[OAR Docket #24-722; filed 7-1-24]

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 1. ADMINISTRIVE OPERATIONS

[OAR Docket #24-750]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 14. Scheduled or Controlled Dangerous Substances Classifications or Exclusions
535:1-14-3. Procedure [AMENDED]
535:1-14-4. Exclusion of Rx Only products not federally scheduled from Oklahoma Controlled dangerous substances scheduling [AMENDED]
AUTHORITY:
Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.3, 353.5 - 353.7, 353.9, 353.11 - 353.20.1, 353.22, 353.24 – 354, 375.1-375.5; Title 75 O.S., Section 302, 305, 307, and 309; Title 63 O.S., Sec 2-201, 2-208 and 2-210; and Title 51 Sec. 24 A.5 (3)
SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:
December 1, 2023
COMMENT PERIOD:
December 22, 2023 through January 22, 2024
PUBLIC HEARING:
January 24, 2024
ADOPTION:
January 24, 2024
SUBMISSION OF ADOPTED RULES TO GOVERNOR AND LEGISLATURE:
January 25, 2024
LEGISLATIVE APPROVAL:
N/A
LEGISLATIVE DISAPPROVAL:
N/A
APPROVED BY GOVERNORS DECLARATION:
Approved by Governor's declaration on June 21, 2024
FINAL ADOPTION:

June 21, 2024
EFFECTIVE:
August 11, 2024
SUPERSEDED EMERGENCY ACTIONS:
SUPERSEDED RULES:
N/A
GUBERNATORIAL APPROVAL:
N/A
REGISTER PUBLICATION:
N/A
DOCKET NUMBER:
N/A
INCORPORATIONS BY REFERENCE:
INCORPORATED STANDARDS:
N/A
INCORPORATING RULES:
N/A
AVAILABILITY:
N/A
GIST/ANALYSIS:
The revision in 535:1-14-3 corrects a cite from 535:1-13-1 to 535:1-8-1. The revision in 535:1-14-4 removes the (a) from the implied (a) to correct formatting as require by the Administrative Rules on Rulemaking (ARR).
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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(7) AND 308(E), WITH AN EFFECTIVE DATE OF AUGUST 11, 2024:

SUBCHAPTER 14. SCHEDULED OR CONTROLLED DANGEROUS SUBSTANCES CLASSIFICATIONS OR EXCLUSIONS

535:1-14-3. Procedure [AMENDED]
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 535:1-8-1 ~~535:1-13-1~~ for rule revision requests.

535:1-14-4. Exclusion of Rx Only products not federally scheduled from Oklahoma Controlled dangerous substances scheduling [AMENDED]
~~(a)~~ "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.

[OAR Docket #24-750; filed 7-5-24]

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

[OAR Docket #24-751]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 5. Interns, Preceptors and Training Areas

535:10-5-3. Intern requirements; licenses [AMENDED]
Subchapter 7. Pharmacist Licensure
535:10-7-2. Definitions [AMENDED]
535:10-7-8. Foreign pharmacy graduate licensure applicants [AMENDED]
Subchapter 9. Pharmaceutical Care
535:10-9-15. ~~Naloxone~~Opioid Antagonist [AMENDED]
Subchapter 11. Pharmacist Administration of Immunizations
535:10-11-3. D.Ph. administered immunization, training and CE requirements [AMENDED]
535:10-11-4. Immunization registration [AMENDED]

AUTHORITY:
Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.7, 353.9, 353.11, 353.16A, 353.18, 353.20, 353.22, 353.24 - 353.26, 353.30 and 364, Title 59 O.S. Sec. 6002 and Title 63 O.S. Section 2-312.25.

SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:
December 1, 2023

COMMENT PERIOD:
December 22, 2023 through January 22, 2024

PUBLIC HEARING:
January 24, 2024

ADOPTION:
January 24, 2024

SUBMISSION OF ADOPTED RULES TO GOVERNOR AND LEGISLATURE:
January 25, 2024

LEGISLATIVE APPROVAL:
N/A

LEGISLATIVE DISAPPROVAL:
N/A

APPROVED BY GOVERNORS DECLARATION:
Approved by Governor's declaration on June 21, 2024

FINAL ADOPTION:
June 21, 2024

EFFECTIVE:
August 11, 2024

SUPERSEDED EMERGENCY ACTIONS:

SUPERSEDED RULES:
N/A

GUBERNATORIAL APPROVAL:
N/A

REGISTER PUBLICATION:
N/A

DOCKET NUMBER:
N/A

INCORPORATIONS BY REFERENCE:

INCORPORATED STANDARDS:
N/A

INCORPORATING RULES:
N/A

AVAILABILITY:
N/A

GIST/ANALYSIS:
The revisions in 535:10-5-3. Adds descriptions of when a graduate is eligible for an intern license and describes the length of time for a graduate intern license. The revisions in 535:10-7.2 and the revision in 535:10-7-8 make changes for the changes in the NABP foreign graduate certification process for licensure in Oklahoma. The revision in 535:10-9-15 make changes in the rule for opioid antagonists to comply with the changes in Title 63 OS 2-312.2. The revisions in 535:10-11-3 (c) adds "or Board approved" continuing education. Section 535:10-11-4. Training and CE requirements were simplified and added to 535:10-11-3 last year. We are corrected the cites in 535:10-11-4 from 535:10-11-5 where the immunization training rules were before to their new location of 535:10-11-3.

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(7) AND 308(E), WITH AN EFFECTIVE DATE OF AUGUST 11, 2024:

SUBCHAPTER 5. INTERNS, PRECEPTORS AND TRAINING AREAS

535:10-5-3. Intern requirements; licenses [AMENDED]

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.

(5) A graduate intern must license as such when;

(A) The intern has graduated from an ACPE College, or School of Pharmacy and their Oklahoma original intern license has expired, and the intern needs to continue working as an intern while preparing to take the exam(s).

(B) The applicant is transferring from another state and needs to work in Oklahoma as an intern prior to completing the Oklahoma licensure process.

(6) The graduate intern license becomes void after two years from the date of issuance or when the graduate intern becomes licensed as a pharmacist.

SUBCHAPTER 7. PHARMACIST LICENSURE

535:10-7-2. Definitions [AMENDED]

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

"FPGEC Certification ~~Certificate~~" means the NABP Foreign Pharmacy Graduate Examination Committee Certification ~~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 certification ~~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.

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

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

~~(3) third, complete~~(2) Complete 1000 hours of internship in Oklahoma within 12 months of licensure as an Oklahoma intern.

(A) The ~~foreign pharmacy graduate intern and the~~Oklahoma licensed pharmacist 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 graduate ~~graduates~~ applicants may apply for licensure by reciprocity once they have met the following:

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

(2) Have passed the NAPLEX Examination; and,

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

SUBCHAPTER 9. PHARMACEUTICAL CARE

535:10-9-15. ~~Naloxone~~Opioid Antagonist [AMENDED]

(a) The purpose of this subsection is to implement Title 63 O.S. 2-312.2 provisions for pharmacists.

(b) Definitions. The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise: **"OpioidAntagonist"** means a drug that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors.

(c) A Pharmacist may prescribe and dispense ~~Naloxone~~an Opioid Antagonist that is approved by the FDA 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. Such Opioid Antagonist ~~Naloxone~~ may only be dispensed by, or under the supervision of, a licensed pharmacist.

SUBCHAPTER 11. PHARMACIST ADMINISTRATION OF IMMUNIZATIONS

535:10-11-3. D.Ph. administered immunization, training and CE requirements [AMENDED]

(a) A D.Ph. must have completed an approved **Accreditation Council for Pharmacy Education**(ACPE) 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 1 hour of immunization related ACPE accredited, or Board approved continuing education annually.

535:10-11-4. Immunization registration [AMENDED]

(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~~535:10-11-3.

(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~~535:10-11-3, 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.

[OAR Docket #24-751; filed 7-5-24]

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

[OAR Docket #24-752]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 3. Pharmacies
535:15-3-2. Pharmacy responsibilities [AMENDED]
Subchapter 4. Remote Medication Order Processing (RMOP) and RMOP Pharmacy for Hospital Pharmacies
535:15-4-2. Definitions [AMENDED]
535:15-4-5. Responsibilities and duties of RMOP pharmacies and pharmacy manager [pharmacist in charge (PIC's)] [AMENDED]
Subchapter 5. Hospital Pharmacies
535:15-5-2. Definitions [AMENDED]
535:15-5-9. Hospital pharmacy physical requirements [AMENDED]
535:15-5-19. Remote medication order processing (RMOP) [AMENDED]
Subchapter 6. Hospital Drug Room
535:15-6-2. Definitions [AMENDED]
535:15-6-6. Physical requirements [AMENDED]
535:15-6-9. Emergency room pre-packaged medications formulary [AMENDED]
535:15-6-20. Remote medication order processing [AMENDED]
Subchapter 7. Drug Supplier Permits
535:15-7-2. Drug supplier requirements [AMENDED]
Subchapter 10. Good Compounding Practices
Part 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PREPARATIONS
535:15-10-1.1. Preparation of compounded drug products for over-the-counter (OTC) sale [NEW]
AUTHORITY:
Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.7, 353.11 - 353.20.1, 353.22, 353.24 - 353.26 - 354, and 367.8.
SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:
December 1, 2023
COMMENT PERIOD:
December 22, 2023 through January 22, 2024
PUBLIC HEARING:
January 24, 2024
ADOPTION:
January 24, 2024
SUBMISSION OF ADOPTED RULES TO GOVERNOR AND LEGISLATURE:
January 25, 2024
LEGISLATIVE APPROVAL:
N/A
LEGISLATIVE DISAPPROVAL:
N/A
APPROVED BY GOVERNORS DECLARATION:
Approved by Governor's declaration on June 21, 2024
FINAL ADOPTION:

June 21, 2024
EFFECTIVE:
August 11, 2024
SUPERSEDED EMERGENCY ACTIONS:
SUPERSEDED RULES:
N/A
GUBERNATORIAL APPROVAL:
N/A
REGISTER PUBLICATION:
N/A
DOCKET NUMBER:
N/A
INCORPORATIONS BY REFERENCE:
INCORPORATED STANDARDS:
N/A
INCORPORATING RULES:
N/A
AVAILABILITY:
N/A
GIST/ANALYSIS:
The revision in 535:15-3.2 (j) implied (1) is renumbered to (1), (2) is added describing a change in the pharmacist in charge (PIC) report is required to the Board within ten days (10 days), (3) is added requiring pharmacies that are closing for lack of staffing or other reasons where the pharmacy will not be open during their normal business hours to report to the Board; and describes what must be included in this report. In 535:15-4-2. the 'Remote medication order processing' and the 'remote medication order processing pharmacy' definitions are changed. For both 535:15-4-5 (1) (G) and 535:15-4-5 (2) (B) the cites are corrected from 535:15-5-9 (1) (B) and (l) (C) to 535:15-5-9.1. In 535:15-5-2. the Remote medication order processing definition in changed. 535:15-5-9. Implied (a) (6) Security adds (A) to the implied (A) and adds (B) requiring electronic alarm and video recording system to protect against theft and diversion. Revised in 535:15-5-19 (d) the cites are corrected from 535:15-5-9 (1) (B) and (l) (C) to 535:15-5-9.1. In 535:15-6-2. the Remote medication order processing definition in changed. Revised in 535:15-6-2 implied (a) the word insure is corrected to ensure. In 535:15-6-2 (a) (2) (A) ', 1 through 5' is deleted. 535:15-6-2 (a) (6) Security adds (A) to the implied (A) and 2 adds (B) requiring electronic alarm and video recording system to protect against theft and diversion. The revision in 535:15-6-9 (b) (9) will allow up to three types of Asthma medication per ER formulary. The revision in 535:15-6-20 (d) the cites are corrected from 535:15-5-9 (1) (B) and (l) (C) to 535:15-5-9.1. Revised 535:15-7-2 (c) adds "name and address of supplier" and "lot number and expiration date of drug". New 535:15-10-1.1 are rules for pharmacist preparation of compounded drug products in the pharmacy for over-the counter (OTC) sale to implement new legislation.
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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(7) AND 308(E), WITH AN EFFECTIVE DATE OF AUGUST 11, 2024:

SUBCHAPTER 3. PHARMACIES

535:15-3-2. Pharmacy responsibilities [AMENDED]
(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.**

(1) 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.

(2) A change in PIC must be reported to the Board in writing within ten (10) days,

(3) A pharmacy that is closing due to lack of staffing or for some other reason and will not be open during normal business hours when patients would expect the pharmacy to be open must email the following information to the Board within twenty-four (24) hours.

(A) License number of the pharmacy.
(B) Name of the pharmacy.
(C) Address of the pharmacy.
(D) Name of the pharmacist in charge (PIC).
(E) Date(s) that the pharmacy will be closed.
(F) Hours the pharmacy will be closed.
(G) Detailed explanation for closing.

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

535:15-4-2. Definitions [AMENDED]

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 employed by ~~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 physician's ~~physicians~~ orders and consulting services under contract for hospitals licensed in Oklahoma or any other state; and which provide services under the direction of a pharmacist in charge or PIC, licensed by the Board.

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

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

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

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)~~ 535:15-5-9.1;
(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)~~ 535:15-5-9.1;
(C) Submitting required reports, required by hospital, by procedures manual and by law or rule;
(D) Quality assurance and performance improvement of the RMOP service;

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

(A) Pharmacists performing remote medication order processing entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1.1(6) and 535:10-3-1.2(a)(16); and,
(B) The hospital shall insure that the remote pharmacist shall have individual pharmacist specific secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the hospital pharmacy is open.

(4) **Record keeping**.

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

(iii) Requests for clinical or other additional information communicated by the remote pharmacist;
(iv) Name or other unique identifier of the remote pharmacist involved in the processing of the RMOP order.

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

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

SUBCHAPTER 5. HOSPITAL PHARMACIES

535:15-5-2. Definitions [AMENDED]

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 employed by ~~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.

535:15-5-9. Hospital pharmacy physical requirements [AMENDED]

A hospital pharmacy shall have sufficient facilities to ensure 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 requirements listed in 535:15-3-4.

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

(2) **Sterile compounds.** For sterile compounded preparations, a hospital must comply with 535:15-10 Part 3.

(3) **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.

(4) **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.

(5) **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.

(6) **Security.**

(A) All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

(B) There shall be access control and video recording systems in place to provide protection against theft and diversion.

535:15-5-19. Remote medication order processing (RMOP) [AMENDED]

(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)~~535:15-5-9.1.

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

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

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

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

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

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

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

(5) Use of a computer workstation e.g. with passwords, firewalls and encryption.
(h) The record of each patient-specific RMOP drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the review and verification of the order.
(i) Remote medication order processing by a pharmacist shall not relieve the hospital pharmacy from employing or contracting with pharmacist(s) to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed or additional pharmacist assistance is needed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist(s).
(j) Pharmacists performing remote medication order processing shall not be included in the ratio of the pharmacist and technician as outlined in 535:15-5-7.2.(e).
(k) A pharmacist employed by or contracting with a hospital pharmacy for on-site services may also provide remote medication order processing services when the hospital pharmacy is closed or additional pharmacist assistance is needed through a remote medication order processing pharmacy.

SUBCHAPTER 6. HOSPITAL DRUG ROOM

535:15-6-2. Definitions [AMENDED]

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

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

535:15-6-6. Physical requirements [AMENDED]

A hospital drug room shall have sufficient facilities to ~~insure~~ensure 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.

(2) **Sterile Compounds.** For compounded sterile preparations:

(A) 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~~.

(B) 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.

(3) **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.

(4) **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.
(5) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked.
(6) **Security.**
(A) All areas occupied by a hospital drug room shall be capable of being locked by key or combination to prevent access by unauthorized personnel.
(B) There shall be access control and video recording systems in place to provide protection against theft and diversion.

535:15-6-9. Emergency room pre-packaged medications formulary [AMENDED]
(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~~three]
(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]

535:15-6-20. Remote medication order processing [AMENDED]
(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).~~ 535:15-6-6.1.

(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.

SUBCHAPTER 7. DRUG SUPPLIER PERMITS

535:15-7-2. Drug supplier requirements [AMENDED]

(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, name and address of supplier, quantity sold, drug description, lot number and expiration date of drug, 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.

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PREPARATIONS

535:15-10-1.1. Preparation of compounded drug products for over-the-counter (OTC) sale [NEW]

(a) A pharmacist licensed by the Oklahoma State Board of Pharmacy may, in accordance with state and federal laws and rules, prescribe non-prescription OTC drugs for the purpose of compounding for a known patient need.

(b) The compounded product shall not contain an ingredient which exceeds recommended strengths and doses for over-the-counter drugs.
(c) The finished compounded OTC product shall not be one for which a prescription is required.
(d) The compounded OTC product shall be labeled with:
(1) Patient name,
(2) Date,
(3) Product name,
(4) Name of all ingredients,
(5) Strength or quantity of all active ingredients,
(6) Package size,
(7) Directions for use,
(8) Use by date,
(9) Name, address, and telephone number of the pharmacy,
(10) Ancillary and cautionary instructions if needed,
(11) Requirements for proper storage, and
(12) An appropriate designation that this is a compounded nonprescription product, such as "Compounded OTC"
(e) The product shall be sold directly to the consumer only after professional interaction or consultation between a pharmacist and a consumer.
(f) The product may be prepared in advance in reasonable amounts in anticipation of estimated needs.
(g) The product shall not be sold to other pharmacies or vendors for resale.
(h) The product shall be stored within the prescription department.
(i) 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.

[OAR Docket #24-752; filed 7-5-24]

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

[OAR Docket #24-753]

RULEMAKING ACTION:
PERMANENT final adoption
RULES:
Subchapter 6. Post and Active Duty Military Service and Their Spouse Applicants
535:25-6-2. Active duty military and their spouse requirements [AMENDED]
Subchapter 7. Rules of Registrant Conduct
535:25-7-7. Reporting [NEW]
AUTHORITY:
Oklahoma State Board of Pharmacy; Title 59 O.S., Sec. 353.7, 353.11 - 353.20.1, 353.22, 353.24 - 353.26 - 354, and 367.8; Title 51 OS 24A et seq.; Title 75 OS, Sec 2-201, 2-208, and 2-210
SUBMISSION OF PROPOSED RULES TO GOVERNOR AND CABINET SECRETARY:
December 1, 2023
COMMENT PERIOD:
December 22, 2023 through January 22, 2024
PUBLIC HEARING:
January 24, 2024
ADOPTION:
January 24, 2024
SUBMISSION OF ADOPTED RULES TO GOVERNOR AND LEGISLATURE:
January 25, 2024
LEGISLATIVE APPROVAL:
N/A
LEGISLATIVE DISAPPROVAL:
N/A

APPROVED BY GOVERNORS DECLARATION:
Approved by Governor's declaration on June 21, 2024
FINAL ADOPTION:
June 21, 2024
EFFECTIVE:
August 11, 2024
SUPERSEDED EMERGENCY ACTIONS:
SUPERSEDED RULES:
N/A
GUBERNATORIAL APPROVAL:
N/A
REGISTER PUBLICATION:
N/A
DOCKET NUMBER:
N/A
INCORPORATIONS BY REFERENCE:
INCORPORATED STANDARDS:
N/A
INCORPORATING RULES:
N/A
AVAILABILITY:
N/A
GIST/ANALYSIS:
The changes in rule 535:25-6-2 include pharmacist score transfer applicants in the rule. The new rule in 535:25-7-7. adds reporting requirements to registrants.
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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(7) AND 308(E), WITH AN EFFECTIVE DATE OF AUGUST 11, 2024:

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

535:25-6-2. Active duty military and their spouse requirements [AMENDED]
(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, pharmacist score transfer license, or technician permit.

SUBCHAPTER 7. RULES OF REGISTRANT CONDUCT

535:25-7-7. Reporting [NEW]

(a) The registrant shall report any theft or significant loss of any drugs to the Board within one day of discovery. The registrant 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.
(b) A change in registrant manager must be reported to the Board in writing within ten (10) days.