compounding personnel are improperly garbed and gloved as outlined by USP.

(D) Sterile water-containing preparations are stored for more than 6 hours before being sterilized.

(E) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or Compendial specifications in unopened or in opened packages of bulk ingredients.

(c) **Immediate use.** The immediate use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level subjects the patient to additional risk due to delays in therapy. Immediate use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate use CSPs. Immediate use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate use CSPs because they are hazardous drugs.

(2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

(3) During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.

(A) Administration begins not later than 1 hour following the start of the preparation of the CSP.

(B) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond use date and time.

(C) If administration has not begun within 1 hour following the start of preparing the CSP; the CSP shall be promptly, properly, and safely discarded.

(d) Opened or needle-punctured single dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 air quality and any remaining contents must be discarded.

(e) Single-dose vials exposed to ISO Class 5 or cleaner air may be used for multiple needle entries up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives.

(f) The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days unless an alternate time period is otherwise specified by the manufacturer. This does not mean the expiration date of the unopened container.

(g) **Quality Assurance.** Quality assurance practices include, but are not limited to the following:

(1) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.

(2) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, such as eye protection and face masks.

(3) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.

(4) Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

(5) All clean rooms must meet NSF/ANSI standard 49. The aseptic processing for sterile preparations shall be in an area separate and distinct from the area used for the compounding of nonsterile drug preparations. 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.

(A) Semiannual certification of the primary engineering controls.

(B) Semiannual certification of nonviable environmental monitoring of all ISO 5, ISO 7, ISO 8 and segregated compounding areas.

(C) Semiannual certification of viable environmental monitoring of all ISO 5, ISO 7, ISO 8 and segregated compounding areas.

(D) Removable prefilters shall be inspected monthly, cleaned or changed at least quarterly or as directed by a qualified certifier, and the date documented.

(E) HEPA filters shall be repaired or replaced when recommended by a qualified certifier.

(6) Initial and annual competence documentation of personnel, including:

(A) Written test

(B) Hand Hygiene and garbing

(C) Gloved fingertip sampling

(D) Aseptic manipulation

(E) Aseptic media-fill test

(F) Cleaning and disinfecting

(G) Surface sampling

(H) Equipment

(I) Routine visual inspection of all compounded sterile preparations

(J) Provision of guidelines to nursing education for competence documentation for nonpharmacy personnel who mix sterile preparations for immediate use.

(h) **Quality control practices will include:**

(1) Daily documentation of temperature in areas where sterile products or sterile preparations are stored or compounded

(2) Daily documentation of the accuracy and precision of devices such as automated compounders and repeater pumps.

(3) Daily documentation of humidity in areas where sterile products or sterile preparations are stored or compounded.

(i) The PIC or designee will prepare a periodic report of infection control procedures to track quality control and quality assurance activities, as appropriate.

(j) Records of laminar air flow workbench maintenance and certification and ante-area, clean-room and buffer area certifications shall be kept in the pharmacy. A certification stamp shall be affixed to the hood.

(k) **Storage.** All pharmacies preparing and dispensing compounded sterile preparations must provide:

(1) Adequate controlled room temperature storage space for all raw materials.

(2) Adequate storage space for all equipment. All drugs and supplies shall be stocked on shelving above the floor.

(3) Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures. Temperature ranges required are 36-46° F or 2-8° C.

(4) Adequate freezer storage space if finished products are to be frozen (e.g. reconstituted antibiotics.) There shall be a procedure to routinely document temperatures.

(l) **Labeling.** In addition to regular labeling requirements, the label shall include:

(1) Sterile compounded preparations shall have the rate of infusion when applicable.

(2) Expiration date (Policies and procedures shall address label change procedures as required by physician orders.)

(3) Storage requirements or special conditions.

(4) Name of ingredients and amounts contained in each dispensing unit.

(5) All products dispensed to outpatients, and removed from the site of preparation for administration different than the site of preparation, shall have label information as required by state law.

(m) **Shipping.** Sterile preparation shipping:

(1) Policies and procedures shall assure preparation storage requirements during delivery.

(2) Pharmacy must assure ability to deliver preparations within an appropriate time frame.

(n) **Home patient care services.** The pharmacist in charge of the pharmacy dispensing sterile compounded preparations solutions shall provide the following or assure that they are provided prior to providing medications.

(1) The pharmacist must assure that the patient is properly trained if self-administering.

(2) In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist in charge must:

(A) Employ a registered nurse.

(B) Assure that proper records are maintained in compliance with laws and regulations.

(C) Make these records available to inspectors from appropriate agencies.

(3) 24-hour service shall be assured by the pharmacy.

(4) Pharmacists shall recommend and monitor clinical laboratory data as requested.

(5) Side effects and potential drug interactions should be documented and reported to the physician.

(6) Patient histories and therapy plans should be maintained.

(o) **Pharmacist-in-charge responsibilities for high-risk Level CSP preparations.** When preparing high risk sterile Level CSP preparations, the pharmacist in charge is responsible for making sure the above procedures, in addition to the following, shall be met:

(1) Compound all medications in one of the following environments:

(A) A separate controlled limited access area with a positive air flow room inspected and certified as meeting ISO Class 7 requirements.

(B) An enclosed room providing an ISO Class 5 environment for compounding.

(C) A barrier isolator that provides an ISO Class 5 environment for compounding. It is recommended that all pharmacies have an anteroom designed to be separate from the buffer room. The anteroom should be available for the decontamination of supplies and equipment, and donning of protective apparel. A sink should be available in the anteroom area so that personnel can scrub prior to entering the buffer room.

(2) Use total aseptic techniques, including gowning, mask, and hair net.

(3) Provide a system for tracking each compounded product including:

(A) Personnel involved in each stage of compounding;

(B) Raw materials used including quantities, manufacturer, lot number, and expiration date;

(C) Labeling;

(D) Compounding records shall be kept for 5 years.

(4) Establishment of procedures for sterilization of all preparations compounded with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the preparation components.

(5) All high-risk Level CSP preparations for administration by injection that are prepared:

(A) in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules, bags, syringes, and/or vials), or;
(B) in multiple dose vials for administration to multiple patients, or;
(C) are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized; shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.

(i) Sterility testing (bacterial and fungal) - The USP Membrane Filtration Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. The pharmacist in charge shall establish written procedures requiring daily observation of the media and 136 requiring an immediate recall if there is any evidence of microbial growth and said procedures must be available to Board inspectors.

(ii) Bacterial endotoxin (pyrogen) testing - The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.

(6) Establishment of procedures for semi-annual testing the techniques of pharmacists using simulated aseptic procedures and documentation thereof.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

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. 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) 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) Daily procedures must be established for cleaning the compounding area. The pharmacy must keep cleaning logs consistent with the minimum cleaning frequency. Logs shall be kept for 2 years:
(11) Minimum frequency of cleaning and disinfecting compounding areas 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.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-10-56. Compounding equipment

(a) Equipment used in the compounding of drug preparations shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning and maintenance.
(b) Compounding equipment shall be of suitable composition so the surfaces that contact components shall neither be reactive, additive or absorptive, therefore not affecting or altering the purity of the compounded preparation.
(c) Equipment and utensils used for compounding shall be thoroughly cleaned promptly after every use to prevent contamination and must be stored in a manner to protect from contamination.
(d) Defective equipment shall be clearly labeled as such.
(e) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated as necessary or checked to ensure proper performance. An equipment calibration log must be maintained.
(f) When drug products with special precautions (antibiotics and hazardous materials) are involved, appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the

meticulous cleaning of equipment prior to its use for the preparation of other drugs. Equipment dedicated for specific use (i.e. penicillin) shall be clearly designated as such.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-57. Component selection requirements

(a) The pharmacist shall first attempt to use USP-NF drug substances and inactive components that have been made in an FDA registered facility.
(b) If components are not obtainable from a FDA registered facility or if the FDA and/or the company cannot document FDA registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing or using drug components that meet official compendia requirements or another high quality source.
(c) If components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, American Chemical Society-certified, or Food Chemicals Codex grade may be used.
(d) Components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-58. Control of drug product containers

(a) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.
(b) Containers and closures shall be of suitable material as to not alter the compounded drug as to quality, strength or purity of the compounded preparation.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-59. Drug compounding controls

(a) There shall be written procedures for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality and purity they purport to have. These procedures should be available in either written form or electronically stored with printable documentation.
(b) The objective of the documentation is to allow another compounder to reproduce the identical prescription at a future date.
(c) Procedures shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. In addition, all equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug shall be listed.
(d) These written procedures shall be followed in the execution of the compounding procedure and are designed to enable a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.
(e) Components shall be accurately weighed, measured, and subdivided as appropriate.These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures.
(f) Written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of variation) to ensure reasonable uniformity and integrity of compounded drug preparations. Unless otherwise indicated or appropriate, compounded preparations

are to be prepared to ensure that each preparation shall contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation.

(1) Such control procedures shall be established to monitor the output and to verify the performance of those compounding processes that may be responsible for causing variability in the final drug preparation. These procedures shall include, but are not limited to, the following (where appropriate):

(A) Adequacy of mixing to assure uniformity and homogeneity;

(B) Clarity, completeness or pH of solutions.

(2) The compounder shall label any excess compounded products so as to reference them to the formula used, the assigned batch number, and beyond use date based on the compounder's appropriate testing, published data, or USP-NF standard.

(g) MSDS (material data safety sheet) files should be easily accessible.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-60. Transfer of sterile compounded prescriptions

(a) If a patient requests a transfer of their prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist.

(b) The information included in the transfer of the prescription shall include:

(1) Active ingredient(s)

(2) Concentration

(3) Dosage Form

(4) Route of delivery

(5) Delivery mechanism

(6) Dosing Duration i.e. Q12H, Q24H, Q72H

(7) Details about the compounding procedure must be reasonably available from the transferring pharmacy.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-61. Beyond use dating (BUD)

(a) BUDs shall be assigned to all compounded sterile preparations. The shorter of the chemical stability (established by the manufacturer, or listed in a current authoritative reference, or established by direct testing following USP standards or equivalent) and microbial limits of sterility (USP <797> standards) shall be used to determine the date. If a pharmacy does not have a program of sterility and endotoxin testing in place and additional documentation for longer dates, then the following BUDs are to be used for compounded sterile preparations as follows and as illustrated in the Appendix B Chart:

(1) If USP <797> Risk Level is "Immediate Use" BUD, and if kept

(A) at room temperature; use within 1 hour,

(B) refrigerated; use within 1 hour, or

(C) in freezer, N/A.

(2) If USP <797> Risk Level is "Low Risk" BUD, and if kept

(A) at room temperature, use within 48 hours,

(B) refrigerated, use within 14 days, or

(C) in freezer, use within 45 days.

(3) If USP <797> Risk Level is "Low Risk with 12 hour or less" BUD, and if kept
(A) at room temperature use within 12 hours or less
(B) refrigerated, use within 12 hours or less, or
(C) in freezer, N/A
(4) If USP <797> Risk Level is "Medium Risk" BUD, and if kept
(A) at room temperature, use within 30 hours,
(B) refrigerated, use within 9 days, or,
(C) in freezer, use within 45 days
(5) If USP <797> Risk Level is "High Risk" BUD, and if kept
(A) at room temperature, use within 24 hours
(B) refrigerated, use within 3 days, or
(C) in freezer, use within 45 days

(b) Reusable compounded preparations that are returned to a hospital pharmacy shall be placed in the refrigerator (unless contraindicated) with the original BUD on the label.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-62. Labeling

(a) If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in, and stored in another container) the new container shall be identified with the:
(1) Component name,
(2) Lot and BUD if available,
(3) Strength and/or concentration, and;
(4) Weight or measure

(b) Preparations prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.
(1) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.
(2) These preparations shall be labeled or documentation referenced with the:
(A) Complete list of ingredients or preparation name and reference,
(B) Preparation date,
(C) Assigned beyond-use date:
(i) Based on published data, or;
(ii) Appropriate testing, or;
(iii) USP-NF standards.
(D) Specific storage conditions dictated by composition and stability shall be specified (refrigerator, freezer, etc.), except where clean dry area is dictated, and;
(E) Batch or lot number.

(c) Upon the completion of the drug preparation operation, the pharmacist shall examine the preparation for correct labeling.

(d) The outpatient prescription label shall contain the following:
(1) Patient name,
(2) Prescriber's name,
(3) Name & address of pharmacy,
(4) Directions for use,
(5) Date filled,
(6) Beyond use date & storage (may be auxiliary labels), and;

(7) An appropriate designation that this is a compounded prescription, such as "Compounded Rx".

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-63. Records and reports

(a) Any procedures or other records required to comply with Good Compounding Practices 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.
(d) Adequate records must be kept showing that compounded drug products have been compounded using ingredients from FDA approved manufacturers.
(e) Adequate records must be kept showing that all ingredients have been purchased from suppliers which are licensed by the Board to lawfully ship such into Oklahoma.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-64. Compounding for institution and/or practitioner administration [REVOKED]

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 30 Ok Reg 2010, eff 7-25-13; Revoked at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-64.1. Compounding veterinarian sterile preparations

(a) Prescriptions for animals may be compounded based on an order or prescription from a licensed prescriber.
(b) Compounded preparations must comply with federal statutes, rules and FDA guidances.
(c) Caution should be taken as to not violate federal patent laws by duplicating an available product in inordinate quantities.
(d) Compounding with bulk chemicals for food-producing animals is not permitted.
(e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.
(f) Veterinarians may not transfer compounded medications to any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-10-65. Compounding of sterile hazardous drugs

(a) Although the potential therapeutic benefits of compounded sterile and non-sterile hazardous drug preparations outweigh the risks of their adverse effects in ill patients, exposed healthcare workers risk similar adverse effects with no therapeutic benefit. Occupational exposure to hazardous drugs can result in:

(1) Acute effects, such as skin rashes;
(2) Chronic effects, including adverse reproductive events; and
(3) Possibly cancer. Each facility must have a communication program that identifies hazardous drugs and communicates this list to all workers that

participate in product acquisition, storage, transportation, housekeeping, and waste disposal.

(b) Hazardous drugs shall be any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, or genotoxicity. A new or investigational drug that has no information on toxicity should be treated as a hazardous drug. At a minimum, the hazardous drug communication list shall be drugs received in the facility that are recognized as such by the National Institute for Occupational Safety and Health (NIOSH).

(c) Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature; thus storage is preferably within a containment area such as a negative pressure room. The storage area should have sufficient general exhaust ventilation, at least 12 air changes per hour (ACPH) to dilute and remove any airborne contaminants.

(d) Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal.

(e) Hazardous sterile drugs shall be prepared in an ISO Class 5 environment with protective engineering controls in place as specified in 535.15-10-55(g). 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.

(f) If a CACI that meets the requirements of this chapter is used outside of an ISO class 7 buffer area, the compounding area shall maintain negative pressure and have a minimum of 12 ACPHs. Manufacturer's guidelines or NSF/ANSI Standard 49 standards shall be followed for isolators, containment hoods and BSC. Quality control certification for proper function shall be performed every six months by NSF/ANSI Standard 49 certified personnel.

(g) When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment, Add-Vantage and PhaSeal) are used, they shall be used within the vented cabinet.

(h) In facilities that prepare a low volume, an average of no more than two per day, of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

(i) Appropriate PPE shall be worn when compounding hazardous drugs. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, gloving with chemotherapy gloves; and compliance with manufacturers' recommendations when using a CACI.

(j) All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous drugs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. Compounding personnel of reproductive capability shall

confirm in writing that they understand the risks of handling hazardous drugs. The training shall include at least the following:

(1) safe aseptic manipulation practices;

(2) negative pressure techniques when utilizing a BSC, powder containment hood or CACI;

(3) correct use of CSTD devices;

(4) containment, cleanup, and disposal procedures for breakages and spills; and,

(5) treatment of personnel contact and inhalation exposure.

(k) Consider a medical surveillance program or allow workers to have routine medical care.

(l) Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

(m) Pharmacies engaging in compounding of hazardous drugs shall be responsible to manage hazardous drug spills according to policies and procedures for each workplace.

(n) Pharmacies engaging in compounding of hazardous drugs shall locate spill kits and other cleanup materials in the immediate area where exposures may occur.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-10-66. Compounding of sterile radiopharmaceuticals

(a)In the case of production of radiopharmaceuticals for positron emission tomography (PET), the USP general test chapter *Radiopharmaceuticals for Positron Emission Tomography-Compounding* <823> supersedes this part 3 of Subchapter 10 or applicable federal manufacturing regulations. Upon release of a PET radiopharmaceutical as a finished drug product from a production facity, the further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.

(b) For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as, and conform to, the standards for '*Low-Risk Level CSPs*'

(c) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. An integrated approach which addresses both aseptic and radiation safety techniques is necessary. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.

(d) These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to permit compliance with applicable state and federal regulations.

(e) Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

(f) Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 or

cleaner air environment.
(g) Direct visual inspection of radiopharmaceutical CSPs shall be conducted in accordance with ALARA.
(h) The handling of radiopharmaceuticals is controlled through the licensing of "Authorized Users" by the Oklahoma Department of Environmental Quality. As such, limited numbers of distribution channels exist to obtain radiopharmaceuticals. It is recognized that there is a special population that is outside the daily distribution range of a commercial nuclear pharmacy and that radiopharmaceuticals are not reasonably available. For these facilities, if the PEC is a CAI, CACI, a LAFWor a BSC that cannot be located within an ISO Class 8 or better buffer area, then only low-risk CSPs pursuant to a physician's order may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. These Low-risk level radiopharmaceutical CSPs with a 12-hour or less BUD shall be prepared in PECs (LAFWs, BSCs, CAIs, CACIs), which shall be certified and maintain ISO Class 5 and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment areas must be cleaned before being brought into controlled compounding area. Other requirements as dictated by Low-Risk Radiopharmaceuticals shall be followed as described in this chapter.
(i) Preparation of radiopharmaceuticals for Immediate-Use category is reserved for radiopharmaceuticals needed for emergency or immediate patient care. Radiopharmaceuticals under this exemption shall apply only to diagnostic radiopharmaceuticals and administration must begin no later than one hour following the start of preparing the CSP. Certain preparations may necessitate more than two punctures into the same septum, i.e. Technetium 99mTc-Red Blood Cell labeling.
(j) Preparation of radio-labeled leukocytes or blood products requires the procedure be performed in an ISO Class 5 PEC that is located in an ISO Class 8 or cleaner air environment. Blood manipulations shall be clearly separated from routine procedures and have specific standard operating procedures to avoid cross contamination.
(k) Labeling requirements for this chapter do not supersede the labeling requirements of 535:15-17-5.

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-67. Compounding of sterile allergen extracts

(a) Allergen extracts as CSPs are single-dose and multiple-dose *intradermal or subcutaneous injections* that are prepared by specially trained physicians and pharmacy personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all *CSP Microbial Contamination Risk Levels* in this chapter only when all of the following criteria are met:

(1) The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).
(2) All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Non-preserved allergen extracts shall comply with the appropriate CSP risk level

requirements in the chapter.
(3) Before beginning compounding activities, personnel perform a thorough hand cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either non-antimicrobial or antimicrobial soap and water.
(4) Compounding personnel don hair covers, facial hair covers, gowns, and face masks.
(5) Compounding personnel perform antiseptic hand cleansing with an alcohol based surgical hand scrub with persistent activity.
(6) Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.
(7) Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.
(8) Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.
(9) The aseptic compounding manipulations minimize direct contact contamination
(e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other non-sterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).
(10) The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.
(11) Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

(b) Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for *CSP Microbial Contamination Risk Levels.* Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected *intradermally or subcutaneously,* these risks are substantially greater if the extract is inadvertently injected *intravenously.*

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-68. Violations

It shall be a violation to fail to comply with State Board of Pharmacy regulations.

[**Source:** Added at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

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.

[**Source:** Added at 10 Ok Reg 3171, eff 6-25-93; Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

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 353.18A.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-13-2. Hospital pharmacy technicians definitions and duties

Hospital pharmacy technician definitions and duties are enumerated in OAC 535:15-5.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94]

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.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-13-4. Pharmacy technician qualifications and training

(a) A pharmacy technician must have satisfactorily completed a high school education, HiSet Examination, or G.E.D. equivalence, and shall be of good moral character, be non-impaired (e.g. alcohol or drugs) and have adequate education to perform assigned duties.

(b) A pharmacy manager employing a currently permitted technician must document training of that technician within 10 days of hire.

(c) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job training (OJT) program described in 535:15-13-13.

(d) To be eligible for a pharmacy technician permit, an applicant must maintain compliance with the requirements in this Title, 535.25 and 535:15.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 39 Ok Reg 2057, eff 9-11-22]

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.

(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 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.

(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.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 38 Ok Reg 2440, eff 9-11-21]

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 data entry, 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) prepackage (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).

(9) any duties auxiliary personnel are allowed to perform;

(10) assist the pharmacist in the annual CDS inventory. The pharmacist remains responsible for completeness and accuracy; and,

(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 and,

(12) fill "Modified unit dose distribution systems", "Automated dispensing systems" and/or "Unit dose distribution systems".

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 33 Ok Reg 1784, eff 9-11-16; Amended at 34 Ok Reg 1882, eff 9-11-17; Amended at 37 Ok Reg 2041, eff 9-11-20; Amended at 38 Ok Reg 2440, eff 9-11-21; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-13-7. Prohibited duties

These duties shall not be performed by supportive personnel:

(1) The pharmacist must interpret the original prescription.

(2) The pharmacist must perform the prospective drug utilization review and determine action to be taken when there is an indication of a drug interaction.
(3) The pharmacist must receive new orally communicated prescriptions from prescribers or their agents.
(4) The pharmacist must determine product selection if substitution is requested or approved.
(5) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. This process shall be completed before the prescription is given to the patient.
(6) The pharmacist must provide patient counseling or drug information as necessary.
(7) The pharmacist must take verbal authorizations from licensed prescriber or licensed prescriber's authorized agent (when allowed) for any refill of a controlled substance or any non-controlled prescription that has changes to strength or directions.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 37 Ok Reg 2041, eff 9-11-20]

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

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

(1) Upon meeting the qualifications listed in 535:15-13-4 and 535:25, applicants shall apply for a pharmacy technician permit on the form provided by the Board. Such application shall be returned accompanied by the fee authorized by the legislature and in the agency fee schedule.
(2) After the pharmacy technician has completed his portion of the application, he must submit it to the pharmacy manager or designated pharmacist who has conducted the technician training for review and signature.
(3) The pharmacy manager or designated pharmacist must first verify the applicant's completion of Phase I of the Board approved pharmacy technician training program. The signature by the pharmacist verifying technician training indicates that there is written training verification in the pharmacy available for Board inspection.
(4) Each pharmacy technician who desires to continue to work as a tech shall annually, on or before the last day of the registrants' birth month, send to the Board the fee authorized by the legislature and in the agency fee schedule, with a completed Board renewal application signed by the supervising pharmacist and the technician. Renewal notice will be sent to the technician's address on file in the Board office either electronically or by mail.

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

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

(2) the furnishing of any false or fraudulent material in any application made to the Board;
(3) suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant;
(4) compliance with permitting requirements under previously granted permits, if any;
(5) any abuse of alcohol or habit-forming drugs or use of an illegal CDS substance or a positive drug screen for such illegal substance or its metabolite; and,
(6) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

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

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 33 Ok Reg 1784, eff 9-11-16]

535:15-13-9. Technician permit display

(a) Each pharmacy technician shall conspicuously display a current original permit issued by the Board in the pharmacy where the tech is actively engaged as a pharmacy technician.
(b) A current 2 x 2 photo shall be attached in the upper right hand corner of the permit while on display in the pharmacy.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-13-10. Technician address and employment change, and training at change of employment

(a) A pharmacy technician must notify the Board, in writing, within ten days of change of employment.
(b) A pharmacy manager employing a currently permitted technician must document training of that technician at the new pharmacy as required in 535:15-13-13 (d).
(c) A pharmacy shall notify the Board, in writing, within ten days of the employment termination of a pharmacy technician. The pharmacist must share any concern about public safety relating to the technician with the Board. (No Board action shall be taken without due process.)
(d) A pharmacy technician must notify the Board, in writing, within ten days, of a change of address.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-13-11. Multiple locations of employment

(a) A pharmacy technician may work in multiple pharmacies providing:
(1) The technician has been properly trained for each location (see 535:15-13-13(d)); and,
(2) The training is documented in each pharmacy.

(b) A technician working in multiple locations regularly or on an emergency relief basis may be issued a duplicate permit on request.

(1) A written request indicating the need for such duplicate shall be sent to the Board by the technician.
(2) A duplicate fee of ten dollars $10 shall accompany each individual duplicate request.
(3) Current and in good standing technicians who have renewed online for the current period may print a duplicate permit online at no additional charge.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 19 Ok Reg 1796, eff 7-1-02; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-13-12. Work schedule display

(a) A work schedule shall be conspicuously displayed in the pharmacy when both a tech and an auxiliary supportive person are working. The schedule shall indicate who is working as a tech and hours worked and who is working as an auxiliary supportive person and hours worked.
(b) The schedule shall indicate the proper ratio of technicians to supervising pharmacists.
(c) If a supportive person is found to be performing duties not listed on the schedule (e.g. an auxiliary supportive person working as a technician), the auxiliary supportive person, the technician, the pharmacy, and the supervising pharmacist will be considered to be in violation of this Chapter.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-13-13. Pharmacy technician training

(a) The pharmacy manager shall be responsible for the development and/or implementation of a pharmacy technician training program.
(1) The instructional text of the training program shall be kept in the pharmacy and only upon request submitted to the Board for approval.
(2) The program shall be designed to train personnel to perform allowed nonprofessional functions, as described in OAC 535:15-5 and 535:15-13.
(3) Minimum standards for technician training programs shall be those set out in the Board approved "Pharmacy Technician Training Guidelines".
(A) Pharmacy technician applicants shall complete Phase I training before they may apply for an Oklahoma Pharmacy Technician permit. A pharmacy technician permit must be received before performing any of the duties of pharmacy technicians authorized in OAC 535:15-5 and 535:15-13.
(B) A technician has not met Board requirements until he has successfully completed Phase II of pharmacy technician training.
(C) A pharmacy technician must complete Phase II within ninety (90) days after issuance of a pharmacy technician permit.
(D) Pharmacy technician applicants shall not have fully received their permits until they have completed Phase II of pharmacy technician training.
(E) If the pharmacy technician fails to complete Phase II within 90 days, the pharmacist manager shall notify the Board in writing,
(i) If the pharmacy technician fails to complete Phase II within 90 days,
(I) the pharmacy technician permit is automatically void; and,

(II) the pharmacy technician shall return such permit to the Board.

(ii) Such pharmacy technician may apply for a new pharmacy technician permit when he has again satisfactorily completed Phase I training with an employing pharmacy, provided the provisions of these rules have not been violated by the pharmacy technician.

(b) The pharmacist manager, or another pharmacist in the pharmacy whom the pharmacist manager may designate, shall conduct the training and attest to its successful completion.

(c) The pharmacist manager shall assure that the pharmacy technician remains competent through annual continuing on-the-job training. The pharmacist manager must document such training in the pharmacy and provide it at inspection.

(d) A pharmacy manager employing a currently permitted technician must document training of that technician within 10 days of hire at such pharmacy. Documentation of this training must be kept in the pharmacy and be available for Board inspection.

(e) The pharmacist manager shall be responsible for assuring proof of annual technician training is maintained in the pharmacy and such proof is available for Board inspection.

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-13-14. Pharmacy technician identification

The pharmacy technician must be identified as set out in 535:15-3-2(e).

[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 14 Ok Reg 3024, eff 7-1-97]

SUBCHAPTER 15. HOME CARE AGENCY PHARMACY AGREEMENTS

535:15-15-1. Definitions

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

"Administer Drugs" means the direct application of a drug as defined in Title 59, O.S., Section 353.1

"Authorized Employee" means any employee of a Home Care Agency who in the course of their duties, is licensed by their appropriate Board to administer legend or dangerous drugs.

"Home Care Agency" or **"HCA"** means an entity required to license under the 1992 Home Care Act with the Oklahoma State Department of Health.

"Pharmacy manager" or **"PIC"** means the PIC as described in 535:15-3-2.

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 34 Ok Reg 1882, eff 9-11-17]

535:15-15-2. Pharmacy agreements with Home Care Agencies (HCA's)

(a) Pharmacies will be allowed to place certain drugs with HCA's for the betterment of public health.

(b) The pharmacy shall remain the legal owner of the drugs.

(c) A written agreement between the pharmacy and the HCA shall document the protocol for handling and storage of these drugs by authorized employees and shall be approved by the pharmacy manager.

(d) The pharmacy manager shall review the protocol to assure safe, secure and accountable handling of the dangerous drugs is maintained under the protocol. The protocol should stress the use of these drugs should not be for routine use, but for emergency use and the need of the patient.
(e) The pharmacy manager or a designated pharmacist shall physically inspect and review the drug storage and handling at the HCA at a minimum of every four months.

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96; Amended at 14 Ok Reg 3024, eff 7-1-97]

535:15-15-3. Home Care Agency protocol

Home Care Agency protocol will include, but not be limited to, the following:

(1) safe and secure storage of drugs;
(2) access to drugs limited to authorized employees;
(3) records of drugs checked out to authorized employees and records of drugs, amounts, to whom and by whom administered;
(4) prompt notification of the pharmacy when a drug is used, including the prescriber, patient, drug, dosage form, directions for use, etc.;
(5) billing information;
(6) procedures for handling drugs beyond expiration date (outdated drugs shall be returned to the pharmacy, quarantined and destroyed in a reasonable time frame); and,
(7) inventory control.

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96]

535:15-15-4. Drug formulary

The following legend or dangerous drugs will be allowed under these agreements:

(1) sterile water for injection or irrigation;
(2) sterile saline solution for injection or irrigation;
(3) acetic acid for irrigation;
(4) heparin flush solution or kits;
(5) diphenhydramine injectable;
(6) epinephrine injectable;
(7) four (4) I.V.solutions
    (A) dextrose 5% in water (D5W)
    (B) dextrose 5% in normal saline solution (D5S)
    (C) lactated ringers solution
    (D) normal saline solution, and
(8) legend medicated dressings.

[**Source:** Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96]

SUBCHAPTER 16. PHARMACY EMERGENCY MEDICATION KITS FOR USE IN A FACILITY

535:15-16-1. Purpose

(a) This subchapter establishes rules regarding drugs that an Oklahoma licensed pharmacy may maintain in an emergency medication kit, as authorized under Title 59 O.S. Section 367.8.

(b) The purpose of these Oklahoma licensed pharmacy emergency medication kits for use in a facility is not to relieve a pharmacist or an Oklahoma licensed pharmacy of the responsibility for timely provision of a facility resident's routine drug needs; but to ensure that an emergency medication kit is available to facility residents in need of urgent or emergency medications.

[**Source:** Added at 29 Ok Reg 1641, eff 7-12-12]

535:15-16-2. Definitions

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

"Emergency medication kits", **"Emergency medication boxes"** **"Emergency medication carts"**, **"emergency kits"**, **"kits"**, **"boxes"** or **"carts"** means those drugs which are allowed under these rules that may be required to meet the immediate emergency therapeutic needs of facility residents; and which are not available from any other authorized source in sufficient time to prevent risk of harm or death to residents.

"Facility" or **"Institution"** means a facility as defined by the Nursing Home Care Act or an Assisted Living Center as defined by the Continuum of Care and Assisted Living Act.

"Remote site" means a facility location where a Oklahoma licensed pharmacy has placed an emergency medication kit.

"Resident" means a patient residing at the facility.

"Single dose injectable medication" means any injectable medication vial in the emergency medication kit.

[**Source:** Added at 29 Ok Reg 1641, eff 7-12-12]

535:15-16-3. Licensing requirements

(a) The Oklahoma licensed pharmacy shall maintain a separate pharmacy emergency medication kit permit for each emergency medication kit maintained at each facility remote site for an annual fee for each set by the Board.
(b) The Oklahoma licensed pharmacy shall contact DEA and OBN and comply with any registration or requirements for each remote site prior to providing a controlled dangerous substance in the emergency medication kit.
(c) The permit for the medication kit will expire at the same time as the license of the pharmacy.

[**Source:** Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-16-4. Policies and procedures for use of emergency medication kit drugs

(a) The drugs in the emergency medication kits shall remain the property of an Oklahoma licensed pharmacy.
(b) Only one Oklahoma licensed pharmacy may provide emergency medication kits to each facility.
(c) Emergency medication kits maintained by an Oklahoma licensed pharmacy within the facility shall be approved by the medical director of the facility and the facility's consultant pharmacist on at least an annual basis.
(d) Medications may be administered from the facility's emergency medication kit only upon a prescriber's order for the emergency medication; and must be administered by a licensed nurse, physician, or physician's assistant.
(e) The facility licensed nurse shall

(1) verbally transmit the order for an emergency drug requiring access to the emergency medication kit to an Oklahoma licensed pharmacist who is an employee of the Oklahoma licensed pharmacy and is physically located within the United States at the time the order is transmitted prior to the removal of a medication from the emergency medication kit,
(2) or may electronically transmit the order to an Oklahoma licensed pharmacy and located within the United States following all federal and state regulations and rules only if the Oklahoma licensed pharmacy is utilizing technology which requires the Oklahoma licensed pharmacist to release the medication from the emergency medication kit by electronic means.

(f) The facility and Oklahoma licensed pharmacy shall have a written agreement that clearly states these drugs should not be used for routine use, but for emergency use and the need of the patient for urgent care.

(1) This written agreement shall contain a policy for record keeping of medications removed from the emergency medication kit.
(2) The Oklahoma licensed pharmacy shall require the facility to maintain a readily retrievable log of usage from the emergency medication kit which shall include for each dose administered from the emergency medication kit, at a minimum:

(A) Name of ordering prescriber
(B) Date and time of order,
(C) Facility resident's name,
(D) Medication name and strength,
(E) Name of person administering medication, and date and time administered,
(F) Such log shall be maintained in the facility and the Oklahoma licensed pharmacy and shall be available for Board inspection.

(3) The facility and Oklahoma licensed pharmacy shall document the nature of the emergency.
(4) Name of person verbally notifying the Oklahoma licensed pharmacy shall be recorded by the Oklahoma licensed pharmacy,
(5) The agreement shall document the protocol for handling and storage of these drugs by authorized employees and shall be approved by the Oklahoma licensed pharmacy manager.
(6) The Oklahoma licensed pharmacy shall review the agreement, recordkeeping and drug storage and handling at a minimum of annually.
(7) The facility and Oklahoma licensed pharmacy shall have a policy on replacement of medication in a timely manner.

(A) Replacement of controlled dangerous substances (CDS) in the emergency medication kit in a facility may be done by a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy.
(B) Replacement of the non-controlled drugs from the licensed Oklahoma pharmacy in the emergency medication kit may be done by a licensed nurseemployed at the facility or an employee of the Oklahoma licensed pharmacy.

(g) The Oklahoma licensed pharmacy shall maintain the following records for each facility remote site where an emergency medication kit is maintained:

(1) A log of facilities for which the Oklahoma licensed pharmacy provides emergency medication kits;

(2) A log of medications stored in each emergency kit at each facility;
(3) The Oklahoma licensed pharmacy shall require the facility to maintain a log of usage from the emergency medication kit; and,
(4) The log of usage from the emergency medication kit shall be auditable and maintained in a readily retrievable manner by the facility.

(h) Expired medications shall be removed from emergency supply by a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy; and shall not be dispensed or administered.

(i) Controlled Dangerous Substances (CDS) may be maintained only in a medication kit that is separate from Non-Controlled Dangerous Substances or within an electronic medication dispensing machine, if allowed, in accordance with Oklahoma Bureau of Narcotics and the federal Drug Enforcement Administration laws and rules.

(j) Emergency medication kits that do not contain controlled dangerous substances may be maintained in an electronic system or in a secure emergency medication kit. A list of drugs in the emergency medication kit shall be attached to the same.

(k) A record of transactions involving the controlled substance emergency medication kit shall be maintained for two (2) years in a readily retrievable manner by the Oklahoma licensed pharmacy and facility. This transaction record is separate from the prescription record which must be maintained for a minimum of 5 years.

[**Source:** Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 30 Ok Reg 2010, eff 7-25-13; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

AGENCY NOTE: *Please pay close attention to 535:15-16-4(i).*

535:15-16-5. Security

(a) Emergency medication kits shall have adequate security and procedures to:
(1) Prohibit unauthorized access;
(2) Comply with federal and state law and regulations; and
(3) Maintain patient confidentiality.

(b) The emergency medication kit shall be sealed with a tamper-evident seal; or,
(1) It shall be locked or sealed in a manner that obviously reveals when the kit has been opened or tampered with; or,
(2) An electronic system may be used, which notifies the Oklahoma licensed pharmacy when the kit has been accessed.
(3) Paper or tape seals are unacceptable.

(c) If an electronic system is utilized, the Oklahoma licensed pharmacy and facility must maintain a written procedure for how the kit can be accessed in the event of downtime.

(d) The emergency medication kit shall be properly sealed, stored, and accessible only to authorized personnel.

(e) The emergency medication kit shall be securely locked in a sufficiently well-constructed cabinet or cart maintained in the medication room, and access to the cabinet or cart shall be available only to the nurse or nurses as determined by the pharmaceutical services committee or its equivalent.

(f) Access to the controlled substances in the emergency medication kit shall be limited to a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy.

(g) Access to non-controlled drugs in the emergency medication kit shall be limited to a licensed nurse employed at the facility, or an employee of the Oklahoma licensed pharmacy.

[**Source:** Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 39 Ok Reg 2057, eff 9-11-22]

AGENCY NOTE: See 535:15-16-4(i) and 535:15-16-6(b)(1)(B).

535:15-16-6. Drugs allowed in emergency medication kits

(a) An Oklahoma licensed pharmacy and its pharmacists shall be responsible for timely provision of a facility resident's routine drug needs.
(b) The drugs allowed in the emergency medication kit, both Controlled Dangerous Substances (CDS) and Non-Controlled dangerous substances (Non-CDS) shall be determined by the medical director of the facility and an Oklahoma licensed pharmacist employed by the Oklahoma licensed pharmacy providing the kit.

(1) The quantity of each Non-CDS drug shall be of sufficient quantity to meet the needs of the patients in that facility.
(2) The quantity of each CDS drug shall not exceed the limit allowed in 59 O.S. Section 367.8 (D) (1).

(c) Before placing Non-CDS or CDS medications in an emergency medication kit the Oklahoma licensed pharmacy and facility must have a written policy indicating what drugs are included; and the reason for their need. This written policy must be available for Board inspection. The Oklahoma licensed pharmacy and the facility must comply with the rules and laws of the Oklahoma Bureau of Narcotics and the Federal Drug Enforcement Administration.
(d) All injectable medications shall be considered a single dose vial; any remainder shall be destroyed as required under Oklahoma or federal law and rules.

[**Source:** Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

AGENCY NOTE: See 535:15-16-4(i) and 535:15-16-6(b)(1)(B).

535:15-16-7. Violations

(a) Theft or diversion of prescription drugs is a violation of state law and these rules.

(1) Violation by a licensed nursing home or licensed Assisted Living Center of these rules will be referred to the Oklahoma State Health Department and/or other proper authorities for possible action.
(2) Violation by a registrant of the Board may result in action under 59 O.S. Section 353.26 and/or other proper authorities for possible action.

(b) Violation of this subchapter by an Oklahoma licensed pharmacy or a facility may result in loss of the ability to have or use emergency medication kits as authorized under these rules.
(c) Violation(s) may be referred for criminal prosecution where appropriate.

[**Source:** Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 32 Ok Reg 1229, eff 8-27-15]

SUBCHAPTER 17. NUCLEAR PHARMACY

535:15-17-1. Purpose

The rules of this Subchapter are to accomplish the purposes of the Oklahoma Pharmacy Act, as specified in 59 O.S., Section 353.18 (A) thereof, by implementing rules of a licensed nuclear pharmacy. Nuclear pharmacy is hereby recognized as a specialty of pharmacy practice. As such, the following rules address those areas specific or unique to this specialty practice. These regulations are intended to supplement the regulations of other state and federal agencies.

[**Source:** Added at 14 Ok Reg 3027, eff 7-11-97]

535:15-17-2. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3024, eff 7-11-97]

535:15-17-3. Definitions

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

"Authentication of Product History" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"Nuclear Pharmacy" means a pharmacy which provides radiopharmaceutical services and shall be licensed by the Board as a retail pharmacy.

"Practice of Nuclear Pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and related drugs.

"Qualified Nuclear Pharmacist" means a pharmacist who holds a current license issued by the Board, and who is either listed as an authorized user on a radioactive material users license or certified as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties or satisfies each of the following requirements:

(A) Meets minimal standards of training for status as an Authorized Nuclear Pharmacist (ANP), as specified by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency.

(B) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a -accredited college of pharmacy, or other training program recognized by the Nuclear Regulatory Commission, with the following subjects covered:

(i) radiation physics and instrumentation,

(ii) radiation protection,

(iii) mathematics pertaining to the use and measurement of radioactivity,

(iv) radiation biology,

(v) radiopharmaceutical chemistry;

(C) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas, as described in the current American Pharmaceutical Association (APhA) Nuclear Pharmacy Practice Standards:

(i) procuring radioactive materials,

(ii) compounding radiopharmaceuticals,

(iii) performing routine quality control procedures,

(iv) dispensing radiopharmaceuticals,

(v) distributing radiopharmaceuticals,

(vi) implementing basic radiation protection procedures,

(vii) consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public;

(D) Keeps documentation of experience and training available in the pharmacy for Board review.

"Quality Assurance Procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

"Quality Control Testing" means the performance of appropriate chemical and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

"Radiopharmaceutical Services" means, the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

"Radiopharmaceutical" means any substance which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radiopharmaceutical" also includes any product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

[**Source:** Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 24 Ok Reg 2262, eff 7-1-07]

535:15-17-4. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3027, eff 7-11-97]

535:15-17-5. General requirements

(a) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The nuclear pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The permit to operate a nuclear pharmacy is effective only so long as the pharmacy also holds a current Radioactive Material License issued by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency. Copies of inspection reports from Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency shall be available for Board inspection.

(c) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping / receiving area; radioactive material storage area; and radioactive waste decay area.

(d) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and must be totally enclosed and lockable.
(e) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with Board and Nuclear Regulatory Commission statutes and regulations.
(f) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance, including compounded sterile products. The Board recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.
(g) A radiopharmaceutical shall be dispensed only to a licensed prescriber authorized by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission or appropriate agreement state nuclear regulatory agency to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed prescriber. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications as described in 535:15-17-5 subsection (k) below. Separate records will be kept for these transfers and sales, see drug supplier permit rules in 535:15-7.
(h) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(1) This writing or record shall contain at least the following:

(A) the name of the institution and prescriber, or prescribers' agent;
(B) the date of dispensing (or calibration) and the calibration time of the radiopharmaceutical;
(C) the name of the procedure;
(D) the name of the radiopharmaceutical;
(E) the dose or quantity of the radiopharmaceutical;
(F) the serial number assigned to the order for the radiopharmaceutical;
(G) any specific instructions; and
(H) the initials of the pharmacist who dispensed the order.

(2) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

(i)

(1) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(A) the name and address of the pharmacy;
(B) the name of the prescriber;
(C) the date of dispensing (or calibration);
(D) the serial number assigned to the order for the radiopharmaceutical;
(E) the standard radiation symbol;
(F) the words "Caution Radioactive Material";
(G) the name of the procedure;
(H) the radionuclide and chemical form;
(I) the amount of radioactivity and the calibration date and time;
(J) if a liquid, the volume;

(K) if a solid, the number of items or weight;
(L) if a gas, the number of ampules or vials;
(M) the BUD and time; and,
(N) the name of the patient or the words e.g. "Per Physician's Orders" in the absence of a patient name.

(2) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this sub-section shall be met when the name of the patient is readily retrievable from the physician upon demand.

(j) The inner container label of a radiopharmaceutical to be dispensed shall be labeled with, but not limited to:

(1) the standard radiation symbol;
(2) the identity of the radionuclide;
(3) the amount of radioactivity and the calibration date and time;
(4) the name of the procedure; and
(5) serial number of the radiopharmaceutical.

(k) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the institutional radiation safety committee or equivalent radioactive use oversight committee approval, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(l) Each nuclear pharmacy shall have an adequate library and a current copy of state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

[**Source:** Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 15 Ok Reg 3272, eff 7-13-98; Amended at 24 Ok Reg 2262, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1882, eff 9-11-17]

535:15-17-6. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3027, eff 7-11-97]

535:15-17-7. Minimum equipment

(a) A nuclear pharmacy shall be exempt from the physical requirements in Section 535:15-3-4, Subsections (3), (6) and (7).

(b) The professional area of the pharmacy shall have at least the following equipment:

(1) Radionuclide Dose Calibrator;
(2) Refrigerator;
(3) Single or multiple channel scintillation counter with solid state detector (e.g. NaI(Tl) or Ge(Li));
(4) Radiochemical fume hood and filter system with suitable air sampling equipment when dispensing or preparing volatile radiopharmaceuticals;
(5) Area survey meter;
(6) At least two GM survey meters (including one high-range meter);
(7) Microscope and hemacytometer, when dispensing or preparing particle size dependent radiopharmaceuticals;
(8) Laminar airflow hood and appropriate supplies to ensure sterile practices for sterile compounded preparation solutions;
(9) Syringe and vial radiation shields;
(10) Appropriate shielded drawing station;

(11) Decontamination supplies;
(12) Appropriate supplies to perform quality assurance testing;
(13) Appropriate transport shields for syringes and vials; and
(14) Transport containers which meet the U.S. Department of Transportation regulations, and other labels and supplies for shipping radioactive materials.

[**Source:** Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 24 Ok Reg 2262, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-17-8. [RESERVED]

[**Source:** Reserved at 14 Ok Reg 3027, eff 7-11-97]

535:15-17-9. Library reference books or computer sources

A pharmacy library shall contain the following current reference books or computer sources:

(1) **Oklahoma law books.** The latest copy of the Oklahoma State Board of Pharmacy, Laws and Rules and Regulations Pertaining to the Practice of Pharmacy and a recent copy of the Oklahoma State Bureau of Narcotics & Dangerous Drug Control's Rules and Regulations.
(2) Reference compendia necessary to practice Nuclear Pharmacy safely within federal and state requirements.

[**Source:** Added at 14 Ok Reg 3027, eff 7-11-97]

SUBCHAPTER 18. CUSTOMIZED ADHERENCE MEDICATION PACKAGE (CAMP)

535:15-18-1. Purpose

The rules of this Subchapter are to provide standards for the preparation and labeling of customized adherence medication packaging by licensed pharmacies, pursuant to orders or prescriptions. Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the requirements of this subchapter.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-18-2. Definitions

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

"Customized Adherence Medication Package" or **"CAMP"** means packaging for dispensed drugs that is comprised of units containing two or more medications and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"USER" means patient or caregiver.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-18-3. Packaging requirements

Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the following requirements:

(1) In place of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a CAMP. The CAMP is designed and labeled to indicate the day and time or period of time that the contents

within each CAMP are to be taken. The dispensing pharmacy shall instruct the patient or caregiver on the use of the CAMP.
(2) In the absence of more stringent packaging requirements for any of the drug products contained in the CAMP, each CAMP shall be in compliance with the United States Pharmacopeia (USP) and National Formulary (NF). Each container shall be designed as to show evidence of tampering. CAMP packaging shall comply with all provisions of the poison prevention packaging act.
(3) When preparing a CAMP, the dispenser shall take into account any applicable USP Compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may affect the simultaneous administration of the medications. Medications shall not be dispensed in CAMP in any of the following situations:
(A) The USP monograph or official labeling of a medication requires dispensing in the original container.
(B) The drugs or dosage forms are incompatible with packaging components or each other.
(C) The drugs are therapeutically incompatible when administered simultaneously.
(4) If two medications have physical characteristics that make them indistinguishable from each other, then the medication shall not be packaged together in the same CAMP.
(5) Medications that have been dispensed in CAMP may not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in the CAMP is changed, then a new appropriately labeled CAMP may be prepared for the patient. Medications that have been dispensed in CAMP are not eligible for donation under the Utilization of Unused Prescription Medications Act.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-18-4. Labeling

(a) Packaging must bear, at a minimum, the labeling requirements as stated in Title 59, Section 353.20.1 (B); and,
(1) Physical description of medication (i.e. imprint, description) or be separately packaged;
(2) Expiration date;
(3) Lot number(s), if required;
(4) Date and time to be given
(b) If packaging is detachable into individual units of administration time, each individual unit must bear:
(1) The name of patient;
(2) The name and strength of the medication(s); and
(3) Date and time to be given.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18; Amended at 37 Ok Reg 2041, eff 9-11-20]

SUBCHAPTER 19. AUTOMATION RULES

535:15-19-1. Purpose

These rules of this Subchapter are to establish standards for automated dispensing systems by licensed pharmacies. Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the rules of this subchapter.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-19-2. Definitions

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

"Automated dispensing system" means an automated system used by a pharmacy licensed by the state of Oklahoma to assist in dispensing a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated dispensing system" does not include automated devices used solely to count medication that is then subject to final product check by a pharmacist prior to dispensing, vacuum tube drug delivery systems, or automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient.

"Electronic verification system" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated dispensing system.

"Manufacturer's unit of use package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

"Prepacked" for the purposes of this chapter means any drug that has been removed from the original packaging of the manufacturer or an FDA repackager and is placed in a properly labeled dispensing container by a pharmacy for the purpose of dispensing to the ultimate user from the pharmacy in which the prepacking occurred.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-19-3. Medication stocking

Automated dispensing systems may be stocked or loaded by a pharmacist, or by an intern or pharmacy technician under the direct supervision of a pharmacist.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

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.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18; Amended at 38 Ok Reg 2440, eff 9-11-21]

535:15-19-5. Policies and procedures

(a) Written policies and procedures shall be established by and reviewed annually by the pharmacist-in-charge, be maintained in the pharmacy, and be available for review upon inspection.

(b) At a minimum, the pharmacy and pharmacy personnel shall establish and follow policies and procedures for the following:

(1) accurate filling, loading, and stocking of the system;

(2) sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(3) investigating and addressing dispensing errors and system malfunctions;

(4) tracking and documenting prescription errors related to the system that are not corrected prior to dispensing to the patient;

(5) testing the proper function of the system and any accompanying electronic verification system; at a minimum, the system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification system that changes or alters the dispensing or electronic verification process;

(6) written documentation of training persons authorized to access, stock, or load the system in equipment use and operations which shall be maintained in the pharmacy and be available for inspection;

(7) preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;

(8) identifying and recording persons responsible for stocking, loading, and filling the system

(9) conducting routine and preventive maintenance and, if applicable, calibration;

(10) removing expired, adulterated, misbranded, or recalled drugs;

(11) ensuring proper drug storage within the system, consistent with the manufacturer's specifications and the USP;

(12) maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification system to ensure proper and accurate functioning; and

(13) ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-19-6. Recordkeeping

Records and documentation required by this chapter shall be maintained in the pharmacy's records electronically or in writing for a minimum of two (2) years. Records shall be made readily available for inspection and produced to the board inspector upon request.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

535:15-19-7. Prepacking by automation

A pharmacist, or an intern or pharmacy technician under the direct supervision of a licensed pharmacist, may prepack drugs for other than immediate dispensing purposes provided that the following conditions are met:

(1) prepacking occurs at the licensed pharmacy utilizing the system;

(2) only products which will be dispensed directly to the patient may be prepacked;
(3) containers utilized for prepacking shall meet standards specified by the USP, which has been incorporated herein by reference (e.g. preservation, packaging, storage and labeling section of the general notices and requirements); and where needed, light resistant containers shall be used;
(4) any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, quantity, NDC number, the expiration date and lot number, and the date prepacked; and
(5) a record of drugs prepacked must be kept, and include the following: the name and strength of the drug, lot number, NDC number, expiration date, date of prepacking, total number of dosage units (tabs, caps) prepacked, quantity per prepacked container, initials of prepacker and of pharmacist performing verification of prepack.

[**Source:** Added at 35 Ok Reg 1918, eff 9-14-18]

APPENDIX A. USP <797> BEYOND-USE DATE LIMITS CHART [REVOKED]

[**Source:** Added at 26 Ok Reg 2276, eff 7-1-09; Revoked at 32 Ok Reg 1229, eff 8-27-15]

APPENDIX B. USP <797> BEYOUND-USE DATE LIMITS CHART

Figure 1

USP <797> Risk Level	Room Temperature	Refrigerated	Freezer
Immediate Use	1 hour	1 hour	N/A
Low Risk	48 hours	14 days	45 days
Low Risk with 12 hour			
or less BUD	12 hours	12 hours	N/A
12 hours	or less	or less	
Medium Risk	30 hours	9 days	45 days
High Risk	24 hours	3 days	45 days

[**Source:** Added at 32 Ok Reg 1229, eff 8-27-15]

CHAPTER 20. MANUFACTURERS, REPACKAGERS, OUTSOURCING FACILITIES, WHOLESALERS, THIRD-PARTY LOGISTICS PROVIDERS, AND MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

[**Authority:** 51 O.S., §§ 24A et seq.; 59 O.S., §§ 353.7, 353.11 through 353.20.1, 353.22, 353.24 through 367.8; 75 O.S., §§ 2-201, 2–208, and 2–210]
[**Source:** Codified 12-31-91]

SUBCHAPTER 1. GENERAL PURPOSE

535:20-1-1. Purpose

(a) The rules in this Chapter regulate the manufacture, repackaging, distribution, compounding and sale or storage of drugs, medicines, chemicals and poisons and the dispensing of drugs and medicines in all places where drugs and medicines are compounded, dispensed or stored. The rules regulate any and all places, including premises, vehicles, equipment, contents and records, where drugs, medicines, chemicals or poisons are sold, stored, vended, given away, compounded, dispensed, manufactured, repackaged or distributed.
(b) The rules in this Chapter further concern the Board's authority and duty to confiscate all drugs, medicines, chemicals or poisons found to be sold, stored, vended, given away, compounded, dispensed, manufactured, repackaged or distributed contrary to the provisions of 59 O.S. Section 353 et seq.
(c) The rules in this Chapter prescribe minimum standards, for the issuance of new or renewal licenses, with respect to floor space and other physical characteristics necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public.
(d) The rules of this Chapter are necessary to protect the health, safety, and welfare of the public.
(e) The rules in this Chapter implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[**Source:** Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 3. MANUFACTURERS

535:20-3-1. Manufacturer permit [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 20 Ok Reg 2488, eff 7-11-03; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Revoked at 26 Ok Reg 2296, eff 7-1-09]

535:20-3-1.1. Purpose

(a) The rules in this Subchapter set out the minimum requirements for licensure as a manufacturer.
(b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[**Source:** Reserved at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-1.2. Definitions

The words or terms defined in 59 O.S. Section 353.1 and in 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[**Source:** Reserved at 26 Ok Reg 2296, eff 7-1-09; Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

535:20-3-2. Registration; manufacturer permit requirement [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at

32 Ok Reg 1233, eff 8-27-15]

535:20-3-3. Manufacturer licensing requirements

(a) If Oklahoma is the state in which a prescription drug is manufactured or is the state from which or into which a prescription drug of a manufacturer is shipped, this prescription drug may not be manufactured in and/or shipped into or out of Oklahoma unless each facility of such manufacturer is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
(b) A manufacturer shall also be licensed as a manufacturer by the Secretary of the U.S. Department of Health and Human Services, Food and Drug Administration.
(c) A manufacturer license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new manufacturer license.
(d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).
(e) When manufacturer operations are conducted at more than one location, each location shall be licensed by the Board.
(f) A manufacturer shall not operate from a place of residence.
(g) The manufacturing facility shall be located apart and separate from any retail pharmacy licensed by the Board.
(h) A manufacturer must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-4. Minimum required information for licensure

(a) A manufacturer applicant must submit a satisfactorily completed Board-approved application together with the required fee.
(1) New applicants shall provide, at least, the following:
(A) Applicant's full name, all trade or business names used, full business address and telephone number;
(B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;
(C) Name(s) of the owner(s) of the applicant, including:
(i) if a person, the name, address, Social Security number and date of birth;
(ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;
(iii) if a corporation, the State of incorporation; and
(iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.
(D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and dates of birth;
(E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;

(F) Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration, and, if applicable, by the state where the applicant is located (home state); and,
(G) Upon the Board's written request, a list of all manufacturers, wholesale distributors, third-party logistics providers and dispensers for whom the manufacturer provides services at such facility.

(2) Renewal applicants shall provide those items listed above.

(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy (NABP), at its discretion, to inspect manufacturers.

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-4.1. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of manufacturers:

(1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;

(2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;

(3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;

(4) The furnishing by the applicant of false or fraudulent material in any application;

(5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by manufacturers;

(6) Any licensee who has no record of manufacturing prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and

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

(b) A manufacturer shall have and follow a diversion detection and prevention plan that includes all prescription drugs.

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

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-5. Personnel [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-5.1. Personnel

(a) Manufacturers 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 manufacturer shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the manufacturer for each location licensed. The facility manager is responsible for all aspects of the operation of the manufacturer.
(c) No manufacturer shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to manufacturing 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 manufacturer shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6. Minimum requirements for Rx Only drug storage, handling, maintenance and records [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.1. Facility requirements [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.2. Multiple licensing [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.3. Security [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-11-10; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.4. Storage [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.5. Examination of materials [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.6. Returned, damaged, and outdated drugs [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.7. Recordkeeping [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.8. Written policies and procedures [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.9. Responsible persons [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.10. Compliance with federal, state and local laws

(a) A manufacturer shall operate in compliance with the Federal Food, Drug, and Cosmetic Act Good Manufacturing Practices, 21 U.S.C. §§ 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. §§ 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211.
(b) A manufacturer shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's Rules, OAC 535.
(c) A manufacturer shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.
(d) A manufacturer shall only ship to the address listed on the licensee's license.

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.11. Salvaging and reprocessing [REVOKED]

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-7. Compressed medical gases

Manufacturers of multiple products that include medical gases shall comply with the requirements in 535:20-9 for medical gas distributors.

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01]

535:20-3-8. Violations and Penalties [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-9. Prohibited conduct

(a) The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.
(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

[**Source:** Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-10. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.
(b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 5. REPACKAGERS

535:20-5-1. Definitions [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 13 Ok Reg 2809, eff 6-27-96; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-1.1. Purpose
(a) The rules in this Subchapter set the minimum requirements for licensure as a repackager.
(b) The rules of this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-2. Registration; packager permit requirements [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-2.1. Definitions
The words or terms defined in 59 O.S. Section 353.1 and 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

535:20-5-3. Minimum required information for permit [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-3.1. Repackager licensing requirement
(a) If Oklahoma is the state in which a prescription drug is repackaged or is the state from which or into which a prescription drug of a repackager is shipped, this prescription drug may not be repackaged and/or shipped into or out of Oklahoma unless each facility of such repackager is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
(b) A repackager shall also be licensed as a repackager by the Secretary of the U.S. Department of Health and Human Services, Food and Drug Administration.
(c) A repackager license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new repackager license.
(d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).

(e) When repackager operations are conducted at more than one location, each location shall be licensed by the Board.
(f) A repackager shall not operate from a place of residence.
(g) The repackaging facility shall be located apart and separate from any retail pharmacy licensed by the Board.
(h) A repackager must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-4. Minimum qualifications [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-4.1. Minimum required information for licensure

(a) A repackager applicant must submit a satisfactorily completed Board-approved application together with the required fee.

(1) New applicants shall provide, at least, the following:

(A) Applicant's full name, all trade or business names used, full business address and telephone number;

(B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;

(C) Name(s) of the owner(s) of the applicant, including:

(i) if a person, the name, address, Social Security number and date of birth;

(ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(iii) if a corporation, the State of incorporation; and

(iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.

(D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and dates of birth;

(E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;

(F) Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration, and, if applicable, by the state where the applicant is located (home state); and,

(G) Upon the Board's written request, a list of all manufacturers, wholesale distributors, third-party logistics providers and dispensers for whom the repackager provides services at such facility.

(2) Renewal applicants shall provide those items listed above.

(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy, (NABP), at its discretion, to inspect repackagers.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-4.2. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of repackagers:

(1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;

(2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;

(3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;

(4) The furnishing by the applicant of false or fraudulent material in any application;

(5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by repackagers;

(6) Any licensee who has no record of repackaging prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and,

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

(b) A repackager shall have and follow diversion detection and prevention plan that includes all prescription drugs.

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

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-5. Personnel [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-5.1. Personnel

(a) Repackagers 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 repackager shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the repackager for each location licensed. The facility manager is responsible for all aspects of the operation of the repackager.

(c) No repackager shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to repackaging 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 repackager shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6. Minimum requirements for storage, handling, maintenance and records [REVOKED]

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.1. Facility requirements [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.2. Multiple Licensing [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.3. Security [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-11-10; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.4. Storage [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.5. Examination of materials [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.6. Returned, damaged, and outdated drugs [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.7. Recordkeeping [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.8. Written policies and procedures [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.9. Responsible persons [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.10. Compliance with federal, state and local laws

(a) A repackager shall operate in compliance with the Federal Food, Drug, and Cosmetic Act Good Manufacturing Practices, 21 U.S.C. §§ 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. §§ 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211.

(b) A repackager shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's Rules, OAC 535.

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

(d) A repackager shall ship only to the address listed on the licensee's license.

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.11. Salvaging and reprocessing [REVOKED]

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-7. Compressed medical gases

Packager of multiple products that include medical gases shall comply with the requirements in 535:20-9 for medical gas distributors.

[**Source:** Added at 9 Ok Reg 2145, eff 6-11-92; Revoked at 10 Ok Reg 3175, eff 6-25-93; Added at 18 Ok Reg 2749, eff 7-1-01]

535:20-5-8. Violations and Penalties [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-9. Prohibited conduct

(a) The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.
(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-10. Violations and Penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.
(b) Rules of conduct, violations of the rules of conduct and other requirements of applicants can be found in 535:25.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 6. OUTSOURCING FACILITIES

535:20-6-1. Purpose

(a) The rules in this Subchapter set out the minimum requirements for licensure as an outsourcing facility.
(b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-2. Definitions

The words or terms defined in 59 O.S. Section 353.1 and 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

535:20-6-3. Outsourcing facility licensing requirement

(a) If Oklahoma is the state in which a prescription drug is compounded or is the state from which or into which a prescription drug of an outsourcing facility is shipped, this prescription drug may not be compounded in and/or shipped into or out of Oklahoma unless each facility of such outsourcing facility is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.

(b) An outsourcing facility shall also be licensed as an outsourcing facility by the Secretary of the U. S. Department of Health and Human Services, Food and Drug Administration.

(c) An outsourcing facility license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new outsourcing facility license.

(d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).

(e) When outsourcing facility operations are conducted at more than one location, each location shall be licensed by the Board.

(f) An outsourcing facility shall not operate from a place of residence.

(g) The outsourcing facility may be located in a facility where a retail pharmacy licensed by the Board is located.

(h) An outsourcing facility which receives patient specific prescriptions and fills the prescriptions in Oklahoma or ships the filled prescriptions into Oklahoma shall also have an Oklahoma pharmacy or non-resident pharmacy license.

(i) An outsourcing facility must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-4. Minimum required information for licensure

(a) An outsourcing facility applicant must submit a satisfactorily completed Board-approved application together with the required fee.

(1) New applicants shall provide, at least, the following:

(A) Applicant's full name, all trade or business names used, full business address, telephone number and unique facility identifier;

(B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;

(C) Name(s) of the owner(s) of the applicant, including:

(i) if a person, the name, address, Social Security number and date of birth;

(ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(iii) if a corporation, the State of incorporation; and

(iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.

(D) Names of designated representatives, facility managers, and, if applicable, pharmacist-in-charge of the applicant, their Social

Security numbers and dates of birth;
(E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;
(F) Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration, and, if applicable, by the state where the applicant is located (home state); and
(G) Upon the Board's written request, a list of all dispensers for whom the outsourcing facility provides services at such facility.

(2) Renewal applicants shall provide those items listed above.

(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy (NABP), at its discretion, to inspect outsourcing facilities.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-5. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of outsourcing facilities:

(1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;

(2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;

(3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;

(4) The furnishing by the applicant of false or fraudulent material in any application;

(5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by outsourcing facilities;

(6) Any licensee who has no record of compounding prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and

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

(b) An outsourcing facility shall have and follow a diversion detection and prevention plan that includes all prescription drugs.

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

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

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.
(d) 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.
(e) The PIC shall be present and practicing at the outsourcing facility for which he holds the PIC position no less than 20 hour 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 hour 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.
(g) A non-resident outsourcing facility registrant may request, in writing, that the Board allow additional time for a new pharmacist-in-charge to obtain an Oklahoma license in emergency or urgent situations. If the Board determines circumstances warrant it, the Board may grant up to a 90-day extension.
(h) 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.
(i) 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.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 34 Ok Reg 1887, eff 9-11-17; Amended at 38 Ok Reg 2457, eff 9-11-21; Amended at 39 Ok Reg 2067, eff 9-11-22]

535:20-6-7. Compliance with federal, state and local laws

(a) An outsourcing facility shall operate in compliance with the Federal Food, Drug, and Cosmetic Act Good Manufacturing Practices, 21 U.S.C. §§ 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. §§ 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211: and meet the requirements of Current Good Manufacturing Practice - Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act or any revision to the document as finalized.
(b) An outsourcing facility shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's Rules, OAC 535.
(c) An outsourcing facility shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.
(d) When shipping to licensees, an outsourcing facility shall ship only to the address listed on the licensee's license.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-8. Prohibited conduct

The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-9. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.
(b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 7. WHOLESALE DISTRIBUTOR RULES

535:20-7-1. Purpose

(a) The rules in this Subchapter set out the minimum requirements for licensure as a wholesaler distributor..
(b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Supply Chain Security Act of 2013, 21 U.S.C. § 360eee, et seq., 21 C.F.R. Part 205, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[**Source:** Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-2. Definitions

The words or terms defined in 59 O.S. Section 353.1 and 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[**Source:** Amended at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

535:20-7-3. Wholesale distributor licensing requirement

(a) If Oklahoma is the state in which a prescription drug is distributed or is the state from which or into which a prescription drug is distributed by a wholesale distributor, that wholesale distributor may not distribute in or into or out of Oklahoma unless each facility of such wholesale distributor is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
(b) If Oklahoma is the state into which a prescription drug is shipped by a wholesale distributor, that wholesale distributor shall also be licensed as a wholesale distributor by the state from which that wholesale distributor ships.
(c) A wholesaler distributor license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new wholesale distributor license.
(d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.)

(e) When wholesale distributor operations are conducted at more than one location, each location shall be licensed by the Board.
(f) A wholesale distributor shall not operate from a place of residence.
(g) The wholesale distributing facility located in Oklahoma shall be located apart and separate from any retail pharmacy licensed by the Board.
(h) A wholesale distributor must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[**Source:** Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

535:20-7-4. Minimum required information for licensure
(a) A wholesale distributor applicant must submit a satisfactorily completed Board-approved application together with the required fee.

(1) New applicants shall provide at least, the following:
(A) Applicant's full name, all trade or business names used, full business address and telephone number;
(B) Type of ownership, e.g. individual, partnership or corporation;
(C) Name(s) of the owner(s) of the applicant including:
(i) if a person; the name, address, social security number and date of birth;
(ii) if other than a person; the name, address, and social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director, and the federal employer identification number;
(iii) if a corporation, the State of incorporation; and,
(iv) if a publicly traded corporation, the information in ((a)(1)(C)(ii) is not required for corporate officers and corporate directors.
(D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and date of birth;
(E)
Evidence of criminal background checks and fingerprinting of the applicant, if a person, and all of applicant's designated facility managers;
(F) Proof of licensure by the state where the applicant is located (home state) and, if applicable, by the U.S. Secretary of Health and Human Services, Food and Drug Administration;
(G) Submission of a surety bond meeting the requirements of the Drug Supply Chain Security Act of 2013, et seq. and the rules promulgated thereunder; and,
(H) Upon the Board's written request, a list of all manufacturers, wholesale distributors and dispensers for whom the wholesale distributor provides services at such facility.
(2) Renewal applicants shall provide those items listed above.
(3) Any other information the Board deems necessary to protect the public health and safety.
(b) The Board may use an outside agency, such as the National Association of Boards of Pharmacy (NABP) program, at its discretion, to inspect wholesale distributors.

[**Source:** Amended at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-5. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of wholesale distributors:

(1) Any findings by a law enforcement or regulatory agency that the applicant or any of its owners has violated or been disciplined by a regulatory agency in any state for violating any federal, state, or local laws;
(2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state, local, or federal laws;
(3) Any finding that the applicant or any of its owners is guilty of or pleaded nolo contendere to violating federal, state, or local laws;
(4) The furnishing by the applicant of false or fraudulent material in any application;
(5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors;
(6) Any licensee who has no record of providing wholesaler distributions during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require registrant appearance before the Board; and,
(7) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) A wholesale distributor shall have and follow a diversion detection and prevention plan that includes all prescription drugs.
(c) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

[**Source:** Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

535:20-7-6. Personnel

(a) Wholesale distributors shall establish and maintain for Board inspection a list of each partner, corporate officer and corporate director or limited liability company member and facilty manager, including a description of their duties and a summary of their qualifications.
(b) Each wholesale distributor shall designate, in writing on a Board-approved form, a person to serve as the facility manager of the wholesale distributor for each location licensed. The facility manager is responsible for all aspects of the operation of the wholesale distributor.
(c) No wholesale distributor shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to providing wholesale distribution of prescription drugs, any felony for violating 21 U.S.C. Section 331(i) or (k) or any felony for violation of 18 U.S.C. Section 1365 relating to product tampering. No wholesale distributor shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirement for licensure that presents a threat of serious adverse health consequences or death to humans.

[**Source:** Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7. Minimum requirements for the storage, handling, transport, and shipment of drugs and/or devices and establishment and maintenance of drug records [REVOKED]

[**Source:** Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.1. Facility requirements [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.2. Multiple Licensing [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.3. Security and anti-counterfeiting [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 27 Ok Reg 2261, eff 7-11-10; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.4. Storage [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.5. Examination of materials [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.6. Drug returns, and returned, damaged, and outdated drugs [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.7. Recordkeeping; including pedigree requirement [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 26 Ok Reg 417, eff 12-11-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.8. Written policies and procedures [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.9. Responsible persons [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Revoked at 24 Ok Reg 2906, eff 8-1-07 (emergency); Revoked at 25 Ok Reg 1976, eff 7-1-08 [1]]

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 license.

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 38 Ok Reg 2457, eff 9-11-21]

535:20-7-7.11. Salvaging and reprocessing [REVOKED]

[**Source:** Added at 18 Ok Reg 2749, eff 7-1-01; Revoked at 24 Ok Reg 2906, eff 8-1-07 (emergency); Revoked at 25 Ok Reg 1976, eff 7-1-08]

535:20-7-8. Compressed medical gases

Wholesalers of multiple products that include medical gases shall comply with the requirements in 535:20-9 for medical gas distributors.

[**Source:** Revoked at 10 Ok Reg 3175, eff 6-25-93; Added at 18 Ok Reg 2749, eff 7-1-01]

535:20-7-9. Violations and penalties [REVOKED]

[**Source:** Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Revoked at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-9.1. Prohibited Conduct

The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including but not limited to, the Drug Supply Chain Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and Board rules, OAC 535.

[**Source:** Added at 24 Ok Reg 2906, eff 8-1-07 (emergency); Added at 25 Ok Reg 1976, eff 7-1-08; Amended at 27 Ok Reg 2261, eff 7-11-10; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-10. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.
(b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 8. THIRD-PARTY LOGISTICS PROVIDERS

535:20-8-1. Purpose

(a) The rules in this Subchapter set out the minimum requirements for licensure as a third-party logistics provider.
(b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Supply Chain Security Act of 2013, 21 U.S.C. § 360eee, et seq., other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-2. Definitions

The words or terms defined in 59 O.S. Section 353.1 and 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

535:20-8-3. Third-party logistics provider licensing requirement

(a) If Oklahoma is the state in which a prescription drug is shipped or is the state from which or into which a prescription drug is shipped by a third-party logistics provider, that third-party logistics provider may not ship in, into or out of Oklahoma unless each facility of such third-party logistics provider is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
(b) If Oklahoma is the state into which a prescription drug is shipped by a third-party logistics provider, that third-party logistics provider shall also be licensed as a third-party logistics provider by the state from which that third-party logistics provider ships.
(c) A third-party logistics provider license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new third-party logistics provider license.
(d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).
(e) When third-party logistics provider operations are conducted at more than one location, each location shall be licensed by the Board.
(f) A third-party logistics provider shall not operate from a place of residence.
(g) The third-party logistics provider facility shall be located apart and separate from any retail pharmacy licensed by the Board.
(h) A third-party logistics provider must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-4. Minimum required information for licensure

(a) A third-party logistics provider applicant must submit a satisfactorily completed Board-approved application together with the required fee.
(1) New applicants shall provide, at least, the following:
(A) Applicant's full name, all trade or business names used, full business address and telephone number;
(B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;
(C) Name(s) of the owner(s) of the applicant, including:
(i) if a person, the name, address, Social Security number and date of birth;
(ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member or corporate officer and corporate director and the federal employer identification number;

(iii) if a corporation, the State of incorporation; and
(iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.

(D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and dates of birth;
(E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;
(F) Proof of licensure by the state where the applicant is located (home state) and/or, if applicable, by the U.S. Secretary of Health and Human Services, Food and Drug Administration; and
(G) Upon the Board's written request, a list of all manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility.

(2) Renewal applicants shall provide those items listed above.
(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy (NABP), at its discretion, to inspect third-party logistics providers.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-5. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of third-party logistics providers:

(1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws;
(2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;
(3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;
(4) The furnishing by the applicant of false or fraudulent material in any application;
(5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by third-party logistics providers;
(6) Any licensee who has no record of providing third-party logistics services involving prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and
(7) Any other factors or qualifications that the Board considers relevant to and consistent with the public health and safety.

(b) A third-party logistics provider shall have and follow a diversion detection and prevention plan that includes all prescription drugs.
(c) The Board shall have the right to deny a license to an applicant if it determines that granting such a license would not be consistent with the public health and safety.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-6. Personnel

(a) Third-party logistics providers 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 third-party logistics provider shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the third-party logistics provider for each location licensed. The facility manager is responsible for all aspects of the operation of the third-party logistics provider.
(c) No third-party logistics provider shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to providing third-party logistics services involving 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 third-party logistics provider shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-7. Compliance with federal, state and local laws

(a) A third-party logistics provider shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Supply Chain Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535. A third-party logistics provider shall comply with the storage practices set out in 21 U.S.C. § 360eee-3(d)(2)(C).
(b) A third-party logistics provider shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.
(c) When shipping to licensees, a third-party logistics provider shall ship only to the address listed on the licensee's license.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-8. Prohibited conduct

The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Drug Supply Chain Security Act of 2013 and rules promulgated thereunder, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-9. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.
(b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[**Source:** Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 9. MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

535:20-9-1. Purpose

This subchapter is to establish rules specific to medical gases due to the fact that its labeling, packaging, distribution and handling is unique.

[**Source:** Added at 10 Ok Reg 3175, eff 6-25-93]

535:20-9-2. Definitions

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

"Drug order" means a prescription drug order issued by a licensed prescriber for medical gas.

"Medical gas" means those gases and liquid oxygen upon which the manufacturer or distributor has, in compliance with federal law and regulations, placed one of several cautions, such as: "RX Only" that replaces "Caution - Federal Law prohibits dispensing without prescription".

"Medical gas distributor" means a person licensed to distribute medical gases on drug orders and to suppliers or other entities licensed to use, administer, or distribute medical gases.

"Medical gas supplier" means a person licensed to supply medical gases only on drug orders.

[**Source:** Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-9-3. Medical gas suppliers

(a) **Licensing requirement.** Before conducting interstate and/or intrastate transactions in Oklahoma, a medical gas supplier shall register annually with the Board.

(1) A medical gas supplier license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location shall require a new medical gas supplier license.

(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas supplier license. A medical gas supplier license entitles the license holder to store and supply medical gas (prescription drugs) at the licensed location.

(4) A medical gas supplier shall not operate from a place of residence.

(5) A medical gas supplier shall not operate from a storage unit.

(b) **License issuance.** Licenses shall be issued only to those medical gas suppliers who satisfy the provisions of: 59 O.S. Section 353.18 (B) (1)(2) et seq., and the requirements under the Act, this Title and the rules in 535:25 for applicants.

(c) **Compliance with federal requirements.** Medical gas supplier applicants and registrants shall meet the federal requirements to handle medical gas, the Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.), and/or any other applicable federal, state, or local laws and regulations. Medical gas supplier applicants and registrants shall be registered with the federal Food and Drug Administration (FDA), if required.

(d) **Minimum required information for licensure.** The minimum required information for medical gas supplier licensure shall be as follows, Medical gas supplier applicants must submit a satisfactorily completed application together with

the required fee annually. This application shall include, at least, the following:

(1) The name, full business address, and telephone number;

(2) All trade or business names used by the manufacturer applicant;

(3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;

(4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the manufacturer applicant; and

(6) Any other information the Board deems necessary to protect the public health.

(e) **Minimum qualifications.** Medical gas suppliers must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Be licensed by the Board;

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

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

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

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

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

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

(h) **Prescription requirement.** Medical gas suppliers shall not supply medical gas without a drug order.

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

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

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

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

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

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

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

(D) All medical gas suppliers shall establish and maintain controls and systems that protect against, detect, and document any

instances of theft, diversion, or counterfeiting. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) The conditions under which the drug has been held, stored or shipped before or during its return; and,
(ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

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

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

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

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

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

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

(A) Medical gas suppliers shall include in their written policies and procedures the following; A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(i) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board;
(ii) Voluntary action by the medical gas supplier to remove defective or potentially defective drugs from the market; or
(iii) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

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

(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(i) This procedure shall provide for written documentation of the disposition of outdated drugs.

(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(7) **Responsible persons.** Medical gas suppliers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(8) **Compliance with federal, state and local laws.** Medical gas suppliers shall operate in compliance with applicable federal, state, and local laws and regulations.

(A) Medical gas suppliers shall permit the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(B) Medical gas suppliers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.

(9) **Salvaging and reprocessing.** Medical gas suppliers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

[**Source:** Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-1-10; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16; Amended at 35 Ok Reg 1925, eff 9-14-18]

535:20-9-4. Medical gas distributors

(a) **Licensing requirement.** Before conducting interstate and or intrastate transactions in Oklahoma, a medical gas distributor shall register annually with the Board.

(1) A medical gas distributor license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location shall require a new medical gas distributor license.

(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas distributor license. Medical gas distributor license entitles the holder to store and distribute medical gas (prescription drugs) at the licensed location.

(4) A medical gas distributor shall not operate from a place of residence.

(5) A medical gas distributor shall not operate from a storage unit.

(b) **License issuance.** Licenses shall be issued only to those medical gas distributors who satisfy the provisions of: 59, O.S. Section 353.18 (B)(1)(2) et seq., and the requirements under the Act, this Title and the rules in 535:25 for applicants.

(c) **Compliance with federal requirements.** Medical gas distributor applicants and registrants shall meet the federal requirements to handle medical gas, the Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or any other applicable federal, state, or local laws and regulations. Medical gas distributor applicants and registrants shall be registered with the federal Food and Drug Administration (FDA), if required.

(d) **Minimum required information for licensure.** The minimum required information for medical gas distributors licensure shall be as follows, Medical gas

distributor applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

(1) The name, full business address, and telephone number;

(2) All trade or business names used by the manufacturer applicant;

(3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;

(4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the manufacturer applicant; and

(6) Any other information the Board deems necessary to protect the public health.

(e) **Minimum qualifications.** Medical gas distributors must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

(f) **Personnel.** Personnel employed by medical gas distributors shall have sufficient education, training, and/or experience to perform assigned functions and comply

with federal, state and local licensing requirements.

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

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

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

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

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

(i) Be licensed by the Board;

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) The outside perimeter of the premises shall be well-lighted.
(C) Entry into areas where drugs are held shall be limited to authorized personnel.
(D) All medical gas distributors shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(E) All medical gas distributors shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:
(i) The medical gas distributor must not ship the customer's order if the order is confirmed as suspicious;
(ii) Each medical gas distributor shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,
(iii) Medical gas distributors shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.

(2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
(A) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.
(C) The recordkeeping requirement in this Chapter for medical gas distributors shall be followed for all stored drugs.

(3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
(A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.
(B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.

(4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.
(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then

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

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

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

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

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

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

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

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

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

(A) Medical gas distributors shall include in their written policies and procedures the following; A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

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

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

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

(B) A procedure to ensure that medical gas distributors prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.
(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.
(i) This procedure shall provide for written documentation of the disposition of outdated drugs.
(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(7) **Responsible persons.** Medical gas distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(8) **Compliance with federal, state and local laws.** Medical gas distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
(A) Medical gas distributors shall permit the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.
(B) Medical gas distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.

(9) **Salvaging and reprocessing.** Medical gas distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210, and 211.

[**Source:** Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-11-10; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16; Amended at 35 Ok Reg 1925, eff 9-14-18]

535:20-9-5. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.
(b) Rules of conduct, violations of the rules of conduct and other requirements of applicants can be found in 535:25.

[**Source:** Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-9-6. Prohibited conduct

(a) The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.

(1) Engaging in medical gas distributing of drugs
(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate record, when required;

(B) destroying, altering, concealing, or failing to maintain complete and accurate records for any drug packaging, when required;
(C) knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, or,
(D) selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s).

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or the commission of any other act with respect to a drug; that results in the drug being misbranded.

(4) supplying, packaging, purchasing, selling, delivering or bringing into the state contraband drug(s), or anyone who illegally possesses any amount of contraband drug(s); or,

(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

[**Source:** Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 Ok Reg 1786, eff 9-11-16]

CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

[**Authority:** 51 O.S., §§ 24A et seq.; 59 O.S., §§ 353.7, 353.11 through 353.20.1, 353.22, 353.24 through 354, and 367.8; 75 O.S., §§ 2-201, 2–208 and 2–210]
[**Source:** Codified 12-31-91]

SUBCHAPTER 1. GENERAL REQUIREMENTS

535:25-1-1. Purpose

(a) The rules of this Chapter regulate the sale of drugs, medicines, chemicals and poisons in order to prevent illegal diversion of dangerous drugs.
(b) The rules of this Chapter describe requirements applicable to various registrants.
(c) The rules of this Chapter describe an inspector's notice to registrants to correct deficiencies and give notice of compliance.
(d) The rules of this Chapter describe minimum qualifications and requirements for all applicants and registrants.
(e) The rules of this Chapter describe registrant conduct and violations of registrant conduct.

[**Source:** Amended at 9 Ok Reg 2147, eff 6-11-92; Amended at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-1-1.1. Definitions

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

"**Applicant**" means a "person" as defined in Title 59, O.S., Section 353.1 who is making application for any registration, certificate, license or permit or renewal of the same.

"**License**" means any license, permit, registration or certificate.

"**Registrant**" means any holder of registration, certificate, license or permit that is regulated by the Board.

[**Source:** Amended at 17 Ok Reg 2636, eff 7-1-00; Amended at 18 Ok Reg 2757, eff 7-1-01]

535:25-1-2. Multiple licenses/permits [AMENDED AND RENUMBERED TO 535:25-3-5]

[**Source:** Amended at 9 Ok Reg 2147, eff 6-11-92; Amended at 10 Ok Reg 3177, eff 6-25-93; Amended at 12 Ok Reg 2601, eff 6-26-95; Amended and renumbered to 535:25-3-5 at 17 Ok Reg 2636, eff 7-1-00]

535:25-1-3. Inspector's warning notice [AMENDED AND RENUMBERED TO 535:25-5-1]

[**Source:** Amended at 9 Ok Reg 2147, eff 6-11-92; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended and renumbered to 535:25-5-1 at 17 Ok Reg 2636, eff 7-1-00]

535:25-1-4. Procedure to return a restricted license to good standing [RENUMBERED]

[**Source:** Added at 9 Ok Reg 2147, eff 6-11-92; Renumbered to 535:25-5-2 at 17 Ok Reg 2636, eff 7-1-00]

SUBCHAPTER 3. APPLICANTS, REGISTRANTS, AND APPLICATIONS

535:25-3-1. [RESERVED]

[**Source:** Reserved at 17 Ok Reg 2636, eff 7-1-00]

535:25-3-2. [RESERVED]

[**Source:** Reserved at 17 Ok Reg 2636, eff 7-1-00]

535:25-3-3. Qualifications and requirements for registrant applicants

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

(1) Any charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under any federal, state, or local laws relating to drug samples, drug distribution, or distribution of controlled substances;

(2) Any felony charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under federal, state, or local laws;

(3) The applicant's or registrant's past experience with prescription drugs, including controlled substances;

(4) The furnishing by the applicant or registrant of fictitious, false, misleading, or fraudulent material in any application (original, new or renewal) or failing to provide information relevant to this application;

(5) The suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant or registrant;

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

(7) Compliance with requirements to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required by rule and law;

(8) Abuse of alcohol or habit-forming drugs, or use of illegal CDS drugs or positive drug screen for such illegal substance or its metabolite;

(9) Practicing as a registrant without reasonable skill and safety by reason of use and/or abuse of drugs, narcotics, chemicals or any other type of

material, or as a result of any mental or physical condition; and,
(10) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

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

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

(d) The applicant shall fully and completely disclose ownership of any pharmacy, wholesaler, distributor, manufacturer, repackager, third-party logistics provider, outsourcing facility, medical gas supplier or medical gas distributor or any other person licensed by the Board.

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

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 18 Ok Reg 2757, eff 7-1-01; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 21 Ok Reg 2460, eff 7-1-04; Amended at 24 Ok Reg 2265, eff 7-1-07; Amended at 27 Ok Reg 2269, eff 7-11-10; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-3-4. Requirements for applicants or registrants who have had Board action taken against any license, permit or certificate

(a) If the Board approves an application of an applicant or registrant who has had a previous registration, license, permit, or certificate which was revoked or subject to Board action, the applicant shall be subject to the following terms: any specific requirements placed on the applicant by the Board based on the previous action, or pending action, and applicant's or registrant's current status.

(b) Any subsequent violations by the applicant or registrant shall subject the applicant or registrant to cumulative action based on previous violation on the previous license and the current violation.

(c) Failure of the applicant or registrant to meet any terms or requirements of the Board shall subject the applicant or registrant to Board action.

(d) The Board shall have the right to order any additional terms or conditions that it determines are required to protect the public health and safety.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 26 Ok Reg 2310, eff 7-1-09; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 33 Ok Reg 1793, eff 9-11-16]

535:25-3-5. Multiple licenses/permits

(a) **Pharmacy, Manufacturer, Repackager, Wholesaler, Distributor or Third-party logistics provider.** A pharmacy located in Oklahoma shall not be licensed in the same location as a manufacturer, repackager, wholesale distributor or third party logistics provider.

(b) **Pharmacy/Pharmacy.** No more than one pharmacy license will be allowed in one location.

(c) **Wholesaler/Wholesaler.** No more than one wholesale distributor license will be allowed in one location.

(d) **Wholesaler/Repackager.** The licensing of a wholesaler distributor and a repackager in the same location will be allowed.

(e) **Pharmacy/Drug Supplier.** The licensing of a pharmacy license and pharmacy drug supplier permit in the same location will be allowed.

(f) **Pharmacy/Outsourcing Facility.** The licensing of a pharmacy and an outsourcing facility will be allowed when state and federal requirements are met.
(g) **Pharmacy/Sterile compounding.** The licensing of a pharmacy and a sterile compounding pharmacy in the same location will be allowed.
(h) **Intern/Technician.** Applicants may not hold an intern license and a technician permit at the same time.
(i) **Pharmacist/Technician.** Applicants may not hold a pharmacist license and a technician permit at the same time. A pharmacist who has had Board action taken against his pharmacist license for whatever reason and no longer holds a current pharmacist license is not eligible for a technician permit.
(j) **Medical Gas Supplier.** No more than one medical gas supplier license will be allowed in one location.
(k) **Medical Gas Distributor.** No more than one medical gas distributor license will be allowed in one location.
(l) **Medical Gas Distributor/Medical Gas Supplier.** A medical gas supplier located in Oklahoma shall not be allowed in the same location as a medical gas distributor.

[**Source:** Amended and renumbered from 535:25-1-2 at 17 Ok Reg 2636, eff 7-1-00; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 33 Ok Reg 1793, eff 9-11-16; Amended at 35 Ok Reg 1931, eff 9-14-18]

535:25-3-6. Individual address change

Every individual applicant and/or registrant (e.g.: pharmacist, intern, technician, etc.) shall notify the Board in writing within 10 days of an address change.

[**Source:** Added at 18 Ok Reg 2757, eff 7-1-01]

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 changes in information must be reported to the Board within ten (10) days: manager, representative contact person, officer(s), phone number, email address, and hours of operation.
(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.

[**Source:** Added at 18 Ok Reg 2757, eff 7-1-01; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 24 Ok Reg 2265, eff 7-1-07; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 38 Ok Reg 2458, eff 9-11-21]

535:25-3-8. Requirements for Licensees

(a) Licensees shall sell, ship, deliver, etc. only to the address listed on the receiving licensee's license.
(b) Licensees that store, ship, sell, deliver, or handle drugs shall not operate from a place of residence.
(c) Licensees shall not receive drugs at other than the address listed on their license.
(d) A licensee representative shall sign the Pharmacy Board inspection report upon completion. The licensee representative shall be responsible to assure that issues noted, if any, are resolved.

[**Source:** Added at 32 Ok Reg 1261, eff 8-27-15; Amended at 39 Ok Reg 2068, eff 9-11-22]

SUBCHAPTER 5. GENERAL REQUIREMENTS OR PROCEDURES

535:25-5-1. Inspector's warning notice

(a) **Purpose.** An inspector's warning notice protects public health by allowing registrants to expeditiously correct violations of laws and rules, and report these corrections to the Board in writing.
(b) **Recipient.** A warning notice may be issued to any registrant found to be violating the rules of this Title (OAC 535), 59O.S. Section 353 et seq., and/or any federal, state or local laws and rules.
(c) **Issuance.** An inspector may issue a warning notice at the time a violation is found.
(d) **Failure to respond.** A recipient's failure to satisfactorily respond within ten days to a warning notice may be referred by the Director to the Board for review or complaint and hearing.
(e) **Board review of warning notices.** Any registrant receiving a warning notice may be referred by the Director to the Board for review or complaint and hearing.

[**Source:** Amended and renumbered from 535:25-1-3 at 17 Ok Reg 2636, eff 7-1-00; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-5-2. Procedure to return a restricted license to good standing

(a) Upon the expiration date of a restriction, the registrant must request in writing that the Board return the license to good standing.
(b) The registrant may be requested to appear before the Board prior to any action being taken on the request.

[**Source:** Renumbered from 535:25-1-4 at 17 Ok Reg 2636, eff 7-1-00]

535:25-5-3. Drug Screening

(a) Any individual registrant who is suspended and/or placed on probation may be required to submit to random drug screening.
(b) Random drug screening required by the Board shall be done at the registrant's expense.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-5-4. Board order(s) due date

Any fine(s) ordered or agreed to in a Final Order, Agreed Order, or any other Order of the Board is due and payable upon receipt of such Order by the registrant; unless otherwise stated in the Order.

[**Source:** Added at 18 Ok Reg 2757, eff 7-1-01]

535:25-5-5. Prescription drug (Rx only) purchases and record requirements

(a) All registrants shall keep adequate records to assure that prescription drugs are legally received and/or distributed or dispensed, as appropriate. Such records shall include, but not be limited to, all prescription drug purchase (e.g. invoices, etc.) and inventory records and shall be maintained and be readily retrievable for a period of at least 2 years.
(b) Prescription drug purchases may only be made from entities licensed to sell prescription drugs. A registrant shall exercise professional judgment regarding the purchase of prescription drugs in order to assure a safe, sanitary and legal prescription drug supply is maintained.

[**Source:** Added at 24 Ok Reg 2265, eff 7-1-07; Amended at 32 Ok Reg 1261, eff 8-27-15]

SUBCHAPTER 6. 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.

[**Source:** Reserved at 32 Ok Reg 1261, eff 8-27-15; Added at 38 Ok Reg 2458, eff 9-11-21]

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.

[**Source:** Reserved at 32 Ok Reg 1261, eff 8-27-15; Amended at 38 Ok Reg 2458, eff 9-11-21]

535:25-6-3. Post-Military service applicants

(a) The Board shall consider the equivalent education, training and experience completed by an applicant for licensure while the applicant was a member of the United States Armed Forces or Reserves, National Guard of any state, the Military Reserves of any state, or the Naval militias of any state, and apply it in the manner most favorable toward satisfying the qualifications for issuance of a license or approval for license examination.
(b) The Board shall expedite the process of licensure by reciprocity for applicants whose spouse is an active duty member of the Armed Forces of the United States if:

(1) the military service member is on active duty within Oklahoma or claims permanent residency within Oklahoma for the six (6) months prior to assignment to active duty or during the period of active duty; and,
(2) the applicant left employment in another state to accompany the military service member spouse to Oklahoma.

[**Source:** Added at 32 Ok Reg 1261, eff 8-27-15]

SUBCHAPTER 7. RULES OF REGISTRANT CONDUCT

535:25-7-1. Scope and purpose

The rules of this subchapter provide standards of registrant conduct.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-7-2. Definitions

The definitions of this subchapter shall be the same as those set out in 535:25-1-1.1.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-7-3. Registrant conduct

(a) Registrants shall conduct business in conformity with all federal, state and municipal laws at all times.
(b) Registrants shall conduct themselves at all times in a manner that will entitle them to the respect and confidence of the community in which they practice.
(c) Abuse of alcohol or drugs, use of an illegal controlled dangerous substance (CDS), or testing positive for such substance or its metabolite is a violation of registrant conduct.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 21 Ok Reg 2460, eff 7-1-04; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 33 Ok Reg 1793, eff 9-11-16]

535:25-7-4. Confidentiality

A registrant shall hold the health and safety of his patrons as his first consideration and will not divulge the nature of the patrons' problems or ailments or any confidence entrusted to him in his licensed capacity except in response to legal requirements or in the best interest of the patron.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-7-5. Practice of medicine

Registrants will refrain from any attempt at diagnosis or treatment that is the legally constituted right or obligation of any licensed practitioner or mid-level practitioner.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-7-6. Governing body

(a) A registrant will recognize the Board as the governing body in the State of Oklahoma and report to them any violation of pharmacy laws or regulations that may come to his attention.
(b) A registrant who fails to report such violations will be subject to Board action against his license, permit or certificate.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 20 Ok Reg 2488, eff 7-11-03; Amended at 32 Ok Reg 1261, eff 8-27-15]

SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT

535:25-9-1. Scope and purpose

The rules of this subchapter describe some violations of the rules of registrant conduct. Violations of registrant conduct include, but are not limited to, those violations described in this subchapter.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-2. Violating confidentiality

A registrant shall not violate patron confidentiality. This does not prevent pharmacies from providing drug therapy information to physicians for their patients, nor does it prevent the provision of information as required by law.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-9-3. Violating laws or rules

A registrant shall not violate directly, (or indirectly, through actions of another), assist or abet in the violation of, or conspire to violate, any provision of the Oklahoma 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.), or federal, state and local laws and rules.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 21 Ok Reg 2460, eff 7-1-04; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-4. False report or record, billing incorrectly, fraudulent billing or reports

The following are violations of registrant conduct:

(1) Making or filing a report or record which a registrant 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 registrant is required to make or file in his capacity as a registrant;

(2) Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed;
(3) Fraudulent billing or submitting false reports to a third party payer of prescription drugs.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-5. Conducting business without reasonable skill and safety

Conducting business in a registrant's capacity 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 is a violation of registrant conduct.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-9-6. Discrimination

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 is a violation of registrant conduct.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-9-7. Theft

Theft while working as a registrant is a violation of registrant conduct.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 25 Ok Reg 1984, eff 7-1-08]

535:25-9-8. Failure to establish and maintain effective controls

The following are violations of registrant conduct:
(1) Failure to establish and maintain effective controls to prevent prescription errors;
(2) Failure to establish and maintain effective controls against the diversion of prescription drugs and/or controlled dangerous drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules;
(3) The sale of dangerous drugs to a person or entity not eligible to receive such drugs;
(4) The purchase of dangerous drugs from a person or entity not eligible to possess such drugs;
(5) Failure to establish and maintain suspicious order monitoring records in a suspicious order monitoring program; and failure to notify the Board of confirmed suspicious orders; .
(6) Shipping orders that are confirmed as suspicious; and,
(7) Shipping to other than the licensees address on the license.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 26 Ok Reg 2310, eff 7-1-09; Amended at 27 Ok Reg 2269, eff 7-11-10; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-9. Prescription or drug order error

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.

[**Source:** Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 34 Ok Reg 1888, eff 9-11-17; Amended at 38 Ok Reg 2458, eff 9-11-21]

535:25-9-10. Patient health and safety

The health and safety of patients shall be a registrant's first consideration

[**Source:** Added at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-11. Arrangements

Registrants shall oppose any arrangements inimical to public health. Such an arrangement could include, but is not limited to, an arrangement between a registrant and a prescriber or any practitioner of the healing arts whereby fees are divided or in which private formulas are concerned.

[**Source:** Added at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-12. Professional fee

A registrant's fee for professional services shall be fair, equitable, and commensurate with the knowledge and skill required to compound and dispense prescriptions and/or to render other professional services.

[**Source:** Added at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-13. Auto refills

A registrant shall not do auto refills of a prescription unless authorized to do so by the patient or the patient's agent. The registrant shall document the authorization to do auto refills of a prescription.

[**Source:** Added at 32 Ok Reg 1261, eff 8-27-15; Amended at 39 Ok Reg 2068, eff 9-11-22]