



OKLAHOMA STATE BOARD OF PHARMACY

4545 Lincoln Blvd., Suite 112, Oklahoma City, OK 73105-3413

Phone: (405) 521-3815 / Fax: (405) 521-3758

www.pharmacy.ok.gov / e-mail: pharmacy@pharmacy.ok.gov

PRECEPTOR CERTIFICATE EXAMINATION

Index

1. Preceptor Examination
2. Return Answer Sheet
3. Rules regarding:
 - a. Interns, Preceptors and Training Areas (**Chapter 10 - Subchapter 5**)
 - b. Pharmaceutical Care (**Chapter 10 - Subchapter 9**)
 - d. Pharmacies (**Chapter 15 - Subchapter 3**)
 - c. Pharmacy Supportive Personnel (**Chapter 15 - Subchapter 13**)

Qualifications

Only a fully registered Oklahoma pharmacist who has been **actively engaged in the practice of pharmacy for at least one year** is qualified to become a preceptor. Assistant pharmacists and Inactive pharmacists are not eligible. Pharmacists currently on probation must contact the Board for instructions.

Procedure and Fee

Complete and return the enclosed **Answer Sheet** with the twenty-five dollar (**\$25**) fee.

A score of 100% must be received. If a perfect score is not received, your Answer Sheet will be returned to the e-mail address provided and incorrect answers must be corrected. (*please keep your copy of the exam & rules until the test has been passed*)

This procedure will be repeated until a score of 100% is received.

Certification and Posting

To practice as a preceptor, **you must be employed in a licensed training area**. Preceptor and training area certificates must be conspicuously displayed at each training site.

Your preceptor permit will expire annually upon the expiration of your pharmacist license and can be renewed for a \$10 fee paid in addition to the \$100 license renewal fee.

EXAMINATION

1. Which of the following statements are true?
 - I. An intern may practice in an approved training area only under the immediate visual supervision of a preceptor
 - II. A preceptor will supervise only one intern at a time in a non pro-practice setting
 - III. Interns shall notify the Board in writing within ten days of termination of employment
 - IV. An intern may obtain a maximum of forty hours a week for credit
 - (A) I and II Only
 - (B) I and III Only
 - (C) I, III, and IV Only
 - (D) All of the Above
2. The number of interns practicing in a training area is limited to the number of preceptors present and on duty.
 - (A) True
 - (B) False

3. Interns pursuing a Pharm.D. degree may obtain up to 1,500 intern hours while completing the degree.
 - (A) True
 - (B) False

4. A faculty preceptor is employed by a school or college of pharmacy.
 - (A) True
 - (B) False

5. Interns shall conspicuously display their intern certificate in their training area.
 - (A) True
 - (B) False

6. The following pharmacy personnel are required to wear a designation tag while working in a pharmacy.
 - I. Pharmacist
 - II. Intern
 - III. Technician
 - IV. Clerk
 - (A) II, III, and IV Only
 - (B) III Only
 - (C) III and IV Only
 - (D) All of the Above

7. If a pharmacy is licensed as a training area but no preceptor is on duty, an intern may function as a:
 - (A) Pharmacist
 - (B) Intern
 - (C) Technician
 - (D) Clerk
 - (E) An intern may not be on duty in any capacity without a preceptor on duty.

8. A pharmacist will have to apply for a new preceptor certificate after completion of probation and/or suspension by the Board.
 - (A) True
 - (B) False

9. If an intern violates provisions of the Oklahoma Pharmacy Act (O.S. Title 59) or the Oklahoma State Board of Pharmacy Administrative Code (OAC Title 535), the Preceptor, Training Area and Intern may be issued a citation.
 - (A) True
 - (B) False

10. An intern shall submit a progress report to the Board every 500 hours.
 - (A) True
 - (B) False

11. To qualify as a preceptor, the applicant must work in a full-time capacity as a pharmacist.
 - (A) True
 - (B) False

12. Which of the following statements are true?
- I. An intern working at a pharmacy not approved as a training area by the Board may only perform the duties of a support person
 - II. An intern working without a preceptor may only perform the duties of a support person
 - III. A pharmacy on probation by the Board may serve as a training area
 - IV. The numbers of interns practicing in a training area is limited to the number of preceptors present and on duty in a training area.
- (A) I and II Only
 - (B) I, II and III Only
 - (C) I, II, and IV Only
 - (D) IV only
 - (E) All of the Above
13. A preceptor should report to the Board any acts of the intern which are contrary to the ethics of his profession.
- (A) True
 - (B) False
14. An intern may perform prospective drug utilization review.
- (A) True
 - (B) False
15. A pharmacy does not need to reapply for a training area license if the ownership changes but the location and name remain the same.
- (A) True
 - (B) False
16. Which of the following statements regarding Training Areas is true?
- I. The pharmacy must make application to the Board for approval as a training area
 - II. Documentation of pro-practice hours shall be provided to the Board by the school or college of pharmacy
 - III. A training area license must be renewed with the pharmacy license after December 31, 2011
 - IV. A pharmacy must reapply for a training area license if the pharmacy moves to another address (i.e. the license is not transferable)
- (A) III Only
 - (B) I and III Only
 - (C) I, II and III Only
 - (D) I, III, and IV Only
 - (E) All of the Above
17. If an intern is not continuously enrolled and in good standing in an accredited school or college of pharmacy, the internship certificate is automatically void and should be returned to the Board.
- (A) True
 - (B) False
18. Preceptors of interns working non-college practice hours shall report those hours to the Board every 500 hours.
- (A) True
 - (B) False
19. A faculty preceptor may supervise up to two interns at a time in a pro-practice setting.
- (A) True
 - (B) False

20. Which of the following statements are true?
- I. An intern must abide by Board intern rules whether they are logging hours for credit or not
 - II. An intern may supervise a technician
 - III. Interns shall report the place of their non-college practice within 10 days of going to work and/or termination
 - IV. A preceptor may not supervise an intern and a technician at the same time
- (A) I and II Only
(B) I and III Only
(C) I, III, and IV Only
(D) All of the Above
21. An intern may not weigh, measure, or calculate ingredients for compounding.
- (A) True
(B) False
22. Intern hours gained in excess of 40 hours in one calendar week shall not be credited.
- (A) True
(B) False
23. Professional conduct rules for interns are the same as required for pharmacists.
- (A) True
(B) False
24. Which of the following statements are true?
- I. A pharmacist must be licensed and engaged in the practice of pharmacy for not less than one year as a minimum in order to apply for a preceptor license
 - II. A pharmacist must make application to the Board and successfully pass a preceptor examination in order to qualify for a preceptor license
 - III. A preceptor's certificate must be conspicuously posted in the training area where employed.
 - IV. A pharmacist who has been convicted of a felony which was drug related may not be approved or continue as a preceptor.
- (A) I Only
(B) I and II Only
(C) I and III Only
(D) I, II, and III Only
(E) All of the Above
25. An intern may certify a completed prescription filled by a technician.
- (A) True
(B) False
26. The following pharmacy personnel are required to identify themselves on phone calls initiated or received by the pharmacy.
- I. Pharmacist
 - II. Intern
 - III. Technician
 - IV. Clerk
- (A) II, III, and IV Only
(B) III and IV Only
(C) All of the Above

27. A person may hold a technician permit and an intern license at the same time.
(A) True
(B) False
28. An intern may prepare multi-ingredient, cytotoxic, and/or experimental drug I.V.'s.
(A) True
(B) False
29. Which of the following statements are true?
I. An intern may accept a new prescription order by telephone
II. An intern may not counsel patients regarding their prescriptions
III. An intern certificate becomes void three years after the date of issuance
IV. At least 2000 hours of pharmacy practice training must be obtained as a licensed intern
- (A) I Only
(B) I, II, and III Only
(C) I, II, and IV Only
(D) All of the Above
(E) None of the Above
30. A preceptor's certificate expires every 3 years on the preceptor's birthday.
(A) True
(B) False

Oklahoma State Board of Pharmacy

PRECEPTOR CERTIFICATE EXAMINATION ANSWER SHEET

FEE: \$25

| FOR OSBP USE ONLY | | | |
|-------------------|--|-----------|--|
| RECEIPT: | | Affidavit | |
| DATE: | | | |
| EXPIRES: | | | |

1. Complete and return this **Answer Sheet** with the twenty-five dollar (**\$25**) fee.
2. A score of 100% must be received. **If a perfect score is not received, your Answer Sheet will be returned to the e-mail address provided and incorrect answers must be corrected.** (please keep your copy of the exam & rules until the test has been passed)
3. This procedure will be repeated until a score of 100% is received.

Circle the correct answer.

- | | | |
|--------------|---------------|---------------|
| 1. A B C D | 11. A B | 21. A B |
| 2. A B | 12. A B C D E | 22. A B |
| 3. A B | 13. A B | 23. A B |
| 4. A B | 14. A B | 24. A B C D E |
| 5. A B | 15. A B | 25. A B |
| 6. A B C D | 16. A B C D E | 26. A B C |
| 7. A B C D E | 17. A B | 27. A B |
| 8. A B | 18. A B | 28. A B |
| 9. A B | 19. A B | 29. A B C D E |
| 10. A B | 20. A B C D | 30. A B |

I certify that I meet the requirements of OAC 535:10-5-8. I am not under suspension or probation by the Board and I have not been convicted of a felony which was drug related. I understand that if the above occurs, my preceptor certificate becomes null and void.

I further certify that I have personally completed the preceptor examination and have read the rules concerning Pharmacy Interns, Preceptors and Training Areas and do hereby make application for certification as a preceptor.

Please PRINT clearly

Printed Name _____ D.Ph. # _____ Date _____

Address _____

E-Mail address: _____

Signature: _____

RETURN TO: OKLAHOMA STATE BOARD OF PHARMACY, 4545 N LINCOLN BLVD, STE 112, OKLAHOMA CITY, OK 73105

PLEASE ALLOW A MINIMUM OF 21 DAYS FROM DATE OF RECEIPT FOR PROCESSING.

Permit will expire annually upon the expiration of your pharmacist license and can be renewed for a \$10 fee paid in addition to the \$100 license renewal fee.

**OKLAHOMA PHARMACY RULES
(as of 07-11-10)**

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

SUBCHAPTER 5. INTERNS, PRECEPTORS AND TRAINING AREAS

Section

535:10-5-1.1. Purpose

535:10-5-1.2. Definitions

535:10-5-2. Intern registration

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

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

535:10-5-4. Intern practice requirements

535:10-5-4.1. Intern identification requirements

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

535:10-5-8. Preceptor requirements

535:10-5-9. Training area requirements

535:10-5-11. Violations

535:10-5-13. Intern file destruction

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 Title 59, 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 PharmD in Pharmacy program to earn the practical experience required for licensure as a pharmacist.

(c) The purpose of an intern license is to allow an registrant to gain the required practical experience, under supervision, to become licensed as a pharmacist.

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 PharmD program and attending classes or pro-practice rotation.

“**Faculty preceptor**” means an Oklahoma licensed pharmacist who is an Oklahoma licensed preceptor employed by a college of pharmacy to conduct a pro-practice rotation.

“**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**” or “**Registered 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 PharmD 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.

“**Pro-practice**” or “**college pro-practice**” means a structured advance practice rotation administered by the faculty of a college of pharmacy.

535:10-5-1.3. Intern experience requirements

Each applicant, before sitting for licensure examination for registration as a pharmacist, shall furnish the Board of Pharmacy 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 of Pharmacy. 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.

535:10-5-2. Intern registration

Interns shall register with the Board of Pharmacy 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 certificate 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.

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.

(1) A written request indicating the need for such duplicate shall be sent to the Board by the intern.

(2) The duplicate certificate for multiple locations will have "Duplicate - M.L." listed on the certificate.

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

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

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

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

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

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

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

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

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

535:10-5-4. Intern practice requirements

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

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

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

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

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

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

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

535:10-5-4.1. 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.

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

(a) **Intern pro-practice hours.** A pharmacy intern pursuing a PharmD degree in an accredited college of pharmacy may obtain up to 1,500 intern hours while completing the degree.

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

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

(b) **Intern non-college practice hours.** Non-college practice 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.

535:10-5-8. Preceptor requirements

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

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

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

(B) After December 31, 2011 all preceptors will have to renew their certification 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.

535:10-5-9. Training area requirements

(a) **Pharmacies.** Any pharmacy desiring approval for the training of interns shall make application to the Board of Pharmacy on a form supplied by the

Board. The Board will consider the requirements and qualifications listed in 535:25-3 at a minimum. A pharmacy approved as a training area shall conspicuously display its training area certificate in the pharmacy, and be subject to the following provisions:

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

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

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

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

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

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

(7) After December 31, 2011, all training areas will renew their certification when the pharmacy license is renewed.

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

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

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.

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.

SUBCHAPTER 9. PHARMACEUTICAL CARE

Section

535:10-9-1. Prospective drug review

535:10-9-2. Counseling

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

535:10-9-4. Purpose

535:10-9-5. Agreements

535:10-9-13. Administer

535:10-9-1. 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.

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.

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

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

535:10-9-4. 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.

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.

535:10-9-13. Administer

(a) A pharmacist may administer drugs that have been dispensed on orders from a prescribing practitioner.

(b) A pharmacist should inform or teach the patient or the patient's caregiver how to administer their drugs.

CHAPTER 15. PHARMACIES SUBCHAPTER 3. PHARMACIES

Section

535:15-3-1.1. Definitions

535:15-3-2. Pharmacy responsibilities

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

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

535:15-3-4.1. Pharmacy licensing Requirement

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

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

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

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

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

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

535:15-3-10. Inventory

535:15-3-11. Prescription drugs

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

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

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

535:15-3-14. Patient records

535:15-3-17. Pharmacy prescription records

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

535:15-3-19. Three prescription files

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

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, Title 63, Section 2-101 et seq.

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

535:15-3-2. Pharmacy responsibilities

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

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

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

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

- (B) establishment of policies and procedures for safekeeping of pharmaceuticals that satisfy Board requirements, including security provisions when the pharmacy is closed;
- (C) proper record keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs;
- (D) proper display of all licenses;
- (E) annual controlled drug inventory; and,
- (F) maintenance of prescription files;

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

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

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

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

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

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

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

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

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

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

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

- (A) name and address of the pharmacy,

(B) name of pharmacy manager,

(C) name of the manufacturer & model of system.

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

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

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

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

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

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

535:15-3-3. 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 a personal dwelling or residence.

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

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

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

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

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

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

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

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

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

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

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

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

535:15-3-4.1. Pharmacy licensing requirement

(a) Every pharmacy conducting intrastate transactions in Oklahoma shall be licensed as required under Title 59, O.S., Section 353.18(A). Every pharmacy shall also be licensed as required by Title 59 O.S. Section 353.18(A) if Oklahoma is the state from which it or to which it delivers, distributes, or dispenses or offers to 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 pharmacy shall list the corporate registered agent and address as required on their new and/or renewal application.

(c) Every applicant for pharmacy license issued under Title 59 O.S. Section 353.18 shall fully and completely disclose ownership as required by the Board on their new and/or renewal application.

535:15-3-4-2. Minimum required information for licensure

(a) Minimum required information for licensure shall be that information required by Title 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.

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.

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

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

The Board of Pharmacy or their authorized representatives shall be the authority to condemn any packages of drugs taken in a criminal action and that these drugs be destroyed and not returned to the owner as these drugs would be unfit for human consumption.

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)"

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

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

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

- (1) make application and receive an annual non-resident pharmacy license at a fee set by the Board;

- (2) maintain in good standing a pharmacy license in its resident state; and,
- (3) comply with the Oklahoma Secretary of State requirements for conducting business in this state.
- (4) be in a commercial location and not a personal dwelling or residence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

535:15-3-11. Prescription drugs

(a) **Authorization; Original and refill prescriptions.** No prescription for a "dangerous drug" (as defined in Title 59, O.S., Section 353.1) shall be filled or refilled without the authorization of a practitioner 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. At 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 either by destruction or by being returned to the supplier.

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, the transfer of original prescription and refill information 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.

(2) the transfer must be communicated orally directly between two licensed pharmacists and/or licensed interns;

(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

(v) as required in federal DEA rules, pharmacies must 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,

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

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

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

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

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

(a) Two or more pharmacies that have established and use a common electronic file to maintain 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) There shall be the ability in the electronic transfer file system for the pharmacist 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.

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 or 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 practitioner acting in the usual course of the practitioner's professional practice.

(d) **Valid patient practitioner relationship.** The pharmacy or 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-practitioner 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.)

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 records 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 be responsible to 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 practitioners 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.(14).

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 breaching 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, the time and date of transmission and the identity of the pharmacy intended to receive the 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.

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 they shall take action to correct the problem.

(b) In order to ensure adequate staffing levels there shall be a staffing report form 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:

(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 the situation warrants earlier Board review the pharmacy manager should inform the Board.

(e) Each pharmacy shall review completed adequate staffing forms and address any issues described as well as documenting any corrective action taken or justification for inaction to assure continual self-improvement. If issue is not staffing related, describe what measures are being taken to address the issue.

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

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

535:15-3-17. Pharmacy prescription records

The original prescription shall be maintained and readily retrievable for five years.

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.

(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.

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 III's, IV's, V's file.

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) Refills 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 the refill information. **Caution:** The pharmacy must maintain complete and retrievable prescription records for five years whether you use logbooks, nightly reports, or a manual system. If the pharmacy elects the automated system certain compliance reports will be required.

(1) **Nightly reports.** Nightly reports will be required for Schedule II's and for Schedule III, IV and V's. 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's reports will include the same information as in (A) above, except patient and prescriber address 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 (b) (3), 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's 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 (b)) 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 (b) 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

SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL

Section

535:15-13-1. Purpose

535:15-13-2. Hospital pharmacy technicians definitions and duties

535:15-13-3. Definitions

535:15-13-4. Qualifications

535:15-13-5. Supervision

535:15-13-6. Duties

535:15-13-7. Prohibited duties

535:15-13-8. Annual permit requirement

535:15-13-9. Permit display

535:15-13-10. Address and employment change, and training at change

535:15-13-11. Multiple locations of employment

535:15-13-12. Work schedule display

535:15-13-13. Pharmacy technician training

535:15-13-14. Pharmacy technician identification

535:15-13-1. Purpose

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

535:15-13-2. Hospital pharmacy technician definitions and duties

Hospital pharmacy technician definitions and duties are enumerated in OAC 535:15-5.

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

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

535:15-13-4. 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) 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.

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

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

(b) A pharmacy technician may perform certain non-judgmental functions of dispensing as enumerated in this Subchapter, provided that whenever the

pharmacist leaves the prescription department, other than for in-pharmacy counseling of a patient, all dispensing functions listed shall cease.

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

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

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

535:15-13-6. Duties

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

- (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.

(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) functions involving reconstitution of single dose units of parenteral products that are to be administered to a given patient as a unit, and functions involving the addition of one manufacturer's prepared unit (whole or in part) to another manufacturer's prepared unit if the unit is to be administered as one dose to a patient. The pharmacist must establish the procedures for parenteral products and certify the ingredients, label and finished product;
- (8) any duties auxiliary personnel are allowed to perform; and
- (9) assist the pharmacist in the annual CDS inventory. The pharmacist remains responsible for completeness and accuracy.

535:15-13-7. Prohibited duties

These duties may 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 prepare multi-ingredient, non-repetitive, cytotoxic or experimental drug I.V.'s, enteral or other sterile multi-ingredient medications and be responsible for weighing, measuring and calculating ingredients for compounding.
- (6) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department.
- (7) The pharmacist must provide patient counseling or drug information as necessary.

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

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

- (1) Upon meeting the qualifications listed in 535:15-13-4 and 535:25, applicants shall apply for a pharmacy technician permit on the form provided by the Board accompanied by such fee authorized by the legislature and in the agency fee schedule.
- (2) After the pharmacy technician has completed their portion of the application they must submit it to the pharmacy manager or designated pharmacist who has conducted the technician training for review and signature.
- (3) The pharmacy manager or designated pharmacist must first verify the applicant's completion of Phase I of the Board approved pharmacy technician training program. The signature by the pharmacist verifying technician training indicates that there is written training verification in the pharmacy available for Board inspection.
- (4) Each pharmacy technician who desires to continue to work as a tech shall annually, on or before the last day of the registrants' birth month, send to the Board of Pharmacy such fee authorized by the legislature and in the agency fee schedule, with a completed Board application signed by the supervising pharmacist and the technician. Renewal

notice will be sent to the technician's address on file in the Board office either electronically or by mail.

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

- (1) any 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; and,
- (5) any use or abuse of an illegal CDS substance or a positive drug screen for such CDS substance or its' metabolite; and,
- (6) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

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

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.

535:15-13-10. Technician address and employment change, and training at change

(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.

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) The duplicate permit for multiple locations will have "Duplicate - M. L." listed on the permit.

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 technician to supervising pharmacist.
- (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.

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 non-professional 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 shall not have met Board requirements until they have 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 they have 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 continuing on-the-job training.

(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 available for Board inspection.

(e) The pharmacist manager shall be responsible for assuring proof of technician training is maintained in the pharmacy and such proof is available for Board inspection.

535:15-13-14. Pharmacy technician identification

The pharmacy technician must be identified as set out in 535:15-3-2 (e).