

OKLAHOMA PHARMACY LAW BOOK

2022

Laws and Rules Pertaining to the Practice of Pharmacy



Oklahoma Statutes
Title 59
Chapter 8 - Pharmacy
UNOFFICIAL

and

Oklahoma Administrative Code (OAC)
Title 535. Oklahoma State Board of Pharmacy
UNOFFICIAL

**Official copies of the laws may be obtained from the statute books. Official copies of the rules may be obtained from the Oklahoma Secretary of State, Office of Administrative Rules.*

Compiled by:
The Oklahoma State Board of Pharmacy
November 2022

Notice

The unofficial laws and rules contained in this book are not to be considered the final authority on the current law. While every effort has been made to ensure the accuracy and completeness of this book, for legal purposes the law should be obtained from the statute books and the rules from the Oklahoma Secretary of State Office of Administrative Rules [www.oar.state.ok.us/oar/codedoc02.nsf].

This book contains the unofficial laws and rules effective November 1, 2022. This book must be kept in the pharmacy for ready reference.

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It is the sincere desire of the members of the Oklahoma State Board of Pharmacy together with the Executive Director and employees to perform a uniform service to the citizens of this state.

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Pharmacy related addresses and phone numbers.

[This list is not intended to be exclusive or exhaustive.]

ACPE, Accreditation Council for Pharmacy Education 312-664-3575
190 S. LaSalle St, Ste 2850 fax 866-228-2631
Chicago, IL 60603 e-mail: ceinfo@acpe-accredit.org / www.acpe-accredit.org

APhA, American Pharmacists Association..... 800-237-2742
2215 Constitution Ave NW fax 844-390-3782
Washington, DC 20037 e-mail: infocenter@aphanet.org / www.pharmacist.com

ASCP, American Society of Consultant Pharmacists 800-355-2727
1240 N. Pitt Street, Third Floor fax 800-220-1321
Alexandria, VA 22314-3563 e-mail: info@ascp.com / www.ascp.com

ASHP, American Society of Health System Pharmacists
7272 Wisconsin Avenue 866-279-0681
Bethesda, MD 20814 e-mail: custserv@ashp.org / www.ashp.org

CPSC, U.S. Consumer Product Safety Commission 301-504-7923
4330 East West Highway Hotline: 800-638-2772
Bethesda, MD 20814 www.cpsc.gov

DEA, US Dept. of Justice Drug Enforcement Administration..... 405-475-7500
901 NE 122nd St, Ste 210..... fax 405-475-7574
Oklahoma City, OK 73114..... www.deadiversion.usdoj.gov
Tulsa 918-459-9600
Registration (OK & TX) 888-336-4704

FDA, Food and Drug Administration
10903 New Hampshire Ave 888-463-6332
Silver Spring, MD 20993 www.fda.gov

NABP, National Association of Boards of Pharmacy 847-391-4406
1600 Feehanville Drive fax 847-391-4400
Mount Prospect, IL 60056 e-mail: help@nabp.pharmacy / www.nabp.pharmacy

NACDS, National Association of Chain Drug Stores 703-549-3001
1776 Wilson Blvd, Ste 200..... fax 703-836-4869
Arlington, VA 22209 e-mail: contactus@nacds.org / www.nacds.org

NCPA, National Community Pharmacists Association 800-544-7447
100 Daingerfield Road fax 703-683-3619
Alexandria, VA 22314 e-mail: info@ncpanet.org / www.ncpanet.org

NCPDP, National Council for Prescription Drug Programs..... 480-477-1000
9240 E Raintree Dr..... fax 480-767-1042
Scottsdale, AZ 85260-7518 e-mail: info@ncpdp.org / www.ncpdp.org

OPhA, Oklahoma Pharmacists Association..... 405-528-3338
3000 E. Memorial Rd..... fax 405-528-1417
Edmond, OK 73013 www.opha.com

OPHP, Oklahoma Pharmacists Helping Pharmacists 405-528-3338
 3000 E. Memorial Rd. fax 405-528-1417
 Edmond, OK 73013 www.opha.com

OU College of Pharmacy..... 405-271-6484
 PO Box 26901 fax 405-271-3830
 Oklahoma City, OK 73126-0901 pharmacy.ouhsc.edu/index.asp

SWOSU College of Pharmacy 580-774-3105
 100 Campus Drive..... fax 580-774-7020
 Weatherford, OK 73096..... e-mail: pharmacy@swosu.edu / www.swosu.edu/pharmacy

USP (USP-NF), U.S. Pharmacopeial Convention..... 800-227-8772
 12601 Twinbrook Parkway www.usp.org
 Rockville, MD 20852-1790

Oklahoma Agency Phone Numbers
[This list is not intended to be exclusive or exhaustive.]

Attorney General
 313 NE 21st St 405-521-3921
 Oklahoma City, OK 73105..... www.oag.state.ok.us

Bureau of Investigation (OSBI) 405-848-6724
 6600 N Harvey fax 405-427-5614
 Oklahoma City, OK 73116..... www.ok.gov/osbi

Chiropractic Board 405-522-3400
 421 NW 13th St, Ste 180..... fax 866-245-2748
 Oklahoma City, OK 73103..... www.ok.gov/chiropracticboard

Dentistry Board 405-522-4844
 2920 Lincoln Blvd, Ste B..... fax 405-524-4614
 Oklahoma City, OK 73105..... www.ok.gov/dentistry

Health Care Authority (OHCA) 405-522-7300
 4345 N Lincoln Blvd 800 522-0114, opt 4
 Oklahoma City, OK 73105..... www.okhca.org
 Medicaid Pharmacy Help Desk 405 522-6205, opt 4
 Pharmacy Information..... 405-522-7325

Health Department
 1000 NE 10th St..... 405-271-4200
 Oklahoma City, OK 73117..... www.ok.gov/health
 Medical Facilities, Rm 1114..... ph 405 271-6576 / fax 405-271-1308
 Consumer Protection Service, OTC, Rm 1214..... ph 405 271-5243 / fax 405-271-3458
 Long Term Care (Nursing Homes)..... ph 405 271-6868 / fax 405-271-3442

Medical Board 405-962-1400
 101 NE 51st..... fax 405-962-1440
 Oklahoma City, OK 73105..... www.okmedicalboard.org
 Complaints 800-381-4519

Narcotics & Dangerous Drugs (OBN)	800-522-8031
419 NE 38th Terr.....	405-521-2885
Oklahoma City, OK 73105.....	www.ok.gov/obndd
Prescription Monitoring Program (PMP) Help Line	877-627-2674
Registration	405-530-3120
 Nursing Board	405-962-1800
2915 N Classen, Ste 524	fax 405-962-1821
Oklahoma City, OK 73106.....	www.ok.gov/nursing
 Optometry Board	405-733-7836
2008 S Post Road, Ste 200	fax 405-741-3060
Midwest City, OK 73130.....	e-mail: optboard@optometry.ok.gov / www.optometry.state.ok.us
 Osteopathic Board (DO)	405-528-8625
4848 N Lincoln Blvd, Ste 100.....	fax 405-557-0653
Oklahoma City, OK 73105-3335	www.ok.gov/osboe
 Poison Control Center	800-222-1222
940 NE 13th St, Ste 3850, Nicholson Tower.....	fax 405-271-1816
Oklahoma City, OK 73104.....	www.oklahomapoison.org
 Tax Commission	
2501 N Lincoln Blvd.....	405-521-3160
Oklahoma City, OK 73194.....	www.oktax.state.ok.us
Sales Tax Division.....	405-521-3160
Professional Licensing Compliance Unit (Tax Hold Releases).....	405-522-6800
 Veterinary Board	405-522-8831
2920 Lincoln Blvd, Ste. C.....	fax 405-522-8034
Oklahoma City, OK 73105.....	www.okvetboard.com

COMPENDIA/ Library Contact Information
[This list is not intended to be exclusive or exhaustive.]

Pharmacy Laws and Rules:

Oklahoma State Board of Pharmacy405-521-3815
2920 Lincoln Blvd, Ste A..... fax 405-521-3758
Oklahoma City, OK 73105-4212 www.pharmacy.ok.gov

Narcotics Rules:

Oklahoma Bureau of Narcotics & Dangerous Drugs Control800-522-8031
419 NE 38th Ter.....405-521-2885
Oklahoma City, OK 73105.....www.ok.gov/obndd
Prescription Monitoring Program (PMP) Help Line877-627-2674

AHFS Drug Information (the “Big Red Book”):

ASHP Customer Service
7272 Wisconsin Ave866-279-0681
Bethesda, MD 20814-4820 www.ashp.org

Electronic Orange Book: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>

Clinical Drug Information: (Lexicomp, Medi-Span, Facts & Comparisons)

Wolters Kluwer Health
77 Westport Plaza, Suite 450.....855-633-0577
St. Louis, MO 63146..... www.factsandcomparisons.com

Truven Health Analytics (formerly Thomson Reuters) products for pharmacists:

Includes DRUGDEX, Martindale, POISONDEX and DRUG-REAX, etc.
..... <http://www.micromedex.com/products/pharmacists/index.html>

USP-NF (United States Pharmacopeia and The National Formulary):

USP (U.S. Pharmacopeial Convention)800-227-8772
12601 Twinbrook Parkway www.usp.org
Rockville, MD 20852-1790

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OKLAHOMA STATUTES

Title 59. Professions and Occupations

Chapter 8 - Pharmacy

OKLAHOMA PHARMACY ACT

353. Short title – Purpose – Profession.

A. Sections 353 through 366 of Title 59 of the Oklahoma Statutes shall be known and may be cited as the “Oklahoma Pharmacy Act”.

B. It is the purpose of the Oklahoma Pharmacy Act to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of dangerous drugs, medication, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

C. In recognition of and consistent with the decisions of the appellate courts of this state, the practice of pharmacy is hereby declared to be a profession.

353.1. Definitions.

For the purposes of the Oklahoma Pharmacy Act:

1. "Accredited program" means those seminars, classes, meetings, work projects, and other educational courses approved by the Board for purposes of continuing professional education;
2. "Act" means the Oklahoma Pharmacy Act;
3. "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient;
4. "Assistant pharmacist" means any person presently licensed as an assistant pharmacist in the State of Oklahoma by the Board pursuant to Section 353.10 of this title and for the purposes of the Oklahoma Pharmacy Act shall be considered the same as a pharmacist, except where otherwise specified;
5. "Board" or "State Board" means the State Board of Pharmacy;
6. "Certify" or "certification of a prescription" means the review of a filled prescription by a licensed pharmacist or a licensed practitioner with dispensing authority to confirm that the medication, labeling and packaging of the are accurate and meet all requirements prescribed by state and federal law. For the purposes of this paragraph, "licensed practitioner" shall not include optometrists with dispensing authority;
7. "Chemical" means any medicinal substance, whether simple or compound or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin;

8. "Compounding" means the combining, admixing, mixing, diluting, pooling, reconstituting or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;
9. "Continuing professional education" means professional, pharmaceutical education in the general areas of the socioeconomic and legal aspects of health care; the properties and actions of drugs and dosage forms; and the etiology, characteristics and therapeutics of the diseased state;
10. "Dangerous drug", "legend drug", "prescription drug" or "Rx Only" means a drug:
- a. for human use subject to 21 U.S.C. 353(b)(1), or
 - b. is labeled "Prescription Only", or labeled with the following statement: "Caution: Federal law restricts this drug except for use by or on the order of a licensed veterinarian".
11. "Director" means the Executive Director of the State Board of Pharmacy unless context clearly indicates otherwise;
12. "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or a patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Dispense includes sell, distribute, leave with, give away, dispose of, deliver or supply;
13. "Dispenser" means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distributions of such entities under common ownership and control that do not act as a wholesale distributor. For the purposes of this paragraph, "dispenser" does not mean a person who dispenses only products to be used in animals in accordance with 21 U.S.C. 360b(a)(5);
14. "Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with 21 U.S.C. 353(b)(1) or the dispensing of a product approved under 21 U.S.C. 360b(b); provided, taking actual physical possession of a product or title shall not be required;
15. "Doctor of Pharmacy" means a person licensed by the Board to engage in the practice of pharmacy. The terms "pharmacist", "D.Ph.", and "Doctor of Pharmacy" shall be interchangeable and shall have the same meaning wherever they appear in the Oklahoma Statutes and the rules promulgated by the Board;
16. "Drug outlet" means all manufacturers, repackagers, outsourcing facilities, wholesale distributors, third-party logistics providers, pharmacies, and all other facilities which are engaged in dispensing, delivery, distribution or storage of dangerous drugs;
17. "Drugs" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and/or internal use in the cure, diagnosis, mitigation, treatment or prevention of disease in humans or animals

and all substances and preparations, other than food, intended to affect the structure or any function of the body of a human or animals;

18. "Drug sample" means a unit of a prescription drug packaged under the authority and responsibility of the manufacturer that is not intended to be sold and is intended to promote the sale of the drug;

19. "Durable medical equipment" has the same meaning as provided by Section 2 of this act;

20. "Filled prescription" means a packaged prescription medication to which a label has been affixed which contains such information as is required by the Oklahoma Pharmacy Act;

21. "Hospital" means any institution licensed as a hospital by this state for the care and treatment of patients, or a pharmacy operated by the Oklahoma Department of Veterans Affairs;

22. "Licensed practitioner" means an allopathic physician, osteopathic physician, podiatric physician, dentist, veterinarian or optometrist licensed to practice and authorized to prescribe dangerous drugs within the scope of practice of such practitioner;

23. "Manufacturer" or "virtual manufacturer" means with respect to a product:

- a. a person that holds an application approved under 21 U.S.C. 355 or a license issued under 42 U.S.C. 262 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product,
- b. a co-licensed partner of the person described in subparagraph a that obtains the product directly from a person described in this subparagraph or subparagraph a,
- c. an affiliate of a person described in subparagraph a or b who receives the product directly from a person described in this subparagraph or in subparagraph a or b; or
- d. a person who contracts with another to manufacture a product;

24. "Manufacturing" means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. The term "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by licensed pharmacies, licensed practitioners or other persons;

25. "Medical gas" means those gases including those in liquid state upon which the manufacturer or distributor has placed one of several cautions, such as "Rx Only", in compliance with federal law;

26. "Medical gas order" means an order for medical gas issued by a licensed prescriber;

27. "Medical gas distributor" means a person licensed to distribute, transfer, wholesale, deliver or sell medical gases on drug orders to suppliers or other entities licensed to use, administer or distribute medical gas and may also include a patient or ultimate user;

28. "Medical gas supplier" means a person who dispenses medical gases on drug orders only to a patient or ultimate user;
29. "Medicine" means any drug or combination of drugs which has the property of curing, preventing, treating, diagnosing or mitigating diseases, or which is used for that purpose;
30. "Nonprescription drugs" means medicines or drugs which are sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government. Such items shall also include medical and dental supplies and bottled or nonbulk chemicals which are sold or offered for sale to the general public if such articles or preparations meet the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., Section 321 et seq.;
31. "Outsourcing facility", including "virtual outsourcing facility" means a facility at one geographic location or address that:
- a. is engaged in the compounding of sterile drugs,
 - b. has elected to register as an outsourcing facility, and
 - c. complies with all requirements of 21 U.S.C. 353b;
32. "Package" means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. For the purposes of this paragraph, "individual saleable unit" means the smallest container of a product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser;
33. "Person" means an individual, partnership, limited liability company, corporation or association, unless the context otherwise requires;
34. "Pharmacist-in-charge" or "PIC" means the pharmacist licensed in this state responsible for the management control of a pharmacy and all other aspects of the practice of pharmacy in a licensed pharmacy as defined by Section 353.18 of this title;
35. "Pharmacy" means a place regularly licensed by the Board of Pharmacy in which prescriptions, drugs, medicines, chemicals and poisons are compounded or dispensed or such place where pharmacists practice the profession of pharmacy, or a pharmacy operated by the Oklahoma Department of Veterans Affairs;
36. "Pharmacy technician", "technician", "Rx tech", or "tech" means a person issued a Technician permit by the State Board of Pharmacy to assist the pharmacist and perform nonjudgmental, technical, manipulative, non-discretionary functions in the prescription department under the immediate and direct supervision of a pharmacist;
37. "Poison" means any substance which when introduced into the body, either directly or by absorption, produces violent, morbid or fatal changes, or which destroys living tissue with which such substance comes into contact;

38. "Practice of pharmacy" means:
- a. the interpretation and evaluation of prescription orders,
 - b. the compounding, dispensing, administering and labeling of drugs and devices, except labeling by a manufacturer, repackager or distributor of nonprescription drugs and commercially packaged legend drugs and devices,
 - c. the participation in drug selection and drug utilization reviews,
 - d. the proper and safe storage of drugs and devices and the maintenance of proper records thereof,
 - e. the responsibility for advising by counseling and providing information, where professionally necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices,
 - f. the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy, or
 - g. the provision of those acts or services that are necessary to provide pharmaceutical care;
39. "Preparation" means an article which may or may not contain sterile products compounded in a licensed pharmacy pursuant to the order of a licensed prescriber;
40. "Prescriber" means a person licensed in this state who is authorized to prescribe dangerous drugs within the scope of practice of the person's profession;
41. "Prescription" means and includes any order for drug or medical supplies written or signed, or transmitted by word of mouth, telephone or other means of communication:
- a. by a licensed prescriber,
 - b. under the supervision of an Oklahoma licensed practitioner, an Oklahoma licensed advanced practice registered nurse or an Oklahoma licensed physician assistant, or
 - c. by an Oklahoma licensed wholesaler or distributor as authorized in Section 353.29.1 of this title;
42. "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution. "Product" does not include blood components intended for transfusion, radioactive drugs or biologics and medical gas;
43. "Repackager", including "virtual repackager", means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without further transaction;
44. "Sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under state and federal law;
45. "Supervising physician" means an individual holding a current license to practice as a physician from the State Board of Medical Licensure and Supervision, pursuant to the provisions of the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, or the State Board of Osteopathic Examiners, pursuant to the provisions of the Oklahoma Osteopathic Medicine Act, who supervises an advanced practice registered nurse as defined in Section 567.3a of this title, and who is not in training as an intern, resident, or fellow. To be eligible to supervise an advanced practice registered nurse, such physician shall remain in compliance with the rules promulgated by the State Board of Medical Licensure and Supervision or the State Board of

Osteopathic Examiners;

46. "Supportive personnel" means technicians and auxiliary supportive persons who are regularly paid employees of a pharmacy who work and perform tasks in the pharmacy as authorized by Section 353.18A of this title;

47. "Third-party logistics provider", including "virtual third-party logistics provider" means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product. For the purposes of this paragraph, "third-party logistics provider" does not include shippers and the United States Postal Service;

48. "Wholesale distributor", including "virtual wholesale distributor" means a person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager engaged in wholesale distribution as defined by 21 U.S.C. 353(e)(4) as amended by the Drug Supply Chain Security Act;

49. "County jail" means a facility operated by a county for the physical detention and correction of persons charged with, or convicted of, criminal offenses or ordinance violations or persons found guilty of civil or criminal contempt;

50. "State correctional facility" means a facility or institution that houses a prisoner population under the jurisdiction of the Department of Corrections;

51. "Unit dose package" means a package that contains a single dose drug with the name, strength, control number, and expiration date of that drug on the label; and

52. "Unit of issue package" means a package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date.

Agency Note: See Title 59 O.S. 353.18 and 355.1 et seq. for dispensing restrictions, Title 59 O.S. 567.3 (a)(6)(7) and (8) et seq. (Nursing Board) and Title 63 O.S. Section 2-312 et seq. (OBND) for Advanced Practice Nurse prescribing authority. Only those licensed in Oklahoma may prescribe. There are limits on quantity and a negative formulary (drugs not allowed to prescribe). See Appendix E.

353.1a. Prescribing Authority for Advanced Practice Nurse- Dispense Prescriptions Prescribed by Advanced Practice Nurse or Physician Assistant.

A. Prescribing authority shall be allowed, under the medical direction of a supervising physician, for an advanced practice nurse recognized by the Oklahoma Board of Nursing in one of the following categories: advanced registered nurse practitioners, clinical nurse specialists, or certified nurse-midwives. The advanced practice nurse may write or sign, or transmit by word of mouth, telephone or other means of communication an order for drugs or medical supplies that is intended to be filled, compounded, or dispensed by a pharmacist. The supervising physician and the advanced practice nurse shall be identified at the time of origination of the prescription and the name of the advanced practice nurse shall be printed on the prescription label.

B. Pharmacists may dispense prescriptions for non-controlled prescription drugs authorized by an advanced practice nurse or physician assistant, not located in Oklahoma, provided that they are licensed in the state in

which they are actively prescribing.

C. Pharmacists may only dispense prescriptions for controlled dangerous substances prescribed by an advanced practice nurse or physician assistant licensed in the State of Oklahoma and supervised by an Oklahoma-licensed practitioner.

353.1b. Certified registered nurse anesthetist – Authority to Order, Select, Obtain and Administer Drugs.

A certified registered nurse anesthetist has authority to order, select, obtain and administer drugs pursuant to rules adopted by the Oklahoma Board of Nursing, only when engaged in the preanesthetic preparation or evaluation; anesthesia induction, maintenance or emergence; or postanesthesia care practice of nurse anesthesia. A certified registered nurse anesthetist may order, select, obtain and administer drugs only during the perioperative or periparturient period.

Agency Note: Only Oklahoma licensed Advanced Practice Nurses (APN) and Oklahoma Certified Registered Nurse Anesthetists (CRNA) may prescribe while supervised by an Oklahoma licensed doctor [see Appendix E]. Oklahoma licensed Certified Registered Nurse Anesthetists (CRNA) see Title 59 O.S. 567.3 in the Nursing Practice Act and Title 63 O.S. 2-312 in the Oklahoma Bureau of Narcotics Act. [No outpatient Schedule II's]

353.3. Board of Pharmacy – Members.

A. The State Board of Pharmacy shall consist of six (6) persons, five who shall be licensed as pharmacists by this state and one who shall be a public member.

1. The pharmacist members shall be appointed by the Governor by and with the advice and consent of the Senate and shall:

- a. be registered and in good standing in the State of Oklahoma, and
- b. have been actively engaged in the practice of pharmacy within this state for a period of not less than five (5) years immediately prior to serving on the Board.

2. The public member shall be appointed by the Governor and shall:

- a. be a resident of the State of Oklahoma for not less than five (5) years, and
- b. not be a pharmacist or be related by blood or marriage within the third degree of consanguinity to a pharmacist.

B. The present members of the Board shall be appointed for a term of five (5) years. The public member of the Board shall serve a term coterminous with the Governor and shall serve at the pleasure of the Governor. The terms of the members of the Board shall expire on the 30th day of June of the year designated for the expiration of the term for which appointed but the member shall serve until a qualified successor has been duly appointed. No person shall be appointed to serve more than two consecutive terms. Appointments of pharmacists to the Board shall be made from a list of ten (10) names representative of the pharmacy profession submitted annually by the Executive Director of the Oklahoma Pharmacists Association after an election has been held by mail ballot.

353.5. Board Officers – Terms of Officer – Travel Expenses – Executive Director.

A. The State Board of Pharmacy shall annually elect a president and vice-president of the Board. The president and vice-president shall serve for a term of one (1) year and shall perform the duties prescribed by the Board.

B. Each member of the Board shall receive necessary travel expenses incurred in the discharge of official duties pursuant to the State Travel Reimbursement Act.

C. The Board shall employ an Executive Director who is a licensed pharmacist in this state. The Executive Director shall serve as the Chief Administrative Officer for the agency, the Chief Executive Officer of the Board, and may serve as the Chief Inspector if certified as a peace officer. The Executive Director shall perform such duties as required by the Board. The Executive Director of the Board shall receive an annual salary to be fixed by the Board.

D. The Executive Director shall:

1. Deposit funds with the State Treasurer to be expended in the manner and for the purposes provided by law; and
2. Report to the Board at each meeting, presenting an accurate monthly account as to the funds of the Board and make available written and acknowledged claims for all disbursements made.

353.7. Powers and Duties of Board.

The State Board of Pharmacy shall have the power and duty to:

1. Regulate the practice of pharmacy;
2. Regulate the sale and distribution of drugs, medicines, chemicals and poisons;
3. Regulate the dispensing of drugs and medicines in all places where drugs and medicines are compounded and/or dispensed;
4. Examine and issue appropriate certificates of licensure as Doctor of Pharmacy to all applicants whom the Board deems qualified under the provisions of the Oklahoma Pharmacy Act;
5. Issue licenses to manufacturers, repackagers, outsourcing facilities, wholesale distributors, third-party logistics providers, pharmacies and other dispensers, medical gas suppliers, medical gas distributors, and suppliers of durable medical equipment;
6. Issue sterile compounding and drug supplier permits for pharmacies at the fee set by the Board, with the expiration date of such permits to coincide with the pharmacy license annual expiration date;
7. Prescribe minimum standards with respect to floor space and other physical characteristics of pharmacies and hospital drug rooms as may be reasonably necessary for the maintenance of professional surroundings and for the protection of the safety and welfare of the public, and to refuse the issuance of new or renewal licenses for failure to comply with such standards. Minimum standards for hospital drug rooms shall be consistent with the State Department of Health, Hospital Standards, as defined in OAC 310:667;
8. Authorize its inspectors, compliance officers and duly authorized representatives to enter and inspect any and all places including premises, vehicles, equipment, contents and records, where drugs, medicines, chemicals or poisons are stored, sold, vended, given away, compounded, dispensed, manufactured, repackaged or transported;
9. Employ the number of inspectors and pharmacist compliance officers necessary in the investigation of criminal activity or preparation of administrative actions at an annual salary to be fixed by the Board, and to authorize necessary expenses. Any inspector certified as a peace officer by the Council of Enforcement Education and Training shall have statewide jurisdiction to perform the duties authorized by this section. In addition, the inspectors shall be considered peace officers and shall have the same powers and authority as that granted to peace officers. In addition, such inspectors or pharmacist compliance officers shall have the authority to take and copy records and the duty to confiscate all drugs, medicines, chemicals or poisons found to be stored, sold, vended, given away, compounded, dispensed or manufactured contrary to the provisions of the Oklahoma Pharmacy Act;
10. Investigate complaints, subpoena witnesses and records, initiate prosecution and hold hearings;

11. Administer oaths in all manners pertaining to the affairs of the Board and to take evidence and compel the attendance of witnesses on questions pertaining to the enforcement of the Oklahoma Pharmacy Act;
12. Reprimand, place on probation, suspend, revoke permanently and levy fines not to exceed Three Thousand Dollars (\$3,000.00) for each count for which any person charged with violating the Oklahoma Pharmacy Act or Oklahoma Board of Pharmacy administrative rules has been convicted in Board hearings. The Board also may take other disciplinary action. The Board may impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees. The Board may also require additional continuing education including attendance at a live continuing education program, and may require participation in a rehabilitation program for the impaired. The Board may take such actions singly or in combination, as the nature of the violation requires;
13. Adopt and establish rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy. Such rules shall be subject to amendment or repeal by the Board as the need may arise;
14. Make and publish rules such as may be necessary for carrying out and enforcing the provisions of the Oklahoma Pharmacy Act, Oklahoma drug laws and rules, federal drug laws and regulations, and make such other rules as in its discretion may be necessary to protect the health, safety and welfare of the public;
15. Establish and collect appropriate fees for licenses, permits, inspections and services provided; and such fees shall be nonrefundable. Such fees shall be promulgated to implement the provisions of the Oklahoma Pharmacy Act and the Oklahoma Abortion-Inducing Drug Certification Program Act under the provisions of the Administrative Procedures Act;
16. Regulate:
 - a. personnel working in a pharmacy, such as interns and supportive personnel including technicians, and issue pharmacy technician permits and intern licenses,
 - b. interns, preceptors and training areas through which the training of applicants occurs for licensure as a pharmacist, and
 - c. such persons regarding all aspects relating to the handling of drugs, medicines, chemicals and poisons;
17. Acquire by purchase, lease, gift, solicitation of gift or by any other manner, and to maintain, use and operate or to contract for the maintenance, use and operation of or lease of any and all property of any kind, real, personal or mixed or any interest therein unless otherwise provided by the Oklahoma Pharmacy Act; provided, all contracts for real property shall be subject to the provisions of [Section 63](#) of Title 74 of the Oklahoma Statutes;
18. Perform other such duties, exercise other such powers and employ such personnel as the provisions and enforcement of the Oklahoma Pharmacy Act may require; and
19. Approve pilot projects designed to utilize new or expanded technology or processes and provide patients with better pharmacy products or provide pharmacy services in a more safe and efficient manner. Such approvals may include provisions granting exemptions to any rule adopted by the Board.

Section 353.9. -Registered Pharmacists—Qualifications—Examination—Reciprocal Certificates of Registration.

- A. All other qualified persons may become licensed as a Doctor of Pharmacy upon passing an examination approved by the State Board of Pharmacy. Before any applicant is allowed to sit for such examinations, such applicant shall submit to the Board sufficient proof that the applicant:

1. Is a graduate of an accredited School or College of Pharmacy approved by the Board, or is a foreign pharmacy school graduate who has received an FPGEC equivalency certification by the National Association of Boards of Pharmacy; and
 2. Has attained experience in the practice of pharmacy, obtained in a place and in a manner prescribed and approved by the Board.
- B. Interns, preceptors and training areas shall make application for a license, and shall pay a fee set by the Board, not to exceed One Hundred Dollars (\$100.00).
 - C. All Doctor of Pharmacy applicants shall make application in the form and manner prescribed by the Board, and deposit with the Executive Director of the Board a fee set by the Board not to exceed Two Hundred Fifty Dollars (\$250.00) plus the purchase price of the examination. Upon passing an examination and meeting such other requirements specified by the Board pursuant to the Oklahoma Pharmacy Act, the applicant shall be granted a license setting forth the qualifications to practice pharmacy. Any applicant failing an examination shall not sit for an additional examination until such applicant has made a new application and paid the fee provided herein.
 - D. The Board shall have the power to issue reciprocal certificates of licensure to applicants licensed in other states having like requirements. Such applicants shall be charged a fee not to exceed Two Hundred Fifty Dollars (\$250.00).
 - E. The Board shall have the power to issue original certificates of licensure to applicants for the score transfer process administered by the National Association of Boards of Pharmacy; provided, such applicants shall provide sufficient proof of compliance with the requirements of paragraphs 1 through 3 of subsection A of this section. Such applicants shall be charged a fee not to exceed Two Hundred Fifty Dollars (\$250.00).

Section 353.10. – “Assistant Pharmacists” Defined.

- A. Any person who was licensed as an assistant pharmacist before July 27, 1961, and who met the standards and requirements for licensure pursuant to the Oklahoma Pharmacy Act may practice as an assistant pharmacist.
- B. Assistant pharmacists shall not manage a pharmacy.
- C. Every assistant pharmacist shall meet the same requirements for pharmacists listed in Sections 353.11, 353.12 and 353.16A of this title.

Section 353.11. – Annual Renewal of Registration – Failure to Renew Registration – Reinstatement.

- A. 1. Every licensed pharmacist who desires to continue in the profession of pharmacy in this state shall, on or before the expiration date of the license, complete a renewal form and remit to the State Board of Pharmacy a renewal fee to be fixed by the Board. Upon compliance with the provisions of the Oklahoma Pharmacy Act and payment of such renewal fee by a licensee in good standing with the Board, a renewal certificate of licensure shall be issued.
 2. Every licensed pharmacist who fails to complete a renewal form and remit the required renewal fee to the Board by the fifteenth day after the expiration of the license shall pay a late fee to be fixed by the Board.
- B. If any pharmacist fails or neglects to procure the renewal of his or her license, as herein required, the Board may, after the expiration of thirty (30) days following the issue of the notice, deprive the person of his or her license and all other privileges conferred by the Oklahoma Pharmacy Act.
- C. In order to regain licensure, the pharmacist shall apply in writing to the Board requesting reinstatement. The pharmacist shall pay all back fees and provide proof of having obtained all delinquent continuing education plus an additional fifteen (15) hours of continuing education. The Board may require the pharmacist to appear before the Board at a regular meeting. The Board may require evidence of competency through examination or impose other requirements for reinstatement.

Section 353.11a. - Continuing Professional Education Requirements – Inactive Status.

- A. No annual renewal certificate shall be issued to a pharmacist until such pharmacist has submitted proof to the State Board of Pharmacy that the pharmacist has satisfactorily completed no less than fifteen (15) clock hours of an accredited or Board-approved program of continuing professional education during the previous calendar year.
- B. The Board may grant alternate methods of obtaining continuing education hours to a pharmacist who meets all necessary requirements for licensure except the continuing education requirements.
- C. 1. Any pharmacist who does not meet the requirements for continuing education may obtain an inactive renewal certificate of licensure.
2. The holder of an inactive renewal certificate of licensure shall not engage in the practice of pharmacy in this state.
3. The holder of an inactive renewal certificate of licensure may apply to the Board to be removed from inactive status.

Section 353.12. - Display of Certificate – Discontinuance or Change of Place of Business – Seizure of Certificates Unlawfully Used.

- A. Every pharmacist, upon receiving a certificate of licensure pursuant to the Oklahoma Pharmacy Act, shall keep such certificate conspicuously displayed in the pharmacy where such pharmacist is actively engaged in the practice of pharmacy or in such a location as is otherwise prescribed by the State Board of Pharmacy. The current renewal receipt for licensure shall be attached to the lower left corner of the original certificate.
- B. Every other registrant shall keep the license or permit conspicuously displayed in the licensee or permit holder's pharmacy or place of business.
- C. Every licensee or permit holder shall, within ten (10) days after discontinuing or changing his or her place of practice, remove his or her license or permit and notify the Executive Director of the Board, in writing, of his or her new place of practice. Upon receipt of the notification, the Executive Director shall make the necessary change in the Board records.
- D. Any member of the Board, inspector or pharmacist compliance officer duly authorized by the Board shall have authority to confiscate and void any certificate of licensure issued by the Board which has been displayed in any place not authorized by the Board, provided that the holder of the certificate, license or permit shall be entitled to a hearing before the Board and show cause why his or her certificate, license or permit should not be canceled.

Section 353.16A. – Actions that May Be Taken because of Incapacity.

The Board may refuse to issue or renew, or may suspend, revoke or restrict the license of any pharmacist because of incapacity of a nature that prevents such pharmacist from engaging in the practice of pharmacy with reasonable skill, competence and safety to the public.

Section 353.17. – Unlawful use of Credentials and Titles.

- A. No person shall take, use or exhibit the title of pharmacist, licensed pharmacist or Doctor of Pharmacy, "D.Ph." or "R.Ph.", either expressly or by implication, except as otherwise authorized by the Oklahoma Pharmacy Act.
- B. No person other than one licensed under the Oklahoma Pharmacy Act shall take, use or exhibit the title "Druggist", "Pharmacy", "Drug Store", "Drug Department", "Drugs", "Drug Sundries", "Prescriptions", or any other term, sign or device or any word in similitude thereof.

Section 353.17A. – Impersonating a Pharmacist – Penalty.

It shall be unlawful to impersonate a pharmacist. If a person impersonates a pharmacist and causes patient harm, then, upon conviction, it shall be a felony.

Section 353.18. – Regulation of the Sale of Drugs and Chemicals – License – Penalty.

A. 1. It shall be unlawful for any person, including, but not limited to, Internet, website or online pharmacies, to sell at retail or to offer for sale, dangerous drugs, medicines, chemicals or poisons for the treatment of disease, excluding agricultural chemicals and drugs, or to accept prescriptions for same, without first procuring a license from the State Board of Pharmacy. This licensure requirement applies whether such sale, offer for sale or acceptance of prescriptions occurs in this state, or such sale, offer for sale, or acceptance of prescriptions occurs out of state and the dangerous drug, medicine, chemical or poison is to be delivered, distributed or dispensed to patients or customers in this state. This licensure requirement shall not apply to the distribution or dispensing of dialysate or peritoneal dialysis devices to patients with end-stage renal disease (ESRD) consistent with subsection F of this section.

2. A pharmacy license shall be issued to such person as the Board shall deem qualified upon evidence satisfactory to the Board that:

- a. the place for which the license is sought will be conducted in full compliance with the law and the rules of the Board,
- b. the location and physical characteristics of the place are reasonably consistent with the maintenance of professional surroundings and constitute no known danger to the public health and safety,
- c. the place will be under the management and control of a licensed pharmacist or pharmacist-in-charge who shall be licensed as a pharmacist in Oklahoma, and
- d. a licensed pharmacist shall be present and on duty at all business hours; provided, however, the provisions of this subparagraph shall not apply to hospital drug rooms.

3. a. An application for an initial or renewal license issued pursuant to the provisions of this subsection shall:

- (1) be submitted to the Board in writing,
- (2) contain the name or names of persons owning the pharmacy, and
- (3) provide other such information deemed relevant by the Board.

b. An application for an initial or renewal license shall be accompanied by a licensing fee not to exceed Three Hundred Dollars (\$300.00) for each period of one (1) year. Prior to opening for business, all applicants for an initial license or permit shall be inspected. An initial licensure applicant shall pay an inspection fee not to exceed Two Hundred Dollars (\$200.00); provided, however, that no charge shall be made for the licensing of any Federal Veterans Hospital in the State of Oklahoma. Non-resident pharmacies shall reimburse the Board for any actual expenses incurred for inspections.

c. A license issued pursuant to the provisions of this subsection shall be valid for a period set by the Board and shall contain the name of the licensee and the address of the place at which such business shall be conducted.

4. A retail pharmacy that prepares drugs shall obtain a pharmacy license, and shall also obtain a sterile compounding permit at a fee set by the Board, not to exceed Seventy-five Dollars (\$75.00). Such pharmacy shall meet requirements set by the Board by rule for sterile compounding permits.

5. An outsourcing facility desiring to dispense prescriptions to patients must additionally license and meet the requirements of a pharmacy.

B. 1. It shall be unlawful for any person to manufacture, repackage, distribute, outsource, warehouse or be a third-party logistics provider of any dangerous drugs, medicines, medical gases, chemicals, or poisons

for the treatment of disease, excluding agricultural chemicals, without first procuring a license from the Board. It shall be unlawful to sell or offer for sale at retail or wholesale dangerous drugs, medicines, medical gases, chemicals or poisons without first procuring a license from the Board. This licensure requirement shall apply when the manufacturing, repackaging, distributing, outsourcing, warehousing, or provision of third-party logistics occurs in this state or out of state for delivery, distribution, or dispensing to patients or customers in this state.

2. A license shall be issued to such person as the Board shall deem qualified upon satisfactory evidence to the Board that:

- a. the place for which the license is sought will be conducted in full compliance with the laws of this state and the administrative rules of the Board,
- b. the location and physical characteristics of the place of business are reasonably consistent with the maintenance of professional surroundings and constitute no known danger to public health and safety,
- c. the place shall be under the management and control of such persons as may be approved by the Board after a review and determination of the persons' qualifications, and
- d. an outsourcing facility shall designate in writing on a Board-approved form a person to serve as the pharmacist-in-charge who is a pharmacist licensed by the Board.

3. a. An application for an initial or renewal license issued pursuant to the provisions of this subsection shall:

- (1) be submitted to the Board in writing,
 - (2) contain the name or names of the owners or the applicants, and
 - (3) provide such other information deemed relevant by the Board,
- b. An application for an initial or renewal license shall be accompanied by a licensing fee no to exceed Three Hundred Dollars (\$300.00) for each period of one (1) year. Prior to opening for business, all applicants for initial or renewal license shall be inspected. An initial licensure applicant shall pay an inspection fee not to exceed Two Hundred Dollars (\$200.00). Non-resident applicants shall reimburse the Board for any actual expenses incurred for inspections.
- c. A license issued pursuant to the provisions of this subsection shall contain the name of the licensee and the address of the place at which such business shall be conducted and shall be valid for a period of time set by the Board.

C. A licensee or permit holder who, pursuant to the provisions of this section, fails to complete an application for a renewal license or permit by the fifteenth day after the expiration of the license or permit shall pay a late fee to be fixed by the Board.

D. 1. The Board shall promulgate rules regarding the issuance and renewal of licenses and permits pursuant to the Oklahoma Pharmacy Act which shall include, but need not be limited to provisions for new or renewal application requirements for its licensees and permit holders. Requirements for new and renewal applications may include, but need not be limited to, the following:

- a. type of ownership, whether individual, partnership, limited liability company or corporation,
- b. names and addresses of principal owners or officers and their Social Security numbers, including applicant's full name, all trade or business names used, full business address, telephone numbers, and email addresses,
- c. names of designated representatives and facility managers and their Social Security numbers and dates of birth,
- d. evidence of a criminal background check and fingerprinting of the applicant, if a person, and all of the applicant's designated representatives and facility managers,

- e. a copy of the license from the applicant's home state, and if applicable, from the federal government,
- f. bond requirements, and
- g. any other information deemed by the Board to be necessary to protect the public health and safety.

2. The Board shall be authorized to use an outside agency, such as the National Association of Boards of Pharmacy (NABP) or the Verified-Accredited Wholesale Distributors (VAWD), to accredit wholesale distributors and repackagers.

E. The Oklahoma Pharmacy Act shall not be construed to prevent the sale of nonprescription drugs in original manufacturer packages by any merchant or dealer.

F. The Oklahoma Pharmacy Act shall not be construed to apply to a facility engaged in the distribution or dispensing to patients of dialysate or peritoneal dialysis devices necessary to perform home peritoneal dialysis, provided the following criteria are met:

1. The dialysate is comprised of dextrose or icodextrin;
2. The dialysate or peritoneal dialysis devices are approved or cleared by the United States Food and Drug Administration;
3. The dialysate or peritoneal dialysis devices are lawfully held by a manufacturer, or the manufacturer's agent, who is properly licensed by the Board as a manufacturer, wholesaler or distributor;
4. The dialysate or peritoneal dialysis devices are held and delivered in their original, sealed packaging from the manufacturing facility;
5. The dialysate or peritoneal dialysis devices are delivered only upon receipt of a physician's prescription by a licensed pharmacy, and the transmittal of an order from the licensed pharmacy to the manufacturer or the manufacturer's agent; and
6. The manufacturer or agent of the manufacturer delivers the dialysate or peritoneal dialysis devices directly to:
 - a. a patient with ESRD or the patient's designee for the patient's self-administration of the dialysis therapy, or
 - b. a health care provider or institution for administration or delivery of the dialysis therapy to the patient with ESRD.

Section 353.18A. – Supportive Personnel – Pharmacy Technicians – Permit – Application – Fee – Renewals – Expiration.

A. Supportive personnel may perform certain tasks in the practice of pharmacy if such personnel perform the tasks in compliance with rules promulgated by the State Board of Pharmacy.

- B.
1. No person shall serve as a pharmacy technician without first procuring a permit from the Board.
 2. An application for an initial or renewal pharmacy technician permit issued pursuant to the provisions of this subsection shall be submitted to the Board and provide any other information deemed relevant by the Board.
 3. An application for an initial or renewal permit shall be accompanied by a permit fee not to exceed Seventy Five Dollars (\$75.00) for each period of one (1) year. A permit issued pursuant to this subsection shall be valid for a period to be determined by the Board.
 4. Every permitted pharmacy technician who fails to complete a renewal form and remit the required renewal fee to the Board by the fifteenth day after the expiration of the permit shall pay a late

fee to be fixed by the Board.

5. A pharmacy technician permit shall be cancelled thirty (30) days after expiration.

6. A person may obtain reinstatement of a cancelled pharmacy technician permit by making application, paying a reinstatement fee, and satisfactorily completing other requirements set by the Board.

353.20. - Pharmaceutical equipment – Record of Prescriptions.

- A. Every pharmacy shall have the proper pharmaceutical equipment so that prescriptions can be filled, and the practice of pharmacy can be properly conducted. The State Board of Pharmacy shall prescribe the minimum professional and technical equipment and library which a pharmacy shall at all times possess. The premises and equipment of such pharmacy shall be kept in a clean and orderly manner. Drugs shall be maintained under conditions recommended by the manufacturer until delivery to the patient. No pharmacy license shall be issued or continued until or unless such pharmacy has complied with the Oklahoma Pharmacy Act.
- B. The Board may from time to time require that scales and balances be condemned, or other specific equipment changes be made. Failure by the pharmacy to comply with such requirements within sixty (60) days may result in revocation of the pharmacy license.
- C. Every dispenser shall keep a suitable book, file or record in which shall be preserved for a period of not less than five (5) years every prescription compounded or dispensed at the pharmacy, and the book or file of prescriptions shall at all times be open to inspection by the members of the Board or its duly authorized agents.

353.20.1. – Prescriptions Received by other than Written Communication – Prescription Label – Language.

- A. Prescriptions received by other than written communication shall be promptly recorded in writing by the pharmacist. The record made by the pharmacist shall constitute the original prescription to be filled by the pharmacist.
- B. A filled prescription label shall include the name and address of the pharmacy of origin, date of filling, name of patient, name of prescriber, directions for administration, and prescription number. The symptom or purpose for which the drug is prescribed may appear on the label if provided by the practitioner and requested by the patient or the patient's authorized representative. If the symptom or purpose for which a drug is prescribed is not provided by the practitioner, the pharmacist may fill the prescription without contacting the practitioner, patient, or patient's representative. Filled prescriptions issued for veterinarian drugs shall be labeled according to rules promulgated by the Oklahoma State Board of Veterinary Medical Examiners. The label shall also include the trade or generic name, prescribed quantity, and prescription strength of the drug therein contained, except when otherwise directed by the prescriber. This requirement shall not apply to prescriptions or medicines and drugs supplied or delivered directly to patients for consumption on the premises of any hospital or mental institution. This requirement shall not apply to dialysate sold, dispensed or delivered in their original, sealed packaging upon receipt of a prescriber's order.
- C. No prescription shall be written in any characters, figures, or ciphers other than in the English or Latin language generally in use among medical and pharmaceutical practitioners.

353.20.2- Limitation on Refill Dosage- Professional Judgement- Dispense without a Prescription- Opioid Prescription

A. Except as provided in subsection C of this section, unless the prescriber has specified on the prescription that dispensing a prescription for a maintenance medication in an initial amount followed by periodic refills is medically necessary, a pharmacist may exercise his or her professional judgment to dispense varying

quantities of medication per fill-up to the total number of dosage units as authorized by the prescriber on the original prescription including any refills.

B. Subsection A of this section shall not apply to scheduled medications or any medications for which a report is required under the controlled substance database. Dispensing of medication based on refills authorized by the physician on the prescription shall be limited to no more than a ninety-day supply of the medication.

C. 1. A pharmacist may dispense without a prescription one or more devices or medications as medically necessary to prevent the death of or serious harm to the health of a patient if the following conditions are met:

- a. the pharmacy which the pharmacist owns or at which the pharmacist is employed has a current record of a prescription for the medication or device prescribed in the name of the patient who is requesting it, but the prescription has expired and a refill requires authorization from the licensed practitioner who issued the prescription and neither the patient nor the pharmacist was able to obtain the refill after reasonable attempts were made to obtain such refill and the pharmacist documents such attempts on a form prescribed by the State Board of Pharmacy,
- b. the failure of the pharmacist to dispense the medication or device reasonably could result in the death of or serious harm to the health of the patient,
- c. the device or medication is listed on the formulary described in paragraph 4 of this subsection,
- d. the patient has been on a consistent medication therapy as demonstrated by records maintained by the pharmacy, and
- e. the amount of the medication or device dispensed is for a reasonable amount of time; provided, if the patient or pharmacist is unable to obtain a refill prescription from the patient's licensed practitioner before the amount prescribed to prevent death or serious harm to the health of the patient is depleted, the pharmacist may dispense an additional amount of the medication or device not more than once in an amount consistent with past prescriptions of the patient.

2. The standard of care required of a pharmacist licensed in this state who is acting in accordance with the provisions of this subsection shall be the level and type of care, skill and diligence that a reasonably competent and skilled pharmacist with a similar background and in the same or similar locality would have provided under the circumstance.

3. Any pharmacist licensed in this state who in good faith dispenses one or more medications or devices to a patient pursuant to the provisions of this subsection shall not be liable for any civil damages or subject to criminal prosecution as a result of any acts or omissions except for committing gross negligence or willful or wanton acts committed in dispensing or failure to dispense the medication or device.

4. The State Board of Pharmacy shall develop and update as necessary an inclusionary formulary of potentially life-saving prescription medications and devices, not to include controlled dangerous substances, for the purposes of this subsection. Such medications and devices shall include but not be limited to:

- a. insulin and any devices or supplies necessary for the administration of insulin,
- b. glucometers and any devices or supplies necessary for the operation of the glucometer, and
- c. rescue inhalers.

5. Dispensing in accordance with this subsection shall be deemed dispensing under a legal prescription for purposes of the Pharmacy Audit Integrity Act, Section 356 et seq. of this title.

D. Upon receipt of a valid Schedule II opioid prescription issued pursuant to the provisions of Section 2-309I of Title 63 of the Oklahoma Statutes, a pharmacist shall fill the prescription to the specified dose, and shall not be permitted to fill a different dosage than what is prescribed. However, the pharmacist maintains the right not to fill the valid opioid prescription.

353.22. – Unlawful Distribution of Poison.

A. It shall be unlawful for:

1. Any person to sell any poison without distinctly labeling the box, vessel or paper in which the poison is contained with the name of the poison, the word "poison", and the name and the place of business of the seller; or

2. Any pharmacist, or other person, to sell any poison without causing an entry to be made in a book kept for that purpose before delivering the same to the purchaser, stating the date of the sale, the name and address of the purchaser, the name of the poison sold, the purpose for which it is represented by the purchaser to be required, and the name of the dispenser. Such book shall always be available for inspection by the proper authorities and shall be preserved for at least five (5) years.

B. The provisions of this section shall not apply to the dispensing of poisons in not unusual quantities or doses upon the prescription of a prescriber.

353.24. – Additional Unlawful Acts Enumerated.

A. It shall be unlawful for any licensee or other person to:

1. Forge or increase the quantity of drug in any prescription, or to present a prescription bearing forged, fictitious or altered information or to possess any drug secured by such forged, fictitious or altered prescription;

2. Sell, offer for sale, barter or give away any unused quantity of drugs obtained by prescription, except through a program pursuant to the Utilization of Unused Prescription Medications Act or as otherwise provided by the State Board of Pharmacy;

3. Sell, offer for sale, barter or give away any drugs damaged by fire, water, or other causes without first obtaining the written approval of the Board or the State Department of Health;

4. No person, firm or business establishment shall offer to the public, in any manner, their services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Nor may the owner of any pharmacy or drug store authorize any person, firm or business establishment to act for them in this manner with these exceptions:

- a. patient-specific filled prescriptions may be delivered or shipped to a prescriber's clinic for pick-up by those patients whom the prescriber has individually determined and documented do not have a permanent or secure mailing address,
- b. patient-specific filled prescriptions for drugs which require special handling written by a prescriber may be delivered or shipped to the prescriber's clinic for administration or pick-up at the prescriber's office,
- c. patient-specific filled prescriptions, including sterile compounded drugs, may be delivered or shipped to a prescriber's clinic where they shall be administered,
- d. patient-specific filled prescriptions for patients with end-stage renal disease (ESRD) may be delivered or shipped to a prescriber's clinic for administration or final delivery to the patient,

- e. patient-specific filled prescriptions for radiopharmaceuticals may be delivered or shipped to a prescriber's clinic for administration or pick-up,
- f. patient-specific filled prescriptions may be delivered or shipped by an Indian Health Services (IHS) or federally recognized tribal health organization operating under the IHS in the delivery of the prescriptions to a pharmacy operated by the IHS or a federally recognized tribal health organization for pick-up by an IHS or tribal patient.

However, nothing in this paragraph shall prevent a pharmacist or an employee of the pharmacy from personally receiving a prescription or delivering a legally filled prescription to a residence, office or place of employment of the patient for whom the prescription was written. Provided further, the provisions of this paragraph shall not apply to any Department of Mental Health and Substance Abuse Services employee or any person whose facility contracts with the Department of Mental Health and Substance Abuse Services whose possession of any dangerous drug, as defined in Section 353.1 of this title, is for the purpose of delivery of a mental health consumer's medicine to the consumer's home or residence. Nothing in this paragraph shall prevent veterinary prescription drugs from being shipped directly from an Oklahoma licensed wholesaler or distributor registered with the Oklahoma Board of Veterinary Medical Examiners to a client; provided, such drugs may be dispensed only on prescription of a licensed veterinarian and only when an existing veterinary-client-patient relationship exists. Nothing in this paragraph shall prevent dialysate and peritoneal dialysis devices from being shipped directly from an Oklahoma licensed manufacturer, wholesaler or distributor to an ESRD patient or patient's designee, consistent with subsection F of Section 353.18 of this title;

- 5. Sell, offer for sale or barter or buy any professional samples except through a program pursuant to the Utilization of Unused Prescription Medications Act;
- 6. Refuse to permit or otherwise prevent members of the Board or such representatives thereof from entering and inspecting any and all places, including premises, vehicles, equipment, contents, and records, where drugs, medicine, chemicals or poisons are stored, sold, vended, given away, compounded, dispensed, repackaged, transported, or manufactured;
- 7. Interfere, refuse to participate in, impede or otherwise obstruct any inspection, investigation or disciplinary proceeding authorized by the Oklahoma Pharmacy Act;
- 8. Possess dangerous drugs without a valid prescription or a valid license to possess such drugs; provided, however, this provision shall not apply to any Department of Mental Health and Substance Abuse Services employee or any person whose facility contracts with the Department of Mental Health and Substance Abuse Services whose possession of any dangerous drug, as defined in Section 353.1 of this title, is for the purpose of delivery of a mental health consumer's medicine to the consumer's home or residence;
- 9. Fail to establish and maintain effective controls against the diversion of drugs for any other purpose than legitimate medical, scientific or industrial uses as provided by state, federal and local law;
- 10. Fail to have a written drug diversion detection and prevention policy;
- 11. Possess, sell, offer for sale, barter or give away any quantity of dangerous drugs not listed as a scheduled drug pursuant to Sections 2-201 through 2-212 of Title 63 of the Oklahoma Statutes when obtained by prescription bearing forged, fictitious or altered information.
 - a. A first violation of this section shall constitute a misdemeanor and upon conviction shall be punishable by imprisonment in the county jail for a term not more than one (1) year and a

fine in an amount not more than One Thousand Dollars (\$1,000.00).

b. A second violation of this section shall constitute a felony and upon conviction shall be punishable by imprisonment in the Department of Corrections for a term not exceeding five (5) years and a fine in an amount not more than Two Thousand Dollars (\$2,000.00);

12. Violate a Board order or agreed order;

13. Compromise the security of licensure examination materials; or

14. Fail to notify the Board, in writing, within ten (10) days of a licensee or permit holder's address change.

B. 1. It shall be unlawful for any person other than a licensed pharmacist or physician to certify a prescription before delivery to the patient or the patient's representative or caregiver.

Dialysate and peritoneal dialysis devices supplied pursuant to the provisions of subsection F of Section 353.18 of this title shall not be required to be certified by a pharmacist prior to being supplied by a manufacturer, wholesaler or distributor.

2. It shall be unlawful for any person to institute or manage a pharmacy unless such person is a licensed pharmacist or has placed a licensed pharmacist in charge of such pharmacy.

3. No licensed pharmacist shall manage, supervise or be in charge of more than one pharmacy.

4. No pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, shall substitute or cause to be substituted for it, without authority of the prescriber or purchaser, any like drug, medicine, chemical or pharmaceutical preparation.

5. No pharmacy, pharmacist-in-charge or other person shall permit the practice of pharmacy except by a licensed pharmacist or assistant pharmacist.

6. No person shall subvert the authority of the pharmacist-in-charge of the pharmacy by impeding the management of the prescription department to act in compliance with federal and state law.

C. 1. It shall be unlawful for a pharmacy to resell dangerous drugs to any wholesale distributor.

2. It shall be unlawful for a wholesale distributor to purchase drugs from a pharmacy.

353.25. – Penalties for Violations.

A. The violation of any provision of the Oklahoma Pharmacy Act for which no penalty is specifically provided shall be punishable as a misdemeanor.

B. Any person who shall willfully make any false representations in procuring or attempting to procure for himself or herself, or for another, licensure under the Oklahoma Pharmacy Act shall be guilty of the felony of perjury.

353.26. – Fines – Reprimand – Revocation or Suspension of Licenses Certificate or Permits.

A. The State Board of Pharmacy may reprimand, place on probation, suspend, revoke permanently and levy fines not to exceed Three Thousand Dollars (\$3,000.00) per count and take other disciplinary action against any person who:

1. Violates any provision of the Oklahoma Pharmacy Act or any other applicable state or federal law;

2. Violates any of the provisions of the Uniform Controlled Dangerous Substances Act;

3. Has been convicted of a felony or has pleaded guilty or no contest to a felony;

4. Engages in the practice of pharmacy while incapacitated or abuses intoxicating liquors or other chemical substances;

5. Conducts himself or herself in a manner likely to lower public esteem for the profession of

pharmacy;

6. Has been disciplined by another State Board of Pharmacy or by another state or federal entity;

7. Has been legally adjudged to be not mentally competent; or

8. Exercises conduct and habits inconsistent with the rules of professional conduct established by the Board.

B. 1. The Board, its employees, or other agents of the Board shall keep confidential information obtained during an investigation into violations of the Oklahoma Pharmacy Act; provided, however, such information may be introduced by the state in administrative proceedings before the Board and the information then becomes a public record. To ensure the confidentiality of such information obtained during the investigation but not introduced in administrative proceedings, this information shall not be deemed to be a record as that term is defined in the Oklahoma Open Records Act, nor shall the information be subject to subpoena or discovery in any civil or criminal proceedings, except that the Board may give such information to law enforcement and other state agencies as necessary and appropriate in the discharge of the duties of that agency and only under circumstances that ensure against unauthorized access to the information.

2. The respondent may acquire information obtained during an investigation, unless the disclosure of the information is otherwise prohibited, except for the investigative report, if the respondent signs a protective order whereby the respondent agrees to use the information solely for the purpose of defense in the Board proceeding and in any appeal therefrom and agrees not to otherwise disclose the information.

C. 1. The Board shall mail by certified mail to respondent at the last address provided by respondent to the Board, postmarked at least ten (10) days before the hearing, the sworn complaint filed with its Executive Director against respondent and notice of the date and place of a hearing thereon. Alternatively, at least ten (10) days before the hearing, the Board may serve respondent personally by any person appointed to make service by the Executive Director of the Board and in any manner authorized by the law of this state for the personal service of summonses in proceedings in a state court. Such service shall be effective upon the personal service or mailing of the complaint and notice, and shall constitute good service. If the Board finds that the allegations of the complaint are supported by the evidence rendered at the hearing, the Board is hereby authorized and empowered to, by written order, revoke permanently or suspend for a designated period, the certificate, license or permit of the respondent and/or reprimand, place on probation and/or fine the respondent.

2. A person whose certificate, license, or permit has been revoked or suspended or who has been reprimanded or placed on probation or fined may appeal such Board order pursuant to the Administrative Procedures Act.

3. The Board's order shall constitute a judgment and may be entered on the judgment docket of the district court in a county in which the respondent has property and may be executed thereon in the same manner as any other judgment of a court of record, unless the fine is paid within thirty (30) days after the appeal time has run.

D. A person, other than a pharmacy technician, whose license or permit has been suspended by the Board or by operation of law shall pay a reinstatement fee not to exceed One Hundred Fifty Dollars (\$150.00) as a condition of reinstatement of the license.

353.29.1. - Veterinary Prescription Drugs.

A. Nothing in the Oklahoma Pharmacy Act shall prevent veterinary prescription drugs from being shipped directly from an Oklahoma licensed wholesaler or distributor to a client, provided such drugs may be supplied

to the client only on the order of a veterinarian licensed in this state and only when a valid veterinarian-client-patient relationship exists.

B. Drugs supplied pursuant to the provision of this section shall not be required to be certified by a pharmacist prior to being supplied by a wholesaler or distributor.

C. It shall be unlawful for a client or the client's authorized agent to acquire or use any prescription drug other than according to the label or outside of a valid veterinarian-client-patient relationship.

D. It shall be unlawful for a wholesaler or distributor licensed in this state to sell a prescription-labeled drug to a client or the client's authorized agent without a valid veterinarian-client-patient relationship in place.

E. Compliance with the Oklahoma Pharmacy Act as it relates to veterinary prescription-labeled drugs shall be pursuant to rules promulgated by the Oklahoma State Board of Veterinary Medical Examiners and in consultation with the State Veterinarian in accordance with state law.

353.29.2. - Prescriptions for Controlled Dangerous Substances for Treatment of Ocular Abnormalities.

A. Pharmacists may dispense prescriptions for dangerous drugs for the treatment of ocular abnormalities, provided that such prescriptions are written by optometrists who are certified by the state in which they are actively practicing. Prescriptions for dangerous drugs issued by licensed optometrists shall include the optometrist's license number.

B. Pharmacists may dispense prescriptions for controlled dangerous substances specified in Section 581 of this title for the treatment of ocular abnormalities, provided that such prescriptions are written by optometrists licensed by the Oklahoma State Board of Examiners in Optometry. Prescriptions for controlled dangerous substances issued by licensed optometrists shall include the optometrist's license number and the optometrist's identification number issued by the United States Drug Enforcement Administration.

353.30. - Use of Agreements - Training Requirements and Administration of Immunizations and Therapeutic Injections.

A. The use of agreements in the practice of pharmacy shall be acceptable within the rules promulgated by the State Board of Pharmacy and in consultation with the State Board of Medical Licensure and Supervision and the State Board of Osteopathic Examiners.

B. The Board shall develop and prepare permanent rules relating to training requirements and administration of immunizations and therapeutic injections in consultation within the State Board of Medical Licensure and Supervision and the State Board of Osteopathic Examiners.

C. A pharmacist who has completed a requisite course of training as approved by the Board in consultation with the State Board of Medical Licensure and Supervision and the State Board of Osteopathic Examiners may administer therapeutic injections on orders from a licensed prescriber, and may administer immunizations that have been approved or authorized by the Food and Drug Administration without a patient-specific prescription, standing order or similar arrangement.

354. – Ownership of Prescription – Refusal to Transfer Prescription or Supply Reference Copy.

A. A prescription is the property of the patient for whom it is prescribed.

B. No pharmacist shall refuse, upon request by that customer in person or through an authorized pharmacist, to transfer a prescription to another pharmacy, or to supply a reference copy in writing or by telephone.

C. No licensed prescriber shall refuse to honor the request of his or her patient to have his or her prescription transmitted to the licensed pharmacist or licensed pharmacy of the patient's choice.

355.1. – Dispensing Dangerous Drugs – Professional Samples – Applicability of Section.

A. Except as provided for in Section 353.1 et seq. of this title, only a licensed practitioner may dispense dangerous drugs to such practitioner's patients, and only for the expressed purpose of serving the best interests and promoting the welfare of such patients. The dangerous drugs shall be dispensed in an appropriate container to which a label has been affixed. Such label shall include the name and office address of the licensed practitioner, date dispensed, name of patient, directions for administration, prescription number, the trade or generic name and the quantity and strength, not meaning ingredients, of the drug therein contained; provided, this requirement shall not apply to compounded medicines. The licensed practitioner shall keep a suitable book, file or record in which shall be preserved for a period of not less than five (5) years a record of every dangerous drug compounded or dispensed by the licensed practitioner.

B. A prescriber desiring to dispense dangerous drugs pursuant to this section shall register annually with the appropriate licensing board as a dispenser, through a regulatory procedure adopted and prescribed by such licensing board.

C. A prescriber who dispenses professional samples to patients shall be exempt from the requirement of subsection B of this section if:

1. The prescriber furnishes the professional samples to the patient in the package provided by the manufacturer;
2. No charge is made to the patient; and
3. An appropriate record is entered in the patient's chart.

D. This section shall not apply to the services provided through the State Department of Health, city/county health departments, or the Department of Mental Health and Substance Abuse Services.

E. This section shall not apply to organizations and services incorporated as state or federal tax-exempt charitable nonprofit entities and/or organizations and services receiving all or part of their operating funds from a local, state or federal governmental entity; provided, such organizations and services shall comply with the labeling and recordkeeping requirements set out in subsection A of this section.

355.2. – Violations – Adoption of Rules and Regulations.

A. A licensed prescriber violating any of the provisions of the Oklahoma Pharmacy Act shall be subject to appropriate actions established in the rules and regulations of his or her licensing board.

B. Rules relating to the Oklahoma Pharmacy Act shall be adopted by the appropriate licensing boards after consultation and review with the Oklahoma State Board of Pharmacy.

Section 355.4 - Interchangeable Biological Product - Definitions - Regulations - Notice – Penalties

A. For the purposes of this section:

1. “Biological product” has the same meaning given to that term in 42 U.S.C., Section 262; and
2. “Interchangeable biological product” means a biological product that the U.S. Food and Drug Administration (FDA):
 - a. has licensed, and determined to meet the standards for interchangeability pursuant to 42 U.S.C., Section 262(k)(4), or
 - b. has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the United States Food and Drug Administration’s (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations.

B. A pharmacist may substitute an interchangeable biological product for a prescribed biological product if:

1. The substituted product has been determined by FDA to be interchangeable, as defined in subsection A of this section, with the prescribed biological product;

2. The prescribing health care provider does not express a preference against substitution in writing, verbally or electronically; and
3. The pharmacy informs the patient of the substitution.

C. The dispensing pharmacist or the pharmacist's designee shall make an entry into an electronic records system of the specific product provided to the patient including the name of the product and the manufacturer. The communication shall be conveyed by making an entry through:

1. An interoperable electronic medical records system;
2. An electronic prescribing technology;
3. A pharmacy benefit management system; or
4. A pharmacy record.

D. Entry into an electronic records system as described in subsection C of this section is presumed to provide notice to the prescriber. If no electronic records system is in use by the pharmacy, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, except that communication shall not be required where:

1. There is no FDA-approved interchangeable biological product for the product prescribed; or
2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

E. The dispensing pharmacist or a prescriber shall not be:

1. Required to show proof that the prescriber has access to the record in any type of payment audit conducted by a payer or pharmacy benefit manager; or
2. Subject to disciplinary action or civil penalties for failure to ensure that the record is accessible or for failure to access the record.

F. The State Board of Pharmacy shall maintain a link on its Internet website to the current list of all biological products determined by the FDA to be interchangeable with a specific biological product.

G. Nothing in this section shall preclude existing approved brand and generic substitutions.

356. - Pharmacy Audit Integrity Act – Short Title.

This act shall be known and may be cited as the "Pharmacy Audit Integrity Act".

356.1. "Pharmacy Benefits Manager" Defined – Purpose and Applicability of Act.

A. For purposes of the Pharmacy Audit Integrity Act, "pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital, medical service organization, insurance company, third-party payor, or a health program administered by a department of this state.

B. The purpose of the Pharmacy Audit Integrity Act is to establish minimum and uniform standards and criteria for the audit of pharmacy records by or on behalf of certain entities.

C. The Pharmacy Audit Integrity Act shall apply to any audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital, medical service organization, insurance company, third-party payor, pharmacy benefits manager, a health program administered by a department of this state, or any entity that represents these companies, groups, or departments.

356.2. Auditor's Duties – Audit Report and Results.

A. The entity conducting an audit of a pharmacy shall:

1. Identify and specifically describe the audit and appeal procedures in the pharmacy contract. Prescription claim documentation and record-keeping requirements shall not exceed the requirements set forth by the Oklahoma Pharmacy Act or other applicable state or federal laws or regulations;
2. Give the pharmacy written notice by certified letter to the pharmacy and the pharmacy's contracting agent, including identification of specific prescription numbers and fill dates to be audited, at least two (2) weeks prior to conducting the audit, including, but not limited to, an on-site audit, a desk audit, or a wholesale purchase audit, request for documentation related to the dispensing of a prescription drug or any reimbursed activity by a pharmacy provider; provided, however, that wholesale purchase audits shall require a minimum of thirty (30) days' written notice. The pharmacy shall have the opportunity to reschedule the audit no more than seven (7) days from the date designated on the original audit notification;
3. Not interfere with the delivery of pharmacist services to a patient and shall utilize every reasonable effort to minimize inconvenience and disruption to pharmacy operations during the audit process;
4. Conduct any audit involving clinical or professional judgment by means of or in consultation with a licensed pharmacist;
5. Not consider as fraud any clerical or record-keeping error, such as a typographical error, scrivener's error or computer error , including, but not limited to, a miscalculated day supply, incorrectly billed prescription written date or prescription origin code, and such errors shall not be subject to recoupment. The pharmacy shall have the right to submit amended claims electronically to correct clerical or record-keeping errors in lieu of recoupment. To the extent that an audit results in the identification of any clerical or record-keeping errors such as typographical errors, scrivener's errors or computer errors in a required document or record, the pharmacy shall not be subject to recoupment of funds by the pharmacy benefits manager unless the pharmacy benefits manager can provide proof of intent to commit fraud . A person shall not be subject to criminal penalties for errors provided for in this paragraph without proof of intent to commit fraud
6. Permit a pharmacy to use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;
7. Not include the dispensing fee amount or the actual invoice cost of the prescription dispensed in a finding of an audit recoupment unless a prescription was not actually dispensed or a physician denied authorization of a dispensing order;
8. Audit each pharmacy under identical standards, regularity and parameters as other similarly situated pharmacies and all pharmacies owned or managed by the pharmacy benefits manager conducting or having conducted the audit;
9. Not exceed one (1) year from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefits manager, a health program administered by a department of this state, or any entity that represents the companies, groups, or departments for the period covered by an audit;
10. Not schedule or initiate an audit during the first seven (7) calendar days of any month unless otherwise consented to by the pharmacy;
11. Disclose to any plan sponsor whose claims were included in the audit any money recouped in the

audit; and

12. Not require pharmacists to break open packaging labeled "for single-patient-use only". Packaging labeled "for single-patient-use only" shall be deemed to be the smallest package size available.

B. 1. Any entity that conducts wholesale purchase review during an audit of a pharmacist or pharmacy shall not require the pharmacist or pharmacy to provide a full dispensing report. Wholesaler invoice reviews shall be limited to verification of purchase inventory specific to the pharmacy claims paid by the health benefits plan or pharmacy benefits manager conducting the audit.

2. Any entity conducting an audit shall not identify or label a prescription claim as an audit discrepancy when:

- a. the National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the drug purchased by the pharmacist or pharmacy as supported by a wholesale invoice,
- b. the pharmacist or pharmacy dispensed the correct quantity of the drug according to the prescription, and
- c. the drug dispensed by the pharmacist or pharmacy shares all but the last two digits of the National Drug Code of the drug reflected on the supplier invoice.

3. An entity conducting an audit shall accept as evidence, subject to validation, to support the validity of a pharmacy claim related to a dispensed drug:

- a. redacted copies of supplier invoices in the pharmacist's or pharmacy's possession, or
- b. invoices and any supporting documents from any supplier as authorized by federal or state law to transfer ownership of the drug acquired by the pharmacist or pharmacy.

4. An entity conducting an audit shall provide, no later than five (5) business days after the date of a request by the pharmacist or pharmacy, all supporting documents the pharmacist's or pharmacy's purchase suppliers provided to the health benefits plan issuer or pharmacy benefits manager.

C. A pharmacy shall be allowed to provide the pharmacy's computerized patterned medical records or the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of supporting the pharmacy record with respect to orders or refills of a legend or narcotic drug.

D. The entity conducting the audit shall not audit more than fifty prescriptions, with specific date of service, per calendar year. The annual limit to the number of prescription claims audited shall be inclusive of all audits, including any prescription-related documentation requests from the health insurer, pharmacy benefits manager or any third-party company conducting audits on behalf of any health insurer or pharmacy benefits manager during a calendar year.

E. If paper copies of records are requested by the entity conducting the audit, the entity shall pay twenty-five cents (\$0.25) per page to cover the costs incurred by the pharmacy. The entity conducting the audit shall provide the pharmacy with accurate instructions, including any required form for obtaining reimbursement for the copied records.

F. The entity conducting the audit shall;

1. Deliver a preliminary audit findings report to the pharmacy and the pharmacy's contracting agent within forty-five (45) calendar days of conducting the audit;
2. Allow the pharmacy at least ninety (90) calendar days following receipt of the preliminary audit findings report in which to produce documentation to address any discrepancy found during the audit; provided, however, a pharmacy may request an extension, not to exceed an additional forty-five (45) calendar days;
3. Deliver a final audit findings report to the pharmacy and the pharmacy's contracting agent signed

by the auditor within ten (10) calendar days after receipt of additional documentation provided by the pharmacy, as provided for in [Section 356.3](#) of this title;

4. Allow the pharmacy to reverse and resubmit claims electronically within thirty (30) days of receipt of the final audit report in lieu of the auditing entity recouping discrepant claim amounts from the pharmacy;

5. Not recoup any disputed funds until after final disposition of the audit findings, including the appeals process as provided for in [Section 356.3](#) of this title; and

6. Not accrue interest during the audit and appeal period.

G. Each entity conducting an audit shall provide a copy of the final audit results, and a final audit report upon request, after completion of any review process to the plan sponsor.

H. 1. The full amount of any recoupment on an audit shall be refunded to the plan sponsor. Except as provided for in paragraph 2 of this subsection, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

2. This subsection does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

a. the plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor, and

b. a commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

I. Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefits manager, health plan or insurer. An auditing vendor contracting with multiple pharmacy benefits managers or health insurance plans shall not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a different pharmacy benefits manager or health insurance plan.

356.3. Appeals – Final Audit Report – Findings of Fraud or Willful Misrepresentation.

A. Each entity conducting an audit shall establish a written appeals process under which a pharmacy may appeal an unfavorable preliminary audit report and/or final audit report to the entity.

B. Following an appeal, if the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further action.

C. Any final audit report, following the final audit appeal period, with a finding of fraud or willful misrepresentation shall be referred to the district attorney having proper jurisdiction or the Attorney General for prosecution upon completion of the appeals process.

D. This act does not apply to any audit, review or investigation that is initiated based on or that involves fraud, willful misrepresentation or abuse.

356.4. Extrapolation Audit.

A. For the purposes of the Pharmacy Audit Integrity Act, “extrapolation audit” means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor.

B. The entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

356.5. Applicability of Audit Criteria and Act.

A. The audit criteria set forth in the Pharmacy Audit Integrity Act shall apply only to audits of claims for services provided and claims submitted for payment after this act becomes law.

B. The Pharmacy Audit Integrity Act shall not apply to any audit, including but not limited to audits conducted by or on behalf of a state agency, which involves fraud, willful misrepresentation, abuse or Medicaid payments including, without limitation, investigative audits or any other statutory provision which authorizes investigations relating to insurance fraud.

357. Pharmacy Benefit Plans – Definitions.

As used in this act:

1. "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization; a health program administered by the state in the capacity of provider of health coverage; or an employer, labor union, or other entity organized in the state that provides health coverage to covered individuals who are employed or reside in the state. This term does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, disability income, or other limited benefit health insurance policies and contracts that do not include prescription drug coverage;
2. "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. A covered individual includes any dependent or other person provided health coverage through a policy, contract or plan for a covered individual;
3. "Department" means the Oklahoma Insurance Department;
4. "Maximum allowable cost" or "MAC" means the list of drug products delineating the maximum per-unit reimbursement for multiple-source prescription drugs, medical product or device;
5. "Multisource drug product reimbursement" (reimbursement) means the total amount paid to a pharmacy inclusive of any reduction in payment to the pharmacy, excluding prescription dispense fees;
6. "Pharmacy benefits management" means a service provided to covered entities to facilitate the provision of prescription drug benefits to covered individuals within the state, including negotiating pricing and other terms with drug manufacturers and providers. Pharmacy benefits management may include any or all of the following services:
 - a. claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals,
 - b. clinical formulary development and management services,
 - c. rebate contracting and administration,
 - d. certain patient compliance, therapeutic intervention and generic substitution programs, or
 - e. disease management programs;
7. "Pharmacy benefits manager" or "PBM" means a person, business or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital, medical service organization, insurance company, third-party payor, or a health program administered by an agency of this state;
8. "Plan sponsor" means the employers, insurance companies, unions and health maintenance organizations or any other entity responsible for establishing, maintaining, or administering a health benefit plan on behalf of covered individuals; and

9. "Provider" means a pharmacy licensed by the State Board of Pharmacy, or an agent or representative of a pharmacy, including, but not limited to, the pharmacy's contracting agent, which dispenses prescription drugs or devices to covered individuals.

358. License to Provide Pharmacy Benefits Management – Powers of Oklahoma Insurance Department.

A. In order to provide pharmacy benefits management or any of the services included under the definition of pharmacy benefits management in this state, a pharmacy benefits manager or any entity acting as one in a contractual or employment relationship for a covered entity shall first obtain a license from the Oklahoma Insurance Department, and the Department may charge a fee for such licensure.

B. The Department shall establish, by regulation, licensure procedures, required disclosures for pharmacy benefits managers (PBMs) and other rules as may be necessary for carrying out and enforcing the provisions of this act. The licensure procedures shall, at a minimum, include the completion of an application form that shall include the name and address of an agent for service of process, the payment of a requisite fee, and evidence of the procurement of a surety bond.

C. The Department may subpoena witnesses and information. Its compliance officers may take and copy records for investigative use and prosecutions. Nothing in this subsection shall limit the Office of the Attorney General from using its investigative demand authority to investigate and prosecute violations of the law.

D. The Department may suspend, revoke or refuse to issue or renew a license for noncompliance with any of the provisions hereby established or with the rules promulgated by the Department; for conduct likely to mislead, deceive or defraud the public or the Department; for unfair or deceptive business practices or for nonpayment of a renewal fee or fine. The Department may also levy administrative fines for each count of which a licensee has been convicted in a Department hearing.

359. Information to be Provided by Pharmacy Benefits Manager to Covered Entity.

A pharmacy benefits manager shall provide, upon request by the covered entity, information regarding the difference in the amount paid to providers for prescription services rendered to covered individuals and the amount billed by the pharmacy benefits manager to the covered entity or plan sponsor to pay for prescription services rendered to covered individuals.

360. Maximum Allowable Cost List.

A. The pharmacy benefits manager shall, with respect to contracts between a pharmacy benefits manager and a provider, including a pharmacy service administrative organization:

1. Include in such contracts the specific sources utilized to determine the maximum allowable cost (MAC) pricing of the pharmacy, update MAC pricing at least every seven (7) calendar days, and establish a process for providers to readily access the MAC list specific to that provider;
2. In order to place a drug on the MAC list, ensure that the drug is listed as "A" or "B" rated in the most recent version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, and the drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and is not obsolete;
3. Ensure dispensing fees are not included in the calculation of MAC price reimbursement to pharmacy providers;
4. Provide a reasonable administration appeals procedure to allow a provider, a provider's representative and a pharmacy service administrative organization to contest reimbursement amounts within fourteen (14) business days of the final adjusted payment date. The pharmacy benefits manager shall not prevent the pharmacy or the pharmacy service administrative organization from filing

reimbursement appeals in an electronic batch format. The pharmacy benefits manager must respond to a provider, a provider's representative and a pharmacy service administrative organization who have contested a reimbursement amount through this procedure within ten (10) business days. The pharmacy benefits manager must respond in an electronic batch format to reimbursement appeals filed in an electronic batch format. The pharmacy benefits manager shall not require a pharmacy or pharmacy services administrative organization to log into a system to upload individual claim appeals or to download individual appeal responses. If a price update is warranted, the pharmacy benefits manager shall make the change in the reimbursement amount, permit the dispensing pharmacy to reverse and rebill the claim in question, and make the reimbursement amount change retroactive and effective for all contracted providers; and

5. If a below-cost reimbursement appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code number from the specific national or regional wholesalers where the drug is available for purchase by the dispensing pharmacy at a price below the PBM's reimbursement price. If the pharmacy benefits manager cannot provide a specific national or regional wholesaler where the drug can be purchased by the dispensing pharmacy at a price below the pharmacy benefits manager's reimbursement price, the pharmacy benefits manager shall immediately adjust the reimbursement amount, permit the dispensing pharmacy to reverse and rebill the claim in question, and make the reimbursement amount adjustment retroactive and effective for all contracted providers.

B. The pharmacy benefits manager shall not place a drug on a MAC list, unless there are at least two therapeutically equivalent, multiple-source drugs, generally available for purchase by dispensing retail pharmacies from national or regional wholesalers.

C. The pharmacy benefits manager shall not require accreditation or licensing of providers, or any entity licensed or regulated by the State Board of Pharmacy, other than by the State Board of Pharmacy or federal government entity as a condition for participation as a network provider.

D. A pharmacy or pharmacist may decline to provide the pharmacist clinical or dispensing services to a patient or pharmacy benefits manager if the pharmacy or pharmacist is to be paid less than the pharmacy's cost for providing the pharmacist clinical or dispensing services.

E. The pharmacy benefits manager shall provide a dedicated telephone number, email address and names of the personnel with decision-making authority regarding MAC appeals and pricing.

367.1. Short Title.

Sections 1 through 7 of this act shall be known and may be cited as the "Utilization of Unused Prescription Medications Act".

367.2. Definitions.

As used in the Utilization of Unused Prescription Medications Act:

1. "**Assisted living center**" has the same meaning as such term is defined in Section 1-890.2 of Title 63 of the Oklahoma Statutes;

2. "**Cancer drugs**" means any of several drugs that control or kill neoplastic cells, commonly referred to as "cancer-fighting drugs"; and includes, but is not limited to, drugs used in chemotherapy to destroy cancer cells;

3. "**Health care professional**" means any of the following persons licensed and authorized to prescribe and dispense drugs or to provide medical, dental, or other health-related diagnoses, care or treatment within the scope of their professional license:

a. a physician holding a current license to practice medicine pursuant to Chapter 11 or Chapter 14 of Title 59 of the Oklahoma Statutes,

- b. an advanced practice nurse licensed pursuant to Chapter 12 of Title 59 of the Oklahoma Statutes,
 - c. a physician assistant licensed pursuant to Chapter 11 of Title 59 of the Oklahoma Statutes,
 - d. a dentist licensed pursuant to Chapter 7 of Title 59 of the Oklahoma Statutes,
 - e. an optometrist licensed pursuant to Chapter 13 of Title 59 of the Oklahoma Statutes, and
 - f. a pharmacist licensed pursuant to Chapter 8 of Title 59 of the Oklahoma Statutes;
4. **"Medically indigent"** means a person eligible to receive Medicaid or Medicare or a person who has no health insurance and who otherwise lacks reasonable means to purchase prescribed medications;
5. **"Charitable clinic"** means a charitable nonprofit corporation or a facility organized as a not-for-profit pursuant to the provisions of the Oklahoma General Corporation Act that:
- a. holds a valid exemption from federal income taxation issued pursuant to Section 501(a) of the Internal Revenue Code (26 U.S.C., Section 501(a)),
 - b. is listed as an exempt organization under 501(c) of the Internal Revenue Code (26 U.S.C., Section 501(c)),
 - c. provides on an outpatient basis for a period of less than twenty-four (24) consecutive hours to persons not residing or confined at such facility advice, counseling, diagnosis, treatment, surgery, care or services relating to the preservation or maintenance of health, and
 - d. has a licensed outpatient pharmacy; and
6. **"Prescription drug"** means a drug which may be dispensed only upon prescription by a health care professional authorized by his or her licensing authority and which is approved for safety and effectiveness as a prescription drug under Section 505 or 507 of the Federal Food, Drug and Cosmetic Act (52 Stat. 1040 (1938), 21 U.S.C.A., Section 301).

367.3. Implementation of Pilot Program and Statewide Program.

A. The Board of Pharmacy shall implement statewide a program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled dangerous substances in Section 2-101 of Title 63 of the Oklahoma Statutes, may be transferred from residential care homes, nursing facilities, assisted living centers, public intermediate care facilities for people with mental retardation (ICF/MR) or pharmaceutical manufacturers to pharmacies operated by a county. If no county pharmacy exists, or if a county pharmacy chooses not to participate, such unused prescription medications may be transferred to a pharmacy operated by a city-county health department or a pharmacy under contract with a city-county health department, a pharmacy operated by the Department of Mental Health and Substance Abuse Services or a charitable clinic for the purpose of distributing the unused prescription medications to Oklahoma residents who are medically indigent.

B. The Board of Pharmacy shall promulgate rules and establish procedures necessary to implement the program established by the Utilization of Unused Prescription Medications Act.

C. The Board of Pharmacy shall provide technical assistance to entities who may wish to participate in the program.

367.4. – Criteria for Accepting Unused Prescription Drugs.

The following criteria shall be used in accepting unused prescription drugs for use under the Utilization of Unused Prescription Medications Act:

1. Only prescription drugs in their original sealed unit dose packaging or unused injectables shall be accepted

- and dispensed pursuant to the Utilization of Unused Prescription Medications Act;
2. The packaging must be unopened, except that cancer drugs packaged in single-unit doses may be accepted and dispensed when the outside packaging is opened if the single-unit-dose packaging has not been opened;
 3. Expired prescription drugs shall not be accepted;
 4. A prescription drug shall not be accepted or dispensed if the person accepting or dispensing the drug has reason to believe that the drug is adulterated;
 5. No controlled dangerous substances shall be accepted; and
 6. Subject to the limitation specified in this section, unused prescription drugs dispensed for purposes of a medical assistance program or drug product donation program may be accepted and dispensed under the Utilization of Unused Prescription Medications Act.

367.5. Participation Eligibility and Resale of Prescription Drugs Prohibition.

A. Participation in the Utilization of Unused Prescription Medications Act by pharmacies, nursing homes, assisted living centers, charitable clinics or prescription drug manufacturers shall be voluntary. Nothing in the Utilization of Unused Prescription Medications Act shall require any pharmacy, nursing home, assisted living center, charitable clinic or prescription drug manufacturer to participate in the program.

B. A pharmacy or charitable clinic which meets the eligibility requirements established in the Utilization of Unused Prescription Medications Act may:

1. Dispense prescription drugs donated under the Utilization of Unused Prescription Medications Act to persons who are medically indigent residents of Oklahoma as established in rules by the Board of Pharmacy; and
2. Charge persons receiving donated prescription drugs a handling fee established by rule by the Board of Pharmacy.

C. A pharmacy or charitable clinic which meets the eligibility requirements established and authorized by the Utilization of Unused Prescription Medications Act which accepts donated prescription drugs shall:

1. Comply with all applicable federal and state laws related to the storage and distribution of dangerous drugs;
2. Inspect all prescription drugs prior to dispensing the prescription drugs to determine that such drugs are not adulterated; and
3. Dispense prescription drugs only pursuant to a prescription issued by a health care professional.

D. Prescription drugs donated under the Utilization of Unused Prescription Medications Act shall not be resold.

E. For purposes of the Utilization of Unused Prescription Medications Act, reimbursement from governmental agencies to charitable clinics shall not be considered resale of prescription drugs.

367.5.1. Resale or Redispensing of Prescription Drugs- Department of Corrections

A. A pharmacy operated by the Department of Corrections or under contract with the Department of Corrections or a county jail may accept for the purpose of resale or redispensing a prescription drug that has been dispensed and has left the control of the pharmacist if the prescription drug is being returned by a state correctional facility or a county jail that has a licensed physician's assistant, a registered professional nurse, or a licensed practical nurse, who is responsible for the security, handling, and administration of prescription drugs within that state correctional facility or county jail and if all of the following conditions are met:

1. The pharmacist is satisfied that the conditions under which the prescription drug has been delivered, stored and handled before and during its return were such as to prevent damage,

deterioration or contamination that would adversely affect the identity, strength, quality, purity, stability, integrity or effectiveness of the prescription drug;

2. The pharmacist is satisfied that the prescription drug did not leave the control of the registered professional nurse or licensed practical nurse responsible for the security, handling, and administration of that prescription drug and that the prescription drug did not come into the physical possession of the individual for whom it was prescribed;

3. The pharmacist is satisfied that the labeling and packaging of the prescription drug are accurate, have not been altered, defaced or tampered with, and include the identity, strength, expiration date and lot number of the prescription drug; and

4. The prescription drug was dispensed in a unit dose package or unit of issue package.

B. A pharmacy operated by the Department of Corrections or under contract with the Department of Corrections or a county jail shall not accept or return prescription drugs as provided under this section until the pharmacist in charge develops a written set of protocols for accepting, returning to stock, repackaging, labeling and redispensing prescription drugs. The written protocols shall be maintained on the premises and shall be readily accessible to each pharmacist on duty and available for review by the Board. The written protocols shall include, but not be limited to:

1. Methods to ensure that damage, deterioration or contamination has not occurred during the delivery, handling, storage and return of the prescription drugs which would adversely affect the identity, strength, quality, purity, stability, integrity or effectiveness of those prescription drugs or otherwise render those drugs unfit for distribution;

2. Methods for accepting, returning to stock, repackaging, labeling and redispensing the prescription drugs returned pursuant to this section; and

3. A uniform system of recording and tracking prescription drugs that are returned to stock, repackaged, labeled, and redistributed pursuant to this section.

C. If the integrity of a prescription drug and its package is maintained, a prescription drug returned pursuant to this section shall be returned to stock and redistributed as follows:

1. A prescription drug that was originally dispensed in the manufacturer's unit dose package or unit of issue package and is returned in that same package may be returned to stock, repackaged and redispensed as needed;

2. A prescription drug that is repackaged into a unit dose package or a unit of issue package by the pharmacy, dispensed and returned to that pharmacy in that unit dose package or unit of issue package may be returned to stock, but it shall not be repackaged. A unit dose package or unit of issue package prepared by the pharmacist and returned to stock shall only be redispensed in that same unit dose package or unit of issue package. A pharmacist shall not add unit dose package drugs to a partially used unit of issue package.

D. This section does not apply to any of the following:

1. A controlled dangerous substance;

2. A prescription drug that is dispensed as part of customized adherence medication packaging;

3. A prescription drug that is not dispensed as a unit dose package or a unit of issue package; or

4. A prescription drug that is not properly labeled with the identity, strength, lot number and expiration date.

367.6. Entities – Donation, Acceptance, or Dispensing of Prescription Drugs.

A. For matters related only to the lawful donation, acceptance, or dispensing of prescription drugs under the

Utilization of Unused Prescription Medications Act, the following persons and entities, in compliance with the Utilization of Unused Prescription Medications Act, in the absence of bad faith or gross negligence, shall not be subject to criminal or civil liability for injury other than death, or loss to person or property, or professional disciplinary action:

1. The Board of Pharmacy;
2. The Department of Mental Health and Substance Abuse Services;
3. Any prescription drug manufacturer, governmental entity, nursing home, or assisted living center donating prescription drugs under the Utilization of Unused Prescription Medications Act;
4. Any prescription drug manufacturer or its representative that directly donates prescription drugs in professional samples to a charitable clinic or a pharmacy under the Utilization of Unused Prescription Medications Act;
5. Any pharmacy, charitable clinic or health care professional that accepts or dispenses prescription drugs under the Utilization of Unused Prescription Medications Act; and
6. Any pharmacy, charitable clinic, city-county pharmacy or other state-contracted pharmacy that employs a health care professional who accepts or can legally dispense prescription drugs under the Utilization of Unused Prescription Medications Act and the Oklahoma Pharmacy Act.

B. For matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the prescription drug manufacturer that is donated by any entity under the Utilization of Unused Prescription Medications Act, a prescription drug manufacturer shall not, in the absence of bad faith or gross negligence, be subject to criminal or civil liability for injury other than for death, or loss to person or property including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

367.7. Promulgation of rules.

A. The Board of Pharmacy shall promulgate emergency rules by December 1, 2004, to implement the Utilization of Unused Prescription Medications Act. Permanent rules shall be promulgated pursuant to the Administrative Procedures Act. Such rules shall include:

1. Eligibility criteria for pharmacies and charitable clinics authorized to receive and dispense donated prescription drugs under the Utilization of Unused Prescription Medications Act;
2. Establishment of a formulary which shall include all prescription drugs approved by the federal Food and Drug Administration;
3. Standards and procedures for transfer, acceptance, safe storage, security, and dispensing of donated prescription drugs;
4. A process for seeking input from the State Department of Health in establishing provisions which affect nursing homes and assisted living centers;
5. A process for seeking input from the Department of Mental Health and Substance Abuse Services in establishing provisions which affect mental health and substance abuse clients;
6. Standards and procedures for inspecting donated prescription drugs to ensure that the drugs are in compliance with the Utilization of Unused Prescription Medications Act and to ensure that, in the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity;
7. Procedures for destruction of medications that are donated which are controlled substances;
8. Procedures for verifying whether the pharmacy and responsible pharmacist participating in the program are licensed and in good standing with the Board of Pharmacy;
9. Establishment of standards for acceptance of unused prescription medications from assisted living centers; and
- 10 Any other standards and procedures the Board of Pharmacy deems appropriate or necessary to

implement the provisions of the Utilization of Unused Prescription Medications Act.

B. In accordance with the rules and procedures of the program established pursuant to this section, a resident of a nursing facility or assisted living center, or the representative or guardian of a resident may donate unused prescription medications, other than prescription drugs defined as controlled dangerous substances by Section 2-101 of Title 63 of the Oklahoma Statutes, for dispensation to medically indigent persons.

367.8. Rules for Emergency Medication Kits.

A. A pharmacy may maintain drugs in an emergency medication kit for dispensation in a facility as provided by this section. The pharmacy shall establish a policy and procedures governing the maintenance and dispensation of such drugs in accordance with the provisions of this section. The drugs may be used only for the emergency medication needs of a resident at the facility. The pharmacy shall maintain the drugs in the emergency medication kit for the facility.

B. The pharmacy may establish a pharmacy designee at the facility who shall be responsible for transmitting required information for dispensation of controlled dangerous substances to the central repository of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control as provided by the Anti-Drug Diversion Act.

C. The pharmacy shall register the emergency medication kit as a pharmacy location with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and shall comply with the requirements for controlled dangerous substances prescribed by rules of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Commission.

D. The State Board of Pharmacy shall promulgate rules relating to emergency medication kits, including, but not limited to:

1. The amount and type of drugs that may be maintained in an emergency medication kit. The total volume of each controlled dangerous substance shall be limited to the lesser of three doses per licensed bed or sixty individual doses. Controlled dangerous substances stored in emergency medication kits must be dispensed pursuant to a valid prescription and shall be reported to the registered pharmacy;
2. Procedures regarding the use of drugs from an emergency medication kit;
3. Recordkeeping requirements; and
4. Security requirements.

E. As used in this section, "facility" means a facility as defined by the Nursing Home Care Act or an assisted living center as defined by the Continuum of Care and Assisted Living Act.

368 - Oklahoma Prescription Drug Discount Program Act of 2005

A. 1. This act shall be known and may be cited as the "Oklahoma Prescription Drug Discount Program Act of 2005".

2. Recognizing that many Oklahomans do not have health insurance coverage for prescription drugs, the Oklahoma Legislature hereby establishes provisions to increase access to prescription drugs for low income Oklahomans.

B. The Oklahoma Health Care Authority shall contract with a pharmacy benefit manager for the administration of a prescription drug discount program. Oklahoma incorporated entities having a strong working relationship with Oklahoma's pharmacies should be given preference when selecting the administering entity to ensure Oklahoma pharmacy's participation and to ensure the success of the program. The prescription drug discount program will:

1. Enable persons without prescription drug coverage to be linked to appropriate manufacturer-sponsored prescription drug programs via the use of computer software;

2. Establish agreements with prescription drug manufacturers that outline available discounts and drugs, and in which prescription drug manufacturers agree to allow the Oklahoma Health Care Authority contracted pharmacy benefit manager to be the means testing agent for their programs;

3. Negotiate prescription drug discounts with manufacturers and utilize Medicaid reimbursement for pharmacy networks and implement a "one-stop" Oklahoma Prescription Drug Discount program for uninsured Oklahomans and their families. All negotiated manufacturer drug discounts shall be provided as a one-hundred-percent pass-through discount to the plan participant. The plan administrator will be required to provide the Oklahoma Health Care Authority full disclosure and transparency of financial relationships with manufacturers for this program, and will include right-to-audit provisions in all contracts with the Oklahoma Health Care Authority;

4. Ensure that one hundred percent (100%) of the savings from prescription drug manufacturers and pharmacies is passed on to the consumer;

5. Enroll persons into a prescription drug discount card program using specialized computer software that will allow the consumer to have access via a single application process to all participating prescription drug manufacturer discount programs;

6. Include outreach and advertising of the program in order to provide access to the program to potential consumers who do not have access to prescription drug coverage; and

7. Charge a basic enrollment fee to cover the administrative costs of the program; provided, however, this provision shall not apply to an applicant whose income is less than 150% of the Federal Poverty Level. Provided further, dispensing fees shall not exceed allowable Medicaid rates.

C. Nothing in this act shall be construed to allow public disclosure of any proprietary pricing information as contained in contractual agreements between a pharmaceutical manufacturer and the Oklahoma Health Care Authority, or a pharmacy benefit manager under contract with the Oklahoma Health Care Authority to be the means testing agent for the program.

369 - Plan B Emergency Contraception - Prohibited for Women Under Age 17 - Prescription Required for Adults.

Plan B One-Step, or its generic equivalent, also known as the "morning-after" emergency contraceptive, shall not be available to women under the age of seventeen (17) without a prescription. Such emergency contraceptive shall be dispensed by pharmacists to women seventeen (17) years of age and older without a prescription.

[Ruled unconstitutional in January 2014 by Case No. CV-2013-1640.]

374 - Procedures for Medication Services in Facilities Operated by the Oklahoma Department of Veterans Affairs.

In facilities operated by the Oklahoma Department of Veterans Affairs, the following medication services procedures shall be utilized:

1. An inventory record shall be maintained for each Schedule II-V medication distributed to a nursing station such that each dose (unit) is documented;

2. For medications which require a prescription, the resident's full name will be affixed to the resident's individual drawer located on the medication cart; and the medication strength, dosage, and directions for use will be located on the medical administration record (MAR);

3. For over-the-counter medications that are prescribed, the resident's full name will be affixed to the resident's individual drawer located on the medication cart; and the medication strength, dosage, and directions for use will be located on the medical administration record (MAR);

4. When a resident is permanently discharged, the unused medication shall be returned to the facility pharmacy as required by United States Department of Veterans Affairs guidelines;

5. Noncontrolled medications prescribed for residents who have died and noncontrolled medications which have been discontinued shall be returned to the facility pharmacy; and

6. Facilities may maintain nonprescription drugs as bulk medications. Bulk medications may include drugs listed in a formulary developed by the facility pharmacist, medical director, and director of nursing. Nonformulary over-the-counter medications may be prescribed if the resident has therapeutic failure, drug allergy, drug interaction or contraindication to the over-the-counter formulary. In addition, bulk dispensing of prescription medications may include controlled and noncontrolled medications. Facilities shall establish policies and procedures to assure the safe administration of all medications and full accountability of controlled medications.

375.1 - Short Title

Sections 2 through 5 of this act shall be known and may be cited as the "Oklahoma Durable Medical Equipment Licensing Act".

375.2 – Definitions

1. "Board" means the State Board of Pharmacy;

2. a. "Durable medical equipment" means equipment for which a prescription is required, including for repair and replacement parts, and that:

- (1) can stand repeated use,
- (2) has an expected useful life of at least three (3) years,
- (3) is primarily and customarily used to serve a medical purpose,
- (4) is not generally useful to a person in the absence of illness or injury,
- (5) is appropriate for use in the home, and
- (6) is intended for use by the consumer.

b. Durable medical equipment includes, but is not limited to:

- (1) ambulating assistance equipment,
- (2) mobility equipment,
- (3) rehabilitation seating,
- (4) oxygen care and oxygen delivery systems,
- (5) respiratory equipment and respiratory disease management devices,
- (6) rehabilitation environmental control equipment,
- (7) ventilators,
- (8) apnea monitors,
- (9) diagnostic equipment,
- (10) feeding pumps,
- (11) beds prescribed by physicians to alleviate medical conditions,
- (12) transcutaneous electrical nerve stimulators, and
- (13) sequential compression devices; and

3. "Supplier" means any person or entity that provides durable medical equipment services or products and that currently bills or plans to bill a claim for reimbursement of services or products to a third party.

375.3 - Supplier License Required - Effective Duration - Inspection - Rules

A. Any supplier of durable medical equipment to a consumer in this state shall possess a durable medical equipment supplier license issued by the State Board of Pharmacy pursuant to the Oklahoma Durable Medical Equipment Licensing Act.

B. Licenses issued by the Board pursuant to the Oklahoma Durable Medical Equipment Licensing Act shall be effective for twelve (12) months from the date of issuance and shall not be transferable or assignable.

C. The Board may initially and periodically inspect the applicant's office or place of business.

D. The Board shall promulgate rules necessary to implement the provisions of the Oklahoma Durable Medical Equipment Licensing Act. Such rules shall prioritize patient safety and quality of durable medical equipment. The Board may provide by rule that any person or entity accredited by organizations recognized by the Centers for Medicare and Medicaid Services is deemed to meet all or some of the requirements of the Oklahoma Durable Medical Equipment Licensing Act.

E. Nothing in this section shall be construed to restrict or prohibit private transactions between two parties.

375.4 - License Requirements - Out-of-State Supplier License Requirements - Fees - Inspection - Revocation or Suspension of License

A. The State Board of Pharmacy may issue a license to an applicant for licensure as a supplier of durable medical equipment if the applicant pays the appropriate license fee established under Section 8 of this act and submits, in a form prescribed by the Board, an application and proof that the applicant:

1. a. Maintains a physical office or place of business within this state, or
- b. For a Medicare or Medicaid enrolled out-of-state supplier, maintains a physical office or place of business within one hundred (100) miles of a resident of this state being served by the supplier;
2. Has obtained a state sales tax permit and any other necessary license or permit as determined by the Board including but not limited to any permit from the State Department of Health; and
3. Meets all state and federal accreditation requirements.

Each individual physical office or place of business owned or operated by the supplier must be licensed separately.

B. 1. The Board may issue a license to a Medicare or Medicaid enrolled out-of-state supplier who has at least one accredited facility within one hundred (100) miles of any resident of this state being served by the supplier.

2. The Board may assess a fee on out-of-state suppliers necessary to cover the cost of inspection of those suppliers. The inspection fee shall be in addition to the licensure fee.

C. A supplier licensed by the Board shall meet all safety standards established by the Board, which shall include, but not be limited to:

1. Ensuring that all personnel engaged in delivery, maintenance, and repair of durable medical equipment receive annual continuing education;
2. Instructing the patient or patient's caregiver about how to use the durable medical equipment provided;
3. Receiving and responding to complaints from patients;
4. Maintaining records of all patients receiving durable medical equipment; and
5. Managing, maintaining, and servicing durable medical equipment.

D. The Board may revoke or suspend a license for:

1. Violation of state or federal law;
2. Violation of rules promulgated pursuant to the Oklahoma Durable Medical Equipment Licensing Act;
3. Permitting, aiding, or abetting any illegal act;
4. Failing to meet the safety standards established by the Board pursuant to the Oklahoma Durable Medical Equipment Licensing Act;
5. Engaging in conduct or practices found by the Board to be detrimental to the health, safety, or welfare of patients;
or
6. Failing to renew a license.

375.5 – Exceptions

The Oklahoma Durable Medical Equipment Licensing Act shall not apply to:

1. Pharmacies and pharmacists;
2. Hospitals;
3. Ambulatory surgical centers;
4. Health care facilities owned or operated by the state or federal government;
5. Skilled nursing facilities;
6. Assisted living facilities;
7. Prosthetic or orthotic practitioners;
8. Health care practitioners who are licensed to practice health care in this state and who provide durable medical equipment within the scope of their health care practice;
9. Manufacturers or wholesale distributors that do not sell or rent durable medical equipment directly to consumers;
10. Suppliers of insulin infusion pumps and related supplies or services; or
11. Suppliers of medical devices approved by the U.S. Food and Drug Administration that are used in the treatment of cancerous tumors.

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[Authority: 51 O.S., §§ 24A et seq.; 59 O.S., §§ 353.3, 353.5 through 353.7, 353.9, 353.11, 353.18, 353.20, 353.22, 353.24 through 353.26, and 353.29; 63 O.S., §§ 2-201, 2-208, and 210; 75 O.S., §§ 302, 305, 307, and 309]
[Source: Codified 12-31-91]

SUBCHAPTER 1. GENERAL PROVISIONS

Section

535:1-1-1. Purpose

535:1-1-1. Purpose

(a) The rules of this Chapter describe the organization and the administrative operation of the Board, the procedures and practices at individual proceedings, the practices at rulemaking hearings, the procedures for requests for rule changes and the procedures for the filing and prompt disposition of petitions for declaratory rulings as to the applicability of any rule or order of the Board as required under the Administrative Procedures Act.

(b) The fee schedule of this Chapter provides the public and registrants access to records, information and fees as required or suggested by the Open Records Act.

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

SUBCHAPTER 3. DESCRIPTION OF ORGANIZATION

Section

535:1-3-1. Creation of Board

535:1-3-2. Board members

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

535:1-3-1. Creation of Board

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

(b) Unless otherwise stated, as used herein, Board means Board of Pharmacy

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

535:1-3-2. Board members

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

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

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

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

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

SUBCHAPTER 5. BOARD ADMINISTRATIVE OPERATIONS

Section

535:1-5-1. Board office

535:1-5-2. Office hours

535:1-5-3. Communication in writing

535:1-5-4. Board meetings

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

535:1-5-5.1. Complaint confidentiality

535:1-5-6. Availability of records

535:1-5-1. Board office

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

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

535:1-5-2. Office hours

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

535:1-5-3. Communication in writing

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

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

535:1-5-4. Board meetings

(a) The Board shall hold at least one regular meeting in each calendar year.

(b) The Board shall hold other meetings as it deems necessary at the Office of the Board in Oklahoma City, Oklahoma, or such other location as the Board desires.

(c) Special meetings may be called by the President and Director, or a majority of the Board.

(d) Four (4) members of the Board constitute the quorum and may transact any business or hold any hearing by simple majority vote of the quorum.

(e) The Board president shall vote only in the case of tie.

[Source: Amended at 11 Ok Reg 3423, eff 6-27-94; Amended at 12 Ok Reg 2587, eff 6-26-95; Amended at 32 Ok Reg 1222, eff 8-27-15; Amended at 35 OK Reg

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

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

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

535:1-5-5.1. Complaint confidentiality

(a) In order to encourage the public and affected individuals to come forward with complaints regarding registrants and fully share the particulars, the Board will hold all informant or complainant names, addresses or other personal information as confidential and shall not release this information.

(b) The Board shall use all complainant and informant information provided in conducting its investigations; and may use this information in cases filed against registrants.

(c) Information obtained during an investigation into violations of the Oklahoma Pharmacy Act is not a record as that term is defined in the Oklahoma Open Records Act nor shall such information be subject to subpoena or discovery in any civil or criminal proceeding.

(d) The respondent may acquire information obtained during an investigation, unless the disclosure of such information is otherwise prohibited, except for the investigation report, if the respondent signs a protective order whereby the respondent agrees to use the information solely for the purposes of defense in the Board proceeding and in any appeal there from and agrees not to otherwise disclose the information.

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

535:1-5-6. Availability of records

(a) **Document location.** All rules and other written statements of policy or interpretations formulated, adopted or used by the Board in the discharge of its functions and all final orders, decisions and opinions will be made available for public inspection at the principal office during regular office hours.

(b) **Official records.** Copies of official records of the Board may be made and certified by the Director or his designee according to the fee schedule enacted by the Board. Any Board records or materials in the Board's office protected from disclosure by state law shall not be released.

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

SUBCHAPTER 7. INDIVIDUAL PROCEEDINGS

Section

535:1-7-1. Complaints

535:1-7-2. Serving of notices

535:1-7-3. Hearings

535:1-7-3.1. Standard of proof

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

535:1-7-5. Subpoenas

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

535:1-7-7. Final orders

535:1-7-8. Appeal

535:1-7-1. Complaints.

(a) **Sworn complaint.** In every individual proceeding a sworn complaint shall be filed naming the person against whom relief is sought and containing a brief statement of the factual allegations and alleged violations.

(b) **Notice of hearing.** The Director shall issue a notice of hearing thereby notifying the person named in the

complaint of said filing and the date, time and the place for the hearing. The notice should comply with the requirements of 75 O.S. Section 309 or its successor.

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

535:1-7-2. Serving of notices

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

- (1) personally by any person appointed to make service by the Director and in any manner authorized by the law of this State for the personal service of summonses in proceedings in a state court; or,
- (2) by certified mail to the respondent at the last address provided to the Board by respondent or to respondent's attorney.

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

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

535:1-7-3. Hearings

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

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

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

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

(c) **Order of procedure.** Hearings shall be conducted in an orderly manner by the President of the Board, or his designee. The order of procedure and rules of evidence shall be those specified by the Oklahoma Administrative Procedures Act.

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

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

535:1-7-3.1. Standard of proof

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

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

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

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

(b) Failure to comply with the Board's order(s) may result in additional sanctions by the Board.

535:1-7-5. Subpoenas

(a) **Issuance; serving.** Subpoenas for the attendance of witnesses, and/or for the furnishing of information required by the Board, and/or for the production of evidence or records of any kind shall be issued by the Director or his designee. Subpoenas shall be served, and a return made in any manner prescribed by Oklahoma Administrative Procedures Act.

(b) **Order to compel.** Upon the failure of any person to obey a subpoena, upon the refusal of any witness to be sworn, or to make an affirmation or to answer a question put to him in the course of a hearing, appropriate judicial proceedings may be instituted under the laws of the State for an order to compel compliance with the subpoena or the giving of testimony. Any scheduled hearing shall proceed, so far as it is possible, but the Board, in its discretion, at any time, may continue the proceeding for such time as may be necessary to secure a final ruling in the judicial proceedings.

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

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

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

(1) The recording of the hearing and the file containing the pleading will be maintained in the Board Office. Such record shall be maintained for such time as to protect the record through judicial review.

(2) A copy of the recording of the hearings shall be provided by the Board at the request of any party to the hearing.

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

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

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

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

535:1-7-7. Final orders

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

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

535:1-7-8. Appeal

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

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

SUBCHAPTER 8. REQUESTS FOR RULE CHANGES

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

- (a) All interested persons may request the Board to promulgate, amend or repeal a rule. Requests are to be made in writing and filed with the Director. Each request shall set forth fully the reasons for its submission; the alleged need or necessity therefor; whether or not the proposal conflicts with any existing rule, and what, if any, statutory provisions are involved.
- (b) Each request to the Board to promulgate, amend or repeal a rule, shall be considered by the Board.
- (c) After consideration of a request to promulgate, amend or repeal a rule the Board may:
- (1) approve the proposed change in compliance with the Oklahoma Administrative Procedures Act; or,
 - (2) determine that the proposal or request is not a necessary rule, amendment or repeal; refuse the same and reflect the decision in the regular minutes of the Board.

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

SUBCHAPTER 9. RULEMAKING HEARINGS

Section

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

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

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

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

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

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

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

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

SUBCHAPTER 11. FEES

Section

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

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

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

535:1-11-4. Other fees

535:1-11-5. Miscellaneous

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

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

- (1) Pharmacist renewal (active or inactive) - \$100
- (2) Senior inactive pharmacist renewal (age 65 or over, retired) - \$20
- (3) Pharmacy license
 - (A) Retail, hospital, non-resident, and remote medication order processing - \$150
 - (B) Charitable clinic - \$ 75
 - (C) Hospital drug room - \$ 40
- (4) Oklahoma licensed pharmacy emergency medication kit placed in an Oklahoma facility remote site [59 O.S. 367.8 (C)] - \$50

- (5) Sterile compounding permit - \$ 75
- (6) Drug supplier permit - \$ 20
- (7) Wholesale distributor permit - \$200
- (8) Repackager license - \$200
- (9) Manufacturer license - \$200
- (10) Medical gas supplier license - \$100
- (11) Medical gas distributor license - \$200
- (12) Outsourcing facility license - \$200
- (13) Third-party logistics provider license - \$200
- (14) Pharmacy technician permit - \$40
- (15) Duplicate renewal receipt, permit, or practical experience certificate:
 - (A) Duplicate for lost, destroyed or damaged original-\$10
 - (B) Duplicate or multiple location copy - \$10

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

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

(a) Pharmacist initial registration fees, as set by the Board, shall be as follows:

- (1) Registration by reciprocity - \$200
- (2) Registration by examination - \$125 + the examination cost
- (3) Registration by score transfer - \$200

(b) Other fees

- (1) Duplicate certificate of registration - \$30
- (2) Pharmacist Reinstatement: Back fees + CE + 15 hours CE penalty + \$100

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

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

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

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

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

535:1-11-4. Other fees

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

(b) Other fees shall be as follows:

- (1) Registrant computer address disk or e-mailed file:
 - (A) Facility (wholesaler, packager, manufacturer) - \$50
 - (B) Pharmacy - \$75
 - (C) Technician - \$100
 - (D) Intern - \$100
 - (E) Pharmacist - \$100
- (2) Photostat copies, per page - \$.25

- (3) Facsimile (Fax) fee, per page - \$1
- (4) Annual subscriptions (7/01 – 6/30 each year)
 - (A) Notification of rulemaking intent - \$18
 - (B) OSBP/NABP Quarterly Voluntary Compliance Newsletter for other than Oklahoma licensed Pharmacists - \$25
 - (C) Board meeting agenda notice - \$18
- (5) Research time, when available (per hour)
 - (A) Staff research time - \$20
 - (B) Computer research time - \$100
- (6) Reproduction of Board meeting recordings, if available;
 - (A) Audio recording, each - \$15
 - (B) Video recording, each - \$15
- (7) Certification of open public record, not certification of grades, \$1.00 per page.
- (8) Certified letters of good standing or licensure verification, \$10
- (c) Board records, which are available and may be obtained from the Board’s website www.pharmacy.ok.gov at no charge.

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

535:1-11-5. Miscellaneous

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

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

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

**SUBCHAPTER 14. SCHEDULED OR CONTROLLED DANGEROUS SUBSTANCES
CLASSIFICATIONS OR EXCLUSIONS**

Section

- 535:1-14-1. Purpose
- 535:1-14-2. Definitions
- 535:1-14-3. Procedure
- 535:1-14-4. Exclusion of Rx Only products not federally scheduled from Oklahoma Controlled dangerous substances scheduling

[Source: Codified 7-1-02]

535:1-14-1. Purpose

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

controlled dangerous substance schedules.

[Source: Amended at 19 Ok Reg 1971, eff 7-1-02]

535:1-14-2. Definitions

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

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

[Source: Amended at 19 Ok Reg 1971, eff 7-1-02]

535:1-14-3. Procedure

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

[Source: Amended at 19 Ok Reg 1971, eff 7-1-02]

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

(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.

[Source: Amended at 19 Ok Reg 1971, eff 7-1-02; Amended at 30 Ok Reg 2009, eff 7-25-13]

SUBCHAPTER 15. DECLARATORY RULINGS

Section

535:1-15-1. Definitions

535:1-15-2. Declaratory rulings

[Source: Codified 6-11-92]

535:1-15-1. Definitions

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

“Declaratory ruling” means an interpretation of a Board’s rule by the Board.

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

535:1-15-2. Declaratory rulings

(a) Any person affected by any of the rules or orders of the Board may request in writing an interpretation or ruling regarding the application of such rules or orders.

(b) Such request shall state fully the facts to which the rule or order may apply, and the particular rule or order about which the question exists.

(c) The request or inquiry will be added to the agenda for the next scheduled Board meeting but may, if necessary, be continued for further consideration to a subsequent meeting.

(d) The Board's interpretation of the rule or order will be furnished in writing to the person making the request within a reasonable time after Board consideration.

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

SUBCHAPTER 17. PILOT PROJECTS

535:1-17-1. Purpose

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

efficient manner.

535:1-17-2. General requirements

(a) These pilot project rules become effective upon the pilot project statute effective date.

(b) A petitioner who wishes the Board to consider a pilot project for approval shall submit to the Board a petition that contains all of the following information:

- (1) The name, address, telephone number, electronic mail address and Oklahoma license number of the pharmacist responsible for overseeing the proposed pilot project.
- (2) The specific location where the proposed pilot project will be conducted. The petitioner shall include the Oklahoma license number of the pharmacy and a statement that the Oklahoma license of the pharmacy and any pharmacist involved with the pilot project is current and is not subject to sanction for violation of federal or state statutes or rules.
- (3) A detailed summary of the proposed pilot project that includes all of the following:
 - (A) The goals and objectives, as applicable, of the proposed pilot project.
 - (B) A full explanation of the proposed pilot project and how the project will be conducted.
 - (C) The initial time frame for the pilot project, including the proposed start date and length of the project, which initial time frame shall not exceed twelve (12) months.
 - (D) All background information and literature review, as applicable, to support the proposed pilot project.
 - (E) If applicable, identification of the rules from which the petitioner is requesting an exception as provided in subsection (c) in order to complete the proposed pilot project and a request for that exception.
 - (F) If applicable, procedures the petitioner will use during the proposed pilot project to ensure that the public's health and safety are not compromised as a result of an exception to a rule being granted under subsection (c).

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

- (1) Expands the definition of the practice of pharmacy.
- (2) Provides for the therapeutic substitution or substitution of medical devices used in patient care.
- (3) Allows a pharmacy or pharmacist to be involved with a pilot project if the pharmacy's or pharmacist's license is not current or is subject to a sanction for a violation of the Pharmacy Act and/or federal or state laws.

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

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

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

under this subsection, the petitioner shall notify patients in the manner required by the Board.

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

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

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

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

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

(i) If determined appropriate by the Board, the specified period of time for conducting a pilot project may be extended for an additional two periods of up to twelve (12) months each. The Board shall not grant an extension that would result in the specified period of time for conducting a pilot project under this section to exceed thirty-six (36) months.

(j) If the Board determines that a pilot project for which an exception to a rule has been granted under subsection (c) should be extended so that rules may be promulgated in order to allow the pilot project to be conducted on a permanent basis, the Board may extend the thirty-six (36) months period of time for conducting a pilot project under subsection (i) for an additional period of up to twelve (12) months in order to promulgate such rules.

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

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

Subchapter	Section
1. General Provisions	535:10-1-1
3. Pharmacists.....	535:10-3-1
5. Interns, Preceptors and Training Areas	535:10-5-1
7. Pharmacist Licensure	535:10-7-1
9. Pharmaceutical Care.....	535:10-9-1
11. Pharmacist Administration of Immunizations	535:10-11-1

[Authority: 59 O.S., §§ 353.7, 353.9, 353.11, 353.16A, 353.18, 353.20, 353.22, 353.24 through 353.26, and 364]

[Source: Codified 12-31-91]

SUBCHAPTER 1. GENERAL PROVISIONS

535:10-1-1. Purpose

(a) The rules of this Chapter regulate the practice of pharmacy by adopting and establishing rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

(b) The rules of this Chapter assure that all applicants for examination and licensure as pharmacists are of good moral character, graduates of an accredited School or College of Pharmacy approved by the Board, and experienced in the practice of pharmacy. These rules further describe the place and manner in which an applicant may receive experience in the practice of pharmacy prior to registration.

(c) The rules of this Chapter include requirements for examination for issuance and renewal of appropriate certificates of registration to all applicants qualified under the provision of 59 O.S. Section 353 et seq.

[Source: Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 33 OK Reg 1775, eff 9-11-16]

SUBCHAPTER 3. PHARMACISTS

Section

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

535:10-3-1.2. Violations of professional conduct

535:10-3-2. Consultant pharmacist

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

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

The rules of professional conduct are as follows:

- (1) **Compliance with laws.** Business conducted as a pharmacist will at all times be in conformity with all federal, state and municipal laws.
- (2) **Substitution.** At no time will a pharmacist substitute or cause to be substituted any drug, medicine, chemical or pharmaceutical preparation without the authority of the prescriber or purchaser.
- (3) **Conduct.** A pharmacist shall conduct himself at all times in a manner which will entitle him to the respect and confidence of the community in which he practices. Evidence of willful untruthfulness in the course of a pharmacist's professional capacity shall presumptively constitute a failure to comply with this standard of professional conduct required of a pharmacist.
- (4) **Unprofessional promotion.** A pharmacist will not lend his support or his name to the promotion or exploitation of objectionable or unworthy products, nor will he participate in any advertising or promotional program which would tend to lower the honor and dignity of his profession.
- (5) **Professional fee.** A pharmacist's fee for professional services will be fair and equitable, and commensurate with his knowledge and skill in the compounding and dispensing of prescriptions, and the rendering of other professional services.
- (6) **Patient Health and Safety and Confidentiality.** The health and safety of patients shall be a pharmacist's first consideration and the nature of their problems or ailments or any confidence entrusted to him in his professional capacity will not be divulged by the pharmacist except in response to legal requirements or in the best interest of the patron.
- (7) **Practice of medicine.** A pharmacist will refrain from any attempt at diagnosis or treatment that might infringe upon the legally constituted right or obligation of any licensed practitioner or mid-level practitioner.
- (8) **Arrangements.** Licensees shall oppose any arrangement inimical to public health. Such an arrangement could include, but is not limited to, an arrangement between a licensee and a prescriber whereby fees are divided or in which private formulas are concerned.
- (9) **Promote profession.** A pharmacist will seek to attract people of good moral character, good habits and high intellect to the profession and share freely of his knowledge and experiences as a further aid to their instruction.
- (10) **Professional services.** A pharmacist will at all times make his professional services available to the allied professions, state and local government agencies and to the office of civilian defense in any project beneficial to public health and the welfare or defense of our country.
- (11) **Governing body.** A pharmacist will recognize the Board as the governing body of the practice of pharmacy in the State of Oklahoma and report to it any violation of pharmacy laws or regulations that may come to his attention.

[Source: Amended and renumbered from 530:10-3-1 at 17 Ok Reg 2618, eff 7-1-00; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 33 OK Reg 1775, eff 9-11-16]

535:10-3-1.2. Violations of professional conduct

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

- (1) The act of violating directly, indirectly, through actions of another, assisting in or abetting the violation of, or conspiring to violate, any provision or term of the Oklahoma Pharmacy Act, 59 O.S. Section 353 et seq., the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, the Prescription Drug Marketing Act (21 U.S.C., Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C., Sec.13 et seq.), and/or federal, state and local laws and rules governing pharmacists or pharmacies.
- (2) Failure to establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.
- (3) Failure to have and follow a written drug diversion detection and prevention policy and procedure.
- (4) Making or filing a report or record which a pharmacist or pharmacy knows or should have known to be false, intentionally or negligently failing to file a report or record required by federal, state or local laws or rules, willfully impeding or obstructing such filing, or inducing another person to violate this rule. Such reports or records include only those which the pharmacist and/or pharmacy are required to make or file in his capacity as a licensed pharmacist or pharmacy.
- (5) Practicing pharmacy without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition.
- (6) Abuse of alcohol or habit-forming drugs, or use of an illegal CDS drug, or a positive drug screen for such illegal substance or its metabolite.
- (7) Knowingly dispensing a prescription drug after the death of a patient.
- (8) Knowingly billing or charging for quantities greater than delivered, or for a brand when a generic or a compounded product is dispensed.
- (9) Submitting fraudulent billing or reports to a third party payor of prescription drugs.
- (10) Refusing to answer reasonable questions or provide information about prescriptions dispensed by the pharmacy when requested by, or for, the patient and which would aid the patient's health in the professional judgement of the pharmacist.
- (11) Not attempting to resolve a possible prescription error; or situation of potential harm to the patient when apparent or should have been apparent to the pharmacist.
- (12) Not attempting to address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that the patient may be dependent or addicted.
- (13) The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.
- (14) The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.
- (15) Discriminating in any manner between patients or groups of patients for reasons of a particular disease, religion, race, creed, color, sex, age or national origin.
- (16) Violating patient confidentiality. This does not prevent pharmacies from providing drug therapy information to prescribers for their patients, nor does it prevent the provision of information as required by law.
- (17) Theft while practicing pharmacy.
- (18) Knowingly dispensing prescription drug refills after the death of a prescriber. (A limited quantity

may be allowed for the patient's health and safety.)

(19) Failure to establish and maintain effective controls to prevent prescription errors.

(20) The prescription error that departs from the standards of care ordinarily exercised by a pharmacist with proof of actual injury not having to be established.

(21) Providing fictitious information, fraud or misrepresentation in applying for or procuring a license, preceptor certificate or permit, or in connection with applying for or procuring periodic re-registration or renewal of the same.

(22) Attempting to cheat or subverting the pharmacist licensure examination, law examination, preceptor examination or any other examination required by the Board.

(23) Allowing a non-pharmacist to perform any of the duties reserved to a pharmacist.

(24) Violation of any voluntary or Board ordered rehabilitation program for the impaired contract, e.g. OPHP contract.

(25) Failure of pharmacist or pharmacy manager (pharmacist in charge) to fulfill the responsibilities as set out in 535:15.

(26) Dispensing outdated prescription drugs.

(27) Failure to cooperate in Board investigations.

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

(29) Auto refilling a prescription without the authorization of the patient or the patient's agent.

[Source: Added at 17 Ok Reg 2618, eff 7-1-00; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 20 Ok Reg 2473, eff 7-11-03; Amended at 21 Ok Reg 2450, eff 7-1-04; Amended at 25 Ok Reg 1974, eff 7-1-08; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 OK Reg 1776, eff 9-11-16; Amended at 38 OK Reg 2439, eff 9-11-21]

535:10-3-2. Consultant pharmacist

(a) A practicing pharmacist may serve as a consultant.

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

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

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

(a) **Certification.** At the time of annual renewal of registration each pharmacist must certify that he has obtained at least 15 clock hours of continuing education credits through satisfactory completion of an accredited program during the previous calendar year (January 1 –December 31).

(b) **Verification forms.** Verification forms of attendance and/or completion of continuing education programs shall be obtained and maintained by the pharmacist.

(c) **Records.** Proof of continuing education will be maintained by the individual pharmacist for a period of two (2) years from renewal date and submitted to the Board only on request.

(d) **Graduate school.** Pharmacists in pharmacy graduate school will be allowed credit for the required fifteen(15) hours continuing education.

(e) **Military personnel.** Military personnel will not be exempt from the continuing education requirement because of the availability of correspondence courses, etc.

(f) **Job credit.** No credit for continuing education will be granted for anything directly connected with a pharmacist's job.

(g) **Journals.** No credit will be allowed for reading, subscribing to or writing articles for various professional and trade journals.

(h) **Meetings.** Requests for approval of credit for individual meetings will be submitted to the Committee on

Continuing Education by the individual pharmacist for review and decision.

(i) **Prior approval.** Prior approval of programs of continuing education shall be obtained by the program sponsor. Each program must be submitted in its entirety, including all materials, in order to be evaluated by the Continuing Education Committee. Continuing education programs sponsored by various drug companies may be acceptable, if the programs are continuing education oriented and not promotional or product oriented.

(j) **Approved programs notice.** Programs approved for credit by the Continuing Education Committee and the Board will be published on the Board's webpage as these programs are approved.

(k) **Colleges of pharmacy.** The two State colleges of pharmacy may review the various continuing education programs and make recommendations to the Continuing Education Committee.

(l) **American Council on Pharmaceutical Education (ACPE).** The Board accepts ACPE approved continuing education (CE) for CE credit.

(m) **Continuing Education Committee.** The Continuing Education Committee will consist of up to six (6) pharmacist members appointed by the Board for a three (3) year minimum term. The committee will meet quarterly or as needed.

(n) **Live Continuing education recommended.** Pharmacists are encouraged to attain three (3) hours or more of live continuing education (CE) each year as part of the fifteen (15) hours required. Live CE is attained in the presence of other pharmacists with a presenter and the possibility of interaction with a peer group. Webinars are considered live CE if the pharmacist can ask questions and get answers from the presenter(s) or the moderator during the webinar.

(o) **Specific Continuing Education requirement.** The Board may, at its discretion, require up to three (3) hours of continuing education on a specific topic. Adequate notice shall be provided to registrants of any specific continuing education when required by the Board.

[Source: Amended at 10 Ok Reg 3167, eff 6-25-93; Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 14 Ok Reg 3020, eff 7-11-97; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 20 Ok Reg 2473, eff 7-11-03; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 OK Reg 1776, eff 9-11-16; Amended at 33 OK Reg 1782, eff 9-11-16; Amended at 39 Ok Reg 2055, eff 9-11-22]

SUBCHAPTER 5. INTERNS, PRECEPTORS AND TRAINING AREAS

Section

535:10-5-1.1. Purpose

535:10-5-1.2. Definitions

535:10-5-1.3. Intern experience requirements

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, 59 O.S. Section 353 et seq. in order to be eligible for licensure as a pharmacist.

(b) These rules allow individuals to work as an intern when they are continuously actively enrolled and participating in a Doctor of Pharmacy program to earn the practical experience required for licensure as a pharmacist.

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

[Source: Added at 17 Ok Reg 2618, eff 7-1-00, Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 OK Reg 1777, eff 9-11-16]

535:10-5-1.2. Definitions

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

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

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

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

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

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

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

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

[Source: Added at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 OK Reg 1777, eff 9-11-16]

535:10-5-1.3. Intern experience requirements

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

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

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

(3) In the case where another state Board of Pharmacy does not track or certify hours earned while

attending that state’s ACPE approved school or college of pharmacy, the applicant may submit the following for review and consideration by the Board:

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

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

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

[Source: Amended and renumbered from 530:10-5-1 at 17 Ok Reg 2618, eff 7-1-00; Amended at 33 OK Reg 1783, eff 9-11-16; Amended at 35 OK Reg 1916, eff 9-14-18]

535:10-5-2. Intern registration

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

(1) Interns shall conspicuously display in their training area the intern license provided by the Board. The intern shall be assumed to be presently practicing as such in the training area, by the Board or its agents, where such certificate is posted.

(2) An intern, to be practicing as such, must abide by the regulations governing same, whether logging hours for credit or not.

[Source: Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 20 Ok Reg 2475, eff 7-11-03; Amended at 33 OK Reg 1778, eff 9-11-16]

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

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

[Source: Added at 20 Ok Reg 2475, eff 7-11-03; Amended at 33 OK Reg 1778, eff 9-11-16]

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

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

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

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

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

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

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

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

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

[Source: Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 27 Ok Reg

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 experiential rotations.

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

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

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

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

[Source: Amended at 11 Ok Reg 543, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 17 Ok Reg 2618, 1-09; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 OK Reg 1778, eff 9-11-16]

535:10-5-4.1. Intern identification requirements

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

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

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

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

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

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

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

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

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

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

[Source: Amended at 11 Ok Reg 543, eff 11-03-93 (emergency); Amended at 11 Ok Reg 3425, eff 6-27-94; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 33 OK Reg 1778, eff 9-11-16]

535:10-5-8. Preceptor requirements

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

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

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

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

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

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

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

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

[Source: Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 15 Ok Reg 3271, eff 7-13-98; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 OK Reg 1779, eff 9-11-16]

535:10-5-9. Training area requirements

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

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

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

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

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

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

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

(7) Training Areas are subject to renewal when their pharmacy license is renewed.

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

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

[Source: Amended at 9 Ok Reg 2135, eff 6-11-92; Amended at 10 Ok Reg 3167, eff 6-25-93; Amended at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 26 Ok Reg 2271, eff 7-1-09; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 OK Reg 1779, eff 9-11-16; Amended at 35 OK Reg 1917, eff 9-14-18]

535:10-5-11. Violations

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

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

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

535:10-5-13. Intern file destruction

(a) An intern file may be destroyed if an intern:

(1) is dropped from a college of pharmacy;

(2) becomes a licensed pharmacist in any state; or transfers by reciprocity or score transfer to another state; or,

(3) license expires.

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

SUBCHAPTER 7. PHARMACIST LICENSURE

Section

535:10-7-1. Purpose

535:10-7-2. Definitions

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

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

535:10-7-6. Reciprocity licensure applicants

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

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

535:10-7-9. Pharmacist renewal

535:10-7-10. Pharmacist reinstatement

535:10-7-1. Purpose

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

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

535:10-7-2. Definitions

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

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

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

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

“NABP” means the National Association of Boards of Pharmacy.

“NAPLEX” means the North American Pharmacist Licensure Examination.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[Source: Added at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 19 Ok Reg 1793, eff 7-1-02; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 OK Reg 1779, eff 9-11-16]

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

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

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

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

(d) All NAPLEX applicants shall meet the requirement for pharmacist licensure in

535:10-7-4, in this Subchapter and Title.

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

535:10-7-6. Reciprocity licensure applicants

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

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

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

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

[Source: Amended and renumbered from 535:10-3-3 at 12 Ok Reg 2589, eff 6-26-95; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2732, eff 7-1-01; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 33 OK Reg 1783, eff 9-11-16]

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

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

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

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

(d) Score transfer applicants shall complete the score transfer process within one year of passing the NAPLEX.

(e) The license issued to a score transfer applicant shall be an original license by examination.

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

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

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

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

- (1) First, submit a copy of applicant's valid NABP FPGEC Certificate to the Board;
- (2) second, apply and be approved for an Oklahoma intern certificate as required by 535:10-5-2; and,
- (3) third, complete 1000 hours of internship in Oklahoma within 12 months of licensure as an Oklahoma intern.

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

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

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

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

- (1) Successfully complete the NABP FPGEC certificate, and submit a copy to the Board;
- (2) Have passed the NAPLEX Examination; and,
- (3) Meet the requirements in 535:10-7-6.

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

535:10-7-9. Pharmacist renewal

- (a) Pharmacist renewal applicants shall meet and maintain the requirements listed in the Oklahoma Pharmacy Act and the rules of this Title.
- (b) The qualifications and requirements for pharmacist renewal applicants shall be the same as those listed in 535:25 and as follows:
- (1) Pharmacist renewal applicants shall possess an Oklahoma pharmacist license
 - (2) Pharmacist renewal applicants shall maintain compliance with the rules of professional conduct and not be involved in violations of the rules of professional conduct.
- (c) Any person who shall make any false representations in procuring or attempting to procure a renewal for himself or for another pharmacist may be deemed ineligible by the Board for any registration or renewal of license, certificate or permit with the Board.
- (d) Any willfully false representations for the same purpose(s) may subject the applicant to felony charges of perjury see 59 O.S. Section 353.25 (B).
- (e) Applicants for pharmacist renewal shall satisfactorily complete and submit a renewal application on a form supplied by the Board together with the fee by the due date.
- (1) Renewal applications received after due date established by the Board shall be subject to the late fee as established in the Board's fee schedule.
 - (2) Renewal applications received after cancellation by the Board shall be subject to reinstatement fees and requirements.
- (f) The Board shall have the right to deny a renewal to any applicant if it determines that the granting of such renewal of license would not be consistent with the public health and safety.

[Source: Added at Ok Reg 2732, eff 7-1-01; Amended at 33 OK Reg 1780, eff 9-11-16]

535:10-7-10. Pharmacist reinstatement

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

[Source: Added at 18 Ok Reg 2732, eff 7-1-01; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 OK Reg 1780, eff 9-11-16]

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

535:10-9-14. Epinephrine

535:10-9-15- Naloxone

[Source: Codified 6-25-93; Added 35 OK Reg 1917, 1918, eff 9-14-18]

535:10-9-1.1. Purpose

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

[Source: Added at 33 OK Reg 1781, eff 9-11-16]

535:10-9-1.2. Prospective drug review

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

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

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

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

[Source: Added at 33 OK Reg 1781, eff 9-11-16]

535:10-9-2. Counseling

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

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

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

- (G) proper storage;
 - (H) prescription refill information;
 - (I) action to be taken in the event of a missed dose; and
 - (J) pharmacist comments on patient's drug therapy.
- (2) The pharmacist shall be responsible to assure that a reasonable effort is made to obtain, record, and maintain patient information generated at the individual pharmacy.
- (A) This information shall include:
 - (i) name, address, telephone number, date of birth or age, and gender;
 - (ii) individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
 - (iii) any additional comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.
 - (B) The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that such offer was accepted and that such counseling was provided;
 - (C) Such information may be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records.
- (3) Alternative forms of information may be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.
- (4) Patient counseling is not required on prescription refill requests, unless deemed appropriate in the pharmacist's professional judgement.
- (5) Patient counseling, as described and defined in this section, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s). Outpatient pharmacies in hospitals are not exempt and counseling will be required for discharged patients exiting the hospital with prescription medication.
- (6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.
- (7) If a pharmacy is routinely filling prescriptions that are being shipped or delivered to patients in another state or if a pharmacy in another state is routinely filling and shipping prescriptions to patients in Oklahoma, the pharmacy will make a reasonable effort to call the patient and counsel by phone. A toll free phone number shall be provided for patients to call and interact with a pharmacist for drug information.

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

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

- (a) Nothing shall restrict licensed interns from performing any and all of the functions in this Subchapter under the supervision of a licensed pharmacist unless otherwise stated in the laws and rules (e.g.: 535:15-5-7.2(g) and 535:10-5-1.2).
- (b) An intern shall not certify a prescription.
- (c) An intern shall not supervise a technician.

[Source: Added at 10 Ok Reg 991, eff 1-27-93 (emergency); Added at 10 Ok Reg 3167, eff 6-25-93; Amended at 22 Ok Reg 2168, eff 7-01-05; Amended at 33 OK Reg 1781, eff 9-11-16]

535:10-9-5. Agreements

- (a) Agreements will be allowed between Oklahoma licensed pharmacists and physicians licensed by the Oklahoma Board of Medical Licensure or the Oklahoma Board of Osteopathic Examiners.
- (b) A copy of the agreement shall be filed in the pharmacy and be available for review by the Board.

(c) The agreement shall not violate any state or federal law.

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

535:10-9-13. Administer

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

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

[Source: Added at 14 Ok Reg 3020, eff 7-11-97; Amended at 33 OK Reg 1781, eff 9-11-16]

535:10-9-14. Epinephrine

a) **Purpose.** The rules in this section implement Title 59 Section 6002 provisions for pharmacists.

b) **Definitions.** The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

1. **“Authorized Entity”**- means any entity or organization at or in connection with allergens capable of causing anaphylaxis may be present, including but not limited to, restaurants, recreation camps, youth sportsleagues, amusement parks, and sports areas.
2. **“Emergency public access station”** or **“EPAS”** means a locked, secure container for the storage of epinephrine auto-injectors under the general oversight of a physician, which allows lay rescuer to consult with a physician in real time by audio, televideo, or other similar means of electronic communication and upon authorization of the consulting physician, may be unlocked to make available the auto-injector.
3. **“Epinephrine auto-injector”** means a single use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

c) A pharmacist may fill a prescription authorized by a prescriber for epinephrine auto-injectors to any authorized entity or organization for storage in an Emergency Public Access Station (EPAS) in accordance with protocols established by the practitioner.

d) The epinephrine must be dispensed, stored, and administered per Section 6002 of Title 59.

[Source: Added 35 OK Reg 1917, eff 9-14-18]

535:10-9-15. Naloxone

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

(b) **Definitions. [RESERVED]**

(c) A Pharmacist may prescribe and dispense Naloxone without a protocol or prescription to any person at risk of experiencing an opioid-related drug overdose, family or friend of an at-risk person, or first responder. Naloxone may only be dispensed by, or under the supervision of, a licensed pharmacist.

[Source: Added 35 OK Reg 1918, eff 9-14-18; Amended at 37 Ok Reg 2041, eff 9-11-20]

SUBCHAPTER 11. PHARMACIST ADMINISTRATION OF IMMUNIZATIONS

Section

535:10-11-1. Purpose

535:10-11-2. Definitions

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

535:10-11-4. Immunization registration

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

535:10-11-6. Records

[Source: Codified 7-11-03]

535:10-11-1. Purpose

(a) The purpose of this Subchapter is to identify standards for the provisions of those acts or services that are necessary for pharmacists to administer immunizations.

(b) The rules in this Subchapter implement a portion of the requirements authorized in 59 O.S. Section 353.30.

[Source: Added at 20 Ok Reg 19 eff 10-16-02 (emergency); Amended at 20 Ok Reg 2473, eff 7-11-03; Amended at 33 OK Reg 1781, eff 9-11-16; Amended at 39 Ok Reg 2055, eff 9-11-22]

535:10-11-2. Definitions

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

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

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

[Source: Added at 20 Ok Reg 19, eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 33 OK Reg 1781, eff 9-11-16]

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

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

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

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

[Source: Added at 20 Ok Reg 19 eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 33 OK Reg 1781, eff 9-11-16; Amended at 39 Ok Reg 2055, eff 9-11-22]

535:10-11-4. Immunization registration

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

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

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

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

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

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

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

[Source: Added at 20 Ok Reg 19 eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 33 OK Reg 1781, eff 9-11-16]

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

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

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

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

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

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

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

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

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

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

[Source: Added at 20 Ok Reg 19 eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 26 Ok Reg 2274, eff 7-1-09]

535:10-11-6. Records

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

- (1) Patient name (Parent name, if patient is a minor)
 - (2) Address of patient
 - (3) Prescribing licensed practitioner or pharmacist
 - (4) Immunization order
 - (5) Name, Manufacturer, Lot no., Expiration Date
 - (6) Date for continued dose regimen if required
- (b) Such records must be readily available for inspection in the pharmacy.
- (c) Records or reports will be sent to the State Health Department, if required.
- (d) Report of immunization to prescribing licensed practitioner, if requested.

[Source: Added at 20 Ok Reg 19 eff 10-16-02 (emergency); Added at 20 Ok Reg 2473, eff 7-11-03; Amended at 24 Ok Reg 2254, eff 7-1-07; Amended at 33 OK Reg 1782, eff 9-11-16; Amended at 39 Ok Reg 2055, eff 9-11-22]

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

Section

535:12-1-1. Purpose

535:12-1-2. Definitions

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

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

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

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

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

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

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

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

535:12-1-11. Labeling

535:12-1-12. Violations

[Authority: Title 59 O.S. Section 367.1 through 367.7]

[Source: Codified 7-01-05]

535:12-1-1. Purpose

(a) The rules of this Chapter describe a statewide program to take unused prescription drugs from nursing homes, assisted living centers; and donated drugs from pharmaceutical manufacturers and utilize them for dispensing to medically indigent Oklahoma residents as authorized under Title 59 O.S. Section 367.1 through 367.7, et seq., the Utilization of Unused Prescription Medication Act.

(b) The rules of this Chapter describe the eligibility to donate. They describe the eligible prescription drug formulary, the eligible recipients, and the protections for participants. They describe pharmacies eligible to accept and dispense such drugs, the requirements for eligible pharmacies, and the responsibilities for

pharmacist managers.

(c) The rules of this Chapter describe safe handling of medications to protect drug integrity, tracking, sanitation, security and dispensing requirements for these unused prescription drugs. The rules of this Subchapter describe confidentiality requirements as well as violations.

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

535:12-1-2. Definitions

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

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

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

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

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

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

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

“Manifest” means an invoice used to list drugs being transferred or destroyed.

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

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

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

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

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

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

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

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

- (A) An application for participation shall be completed by the consultant pharmacist of the ALC and submitted to the Board.
- (B) Only those ALC’s that maintain prescription drugs under the control of licensed healthcare professionals in sanitary and secure conditions in a manner similar to the OSDH rules for nursing home drug control may be approved.
- (C) Such application must show adequate controls exist in ordering, storage, security, etc.
- (D) Application must be reviewed and approved by OSBP with the advice of the Oklahoma State Health Department.

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

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

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

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

(1) Patient has died; or,

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

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

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

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

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

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

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

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

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

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

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

(C) Drugs can be identified, and

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

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

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

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

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

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

(C) Expiration date of the EPD;

(D) Number of tablets or capsules or volume if liquid or injectable; and

(5) A copy of this manifest shall be provided to the pharmacy and a copy shall be maintained by the nursing home or ALC for two years;

(6) Assure controlled dangerous substances (CDS), also known as Scheduled drugs, are not transferred but handled as required under state and federal law;

(7) Assure that the selected pharmacy is eligible to receive unused prescription medications under these rules; and,

(8) Notify the eligible pharmacy when the drugs are ready to be picked up. The transportation of the unused drugs shall be the responsibility of the eligible receiving pharmacy. Such eligible pharmacy shall pick up donated drugs in an expedient manner.

(c) The consultant pharmacist and Director of Nursing [D.O.N.] (or designee) of the Nursing Home will initiate a manifest of the unused prescription drugs to be sent to the eligible pharmacy as described in (b)(4)

and (5) above. They will be responsible for determining that the patient has authorized the donation of the drugs.

(d) The consultant pharmacist and the D.O.N. shall assure the name of the patient, name of the pharmacy, and directions on the label will be redacted with black ink or removed before sending to the eligible receiving pharmacy to protect confidentiality.

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

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

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

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

(b) Compounded drugs shall not be eligible for transfer.

(c) Cancer Drugs as approved by the Board and American Cancer Society representatives.

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) All eligible pharmacies prior to beginning or terminating participation shall send written notice to the Board. A list of these eligible pharmacies will be posted on the Board website.

(c) The Board will request input and consult with the Oklahoma State Health Department regarding rules for City-County Health Department pharmacies.

(d) The Board will request input and consult with the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS) regarding rules for ODMHSAS pharmacies.

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

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

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

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

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

- (1) See expiration dating requirements in labeling 535:12-1-11.
- (2) The removal of the medication from the bingo card (UDP) may only be done by the dispensing pharmacy's licensed pharmacist or permitted pharmacy technician.
- (3) Samples must remain in original package as required under federal law, and cannot be removed from original packaging for dispensing.

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

- (1) May limit the number of prescriptions per patient per visit or per month, to allow a greater number of individuals access to such prescription drugs.
- (2) When established, this should be a written policy that is enforced equally to prevent discrimination.

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

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

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

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

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

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

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

- (1) Coordinate retrieval of donated unused prescription drugs from nursing homes and eligible ALC.

Such retrieval shall be in an expedient manner;

- (2) Check unused prescription drugs (UPD) against the manifest and resolve any discrepancy;
- (3) Store and secure these UPD as required under state and federal law and rules;
- (4) Check the unused prescription drugs for adulteration;
- (5) Assure expired, adulterated, lost identity drugs are not dispensed;
- (6) Assure such unacceptable drugs are not put in dispensing stock. Destroy such unacceptable drugs within 14 days as described in 535:12-1-10 (a) (8).
- (7) Assure safety in drug recalls. If a drug is recalled and the eligible pharmacy does not have the lot number on the label to differentiate between the recall and non-recalled, all such donated recalled drug shall be destroyed.
- (8) Assure destruction of expired, adulterated, and/or recalled unused prescription medications.
 - (A) A manifest shall be made of unused prescription drugs expired, adulterated and/or recalled to be destroyed.
 - (B) Following destruction such manifest shall be signed by the pharmacist manager and witness verifying such destruction.
 - (C) Drug destruction manifest shall be kept in the files of the pharmacy for two (2) years.

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

535:12-1-11. Labeling

- (a) All previous patient or pharmacy labeling on an unused prescription drug will be redacted or removed by dispensing eligible pharmacy.
- (b) Dispensed prescription for a medically indigent patient will clearly indicate the final dispensing pharmacy and the current patient information to assure clarity for receiving patient and shall be properly labeled.
- (c) Expiration date is required on all unused prescription drugs dispensed.
 - (1) The expiration date is brought forward to the filled prescription if only one expiration date is used in the filling of the prescription.
 - (2) If multiple packages of unused prescription drugs are used to fill a single prescription with varied expiration dates, the shortest expiration date is used for the dispensed prescription.

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

535:12-1-12. Violations

- (a) Theft or diversion of any of the unused prescription drugs is a violation of these rules. This includes any expired, lost identity drug, recalled drug, or other drug found to be unusable under the requirements of this Subchapter.
 - (1) Such violation by a licensed nursing home or licensed Assisted Living Center of these rules will be referred to the Oklahoma State Health Department and/or other proper authorities for possible action.
 - (2) Such violation by the Oklahoma Department of Mental Health and Substance Abuse Services facility of these rules will be reported to the Oklahoma Department of Mental Health and Substance Abuse Services and/or other proper authorities for possible action.
 - (3) Such violation by a registrant of the Board may result in action under Title 59 O.S. Section 353.26.
- (b) Dispensing of expired unused prescription drugs is a violation of these rules.
- (c) Sale, trade, offer for sale or trade (except transfer as allowed in 535:12-1-9 (d) between licensed eligible pharmacies) any of the drugs obtained pursuant to this Subchapter and shall include any expired, lost identity, recalled or other such drug unacceptable for dispensing that comes into the program shall be a violation of

these rules.

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

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

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

CHAPTER 13. EMERGENCY/ DISASTER PRESCRIPTION DRUG RULES

Section

535:13-1-1. Purpose

535:13-1-3. Declaration of emergency

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

[Authority: Title 59 O.S. Section 353.7, 353.13, 353.13A, 353.16A, 353.17, 353.18, 353.20, 353.22, 353.24-353.26, 353.29 and 354.]

[Source: Codified 7-01-07]

535:13-1-1. Purpose

(a) The rules of this chapter define what procedures pharmacies, pharmacists, medical gas suppliers, and medical gas distributors may use to accommodate patient medication needs in the event of an emergency / disaster situation which disrupts the normal prescription drug distribution channels.

(b) The rules of this chapter will maintain controls to protect public health while allowing emergency actions to accommodate patient medication needs during such emergencies or disasters.

[Source: Added at 24 Ok Reg 2256, eff 7-01-07; Amended at 30 Ok Reg 2009, eff 7-25-13]

535:13-1-3. Declaration of emergency

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

[Source: Added at 24 Ok Reg 2256, eff 7-01-07; Amended at 30 Ok Reg 2009, eff 7-25-13]

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

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

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

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

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

(b) If a patient from the area affected by the emergency / disaster requests refills of controlled dangerous substance (CDS), the pharmacist should make an attempt to contact the original prescriber for authorization to dispense refills.

(c) If the pharmacist is unable to contact the prescriber regarding a CDS prescription, then they must check with the federal Drug Enforcement Agency (DEA) and Oklahoma Bureau of Narcotics (OBN) to see if they have approved an emergency dispensing of CDS for patients affected by the emergency / disaster.

(1) If the federal DEA and OBN approve dispensing CDS in an emergency or disaster situation; and, if in the pharmacist’s professional judgment the dispensing of the medication is essential to the patient’s health and safety, the pharmacist may dispense up to the allowed limit set by DEA and OBN not to exceed a ten (10) day supply of CDS medication.

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

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

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

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

CHAPTER 15. PHARMACIES

Subchapter	Section
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17. Nuclear Pharmacy	535:15-17-1

[Authority: 59 O.S., §§ 353.7, 353.9A, 353.13, 353.13A, 353.16A, 353.17, 353.18, 353.20, 353.22, 353.24-353.26, 353.29, and 354]

[Source: Codified 12-31-91]

SUBCHAPTER 1. GENERAL PROVISIONS

535:15-1-1. Purpose

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

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

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

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

(e) Compliance with the rules of this Chapter is the responsibility of both the pharmacy and pharmacy

manager, and in some cases, the pharmacist working in the pharmacy.

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

SUBCHAPTER 3. PHARMACIES

Section

535:15-3-1.1. Definitions

535:15-3-2. Pharmacy responsibilities

535:15-3-2.1. Shared Services

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

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

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

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

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

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

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

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, O.S. Section 2-101 et seq.

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

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

535:15-3-2. Pharmacy responsibilities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(h) **Remodel.** The pharmacy and the PIC are responsible to notify the Board in writing in advance of any remodel in the pharmacy that would result in a change in square footage, ~~plumbing~~, or additional storage areas. Such pharmacy shall be subject to inspection by the Board and shall be required to pay an 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 the closing of a pharmacy. The notification shall include, but not be limited to:

(1) Date of closing,

(2) Copy of final CDS inventory,

(3) Disposition of pharmacy records,

(4) Disposition of prescription drugs, and

(5) Return of pharmacy license.

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

[Source: Added at 17 Ok Reg 2626, eff 7-1-00; Amended at 17 Ok Reg 2618, eff 7-1-00; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 19 Ok Reg 1796, eff 7-1-02; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1882, eff 9-11-17; Added at 35 OK Reg 1919, eff 9-14-18; Amended at 37 OK Reg 2042, eff 9-11-20]; Amended at 38 OK Reg 2442, eff 9-11-21]

535:15-3-2.1. Shared Services.

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

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

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

(1) Have the same owner, or

(2) Have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy statutes and rules; and,

(3) Share a common electronic file or technology that allows access to information necessary or required to perform shared services in conformance with the pharmacy act and the State Board of Pharmacy

regulations.

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

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

[Source: Amended at 38 OK Reg 2443, eff 9-11-21]

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

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

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

The following are physical requirements for pharmacies:

- (1) **Size.** The prescription department shall occupy no less than 125 square feet and shall be in a commercial location and not in a personal dwelling or residence.
- (2) **Sanitary facilities.** There shall be installed the proper sanitary facilities which shall include a sink with hot (minimum 104 degrees F) and cold running water separate from the restroom facilities.
- (3) **Balances.** There shall be one set of prescription balances with capacity from 1/10 grain to at least one (1) ounce. If the pharmacy proves to the Board that the practice of pharmacy at this particular site does not require weighing of drugs and/or ingredients, an exception may be made by the Executive Director of the Board to the balances requirement.
- (4) **Library.** There shall be the necessary library which has been prescribed and standardized by the Board in Section 535:15-3-6.
- (5) **Refrigeration.** There shall be sufficient refrigeration facilities to store all necessary biologicals, injectables, suppositories and other products requiring refrigeration. This refrigerator shall be entirely separate from the storage of any food products in open packages.
- (6) **Exempt narcotic book.** There shall be a book suitable for the registration of all sales of exempt narcotics if such are sold or dispensed.
- (7) **Poison Book.** There shall be a book suitable for the registration of all sales of poisons in accordance with applicable laws if such are sold or dispensed.
- (8) **Filing.** There shall be a system of filing for all prescriptions which shall be kept for a period of not less than five (5) years.
- (9) **Containers.** There shall be sufficient stock of containers suitable for the dispensing of all prescriptions both for internal and external usage.
- (10) **Labels.** There shall be sufficient stock of labels both for the dispensing of prescriptions and the sale of medicines and chemicals. Label requirements are described in the Act.
- (11) **E-Prescribing of Controlled Substances (EPCS).** Any pharmacy that dispenses controlled

dangerous substances shall have computer software that supports EPCS by January 1, 2019.

[Source: Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Added at 35 OK Reg 1920, eff 9-14-18]; Amended at 38 OK Reg 2443, eff 9-11-21]

535:15-3-4.1. Pharmacy licensing requirement

(a) Every pharmacy conducting intrastate transactions in Oklahoma shall be licensed as required under 59 O.S. Section 353.18(A). Every pharmacy shall also be licensed as required by 59 O.S. Section 353.18(A) if Oklahoma is the state from which or into which it delivers, distributes, or dispenses or offers to sell, sale, deliver, distribute, or dispense dangerous drugs, medicines, chemicals or poisons for the treatment or prevention of diseases, excluding agricultural chemicals and drugs.

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

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

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

(a) Minimum required information for licensure shall be that information required by 59 O.S. Section 353.18(A) and the rules in 535:25-3.

(b) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g.: manager, contact person, phone, etc.)

(c) Changes of location, name, or ownership shall require a new license.

(d) Each location and/or pharmacy shall require a license.

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

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

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

(1) **Separate area.** The prescription room shall be separated from other departments of the store by a floor to ceiling partition which shall be a secure partition, secured by lock from other departments of the store.

(2) **Space.** No prescription department shall occupy less than 125 square feet of space, all of which must be contiguous and on the same floor level.

(3) **Responsibility.** The prescription department or pharmacy will be under the direction and in the charge of a registered pharmacist or assistant pharmacist at all times the department is open for business.

(4) **Minimum hours.** The hours of said department shall be a minimum of forty (40) hours per week five (5) days per week, excluding holidays.

(5) **Posting of hours.** The business hours of the prescription department shall be plainly posted on all entrances to such department and no unregistered personnel will have access to this department either before or after these hours.

(6) **Equipment.** The equipment of such pharmacy departments shall be the same as specified in the regular application for pharmacy license contained in 535:15-3-4.

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

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

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

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

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

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

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

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

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

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

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

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

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

“This drug store closed by order of the Oklahoma State Board of Pharmacy for (violation stated) which is a direct violation of (pharmacy law section)”[Source: Amended at 32 Ok Reg 1229, eff 8-27-15]

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

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

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

- (1) make application and receive an annual non-resident pharmacy license at a fee set by the Board;
- (2) maintain in good standing a pharmacy license in its resident state;
- (3) comply with the Oklahoma Secretary of State requirements for conducting business in this state.
- (4) submit on initial licensure and on renewals a written report of an inspection conducted within the previous twenty-four (24) months by the non-resident’s state or by any organization approved by the

Board;

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

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

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

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

(1) The pharmacist manager (also called pharmacist-in-charge (PIC)) and all other pharmacists performing pharmacist-only functions in Oklahoma licensed non-resident pharmacies must be currently licensed in the state in which the non-resident pharmacy is located. The PIC must also be licensed by the Oklahoma Board.

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

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

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

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

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

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

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

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

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

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

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

(h) Written drug diversion detection and prevention. The pharmacy and the pharmacy manager shall implement and follow a written drug diversion detection and prevention policy and procedure. This policy

and procedure shall be available for Board review.

(i) Pharmacy refrigerator and freezer temperature logs.

- (1) All refrigerators and freezers used to store medications shall have a sensor or thermometer capable of reading internal temperatures.
- (2) The internal temperatures maintained in the refrigerators and freezers shall be appropriate for the products stored.
- (3) Temperatures in refrigerators and freezers shall be logged twice daily (AM and PM) on days the pharmacy is open for business or shall have continuous temperature monitoring.
 - (A) Pharmacy name, date, time, temperature, and staff person taking reading shall be logged at a minimum for paper logs.
 - (B) Temperature logs shall be maintained on paper or electronically for two years and be available for inspection.
- (4) If there is a temperature reading that falls outside of appropriate ranges, a notation must be made on the temperature log detailing the corrective measures which were taken.
- (5) It is the PIC's responsibility to review the temperature readings to ensure compliance with appropriate storage temperatures.

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

1. No prescription shipped to a citizen of Oklahoma should have a temperature excursion that exceeds the temperature storage conditions outlined in the package insert or by the manufacturer of the drug product.
2. A pharmacy or pharmacist shall refuse to deliver by mail or common carrier a prescription drug which, in the professional opinion of the pharmacy or pharmacist, may be therapeutically compromised by delivery by mail or common carrier.
3. A mail order or non-resident pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 13 Ok Reg 2807, eff 6-27-96; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1231, eff 8-27-15; Amended at 35 OK Reg 1920, eff 9-14-18; Amended at 37 Ok Reg, 2043, eff 9-11-20]; Amended at 38 OK Reg 2444, eff 9-11-21; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-3-10. Inventory

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

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

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

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

[Source: Added at Ok Reg 2593, eff 6-26-95; Amended at 26 Ok Reg 2274, eff 7-1-09; Added at 35 OK Reg 1921, eff 9-14-18]; Amended at 38 OK Reg 2445, eff 9-11-21]

535:15-3-11. Prescription drugs

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

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

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

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

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

- (1) Insulin and any devices or supplies necessary for the administration of insulin;
- (2) Glucometers and any devices or supplies necessary for the operation of the glucometer;
- (3) Rescue inhalers and any devices utilized that are necessary for the administration of a rescue inhaler;
- (4) Inhalers for chronic asthma and chronic obstructive pulmonary disease (COPD) and any devices or supplies necessary for administration;
- (5) Medication for nebulizers that treat acute and chronic pulmonary conditions and any devices necessary for administration; or
- (6) Ophthalmic products for topical treatment of chronic conditions.
- (7) No CDS medications can be dispensed pursuant to 353.20.2 (C) (4).
- (8) A form will be posted on the Board website for the Pharmacist to complete to document attempts to obtain refill authorization from the prescriber by the patient and by the pharmacist. This completed form shall be maintained in the pharmacy and be available for inspection.

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 37 Ok Reg 2044, eff 9-11-20]

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

- (1) No prescription shipped to a citizen of Oklahoma should have a temperature excursion that exceeds the temperature storage conditions outlined within the package insert or by the manufacturer of the drug product.
- (2) A pharmacy or pharmacist shall refuse to deliver by mail or common carrier a prescription drug which, in the professional opinion of the pharmacy or pharmacist may be therapeutically compromised by delivery by mail or common carrier.
- (3) A mail order or non-resident pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy.

[Source: Added at 38 OK Reg 2445, eff 9-11-21]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) the date of the transfer; and

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

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

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

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

- (i) the date of the original prescription (refills are allowed only as prescribed for a one-year maximum from original prescription date on non-scheduled, as stated in 535:15-3-11 (b) et seq. and up to five refills for no more than six months on Schedule III-V, as stated in 475:30-1-11 (a));
- (ii) the original prescription number and the number of refills authorized on the original prescription drug order;
- (iii) the number of valid refills remaining and the date of last refill;
- (iv) the name and address of the pharmacy from which such prescription information is transferred;
- (v) the last name and registration number of the pharmacist transferring the prescription drug order information; and,

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

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

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

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

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 14 Ok Reg 3024, eff 7-1-97; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 19 Ok Reg 1796, eff 7-1-02; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 30 Ok Reg 2010, eff 7-25-13; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2446, eff 9-11-21]

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

(a) Two or more pharmacies that have established and use a common electronic file 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) In the electronic transfer file system the pharmacist shall be able to void the original prescription and identify the pharmacy and pharmacist taking the prescription refill information.
- (3) The original pharmacy shall be notified electronically of the transfer.
- (4) The rules in 535:15-3-12 (1), (3) and (5)(B),(i),(ii), (iii) apply to electronic transfers.

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

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

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

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

in attendance.

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

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

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

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

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

535:15-3-14. Patient records

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

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

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

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

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

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

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

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

(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, and the time and date of transmission.

(c) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of a prescription drug order transmitted consistent with federal, state and local laws and rules.

(d) All equipment for receipt of prescription drug orders shall be maintained so as to ensure against unauthorized access.

(e) Prescriptions may be transferred if all requirements of federal, state and local laws and rules are met.

(f) No agreement between a prescribing practitioner and a pharmacy or device and medical equipment holder shall require that prescription orders be transmitted from the prescribing practitioner to only that pharmacy or device or medical equipment permit holder.

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

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

(a) Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an unsafe manner they shall take action to correct the problem.

(b) In order to ensure adequate staffing levels a staffing report form shall be available in each pharmacy. A copy of this form, when executed, will be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection.

(1) Such form shall include, but not be limited to the following:

(A) Date and time the inadequate staffing occurred;

(B) Number of prescriptions filled during this time frame;

(C) Summary of events; and

(D) Any comments or suggestions.

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

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

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

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

(B) excessive workload;

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

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

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

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

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

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

535:15-3-17. Pharmacy prescription records

- (a) The original prescription [as defined in 353.1] shall be maintained and readily retrievable for five years.
- (b) Faxed prescriptions received in electronic format (which have not been printed) or electronically transmitted prescriptions may be electronically stored and maintained in a readily retrievable format for five years.
- (c) Prescriptions for controlled dangerous substances (CDS) must additionally meet the requirements of the federal Drug Enforcement Administration (DEA) and the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBND).

[Source: Added at 12 Ok Reg 3024, eff 7-11-97; Amended at 17 Ok Reg 2626, eff 7-1 00; Amended at 29 Ok Reg 1641, eff 7-12-12; Amended at 34 Ok Reg 1883, eff 9-11-17]

[Note: DEA does not consider a faxed prescription to be an electronically transmitted prescription. Faxed prescriptions for CDS must be printed and maintained as original printed prescriptions.]

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

- (a) All prescription purchases (e.g. invoices, etc.) and inventory records shall be maintained and be readily retrievable for a period of at least 2 years. Invoices for non-controlled drugs may be maintained electronically.
- (b) A pharmacist and/or pharmacy shall exercise careful professional judgment regarding where they purchase the pharmacy's drugs to assure a safe and sanitary drug supply is maintained. Prescription drug purchases may only be made from entities licensed to sell such drugs.

[Source: Reserved at 14 Ok Reg 3024, eff 7-1-97; Added at 24 Ok Reg 2260, eff 7-1 07; Amended at 33 OK Reg 1784, eff 9-11-16]

535:15-3-19. Three prescription files

Three prescriptions files will be kept as follows:

- (1) Dangerous Drugs file,
- (2) Controlled Dangerous Substances (CDS) - Schedule II's file, and
- (3) Controlled Dangerous Substances (CDS) - Schedule III's, IV's, V's file.

[Source: Added at 12 Ok Reg 3024, eff 7-11-97]

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

(a) Dangerous drugs.

- (1) Refills may be entered on the back of each original prescription.
- (2) Refill records may be kept by using an automated data processing system to maintain the refill information.

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

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

(d) **CDS automated data processing method.** A pharmacy may elect to use an automated data processing system to maintain the prescription files including the original information and the refill information.

Caution: The pharmacy must maintain complete and retrievable prescription records for five years whether logbooks, nightly reports, or a manual system are used. If the pharmacy elects the automated system certain compliance reports are required.

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

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

- (B) Schedule III, IV and V reports will include the same information as in (A) above, except patient and prescriber addresses are not required. These reports may be mixed or be Schedule III, IV or V specific.
 - (C) These nightly reports shall be verified, signed and dated by the pharmacist as required. (See CFR 1306.22 (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 provided in 535:15-3-21, the pharmacy may choose to use the following method:
- (A) The pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such refill dispensing shall sign a statement (in the manner described in CFR 1306.22) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by them and is correct as shown.
 - (B) Such a book or file must be maintained at the pharmacy employing such a system for a period of five years after the date of dispensing the appropriately authorized refill.
- (3) **Refill reports.** Any pharmacy using an automated data processing system to track refills shall be able to print such reports as required in CFR 1306.22 et seq.
- (4) **Audit reports.** If an automated data processing system is used to maintain refill information, the ability to print upon request the following Controlled Dangerous Substance (CDS) audit reports is required. The following required audit reports must include the information in ASAP/NABP Committee on Standardization's Computerized Compliance Reports:
- (A) CDS Audit Report by Drug
 - (B) CDS Audit Report by Prescriber
 - (C) CDS Audit Report by Pharmacist
 - (D) Patient Profile Report

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

- (a) All refrigerators and freezers used to store medications shall have a sensor or thermometer capable of reading internal temperatures.
- (b) The internal temperatures maintained in the refrigerators and freezers shall be appropriate for the products stored.
- (c) Temperatures in refrigerators and freezers shall be logged twice daily (AM and PM) on days the pharmacy is open for business or shall have continuous temperature monitoring.
 - (1) Pharmacy name, date, time, temperature and staff person taking reading shall be logged at a minimum for paper logs.
 - (2) Temperature logs shall be maintained on paper or electronically for two years and be available for inspection.
- (d) If there is a temperature reading that falls outside of appropriate ranges, a notation must be made on the temperature log detailing the corrective measures which were taken.
- (e) It is the PIC's responsibility to review the temperature readings to ensure compliance with appropriate storage temperatures.

[Source: Added at 14 Ok Reg 3024, eff 7-1-97; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 37 Ok Reg 2041, eff 9-11-20; Added at 37 Ok Reg 2045, eff 9-11-20]

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

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

- b) This allows verification of compliance with the law, the State Board of Pharmacy regulations, and such other standards as may be appropriate to insure that the health, safety and welfare of patients serviced by the pharmacy.
- c) Any discrepancies or deficiencies noted at inspection shall be corrected.

[Source: added at 38 OK Reg 2447, eff 9-11-21]

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

Section

535:15-4-1. Purpose

535:15-4-2. Definitions

535:15-4-3. Registration

535:15-4-4. Staffing requirements

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

535:15-4-6. Governing body

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

535:15-4-1. Purpose

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

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

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

535:15-4-2. Definitions

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

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

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

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

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

processing the medication order from a remote site.

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

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

535:15-4-3. Registration

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

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

535:15-4-4. Staffing requirements

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

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

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

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

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

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

- (A) Complying with federal and state laws and regulations;
- (B) Establish and maintain minimum technical standards and specifications, e.g. RMOP processes, passwords, encryption and firewalls;
- (C) Establish and maintain procedures for handling computer system or connectivity downtime;
- (D) Establish and maintain confidentiality, privacy, and security to meet HIPAA standards;
- (E) Establish and maintain pharmacist training, orientation and competencies;
- (F) Establish and maintain workload balancing and staffing levels e.g. when will RMOP be triggered and how will workload or staff balancing be done;
- (G) Establish and maintain access to either hard-copy or online references as described in 535:15-5-9 (1) (B) and 535:15-5-9 (1) (C);
- (H) Establish and maintain hospital staff training and orientation to the remote medication order process;
- (I) Establish and maintain a process that documents issues or problems which includes issue escalation and problem resolution to resolve such;
- (J) Establish and maintain on-call assistance and communication between the hospital and remote site personnel;
- (K) Establish and maintain internal quality assurance and medication error reporting systems;
- (L) Clarification of medication orders;
- (M) Establish and maintain access to Hospital policy resources, policies and procedures;

- (N) Establish and maintain records and reports; and,
 - (O) Establish and maintain annual review of the remote medication order processing and documentation.
- (2) **General responsibility.** The remote medication order processing pharmacy and PIC shall be responsible for the provision of services to the hospital(s), including but not limited to establishing and maintaining:
- (A) Establishing and scheduling appropriate RMOP pharmacy staffing levels;
 - (B) Performance of RMOP duties which include establishing and maintaining:
 - (i) Review of the patient's profile;
 - (ii) Clarification of medication orders;
 - (iii) Reporting of potential drug interactions or allergies;
 - (iv) Order entry and/or order review;
 - (v) Monitoring of clinical information, lab values, or dosing issues; and
 - (vi) Provision of drug information to the pharmacist(s) performing remote medication order entry, by establishing and maintaining access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).
 - (C) Submitting required reports, required by hospital, by procedures manual and by law or rule;
 - (D) Quality assurance and performance improvement of the RMOP service;
- (3) **Confidentiality.** The remote medication order processing pharmacy and PIC shall have responsibility for establishing policies and procedures for the security and integrity of any patient information, confidential and non-confidential and must abide by all applicable state and federal laws and rules. In addition, the following must be met:
- (A) Pharmacists performing remote medication order processing entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1.1(6) and 535:10-3-1.2(a)(16); and,
 - (B) The hospital shall insure that the remote pharmacist shall have individual pharmacist-specific secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the hospital pharmacy is open.
- (4) **Record keeping.**
- (A) The remote medication order processing pharmacy shall ensure that records of any and all orders processed for the hospital are maintained for a minimum of two (2) years, and such records shall be readily available for inspection, copying by, or production of upon request by the Board, its designee, or a representative of the Board upon request, including, but not limited to:
 - (i) Medication orders reviewed or verified by the remote pharmacist;
 - (ii) Interventions communicated by the remote pharmacist;
 - (iii) Requests for clinical or other additional information communicated by the remote pharmacist;
 - (iv) Name or other unique identifier of the remote pharmacist involved in the processing of the RMOP order.
 - (B) The records required in Section 535:15-4-5(4)(A) above may be kept at either the remote medication order processing pharmacy or the hospital so long as the records are maintained and readily available.

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

[Source: Added at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2447, eff 9-11-21]

535:15-4-6. Governing body

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

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

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

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

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

SUBCHAPTER 5. HOSPITAL PHARMACIES

Section

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- 535:15-5-18. Drug rooms
- 535:15-5-19. Remote medication order processing (RMOP)

[Source: Amended at 27 Ok Reg 2256, eff 7-11-2010]

535:15-5-1. Purpose

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

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

535:15-5-2. Definitions

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

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

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

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

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

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

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

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

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

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

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

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

Board.

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

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

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

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

[Source: Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 20 Ok Reg 2479, eff 1-1-04; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15, Amended at 34 Ok Reg 1883, eff 9-11-17; Amended at 37 Ok Reg 2045, eff 9-11-20]

535:15-5-3. Applicability

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

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

535:15-5-4. Registration

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

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

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

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

(a) Each hospital pharmacy shall be directed by a pharmacist hereinafter referred to as the Director of Pharmacy. The Director of Pharmacy shall be responsible for all activities of the hospital pharmacy, and for meeting the requirements of the Oklahoma Pharmacy Act and the rules of this Title.

(b) A hospital pharmacy manager's responsibilities are the same as those set out in Section 535:15-3-2 and the rules of this Subchapter.

(c) When the Director of Pharmacy and the pharmacy manager are separate individuals and the pharmacy manager is under the direction of the Director of Pharmacy, both individuals will be cited when action is taken against the pharmacy and/or the pharmacy manager.

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

535:15-5-7. Supportive personnel

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

other rules of this Title.

[Source: Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-24-03; Amended at 21 Ok Reg 2454, eff 7-1-04]

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

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

(b) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job training (OJT) program as described in 535:15-13-13.

(c) The Director of Pharmacy must demonstrate that the pharmacy technician has been given additional training before being allowed to prepare sterile products and that the training given is at a level consistent with the scope of pharmaceutical product being prepared.

(d) A pharmacy technician, to be eligible for a technician permit, must comply with the requirements in this Title and 535:25.

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

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

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

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

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

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

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

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

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

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

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

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

Auxiliary supportive personnel may perform the following tasks:

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

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

535:15-5-7.4. Pharmacy technician tasks

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

- (1) Any tasks auxiliary supportive personnel are allowed to perform;
- (2) Count and/or pour medications;
- (3) Affix prescription label to the final container;
- (4) Affix auxiliary labels to the container as directed by the pharmacist;
- (5) Assist the pharmacist in the management of the controlled dangerous substance (CDS) inventory. The pharmacist remains responsible for completeness and accuracy;
- (6) Fill “Modified unit dose distribution systems”, “Automated dispensing systems” and/or “Unit dose distributions systems”;
- (7) Prepackage and label multi-dose and unit-dose packages of medication as directed by pharmacist-established procedures for such, including selection of containers, labels and lot numbers, with provisions for the pharmacist to check the finished task prior to dispensing to the patient. (While a pharmacy technician may package and label the drug, the certification is the responsibility of the pharmacist.)
- (8) Perform bulk reconstitution of prefabricated non-injectable medication utilizing a pharmacist established procedure for the bulk reconstitution of prefabricated noninjectable medications.
- (9) Perform bulk compounding, including such items as sterile bulk solutions for small-volume injectables, sterile irrigation solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for other departments of the hospital facility. Such intermediate and large scale compounding may be done by a pharmacy technician through the use of a procedural manual and a system of in-process and final checks and controls developed or approved by the pharmacist and which are carefully and systematically enforced.
- (10) Technician training and requirements for technician participation in non-sterile compounding is described in 535:15-10-3 (a) - (h).
- (11) Technician training and requirements for technician participation in sterile compounding is described in 535:15-10-52 (a) - (h).
- (12) Prepare sterile compounded preparations utilizing a policy and procedure that addresses the verification of the pharmaceutical constituents, the prepared label and the final product by the pharmacist following documented training and demonstrated competency as required in OAC 535:15-10-52(d).
- (13) Record patient or medication information for later validation by the pharmacist pursuant to procedures which prevent the information from being utilized in any way until it is validated by the pharmacist. Exempt from the necessity of pharmacist validation shall be records, such as financial, inventory control, etc., which can in no way affect the safety and accuracy of medication administration to patients.
- (14) Select prepackaged and pre-labeled doses of medication from storage areas and place and transport to the patient area such doses in containers bearing a patient's name in a unit dose distribution system or a modified unit dose distribution system if the pharmacist personally checks and verifies by signature or initial all patient medication before it is administered to the patient.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 OkReg 1229, eff 8-27-15; Amended at 35 OK Reg 1921, eff 9-14-18; Amended at 37 Ok Reg 2046, eff 9-11-20]; Amended at 38 OK Reg 2448, eff 9-11-21]

535:15-5-7.5. Prohibited duties

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

personnel:

- (1) Final interpretation of the prescriber's original order.
- (2) Performance of the prospective drug utilization review and determination of action to be taken when there is an indication of a drug interaction.
- (3) Receipt of new phone-in prescriptions from prescribers or their agents.
- (4) Determination of product selection if substitution is requested or approved.
- (5) Certification of the completed prescription or medication order for accuracy and completeness before dispensing from the pharmacy department.
- (6) Provision of patient counseling or drug information as necessary.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2984, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

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

- (a) Annual permit requirements for pharmacy technicians are set forth in this Title, in 535:15-13-8 and in 535:25.
- (b) No pharmacy technician permit shall be issued or continued for an applicant or permit holder who fails to meet and maintain the requirements in 535:25-3 and 535:25-7 or who violates the rules in 535:25-9.
- (c) A pharmacy technician must be employed in a licensed pharmacy located in Oklahoma to be eligible to renew their pharmacy technician permit.

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

535:15-5-7.7. Permit display

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

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

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

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

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

535:15-5-7.9. Multiple employment locations

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

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

535:15-5-7.10. Work schedule display

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

[Source: Added at 18 Ok Reg 27]

535:15-5-7.11. Technician training

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

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

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

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

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

535:15-5-8. Absence of pharmacist

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

- (1) **Night cabinets.** IF NIGHT CABINETS ARE USED THE FOLLOWING SHOULD

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

- (A) such drugs available therein are properly labeled;
- (B) only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;
- (C) whenever access to such cabinet(s) shall have been gained, written physician's orders and proofs of use, if applicable, are provided; and,
- (D) proper inventories and a complete review of all activity concerning such cabinet(s) are conducted no less than once per month.

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

- (A) a record of the removal of any drug from the pharmacy by an authorized nurse on a suitable form showing patient name, room number, name of drug, strength, amount, date, time and signature of nurse; and,
- (B) such form shall be left with the container from which the drug was removed, both placed conspicuously so that it will be found by a pharmacist and checked properly and promptly.

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

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

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

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

- (A) For sterile compounded preparations a hospital must comply with 535:15-10 Part 3.
- (B) A library shall be maintained which includes four of the following current references (not more than 2 years old or most recent). Current electronic sources may be substituted for two hard copy information sources:
 - (i) Drug interactions;
 - (ii) Drug compatibility;
 - (iii) Poison and antidote information;
 - (iv) Toxicology;

- (v) Pharmacology;
- (vi) Bacteriology;
- (vii) Patient counseling;
- (viii) Rational therapy;
- (ix) Dispensing information; and,
- (x) Available U.S.P. standards

(C) The library shall include the latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy and a recent copy of Oklahoma State Bureau of Narcotics & Dangerous Drugs Control Rules.

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

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

(4) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked and inspected on a regular schedule of at least monthly as directed by the Director of Pharmacy.

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

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

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

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

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

The Director shall be responsible for, at a minimum, the following:

- (1) Preparing and sterilizing sterile compounded preparations prepared within the hospital facility.
- (2) Admixing sterile compounded preparations, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of sterile compounded preparations is not accomplished within the hospital pharmacy.
- (3) Preparing drug products including unit dose.
- (4) Establishing specifications for procurement of all materials, including drugs, chemicals and biologicals used within pharmacy practice, subject to approval of the appropriate committee of the hospital facility.
- (5) Participating in the development and maintenance of a formulary for use within the hospital facility.

- (6) Filling and dispensing all drugs which are to be administered within the hospital facility.
- (7) Maintaining and making available a sufficient inventory of pharmaceuticals, including antidotes and other emergency drugs, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.
- (8) Maintaining records of all transactions of the hospital pharmacy required by applicable local, state, and federal law, and necessary to maintain accurate control and accountability for all pharmaceutical materials.
- (9) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to pharmaceutical material utilization and effectiveness.
- (10) Cooperating fully with teaching and/or research programs in the hospital facility, if any.
- (11) Implementing the policies and decisions of the appropriate committees of the hospital, which deal with drug distribution and drug utilization.
- (12) Meeting all inspection and other requirements of the Act, and the rules and regulations governing the practice of pharmacy within a hospital facility.
- (13) Establishing guidelines for the safe and effective distribution of drugs intended for floor stock, and their subsequent administration.
- (14) Initial and continuing training of pharmacy technicians.

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

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

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

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

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

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

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

(h) **Drug recall procedures.** The Director of Pharmacy shall develop and implement a written recall

procedure that can be readily activated which assures that drugs involved, inside or outside of the facility, are returned to the pharmacy for proper disposition. All actions taken in this area are to be properly documented and maintained for 36 months for Board review.

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

- (1) Adverse drug reaction reports.
- (2) Floor stock inventories of night cabinets and emergency boxes.
- (3) Inventory listing of the pharmacy.
- (4) Controlled substance inventory.
- (5) Ethyl alcohol inventory.
- (6) Pharmacy and therapeutic committee minutes.
- (7) Reports and records as required by law and/or rules.
- (8) Outpatient prescriptions shall contain all information required by pharmacy law and rule.

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

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

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

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

535:15-5-10.1. Labeling

Hospital pharmacies shall label drugs in the following manner:

- (1) **For use inside the hospital facility.** All drugs dispensed by a hospital pharmacy to any department of the hospital system, intended for use within the facility, shall be adequately labeled.
- (2) **For use outside the hospital facility.** All drugs dispensed by a hospital pharmacy whose patients are about to be discharged, or patients that receive emergency treatment, or to whom it is certain will take the drug dispensed outside of the facility, shall be labeled with the following information:
 - (A) Name and address of the hospital pharmacy,
 - (B) Date and identifying serial number,

- (C) Name of the patient,
- (D) Directions for use to the patient,
- (E) Name of the prescriber,
- (F) Initials of the dispensing pharmacist,
- (G) Required precautionary information regarding controlled substances,
- (H) Such other accessory or cautionary information as may be required or desirable for proper use and safety to the patient, and
- (I) The name of the drug, its strength, and the number of units dispensed.

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

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

535:15-5-10.2. Medication orders

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

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

(A) **Authorization.** The appropriate hospital committee shall designate the prescribers authorized to issue orders for hospital patients.

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

(2) Orders for drugs for outpatients shall be considered prescriptions and must fulfill all of the requirements of a prescription identified within the Pharmacy Practice Act of the State of Oklahoma and the rules of this Title.

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

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

(a) Written policies and procedures of the Department of Pharmacy shall reflect the scope of non-distributive roles carried out by the pharmacists of the institution and be readily available for inspection by the Board.

(b) These policies shall include a description of the credentials and certifications required of pharmacists by the appropriate hospital committees.

(c) These policies shall include the process for pharmacist credentialing and/or certifying and must comply with state and federal regulation.

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

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

(a) General provisions. Drugs shall be administered at a hospital facility in accordance with the policies and procedures of that facility.

(b) Self-administration. Self-administration of drugs by patients shall be permitted only when specifically authorized by the prescribing physician, provided a pharmacist or physician has identified the drugs.

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

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

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

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

(b) Emergency sources of medications. Procedures shall be made, in writing, for the hospital facility to obtain emergency items from a neighboring facility, retail pharmacy, or other source of pharmaceuticals. (Unit dose packaging is recommended).

(c) Medications from home. Whenever patients bring drugs into a hospital facility, such drugs shall not be administered unless they can be precisely identified and the physician has specifically indicated on the patient chart that the patient is to take their own medication.

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

535:15-5-14. Performance improvement

(a) **Purpose.** As a part of the hospital or health system's performance improvement program, the quality and appropriateness of patient care services provided by the Department of Pharmacy shall be monitored and evaluated through a planned and systematic approach to improving performance.

(b) **Responsibility.** The Director of Pharmacy is responsible for assuring that the process described in this Section is implemented to assure safe use of drugs for good patient outcomes.

- (1) The Board recommends the Director of Pharmacy serve as a voting member of the hospital wide Performance Improvement Committee.
- (2) The Board recommends the Director of Pharmacy assume a leadership role within the hospital or health system for the medication-use process performance improvement (including dispensing, administration, monitoring, prescribing, and education) across the continuum of care.
- (3) The Director of Pharmacy shall work in collaboration with patients, prescribers, nurses, and other health care providers in improving the medication use process.

(c) **Measurement.** The pharmacy department shall have a systematic process in place to collect data and measure performance related to the medication-use process.

(d) **Assessment.** The Pharmacy Department shall assess data to identify ways to improve the medication-use process.

(e) **Performance improvement.** The Pharmacy Department shall monitor, achieve and sustain improved performance in the medication-use process towards safe drug use with good patient medication-use outcomes.

(f) **Documentation.** The process described in (a) through (e) of this Section is recorded and documented in a manner consistent with the facility's overall performance improvement program.

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

535:15-5-15. Investigational drugs

(a) Use within hospital. Policies and procedures of the Department of Pharmacy shall reflect the use of investigational drugs within the hospital facility. The Director of Pharmacy shall maintain a list of investigational drug protocols and agents being used in the hospital readily available for review by the Board.

(b) Approval for use. The appropriate committee of the hospital shall approve all investigational drugs for use within a hospital.

(c) Labeling and administration. All investigational drugs shall be labeled in accordance with this Chapter with the drug's investigational status identified on the label. In addition, the individual responsible for the administration of the drug must be provided with complete information regarding its use.

(d) Storage. Investigational drugs shall be stored in an area separated from approved pharmaceuticals and shall have the capacity to be locked and secured.

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

535:15-5-16. Monthly inspections

The Director of Pharmacy, or his appropriate designee, shall conduct an inspection of all areas of the hospital on at least a monthly basis. This inspection shall include, but not be limited to, the following (see 535:15-5-10 for additional requirements):

- (1) Drugs for internal use are stored separately from drugs and disinfectants for external use.
- (2) Drugs requiring special storage conditions to insure their stability are properly stored.
- (3) No outdated drugs are stocked in the facility.
- (4) Distribution, administration, and wastage of controlled substances are properly and adequately documented and reported.
- (5) Emergency drugs, designated pursuant to 535:15-5-8, are adequate and in proper supply.
- (6) All necessary and required security and storage standards are met.
- (7) Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
- (8) Policies and procedures of the Department of Pharmacy of the hospital facility are followed.

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

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

- a) The Board's qualified designee shall inspect all aspects of the management and operation of all hospital pharmacies in the State of Oklahoma.
- b) This allows verification of compliance with the law, the State Board of Pharmacy regulations, and such other standards as may be appropriate to insure the health, safety and welfare of patients of the facility serviced by the hospital pharmacy
- c) Any discrepancies or deficiencies noted at inspection shall be corrected.

[Source: Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2449, eff 9-11-21]

535:15-5-18. Drug rooms

- (a) A drug room, as defined in 535:15-5-2, shall comply with all federal, state and local rules for drug rooms.
- (b) At a minimum there shall be a consultant pharmacist on duty as required by the rules of the Oklahoma State Department of Health.
- (c) The drugs dispensed from a drug room shall be for administration only to patients in the facility hospital.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2479, eff 1-1-04]

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

- a) Hospitals, the pharmacist manager and the director of pharmacy at the hospital that allow remote medication order processing shall establish and maintain policies and procedures related to remote medication order processing.
 - (1) Such registrants remain responsible to assure the hospital pharmacy meets requirements under Oklahoma laws and rules.
 - (2) Such registrants shall be responsible to assure RMOP, if used, is reviewed at least annually and

that proper credentialing, review and that oversight is established, maintained and exercised.

- b) Prior to implementation of RMOP services, training shall be provided by the hospital, and the relevant portions of the hospital pharmacy's policy and procedure manual shall be established and maintained on RMOP; and such shall be reviewed by the Pharmacist providing RMOP entry services at least annually.
- c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:
 - (1) Pharmacists performing RMOP entry must be licensed by the Board.
 - (2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1.1(6) and 535:10-3-1.2(a)(16)).
 - (3) The hospital shall ensure the pharmacist performing remote medication order processing has individual, pharmacist-specific access to the hospital pharmacy's patient information system and to other electronic systems that on-site pharmacists have access to during the hours of operation of the hospital pharmacy.
- (d) The hospital will make available to the pharmacist(s) performing RMOP entry, access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).
- (e) The hospital's computer system shall have the ability to audit the activities of each pharmacist(s) remotely processing the RMOP orders.
- (f) A hospital pharmacy may allow RMOP for the patient population served under the hospital's pharmacy license by a pharmacist employed by the same licensed hospital pharmacy. Remote medication order processing performed for patients served under a different hospital pharmacy licensure requires a contractual arrangement fulfilling the responsibilities as outlined in 535:15-4-5.
- (g) All Pharmacists who engage in RMOP shall ensure the following minimum information technology standards and specifications are met and maintained at the remote site:
 - (1) Availability of internet, phone, and scan or fax access to the hospital.
 - (2) Ability to access the hospital facility via the hospital's information system.
 - (3) To the extent possible, have redundant systems in place to ensure remote medication order processing service availability (e.g. internet connectivity, other information systems used to facilitate remote medication order processing).
 - (4) Have secure electronic access to the hospital's patient information system and to all other electronicsystems 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

Section

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[Source: Codified 1-1-04]

535:15-6-1. Purpose

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

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-2. Definitions

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

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

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

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

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

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

"Remote medication order processing" or **"RMOP"** means the processing of a medication order for a

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

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

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2256, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-3. Registration

(a) All Oklahoma hospital drug rooms shall be licensed annually with the Board of Pharmacy at a fee set by the Board.

(b) A hospital drug room license shall be issued only to those drug rooms that satisfy and maintain compliance with the provisions of Title 59 O.S. Section 353.18 (a), OAC Title 535, 535:25 for rules regarding registrants, and the rules of this Subchapter.

(c) Each drug room, in order to obtain and maintain a hospital drug room license shall have an Oklahoma D.Ph. as the PIC.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-4. Staffing requirements

(a) The PIC shall be assisted by a sufficient number of additional pharmacists (D.Ph.s) to operate such a drug room competently, safely and adequately to meet the needs of the patients of the hospital facility.

(b) Each hospital drug room shall have oversight by a PIC who shall be responsible for certifying that the drug room meets the requirements of the Oklahoma Pharmacy Act and the rules of this Title. The PIC shall notify the Board, in writing, within 10 days of any change of employment.

(c) A drug room supervisor must be assigned as designated in the rules of the Oklahoma Department of Health under OAC 310:667-21-2(c) et seq.

(1) Designation of the drug room supervisor must be reported to the Board, in writing, on the Hospital Drug Room initial application and on each subsequent renewal application.

(2) Written notice of change of drug room supervisor must be provided to the Board within 10 days of the change.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

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

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

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

responsibility.

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

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

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

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

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

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

(B) No more than 5 visits in any one month count toward the 52 visit total for the year.

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

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

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

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

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

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

(1) The training duties of the PIC are:

(A) Competency training regarding preparation and sterilization of sterile compounded preparations prepared by appropriate hospital staff;

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

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

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

(ii) Such responsibilities for confidentiality shall be as set forth in 535:10-3-1.1(6) and 535:10-3-1.2(a)(16) and the rules of this Title.

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

(2) Repackaging drug products including unit dose.

- (3) Establishing procedures for procurement of all medicines used within the hospital system subject to approval of the medical and professional staff.
- (4) Participating in the development and maintenance of a formulary for use within the hospital system.
- (5) Maintaining and making available a sufficient inventory of medicines including antidotes and other emergency drugs approved by the medical and professional staff, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.
- (6) Maintaining oversight of the records of all transactions of the drug room required by applicable local, state, and federal law, and necessary to maintain accurate control and accountability for all medications.
- (7) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to medicine utilization and effectiveness.
- (8) Cooperating fully with teaching and/or research programs in the hospital facility, if any.
- (9) Implementing the policies and decisions of the appropriate committees of the medical and professional staff that deal with drug distribution.
- (10) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and those rules and regulations governing the practice of pharmacy within a hospital facility.
- (11) Establishing guidelines for the safe and effective distribution of medicines intended for floor stock, and their subsequent administration.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 37 Ok Reg 2047, eff 9-11-20]

535:15-6-6. Physical and library requirements

A hospital drug room shall have sufficient facilities to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this Chapter.

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

(A) For compounded sterile preparations:

(i) If a laminar hood is used, a hospital drug room shall comply with 535:15-9-6 and 535:15-9-10, 1 through 5.

(ii) If a laminar hood is not used, a closed system for parenteral admixtures should be utilized. If sterile compounding must be done, an area must be designated for that activity. This area must be at least a counter used for only this purpose and be away from patient care areas. Acceptable aseptic techniques shall be used.

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

hard copy information sources:

- (i) Drug interactions;
- (ii) Drug compatibility;
- (iii) Poison and antidote information;
- (iv) Toxicology;
- (v) Pharmacology;
- (vi) Microbiology;
- (vii) Patient counseling;
- (viii) Rational therapy;

- (ix) Dispensing information; and,
- (x) Applicable USP standards

(C) The library shall include the latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy and a recent copy of Oklahoma State Bureau of Narcotics & Dangerous Drugs Control Rules.

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

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

(4) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked.

(5) **Security.** All areas occupied by a hospital drug room shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 22 Ok Reg 2172, eff 7-1-05; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

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

(b) **Responsibility.** The PIC shall be responsible for the safe and efficient distribution, control, and accountability of drugs, see 535:15-6-5.

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

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

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

(A) Name and address of the hospital facility,

(B) Date and identifying number,

(C) Name of the patient,

(D) Directions for use to the patient,

(E) Name of the prescriber,

(F) Initials of the dispenser,

(G) Required precautionary information regarding controlled substances,

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

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

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

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

to the drug room for proper disposition.

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

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

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

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

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

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

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

(h) **Records and reports.** The PIC shall develop a mechanism for maintaining and submitting as appropriate, such records and reports as are required to insure patient health, safety, and welfare. These should include the following:

(6) Adverse drug reaction reports,

(7) Floor stock inventories of night cabinets and emergency boxes,

(8) Drug list or formulary of the hospital drug room as required by state health department rules,

(9) Controlled substance inventory,

(10) Ethyl alcohol inventory,

(11) Pharmacy and therapeutics committee minutes; and

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

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2449, eff 9-11-21]

535:15-6-8. Emergency dispensing and pre-packaged medications

(a) **Emergency dispensing.** A pharmacist or licensed practitioner on duty may label and dispense an appropriate supply of a medication from the hospital drug room when ordered by a prescriber for a patient of the hospital to take with them when dismissed. An appropriate supply would include only sufficient doses required from the time of dismissal until resumption of normal business hours of local pharmacies.

(b) **Pre-packaged medications.** A pharmacist may pre-package medications in sufficient amounts to meet the immediate needs of patients of the hospital. The pre-dispensed medications must be labeled and packaged properly as required under sub-section 535:15-6-7 (c) Labeling, excepting items B, C, D, and E, and adding the medication expiration date and lot number. Such pre-packaged medications shall be securely stored, and an accurate accounting of their use shall be kept.

(1) When such medications are ordered by prescriber, to be used after dismissal from the hospital, the prescriber [with dispensing privileges] shall complete the medication label with the appropriate information including the patient's name, the prescriber's name, appropriate directions for use, the date

the medication is distributed to the patient, and an identifying number.

(2) The prescriber who orders the medication shall be responsible for appropriate patient counseling and drug information dissemination.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1884, eff 9-11-17]

535:15-6-9 Emergency room pre-packaged medications formulary

(a) Each hospital drug room may choose the medicines to be included in their emergency room (ER) pre-packaged medications formulary within the requirements and limits listed below. This formulary shall be included within the policies and procedures of the hospital drug room. These pre-packaged medications shall be administered only as allowed in 535:15-6-8 for a maximum of a 72-hour supply.

(b) Type of Medication defined or parameters for choice [Limits]

(1) Controlled Dangerous Substances (CDS):

(A) Codeine/acetaminophen combination [one]

(B) Tramadol [one]

(C) Codeine containing antitussive preparation [one]

(2) ACE inhibitor: per ER formulary [two]

(3) Anti-nausea: per ER formulary [two]

(4) Anti-viral: per ER formulary [two]

(5) Anti-coagulant: per ER formulary [two]

(6) Antihistamine: per ER formulary [two]

(7) Anti-hypertensive: per ER formulary [three]

(8) Antimicrobial: per ER formulary [unlimited]

(9) Asthma: per ER formulary [one]

(10) Beta blocker: per ER formulary [two]

(11) Diuretic: per ER formulary [two]

(12) Ear: antibiotic/steroid or antibiotic/ steroid/pain combination

(13) Eye: antibiotic or antibiotic/steroid combination

(14) Miscellaneous:

(A) terbutaline

(B) oral contrast media

(15) Muscle relaxant: per ER formulary [two non-CDS]

(16) Pain: per ER formulary [two non-CDS]

(17) Proton pump inhibitor per ER formulary [one]

(18) Steroid: per ER formulary [three]

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 29 Ok Reg 1641, eff 7-12-12; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-10. Access to drugs in absence of PIC or drug room supervisor

(a) **Absence of the PIC or the drug room supervisor.** Advance arrangements shall be made for provision of drugs to the medical staff and other authorized personnel of the hospital facility by use of night cabinets and in emergency circumstances, by access to the drug room by authorized personnel during such times as the drug room may be unattended.

(b) **Night cabinets.** IF NIGHT CABINETS ARE USED THE FOLLOWING SHOULD PREVAIL:

(1) In the absence of a pharmacist (D.Ph.), a supply of controlled dangerous substances may be kept in locked cabinet(s) or other enclosure(s) constructed and located outside of the hospital drug room area, to which only specifically authorized personnel may obtain access by key or combination, and

which is sufficiently secure to deny access to an unauthorized person by force or otherwise.

(2) The PIC shall, in conjunction with the appropriate committee of the hospital facility, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(A) Such drugs, available therein, are properly labeled;

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

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

(D) A method of documenting responsibility for the key(s) at all times, and their transfer from one authorized person to another, is established;

(E) All drugs therein are monitored weekly, and discrepancies are reported in the PIC's report.

(F) A complete review of all activity concerning such cabinet(s) is conducted no less than once per month; and,

(G) Written policies and procedures are established to implement the requirements of this paragraph.

(c) **Access to drug room.** Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the drug room in accordance with the requirements of this paragraph.

(1) One supervisory registered professional nurse and only one in any given shift is responsible for removing drugs from the hospital drug room. The responsible nurse may, in time of emergency, delegate this duty to another nurse.

(2) The responsible nurse shall, prior to being permitted to obtain access to the drug room, be designated by position in writing by the appropriate committee of the hospital facility; and shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required from the PIC.

(3) Such education and training shall be given by the PIC.

(4) The PIC shall require, at a minimum, the following records and procedures:

(A) The removal of any drug from the hospital drug room by an authorized licensed nurse must be recorded on a suitable record showing patient name, room number, name of drug, strength, amount, date, time and signature of nurse; and

(B) The drug room supervisor or the pharmacist shall properly and promptly check such record.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-11. Administration of drugs to patients

(a) **General provisions.** Drugs shall be administered at a hospital facility in accordance with the policies and procedures of that facility.

(b) **Self-Administration.** Self-administration of drugs by patients shall be permitted per hospital policy only when specifically authorized by the prescriber per hospital policy, provided the drugs to be self-administered have been identified by a licensed pharmacist or prescriber.

(c) **Administration only.** The drugs supplied or provided from a drug room shall be for administration only to patients of the hospital. No drugs may be provided to employees nor to individuals who are not patients of the hospital.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 26 Ok Reg 2274, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-12. Medication from other sources

(a) **Drugs from outside sources.** Whenever drugs or pharmaceutical services are obtained from outside of

the hospital facility on a regular basis, arrangements shall be made to insure that such outside pharmacists provide their services in a manner that assures the safety of the patients and properly serves the need of the hospital drug room. Such arrangements shall be made in writing and shall at a minimum specify that:

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

(b) **Emergency sources of medications.** Procedures shall be made, in writing, for the hospital facility to obtain emergency medications from a neighboring facility, retail pharmacy, or other source of drugs. (Unit dose packaging is recommended.)

(c) **Medications from home.** Whenever patients bring drugs into a hospital facility, such drugs shall not be administered unless they can be precisely identified and the prescriber has specifically indicated on the patient chart that the patient is to receive their own medications.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-13. Investigational drugs

(a) **Use within hospital.** Policies and procedures of the drug room shall reflect the use of investigational drugs within the hospital facility.

(b) **Approval for use.** The appropriate committee of the hospital shall approve all investigational drugs for use within a hospital.

(c) **Labeling and administration information.** All investigational drugs shall be labeled in accordance with this Subchapter with the drug's investigational status identified on the label. In addition, the individual responsible for the administration of the drug must be provided with complete information regarding its use.

(d) **Storage.** Investigational drugs shall be stored in an area separated from approved pharmaceuticals and shall be secured.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-14. Drug storage stock inspections

(a) The PIC or his appropriate designee shall conduct an inspection of all drug storage areas within the hospital on at least a monthly basis.

(b) This monthly drug storage area stock inspection shall verify at least the following (see 535:15-6-5 (a) for additional requirements):

- (1) Drugs for internal use are stored separately from drugs and disinfectants for external use.
- (2) Drugs requiring special storage conditions to insure their stability are properly stored.
- (3) No outdated drugs are stocked in the facility and are removed from the facility not more than 6 months after the expiration date.
- (4) Distribution and administration of controlled substances are properly and adequately documented and reported.
- (5) Emergency drugs are adequate and in proper supply.
- (6) All necessary and required security and storage standards are met.
- (7) Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
- (8) Policies and procedures of the hospital drug room are followed.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-15. Non-distributive roles of pharmacists

The policies and procedures of the hospital drug room shall reflect the scope of non-distributive roles carried out by the pharmacist of the hospital system.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-6-16. Performance improvement

(a) **Purpose.** As a part of the hospital or health system's performance improvement program, the quality and appropriateness of patient care services provided by the drug room shall be monitored and evaluated through a planned and systematic approach to improving performance.

(b) **Responsibility.** The PIC is responsible for assuring that the process described in this section is implemented to assure safe use of drugs for good patient outcomes.

(1) The Board recommends the PIC serve as a voting member of the hospital wide Performance Improvement Committee.

(2) The Board recommends the PIC assume a leadership role within the hospital or health system for the medication-use process performance improvement (including dispensing, administration, monitoring, prescribing, and education) across the continuum of care.

(3) The PIC shall work in collaboration with patients, prescribers, nurses, and other health care providers in improving the medication use process.

(c) **Measurement.** The drug room shall have a systematic process in place to collect data and measure performance related to the medication-use process.

(d) **Assessment.** The drug room shall assess data to identify ways to improve the medication-use process.

(e) **Performance improvement.** The drug room shall achieve and sustain improved performance in the medication-use process.

(f) **Documentation.** The process described in (a) through (e) of this Section is recorded and documented in a manner consistent with the facility's overall performance improvement plan.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

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

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

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

[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2450, eff 9-11-21]

535:15-6-18. Drug room training area

(a) A licensed hospital drug room may apply for a training area certificate after meeting the requirement in 535:10-5 and 535:25.

(b) If approved by the Board, such training area certificate enables the drug room to serve as a licensed training area so long as a qualified pharmacist preceptor is present and supervising each intern working in the drug room, as required in 535:10-5.

(c) Each drug room training area, pharmacist preceptor and intern shall meet requirements in 535:10-5.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-19. Violations

(a) Unlawful acts are described in the Oklahoma Pharmacy Act.

(b) Hospital drug room rules of conduct, violations of rules of conduct, and rules for all applicants are found

in 535:25.

(c) Rules of conduct and violations of rules of conduct for PIC are found in 535:10-3.

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

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

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

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

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

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

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

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

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

(2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1.1(6) and 535:10-3-1.2(a)(16).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUBCHAPTER 7. DRUG SUPPLIER PERMITS

Section

535:15-7-1. Definitions

535:15-7-2. Drug supplier requirements

535:15-7-3. Drug supplier restriction

535:15-7-1. Definitions

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

“**Drug supplier**” means a licensed retail pharmacy which supplies legend drugs to licensed prescribers for their office administration and/or which supplies legend drugs to hospitals and other licensed pharmacies for their dispensing.

“**Legend drugs**” means including, but not limited to, drugs, medicines, poisons, and/or chemicals (as defined in 59 O.S., Section 353 et seq.) which bear the legend “Caution: Federal Law Prohibits Dispensing Without Prescription” or “RX Only”, or any other label FDA may require which restricts drugs to dispensing with a practitioner's prescription.

[Source: Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-7-2. Drug supplier requirements

(a) Permit eligibility. In order to obtain and maintain a drug supplier permit, the applicant must have a valid retail pharmacy license

(b) Total annual sales. The total annual sales of the drug supplier shall not exceed five percent (5%) of the total annual sales of the pharmacy.

(c) Records. Separate records of sales will be kept on file by the pharmacy. The files will include, but not be limited to, invoices of sales with name and address of purchaser, quantity sold, drug description, price, and date of transaction. These files must be readily available for inspection.

(d) Controlled Dangerous Substances. Sales of controlled dangerous substances must conform with statutes and regulations of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, the Federal Drug Enforcement Administration and/or any other federal, state or municipal laws, ordinances or regulations.

535:15-7-3. Drug supplier restriction

(a) Retail pharmacies shall not sell or otherwise supply or provide dangerous substances, prescription drugs,

controlled dangerous substances, or a compounded preparation to a wholesaler, manufacturer or repackager, outsourcing facility or logistics provider. Return of a drug to the wholesaler from whom it was purchased is allowed.

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

[Source: Added at 32 Ok Reg 1229, eff 8-27-15; Amended at 33 OK Reg 1784, eff 9-11-16]; Amended at 38 OK Reg 2450, eff 9-11-21]

SUBCHAPTER 9. STERILE COMPOUNDED PREPARATIONS PHARMACY PERMITS

Section

535:15-9-1. Scope and purpose

535:15-9-2. Definitions

535:15-9-3. Sterile compounding preparation permit requirements

535:15-9-4. Permit issuance

535:15-9-5. Policy and procedure manual

535:15-9-6. Pharmacy sterile compounding physical requirements

535:15-9-7. Manager

535:15-9-8. Pharmacist accessibility

535:15-9-9. Drug distribution and control

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

535:15-9-11. Quality assurance

535:15-9-12. Pharmacist manager responsibility

535:15-9-1. Scope and purpose

The rules of this Subchapter provide standards for the preparation, labeling, and distribution of sterile compounded preparations by licensed retail pharmacies, pursuant to an order or prescription. These standards are intended to apply to all sterile compounded preparations, notwithstanding the location of the patient.

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

535:15-9-2. Definitions

The definitions of this Subchapter shall be the same as those defined in 535:15-10-51, as well as the following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

“Sterile preparation pharmacy” means a licensed retail pharmacy with an additional specialized board-approved sterile preparation permit to allow the compounding and dispensing of sterile preparations by an Oklahoma licensed pharmacist pursuant to a prescription order.

“Sterile preparations” means sterile compounded preparations and may include nutrition and/or hazardous or antineoplastic agents and/or sterile irrigation solutions and/or sterile solutions for nebulization and/or sterile eye drops, which are free from living micro-organisms (aseptic) and for parenteral preparations pyrogen and endotoxin free as well.

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

535:15-9-3. Sterile compounding preparation permit requirements

The following are required to obtain and maintain a sterile compounding preparation pharmacy permit:

- (1) **Valid retail license.** The applicant must have a valid retail or non-resident pharmacy license
- (2) **Equipment and supplies.** The pharmacy must have the required equipment and supplies pursuant to the rules and regulations of the Oklahoma Board regarding sterile compounding preparation pharmacy permits.
- (3) **Manager.** The pharmacy manager of the sterile compounding preparation pharmacy will have

sufficient knowledge, education and/or experience in the practice of sterile compounding preparation pharmacy.

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

535:15-9-4. Permit issuance

(a) **Required permit.** A sterile compounding preparation pharmacy permit will be required of all pharmacies compounding sterile preparations.

(b) **Fee.** The sterile compounding preparation permit fee will be set by the Board.

(c) **Renewal.** The sterile compounding preparation pharmacy permit will be renewed annually with the retail or non-resident pharmacy license.

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

535:15-9-5. Policy and procedure manual

(a) **Availability.** To obtain a sterile compounding preparation pharmacy permit, a policy and procedure manual as it relates to sterile preparations and services that are provided shall be available for inspection at the pharmacy location.

(b) **Review.** The policy and procedure manual shall be reviewed and/or revised on an annual basis. A copy of the policy and procedure manual shall be available for inspection and submitted to the Board upon request by the Board.

(c) **Pre-approval by Board.** The Board may choose to pre-approve all policy and procedure manuals prior to inspection of the sterile preparation pharmacy area.

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

535:15-9-6. Pharmacy sterile compounding physical requirements

(a) Pharmacies and personnel who engage in sterile compounding are responsible for complying with State Board of Pharmacy regulations.

(b) **Reference materials.**

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

- (A) Handbook of Injectable Drugs
- (B) King's Guide to Parenteral Admixtures
- (C) MicroMedex
- (D) Lexicomp
- (E) Applicable USP standards

(2) Electronic versions are acceptable.

[Source: Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 14 Ok Reg 3024, eff 7-1-97; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2450, eff 9-11-21]

535:15-9-7. Manager

Each sterile compounding preparations pharmacy shall be managed by a pharmacist who is licensed to practice pharmacy in the State of Oklahoma, and who is knowledgeable in the specialized functions of compounding, preparing and dispensing sterile preparations, including the principles of aseptic technique and quality assurance. This knowledge may be obtained through residency training programs, continuing education programs and/or experience in an infusion admixture facility.

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

535:15-9-8. Pharmacist accessibility

Each sterile compounding pharmacy and pharmacy manager shall assure that a qualified pharmacist is accessible and available to respond to patients and healthcare professional questions and needs at all times. A 24-hour telephone number shall be provided.

535:15-9-9. Drug distribution and control

(a) **Labeling.** Each preparation dispensed to patients by a sterile compounding preparation pharmacy shall be labeled with the following information with a permanent label:

- (1) Name, address, and telephone number of the pharmacy;
- (2) Date and prescription number;
- (3) Patient's name;
- (4) Name, strength, and amount of each drug;
- (5) Directions for use, including infusion rate where applicable;
- (6) Prescriber's name;
- (7) Required controlled substance transfer warnings, where applicable;
- (8) Date of compounding;
- (9) Expiration date and time;
- (10) Identity of pharmacist compounding and dispensing;
- (11) Storage requirements;
- (12) Auxiliary labels, where applicable;
- (13) Hazardous drug auxiliary labels, where applicable.

(b) **Delivery service.** The pharmacy manager shall assure the environmental control of all products shipped. Therefore, any compounded, sterile preparation or pharmaceutical must be shipped in appropriate containers to insure minimal temperature fluctuation (as defined by USP standards), and stored appropriately in the patient's home. Chain of possession for the delivery of Schedule II controlled substances via courier must be documented.

(c) **Disposal of infectious waste.** The pharmacy manager is responsible for assuring that there is a system for the disposal of infectious waste in a manner so as not to endanger the public health.

[Source: Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

Pharmacies and personnel who engage in sterile compounding are responsible for complying with State Board of Pharmacy regulations.

[Source: Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2450, eff 9-11-21]

535:15-9-11. Quality assurance

Pharmacies and personnel who engage in sterile compounding are responsible for complying with State Board of Pharmacy regulations.

[Source: Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2450, eff 9-11-21]

535:15-9-12. Pharmacist manager responsibility

The pharmacist manager of the pharmacy dispensing sterile compounded preparations shall provide the following or assure that they are provided prior to providing medications.

- (1) **Training.** The pharmacist must assure that the patient is properly trained, if self-administering.
- (2) **Nurses.** In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacy manager must:
 - (A) Employ a registered nurse.
 - (B) Assure that proper records are maintained and are in compliance with laws and regulations.
 - (C) Make these records available to inspectors from appropriate agencies.
- (3) **Twenty-four hour service.** Twenty-four (24) hour service shall be assured by the pharmacy.
- (4) **Laboratory data.** Pharmacists shall recommend and monitor clinical laboratory data as needed.

(5) **Side effects and potential drug interactions.** Side effects and potential drug interactions should be documented and reported to the physician.

(6) **Patient histories.** Patient histories and therapy plans should be maintained.

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

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

Section

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PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PREPARATIONS

535:15-10-1. Purpose

The rules of this subchapter describe the requirements of minimum current good compounding practices for the compounding of drug preparations by Oklahoma licensed pharmacies for dispensing and/or administration to humans or animals.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 35 OK Reg 1250, eff 9-14-18]

535:15-10-2. Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

"USP" means "United States Pharmacopeia"

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2451, eff 9-11-21]

535:15-10-3. Pharmacist responsibilities

(a) All Pharmacists who engage in drug compounding, shall be proficient in compounding and should

continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

(b) All pharmacists and personnel engaging in drug compounding shall be familiar with State Board of Pharmacy regulations and should be familiar with patent regulations.

(c) The pharmacist has the responsibility to:

- (1) ensure the validity of all prescriptions
- (2) certify all prescriptions.
- (3) approve or reject all components, drug product containers, closures, in-process materials, and labeling.
- (4) ensure preparations are of acceptable strength, quality, and purity.
- (5) verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation.
- (6) prepare and review all compounding records to ensure that no errors have occurred in the compounding process.
- (7) ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.
- (8) ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and,
- (9) ensure only authorized personnel shall be in the immediate vicinity of the drug compounding operation.
- (10) perform final check of preparations prior to their release from the pharmacy.

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

(B) A visual examination procedure must ensure:

- (i) Comparison with original order for initial dispensing;
- (ii) Accuracy of calculations;
- (iii) Use of proper solutions, additives and equipment;
- (iv) Labels are complete;
- (v) Proper assignment of beyond use date and time;
- (vi) The integrity of the container, including checking for visual defects;
- (vii) Proper storage; and,
- (viii) Absence of particulate matter, precipitates, turbidity, discoloration, evidence of contamination or other signs that the preparation should not be used.

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

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

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

- (1) Competency shall be demonstrated prior to preparing any products for patient use, and
- (2) Whenever the quality assurance program yields unacceptable results the compounder shall be immediately instructed and reevaluated, and
- (3) Whenever unacceptable or questionable techniques are observed the compounder shall be immediately instructed and reevaluated.

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

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

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

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

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

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

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

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

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

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

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

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

(g) All pharmacists and personnel who engage in non-sterile compounding are responsible for complying with State Board of Pharmacy regulations.

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

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 30 Ok Reg 2010, eff 7-25-13; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2451, eff 9-11-21]

535:15-10-4. Drug compounding facilities

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

(b) The area used for the compounding of non-sterile compounded preparations shall be in an area separate and distinct from the area used for the compounding and aseptic processing of sterile preparations.

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

(d) Hazardous drugs shall be prepared within a certified Biological Safety Cabinet (Powder Containment

hood). Hazardous drug compounding shall be prepared in compliance with applicable USP standards. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. Do not use a ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatilize while they are being handled or after they are captured by the HEPA filter.

(e) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area, under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers). Bulk drugs shall also be stored such that they are protected from contamination.

(f) Adequate lighting and ventilation shall be provided in all compounding areas.

(g) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug preparation.

(h) Purified water must be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-5. Compounding equipment

(a) Equipment used in the compounding of drug preparations shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning and maintenance.

(b) Compounding equipment shall be of suitable composition so the surfaces that contact components shall neither be reactive, additive nor absorptive therefore not affecting or altering the purity of the compounded preparation.

(c) Equipment and utensils used for compounding shall be thoroughly cleaned promptly after every use to prevent contamination and must be stored in a manner to protect them from contamination. A cleaning log is recommended.

(d) Defective equipment shall be clearly labeled as such.

(e) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated as necessary or checked to ensure proper performance. An equipment calibration log must be maintained.

(f) When drug products with special precautions (antibiotics and hazardous materials) are involved appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs. A cleaning log must be maintained. Equipment dedicated for specific use (i.e. penicillin) shall be clearly designated as such.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-6. Component selection requirements

(a) The pharmacist shall first attempt to use USP-NF drug substances and inactive components that have been made in an FDA registered facility.

(b) If components are not obtainable from an FDA registered facility or if the FDA and/or the company cannot document FDA registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing or using drug components that meet official compendia requirements or another high quality source.

(c) If components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, American Chemical Society certified, or Food Chemicals Codex

grade may be used.

(d) Components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-7. Control of drug product containers

(a) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.

(b) Containers and closures shall be of suitable material as to not alter the compounded drug as to quality, strength or purity of the compounded preparation.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-8. Drug compounding controls

(a) There shall be written procedures for the compounding of drug preparations to assure that the finished products have the identity, strength, quality and purity they purport to have. These procedures should be available in either written form or electronically stored with printable documentation.

(b) The objective of the documentation is to allow another compounder to reproduce an equivalent prescription at a future date.

(c) Documentation shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process (e.g. log, formula worksheet, original prescription, etc.) In addition, all equipment and utensils and the container/closure system, relevant to the compounding procedure shall be listed.

(d) These written procedures shall be followed in the execution of the compounding procedure and are designed to enable a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.

(e) Components shall be accurately weighed, measured, and subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist, at each stage of the process, to ensure that each weight and measure is correct as stated in the written compounding procedures.

(f) Written procedures shall be established and followed that describe the tests or examinations to be conducted on the preparation compounded (e.g., degree of weight variation among capsules) to assure reasonable uniformity and integrity of compounded drug preparations. Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation.

(1) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug preparation. These procedures shall include, but are not limited to, the following (where appropriate):

(A) Capsule weight variation to ensure that each unit shall be not less than 90% and not more than 110% of the theoretically calculated weight for each unit;

(B) Adequacy of mixing to assure uniformity and homogeneity;

(C) Clarity, completeness or pH of solutions.

(2) The compounder shall label any excess compounded preparation so as to reference them to the formula used, the assigned batch number, and beyond use date based on the compounder's appropriate testing, published data, or USP-NF standard.

(g) Material safety data sheet (MSDS) files should be easily accessible.

(h) General requirements:

(1) Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product is generally prohibited unless patient therapy is compromised.

(2) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is different from an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient's specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available.

(A) The unavailability of such drug product must be documented prior to compounding.

(B) This or similar documentation must be available when requested by the Board.

(3) Except for those preparations where stability prohibits advanced compounding, all preparations dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

(4) Compounding may be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(5) Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(6) Reconstitution of commercial products is not considered compounding for the purposes of this subchapter.

(7) Manipulation of commercial available products according to or beyond the manufacturer's instructions or copying commercial products for the reason of non-availability or component specifications would be considered compounding as pertaining to a practitioner / patient / compounder relationship.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-8.1. Transfer of compounded prescriptions

(a) If a patient requests a transfer of their prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist.

(b) The information included in the transfer of the prescription shall include:

(1) Active ingredient(s),

(2) Concentration,

(3) Dosage Form e.g. capsule, cream, suspension, injectable, etc.

(4) Route of delivery e.g. oral, injectable, topical, vaginal, etc.

(5) Delivery mechanism e.g. topical, transdermal, immediate release, sublingual, etc.

(6) Dosing duration e.g. Q12H, Q24H, Q72H, etc.

(7) Details about the compounding procedure must be reasonably available from the transferring pharmacy.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09]

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

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

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

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

through (g) below:

- (1) The USP-NF standards listed above may be exceeded when there is supporting scientific stability information that is directly applicable to the specific preparation (e.g., the same drug concentration range, pH, excipients, vehicle, water content, etc.)
 - (2) Information to be considered when assigning a BUD includes chemical, physical and microbiological stability; nature of the drug, its chemical degradation mechanism, the container in which it is packaged, expected storage conditions, and the intended duration of therapy.
- (d) Non-aqueous Formulations. The BUD for non-aqueous formulations is not later than the time remaining until the earliest expiration date of any ingredient utilized or 6 months, whichever is earlier.
- (e) Water-Containing Oral Formulations. The BUD for water-containing oral formulations is not later than 14 days when stored at controlled cold temperatures.
- (f) Water-Containing Topical / Dermal and Mucosal Liquid and Semisolid formulations. The BUD for water-containing topical / Dermal and Mucosal Liquid and semisolid formulations is not later than 30 days.
- (g) If water is not added to a topical compounded preparation itself then the compound could be considered anhydrous with a BUD of 6 months or the earliest expiration of products used, whichever is less.
- [Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2451, eff 9-11-21]

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

- a) Every pharmacy shall document the drug compounding controls required in 535:15-10-8. Each pharmacy shall complete a compounding record/ log/ formula worksheet for each preparation which will include, but not be limited to, the following:
1. The assigned name of the preparation.
 2. The name and actual measured quantity of each ingredient used.
 3. The lot number, expiration date and manufacturer of each ingredient used.
 4. The total quantity compounded.
 5. The name/initials of the employee that compounded the preparation and the name/initials of the supervising pharmacist that approved the preparation.
 6. The date the compound is prepared.
 7. The lot/batch number assigned to the preparation.
 8. The assigned beyond use date (BUD).
- b) If an assigned BUD exceeds the allowable BUD according to 535:15-10-8.2, then you must include documentation of the source of the assigned BUD.
- c) The assigned BUD cannot exceed the expiration date of any ingredient utilized to compound the preparation.
- d) Compounding record/ log/ formula worksheet(s) shall be maintained in the pharmacy as required in 535:15-10-10.

[Source: added at 38 OK Reg 2453, eff 9-11-21]

535:15-10-9. Labeling

- (a) If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in, and stored in another container) the new container shall be identified with the:
- (1) Component name,
 - (2) Lot and BUD if available,

- (3) Strength and/or concentration, and;
 - (4) Weight or measure
- (b) Preparations prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.
- (1) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.
 - (2) These preparations shall be labeled or documentation referenced with the:
 - (A) Complete list of ingredients or preparation name and reference,
 - (B) Preparation date,
 - (C) Assigned BUD:
 - (i) Based on published data, or;
 - (ii) Appropriate testing, or;
 - (iii) USP-NF standards.
 - (D) Specific storage conditions dictated by composition and stability shall be specified (refrigerator, freezer etc), except where clean dry area is dictated, and;
 - (E) Batch or lot number.
- (c) Upon the completion of the drug compounding operation, the pharmacist shall examine the preparation for correct labeling.
- (d) The containers and closures shall be of suitable material so as not to alter the quality, strength, or purity of the compounded drug.
- (e) The outpatient prescription label shall contain the following:
- (1) Patient name,
 - (2) Prescriber's name,
 - (3) Name & address of pharmacy,
 - (4) Directions for use,
 - (5) Date filled,
 - (6) BUD & storage (may be auxiliary labels), and;
 - (7) An appropriate designation that this is a compounded prescription, such as "Compounded Rx" unless the product is a radiopharmaceutical prepared from an FDA approved commercially manufactured radiopharmaceutical drug. In such case labeling requirements can be found in 535:15-17.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-10. Records and reports

- (a) Any procedures or other records required to comply with State Board of Pharmacy regulations shall be retained for the same period of time as required for retention of prescription records; and copies of such records, shall be readily available for authorized inspection.
- (b) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.
- (c) Perpetual inventory is required for all controlled dangerous substances (CDS) and all bulk CDS's utilized for compounding.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2282, eff 7-1-09]; Amended at 38 OK Reg 2453, eff 9-11-21]

535:15-10-13. Compounding veterinarian preparations

- (a) Prescriptions for animals may be compounded based on an order or prescription from a licensed prescriber.
- (b) Compounded preparations must comply with federal statutes, rules and FDA guidances.

(c) Caution should be taken ~~as~~ to not violate federal patent laws by duplicating an available product in inordinate quantities.

(d) Compounding with bulk chemicals for food-producing animals is not permitted.

(e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.

(f) Veterinarians may not transfer compounded medications to any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1885, eff 9-11-17; Added at 35 OK Reg 1922, eff 9-14-18]

535:15-10-14. Compounding of non-sterile hazardous drugs

Pharmacies engaging in compounding of hazardous drugs shall be responsible for meeting the following criteria:

(1) Non-sterile hazardous drugs shall include the NIOSH list of hazardous drugs as well as any individual products named per each individual pharmacy by referencing MSDS sheets or any other reference relating to above definition.

(2) Exposure control shall begin when hazardous drugs enter the facility. The PIC shall be responsible to confirm that medical products have labeling on the outer container that can be understood by all workers who will be separating hazardous from nonhazardous drugs.

(3) All individuals must wear PPE when opening containers to unpack hazardous drugs. Individuals must also wear chemotherapy gloves to prevent contamination when transporting the drug to the work area.

(4) Hazardous drugs must be stored separately from other drugs, as recommended by current ASHP guidelines on handling hazardous drugs. Hazardous drugs must be stored and transported in closed containers that minimize the risk of breakage.

(5) Pharmacies and pharmacist shall make sure the storage area has sufficient general exhaust ventilation to dilute and remove any airborne contaminants. Use a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. Do not use a ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatilize while they are being handled or after they are captured by the HEPA filter.

(6) Staff should be fully trained and procedures established for their particular equipment and unique workplace setting.

(7) All staff shall wear PPE while working with hazardous drugs.

(8) Mix, prepare, and otherwise manipulate, count, crush, compound powders, or pour liquid hazardous drugs inside a ventilated cabinet designed to prevent hazardous drugs from being released into the work environment.

(9) Do not use supplemental engineering or process controls (such as needleless systems, glove bags and closed-system drug transfer devices) as a substitution for ventilated cabinets, even though such controls may reduce the potential for exposure when preparing and administering hazardous drugs.

(10) Use a high-efficiency particulate air filter (HEPA filter) for the exhaust from these controls.

(11) When drug preparation is complete, seal the final product in a plastic bag or other sealable container for transport before taking it out of the ventilated cabinet.

(12) Wash hands with soap and water immediately before donning and after removing gloves.

(13) Develop a written safety plan for all routine maintenance activities performed on equipment that could be contaminated with hazardous drugs.

(14) Manage hazardous drug spills according to policies and procedures for each workplace according to size of spill, possible spreading etc. Locate spill kits and other cleanup materials in the immediate area where exposures may occur.

(15) Consider a medical surveillance program or allow workers to have routine medical care.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-15. Compounding of non-sterile radiopharmaceuticals

(a) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.

(b) Radiopharmaceuticals prepared for oral administration shall be designated as, and conform to, the standards for non-sterile preparations. Any variation in certain chapter standards may be required to meet radiation safety concerns to operators and shall be documented with supporting evidence upon request.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-16. Violations

It shall be a violation to fail to comply with State Board of Pharmacy regulations.

[Source: Added at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2453, eff 9-11-21]

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PREPARATIONS

535:15-10-50. Purpose

(a) The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (non-sterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins they are potentially most hazardous to patients when administered into the central nervous system.

(b) To achieve the above five conditions and practices, this part 3 of subchapter 10 provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this part 3 of subchapter 10 is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this part 3 of subchapter 10 do not pertain to the clinical administration of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. For the purposes of this chapter, CSPs include, but are not limited to the following:

(1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

(2) Manufactured sterile products prepared according to the instructions in manufacturers' approved

labeling. Product package inserts usually refer to aseptic technique, but do not usually describe environmental quality controls, storage, or BUD and times for radiopharmaceuticals.

(c) All personnel who prepare CSPs shall be responsible for understanding these fundamental practices and precautions, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-51. Definitions

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

"ACPH" means "air changes per hour".

"ALARA" means "as low as reasonably achievable".

"Ante-Area" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

"Beyond-use date (BUD)" means the date and time, as appropriate, after which administration is not to begin of a compounded preparation; and such date is determined from the date the preparation is compounded. **"Biological Safety Cabinet (BSC)"** means a ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

"Buffer Area" means an ISO Class 7 or better area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the staging of components and supplies used when compounding CSPs.

"Clean Room" means an ISO Class 5 or better room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

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

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

"Compounding" means Compounding as defined in 59 O.S. Section 353.1

"Compounding Aseptic Containment Isolator (CACI)" means a compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

"Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially

retentive filter (HEPA minimum).

"Critical Site" means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.

"CSP" means "Compounded Sterile Preparation".

"CSTD" means "Closed-System Vial-Transfer Device".

"FDA" means the federal "Food and Drug Administration".

"Hazardous drug" means any drug listed as such by NIOSH and/or any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity.

"HEPA" means "High Efficiency Particulate Air".

"Immediate Use" means "administration begins not later than 1 hour following the start of the compounding procedure".

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

"ISO" means "International Organization for Standardization"

"ISO 5" means air containing no more than 100 P/ft of air of a size at least 0.5 micron or larger in diameter (3520 P/m³), formerly FS209e Class 100.

"ISO 7" means air containing no more than 10,000 P/ft of air of a size at least 0.5 micron or larger in diameter (352,000 P/m³), formerly FS209e Class 10,000.

"ISO 8" means air containing no more than 100,000 P/ft of air of a size at least 0.5 micron or larger in diameter (3,520,000 P/m³), formerly FS209e Class 100,000.

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

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

"LAFW" means "Laminar Airflow Workbench".

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

"MDV" means 'Multiple Dose Vial'.

"Media-Fill Test" means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

"Multiple-Dose Container" means a multiple-unit container for articles or preparations intended for sterile compounded preparations administration only and usually containing antimicrobial preservatives.

"Negative Pressure Room" means a room that is at a lower pressure than the adjacent spaces and therefore, the net flow of air is into the room.

"National Safety Foundation" or **"NSF"** means the foundation that certifies that Biological or Class II safety cabinets meet NSF Standard 49.

"NIOSH" means "National Institute for Occupational Safety and Health"

"PEC" means "Primary Engineering Control".

"PET" means "Positron Emission Tomography".

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

"Primary Engineering Control (PEC)" means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

"Preparation" means an article compounded in a licensed pharmacy pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

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

"Positive Pressure Room" means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

"Single-dose container" means a single-dose, or a single-unit, container for articles or preparations intended for sterile compounded preparations administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

"Segregated Compounding Area" means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

"Terminal Sterilization" means the application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6} , or a probability of less than one in one million of a non-sterile unit.

"Unidirectional Flow" means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

"USP" means "United States Pharmacopeia".

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-52. Pharmacist responsibilities

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

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

(c) The pharmacist has the responsibility to:

- (1) ensure the validity of all prescriptions
- (2) certify all prescriptions.

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

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

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

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

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

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

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

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

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

(B) A visual examination procedure must ensure:

(i) Comparison with original order for initial dispensing;

(ii) Accuracy of calculations;

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

(iv) Labels are complete;

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

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

(vii) Proper storage; and,

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

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

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

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

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

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

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

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

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

- (2) Certify that all participating pharmacists, interns and technicians have completed training and testing program in sterile product preparation. Documentation of training and testing shall be available for review.
 - (3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.
- (f) Staff will be trained and evaluated as follows:
- (1) Training is required for any individual who compounds sterile preparations. This training must be completed before the individual is allowed to compound sterile preparations.
 - (2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards,
 - (3) A written test shall be administered and passed based on the material referenced above upon initial hire or prior to assignment to compound sterile preparations.
 - (4) Media-fill challenge tests will be used to evaluate sterile technique.
 - (5) Results of the media challenge tests shall be documented and logged.
 - (6) End product testing that results in a failure, will result in a review of the aseptic technique of the individual involved.
 - (7) Testing involving media challenge tests will be conducted annually for every individual involved in sterile preparation compounding. Semiannual testing will be conducted for personnel involved in high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately instructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.
 - (8) Glove fingertip sampling using processes compliant with the most current USP standards required procedures shall be used to evaluate competency of personnel in performing hand hygiene and garbing procedures initially and at least annually. Such test shall be repeated until the required number of consecutive negative culture results are obtained.
 - (9) An 'Individual Training Record' shall be maintained for every individual involved in sterile preparation compounding.
 - (10) Nothing in these regulations shall prohibit a licensed student pharmacy intern engaged in experiential classes from assisting a properly qualified pharmacist in compounding sterile preparations under that pharmacist's direct supervision.
 - (11) Complete documentation by a pharmacist of training and testing shall be available for inspection.
- (g) All pharmacists who engage in sterile compounding are responsible for complying with all aspects of State Board of Pharmacy regulations.
- (h) Pharmacy technicians and interns participating in the compounding of sterile preparations shall have completed a pharmacist supervised training and testing program in sterile compound preparation. Completed documentation by a pharmacist of training and testing shall be available for inspection.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2453, eff 9-11-21]

535:15-10-53. General requirements

- (a) Compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product is generally prohibited unless patient therapy is compromised.
- (b) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is different from an FDA-approved drug that is commercially available based on documentation provided by

the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available.

(1) The unavailability of such drug product must be documented prior to compounding.

(2) This or similar documentation must be available when requested by the Board.

(c) Except for those preparations where stability prohibits advanced compounding, all preparations dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

(d) Compounding may be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(e) Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(f) Reconstitution of commercial products is not considered compounding for the purposes of this subchapter.

(g) Manipulation of commercial available products beyond the manufacturer's instructions or copying commercial products for the reason of non-availability or component specifications would be considered compounding as pertaining to a practitioner / patient / compounder relationship.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-54. CSP microbial contamination risk levels

(a) **Sterile preparations.** Pharmacies and pharmacists dispensing sterile preparations shall comply with all applicable federal, state, and local law and regulation concerning pharmacy. If the PEC (primary engineering control) is a compounding aseptic isolator that does not meet the environmental requirements described in USP <797> or is a laminar air-flow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous CSPs pursuant to a physician's order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. Low-risk level CSPs with a 12-hour or less BUD shall meet all of the following criteria:

(1) PECs (LAFWs, BSCs, CAIs, CACIs,) shall be certified and maintain ISO Class 5 as described in USP <797> for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.

(2) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction. Sinks should not be located adjacent to the ISO Class 5 PEC. Sinks should be separated from the immediate area of the ISO Class 5 PEC device.

(3) Personnel shall follow proper procedures for personnel cleansing and garbing prior to compounding and maintain proper competency of aseptic work practices.

(4) Personnel will follow proper procedures in ensure cleaning and disinfection of sterile compounding areas. Additionally, viable and non-viable environmental air sampling must be performed according to facility written procedures.

(b) **Risk level.** Requirements for compounding of sterile preparations will be based on the distinction of sterile products as either low-risk, medium-risk or high-risk preparations. These risk levels apply to the quality of CSPs immediately after the final aseptic mixing or filling or immediately after the final sterilization, unless precluded by the specific characteristics of the preparation.

(1) **Low-Risk Level CSPs.** Sterile preparations compounded under all of the following conditions are at a low risk of contamination:

(A) The CSPs are compounded with aseptic manipulations entirely within an ISO Class 5 environment or better air quality using only sterile ingredients, products, components, and devices.

(B) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.

(C) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and package containers of other sterile products, and containers for storage and dispensing.

(2) **Medium-Risk Level CSPs.** When CSPs compounded aseptically under low-risk conditions, and one or more of the following conditions exists, such CSPs are at a medium risk of contamination.

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile product that will be administered either to multiple patients or to one patient on multiple occasions.

(B) The compounding process includes complex aseptic manipulations other than the single volume transfer.

(C) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogeneous mixing.

(3) **High-risk Level CSPs.** CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.

(A) Non-sterile ingredients are incorporated, or a non-sterile device is employed before terminal sterilization

(B) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour

(i) Sterile contents of commercially manufactured products,

(ii) CSPs that lack effective antimicrobial preservatives, and

(iii) Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

(C) Compounding personnel are improperly garbed and gloved as outlined by USP.

(D) Sterile water-containing preparations are stored for more than 6 hours before being sterilized.

(E) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or Compendial specifications in unopened or in opened packages of bulk ingredients.

(c) **Immediate use.** The immediate use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level subjects the patient to additional risk due to delays in therapy. Immediate use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate use CSPs. Immediate use CSPs are exempt from the requirements described for *Low-Risk Level*

CSPs only when all of the following criteria are met:

- (1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate use CSPs because they are hazardous drugs.
- (2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
- (3) During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
 - (A) Administration begins not later than 1 hour following the start of the preparation of the CSP.
 - (B) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond use date and time.
 - (C) If administration has not begun within 1 hour following the start of preparing the CSP; the CSP shall be promptly, properly, and safely discarded.
- (d) Opened or needle-punctured single dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 air quality and any remaining contents must be discarded.
- (e) Single-dose vials exposed to ISO Class 5 or cleaner air may be used for multiple needle entries up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives.
- (f) The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days unless an alternate time period is otherwise specified by the manufacturer. This does not mean the expiration date of the unopened container.
- (g) **Quality Assurance.** Quality assurance practices include, but are not limited to the following:
 - (1) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.
 - (2) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, such as eye protection and face masks.
 - (3) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.
 - (4) Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.
 - (5) All clean rooms must meet NSF/ANSI standard 49. The aseptic processing for sterile preparations shall be in an area separate and distinct from the area used for the compounding of non-sterile drug preparations. A primary engineering control (PEC), (laminar airflow workbench (LAFW), biological safety cabinet (BSC), compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)) will be used to prepare all sterile preparations, except those compounded

for Immediate Use.

- (A) Semiannual certification of the primary engineering controls.
- (B) Semiannual certification of nonviable environmental monitoring of all ISO 5, ISO 7, ISO 8 and segregated compounding areas.
- (C) Semiannual certification of viable environmental monitoring of all ISO 5, ISO 7, ISO 8 and segregated compounding areas.
- (D) Removable prefilters shall be inspected monthly, cleaned or changed at least quarterly or as directed by a qualified certifier, and the date documented.
- (E) HEPA filters shall be repaired or replaced when recommended by a qualified certifier.
- (6) Initial and annual competence documentation of personnel, including:
 - (A) Written test
 - (B) Hand Hygiene and garbing
 - (C) Gloved fingertip sampling
 - (D) Aseptic manipulation
 - (E) Aseptic media-fill test
 - (F) Cleaning and disinfecting
 - (G) Surface sampling
 - (H) Equipment
 - (I) Routine visual inspection of all compounded sterile preparations
 - (J) Provision of guidelines to nursing education for competence documentation for non-pharmacy personnel who mix sterile preparations for immediate use.
- (h) **Quality control practices will include:**
 - (1) Daily documentation of temperature in areas where sterile products or sterile preparations are stored or compounded
 - (2) Daily documentation of the accuracy and precision of devices such as automated compounders and repeater pumps.
 - (3) Daily documentation of humidity in areas where sterile products or sterile preparations are stored or compounded.
- (i) The PIC or designee will prepare a periodic report of infection control procedures to track quality control and quality assurance activities, as appropriate.
- (j) Records of laminar air flow workbench maintenance and certification and ante-area, clean-room and buffer area certifications shall be kept in the pharmacy. A certification stamp shall be affixed to the hood.
- (k) **Storage.** All pharmacies preparing and dispensing compounded sterile preparations must provide:
 - (1) Adequate controlled room temperature storage space for all raw materials.
 - (2) Adequate storage space for all equipment. All drugs and supplies shall be stocked on shelving above the floor.
 - (3) Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures. Temperature ranges required are 36-46° F or 2-8° C.
 - (4) Adequate freezer storage space if finished products are to be frozen (e.g. reconstituted antibiotics.) There shall be a procedure to routinely document temperatures.
- (l) **Labeling.** In addition to regular labeling requirements, the label shall include:
 - (1) Sterile compounded preparations shall have the rate of infusion when applicable.
 - (2) Expiration date (Policies and procedures shall address label change procedures as required by physician orders.)

- (3) Storage requirements or special conditions.
 - (4) Name of ingredients and amounts contained in each dispensing unit.
 - (5) All products dispensed to outpatients, and removed from the site of preparation for administration different than the site of preparation, shall have label information as required by state law.
- (m) **Shipping.** Sterile preparation shipping:
- (1) Policies and procedures shall assure preparation storage requirements during delivery.
 - (2) Pharmacy must assure ability to deliver preparations within an appropriate time frame.
- (n) **Home patient care services.** The pharmacist in charge of the pharmacy dispensing sterile compounded preparations solutions shall provide the following or assure that they are provided prior to providing medications.
- (1) The pharmacist must assure that the patient is properly trained if self-administering.
 - (2) In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist in charge must:
 - (A) Employ a registered nurse.
 - (B) Assure that proper records are maintained in compliance with laws and regulations.
 - (C) Make these records available to inspectors from appropriate agencies.
 - (3) 24-hour service shall be assured by the pharmacy.
 - (4) Pharmacists shall recommend and monitor clinical laboratory data as requested.
 - (5) Side effects and potential drug interactions should be documented and reported to the physician.
 - (6) Patient histories and therapy plans should be maintained.
- (o) **Pharmacist-in-charge responsibilities for high-risk Level CSP preparations** When preparing high-risk sterile Level CSP preparations, the pharmacist in charge is responsible for making sure the above procedures, in addition to the following, shall be met:
- (1) Compound all medications in one of the following environments:
 - (A) A separate controlled limited access area with a positive air flow room inspected and certified as meeting ISO Class 7 requirements.
 - (B) An enclosed room providing an ISO Class 5 environment for compounding.
 - (C) A barrier isolator that provides an ISO Class 5 environment for compounding. It is recommended that all pharmacies have an anteroom designed to be separate from the buffer room. The anteroom should be available for the decontamination of supplies and equipment, and donning of protective apparel. A sink should be available in the anteroom area so that personnel can scrub prior to entering the buffer room.
 - (2) Use total aseptic techniques, including gowning, mask, and hair net.
 - (3) Provide a system for tracking each compounded product including:
 - (A) Personnel involved in each stage of compounding;
 - (B) Raw materials used including quantities, manufacturer, lot number, and expiration date;
 - (C) Labeling;
 - (D) Compounding records shall be kept for 5 years.
 - (4) Establishment of procedures for sterilization of all preparations compounded with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the preparation components.
 - (5) All high-risk Level CSP preparations for administration by injection that are prepared:
 - (A) in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules, bags, syringes, and/or vials), or;

(B) in multiple dose vials for administration to multiple patients, or;
(C) are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized; shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.

(i) Sterility testing (bacterial and fungal) - The USP Membrane Filtration Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. The pharmacist in charge shall establish written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth and said procedures must be available to Board inspectors.

(ii) Bacterial endotoxin (pyrogen) testing - The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.

(6) Establishment of procedures for semi-annual testing the techniques of pharmacists using simulated aseptic procedures and documentation thereof.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-10-55. Drug compounding facilities

- a) Pharmacies engaging in compounding shall have a specifically designated and adequate space for the orderly compounding of prescriptions, including the placement and storage of equipment and materials.
- b) The aseptic processing for sterile preparations shall be in an area separate and distinct from the area used for the compounding of non-sterile drug preparations. A primary engineering control (PEC), (laminar airflow workbench (LAFW), biological safety cabinet (BSC), compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)) will be used to prepare all sterile preparations, except those compounded for Immediate Use.
- c) The area(s) used for the compounding of drugs shall be maintained in a good state of repair. These area(s) shall also be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided and sewage, trash and other refuse in the compounding area is to be disposed of in a safe, sanitary, and timely manner.
- d) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers.) Bulk drugs shall also be stored such that they are protected from contamination.
- e) Adequate lighting and ventilation shall be provided in all compounding areas.
- f) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug preparation.
- g) Work area and equipment. Any pharmacy dispensing compounded sterile preparations shall meet or exceed the following requirements:
 - (1) A transition area from the general pharmacy (also called ante area or ante room) shall have a certified and inspected ISO Class 8 or better area which may contain a sink. All personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high- particulate-

- generating activities are performed in the ante area. Drugs and other materials, taken into the transition area shall be removed from corrugated cardboard and other particle-generating materials before being taken into the area.
- (2) A separate controlled limited access area (also called a buffer area or buffer room) shall have a certified and inspected ISO Class 7 or better environment for compounding sterile solutions. The buffer room shall be of adequate space. Cleanliness of the area is of critical importance.
 - (3) A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have controlled temperature. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.
 - (4) The controlled limited access area shall have a certified and inspected ISO Class 5 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting ISO Class 5 requirements) used for the preparation of all compounded sterile products. The ISO Class 5 environment device or area is to be inspected and certified semiannually. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.
 - (5) A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the clean room and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.
 - (6) Hazardous drugs shall be prepared within a certified Class II, Type A (exhaust may be discharged to the outdoors) or Class II, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. Hazardous drug compounding shall have negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas, thus providing inward airflow to contain any airborne drug. All vented cabinets shall be vented through HEPA filtration, preferably to outside air or through use of suitable technology or equipment. Ventilation exhaust shall be placed as not to reenter the facility at any point.
 - (7) The area shall be designed to avoid excessive traffic and airflow disturbances.
 - (8) The area shall be ventilated in a manner not interfering with laminar flow hood conditions.
 - (9) PECs should be left on continuously. If a PEC has been turned off, allow the blowers to run continuously for at least 30 minutes before using.
 - (10) Daily procedures must be established for cleaning the compounding area. The pharmacy must keep cleaning logs consistent with the minimum cleaning frequency. Logs shall be kept for 2 years.
 - (11) Minimum frequency of cleaning and disinfecting compounding areas are listed below:
 - (A) ISO Class 5 [Primary Engineering Control (e.g. LAFW, BSC, CAI, CACI)] shall be cleaned and disinfected at the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities occur, after spills, and when surface contamination is known or suspected.

- (B) Counters and easily cleanable work surfaces shall be cleaned and disinfected daily.
- (C) Floors shall be cleaned and disinfected daily.
- (D) Walls shall be cleaned and disinfected monthly.
- (E) Ceilings shall be cleaned and disinfected monthly.
- (F) Storage shelving shall be cleaned and disinfected monthly.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2454, eff 9-11-21; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-10-56. Compounding equipment

- (a) Equipment used in the compounding of drug preparations shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning and maintenance.
- (b) Compounding equipment shall be of suitable composition so the surfaces that contact components shall neither be reactive, additive or absorptive, therefore not affecting or altering the purity of the compounded preparation.
- (c) Equipment and utensils used for compounding shall be thoroughly cleaned promptly after every use to prevent contamination and must be stored in a manner to protect from contamination.
- (d) Defective equipment shall be clearly labeled as such.
- (e) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated as necessary or checked to ensure proper performance. An equipment calibration log must be maintained.
- (f) When drug products with special precautions (antibiotics and hazardous materials) are involved, appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs. Equipment dedicated for specific use (i.e. penicillin) shall be clearly designated as such.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-57. Component selection requirements

- (a) The pharmacist shall first attempt to use USP-NF drug substances and inactive components that have been made in an FDA registered facility.
- (b) If components are not obtainable from a FDA registered facility or if the FDA and/or the company cannot document FDA registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing or using drug components that meet official compendia requirements or another high quality source.
- (c) If components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, American Chemical Society-certified, or Food Chemicals Codex grade may be used.
- (d) Components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-58. Control of drug product containers

- (a) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.
- (b) Containers and closures shall be of suitable material as to not alter the compounded drug as to quality, strength or purity of the compounded preparation.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-59. Drug compounding controls

(a) There shall be written procedures for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality and purity they purport to have. These procedures should be available in either written form or electronically stored with printable documentation.

(b) The objective of the documentation is to allow another compounder to reproduce the identical prescription at a future date.

(c) Procedures shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. In addition, all equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug shall be listed.

(d) These written procedures shall be followed in the execution of the compounding procedure and are designed to enable a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.

(e) Components shall be accurately weighed, measured, and subdivided as appropriate.

These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures.

(f) Written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of variation) to ensure reasonable uniformity and integrity of compounded drug preparations. Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation.

(1) Such control procedures shall be established to monitor the output and to verify the performance of those compounding processes that may be responsible for causing variability in the final drug preparation. These procedures shall include, but are not limited to, the following (where appropriate):

(A) Adequacy of mixing to assure uniformity and homogeneity;

(B) Clarity, completeness or pH of solutions.

(2) The compounder shall label any excess compounded products so as to reference them to the formula used, the assigned batch number, and beyond use date based on the compounder's appropriate testing, published data, or USP-NF standard.

(g) MSDS (material data safety sheet) files should be easily accessible.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-60. Transfer of sterile compounded prescriptions

(a) If a patient requests a transfer of their prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist.

(b) The information included in the transfer of the prescription shall include:

(1) Active ingredient(s)

(2) Concentration

(3) Dosage Form

(4) Route of delivery

(5) Delivery mechanism

(6) Dosing Duration i.e. Q12H, Q24H, Q72H

(7) Details about the compounding procedure must be reasonably available from the transferring pharmacy.

535:15-10-61. Beyond use dating

(a) BUDs shall be assigned to all compounded sterile preparations.

The shorter of the chemical stability (established by the manufacturer, or listed in a current authoritative reference, or established by direct testing following USP standards or equivalent) and microbial limits of sterility (USP <797> standards) shall be used to determine the date. If a pharmacy does not have a program of sterility and endotoxin testing in place and additional documentation for longer dates, then the following BUDs are to be used for compounded sterile preparations as follows and as illustrated in the Appendix B

Chart:

- (1) If USP <797> Risk Level is 'Immediate Use' BUD, and if kept
 - (A) at room temperature; use within 1 hour,
 - (B) refrigerated; use within 1 hour, or
 - (C) in freezer, N/A.
- (2) If USP <797> Risk Level is 'Low Risk' BUD, and if kept
 - (A) at room temperature, use within 48 hours,
 - (B) refrigerated, use within 14 days, or
 - (C) in freezer, use within 45 days.
- (3) If USP <797> Risk Level is 'Low Risk with 12 hour or less' BUD, and if kept
 - (A) at room temperature use within 12 hours or less
 - (B) refrigerated, use within 12 hours or less, or
 - (C) in freezer, N/A
- (4) If USP <797> Risk Level is 'Medium Risk' BUD, and if kept
 - (A) at room temperature, use within 30 hours,
 - (B) refrigerated, use within 9 days, or,
 - (C) in freezer, use within 45 days
- (5) If USP <797> Risk Level is 'High Risk' BUD, and if kept
 - (A) at room temperature, use within 24 hours
 - (B) refrigerated, use within 3 days, or
 - (C) in freezer, use within 45 days

(b) Reusable compounded preparations that are returned to a hospital pharmacy shall be placed in the refrigerator (unless contraindicated) with the original BUD on the label.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-62. Labeling

(a) If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in, and stored in another container) the new container shall be identified with the:

- (1) Component name,
- (2) Lot and BUD if available,
- (3) Strength and/or concentration, and;
- (4) Weight or measure

(b) Preparations prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.

- (1) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.

- (2) These preparations shall be labeled or documentation referenced with the:
 - (A) Complete list of ingredients or preparation name and reference,
 - (B) Preparation date,
 - (C) Assigned beyond-use date:
 - (i) Based on published data, or;
 - (ii) Appropriate testing, or;
 - (iii) USP-NF standards.
 - (D) Specific storage conditions dictated by composition and stability shall be specified (refrigerator, freezer, etc.), except where clean dry area is dictated, and;
 - (E) Batch or lot number.
- (c) Upon the completion of the drug preparation operation, the pharmacist shall examine the preparation for correct labeling.
- (d) The outpatient prescription label shall contain the following:
 - (1) Patient name,
 - (2) Prescriber's name,
 - (3) Name & address of pharmacy,
 - (4) Directions for use,
 - (5) Date filled,
 - (6) Beyond use date & storage (may be auxiliary labels), and;
 - (7) An appropriate designation that this is a compounded prescription, such as 'Compounded Rx'.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-63. Records and reports

- (a) Any procedures or other records required to comply with Good Compounding Practices shall be retained for the same period of time as required for retention of prescription records and copies of such records shall be readily available for authorized inspection.
- (b) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.
- (c) Adequate records must be kept of controlled dangerous substances (Scheduled drugs) used in compounding.
- (d) Adequate records must be kept showing that compounded drug products have been compounded using ingredients from FDA approved manufacturers.
- (e) Adequate records must be kept showing that all ingredients have been purchased from suppliers which are licensed by the Board to lawfully ship such into Oklahoma.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-64.1. Compounding veterinarian sterile preparations

- (a) Prescriptions for animals may be compounded based on an order or prescription from a licensed prescriber.
- (b) Compounded preparations must comply with federal statutes, rules and FDA guidances.
- (c) Caution should be taken as to not violate federal patent laws by duplicating an available product in inordinate quantities.
- (d) Compounding with bulk chemicals for food-producing animals is not permitted.
- (e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.
- (f) Veterinarians may not transfer compounded medications to any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.

535:15-10-65. Compounding of sterile hazardous drugs

(a) Although the potential therapeutic benefits of compounded sterile and non-sterile hazardous drug preparations outweigh the risks of their adverse effects in ill patients, exposed healthcare workers risk similar adverse effects with no therapeutic benefit.

Occupational exposure to hazardous drugs can result in:

- (1) Acute effects, such as skin rashes;
- (2) Chronic effects, including adverse reproductive events; and
- (3) Possibly cancer.

Each facility must have a communication program that identifies hazardous drugs and communicates this list to all workers that participate in product acquisition, storage, transportation, housekeeping, and waste disposal.

(b) Hazardous drugs shall be any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, or genotoxicity. A new or investigational drug that has no information on toxicity should be treated as a hazardous drug. At a minimum, the hazardous drug communication list shall be drugs received in the facility that are recognized as such by the National Institute for Occupational Safety and Health (NIOSH).

(c) Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature; thus storage is preferably within a containment area such as a negative pressure room. The storage area should have sufficient general exhaust ventilation, at least 12 air changes per hour (ACPH) to dilute and remove any airborne contaminants.

(d) Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal.

(e) Hazardous sterile drugs shall be prepared in an ISO Class 5 environment with protective engineering controls in place as specified in 535.15-10-55(g). Hazardous drug compounding shall have negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas, thus providing inward airflow to contain any airborne drug. All vented cabinets shall be vented through HEPA filtration, preferably to outside air or through use of suitable technology or equipment. Ventilation exhaust shall be placed as not to reenter the facility at any point.

(f) If a CACI that meets the requirements of this chapter is used outside of an ISO class 7 buffer area, the compounding area shall maintain negative pressure and have a minimum of 12 ACPHs. Manufacturer's guidelines or NSF/ANSI Standard 49 standards shall be followed for isolators, containment hoods and BSC. Quality control certification for proper function shall be performed every six months by NSF/ANSI Standard 49 certified personnel.

(g) When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment, Add-Vantage and PhaSeal) are used, they shall be used within the vented cabinet.

(h) In facilities that prepare a low volume, an average of no more than two per day, of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

(i) Appropriate PPE shall be worn when compounding hazardous drugs. PPE should include gowns, face

masks, eye protection, hair covers, shoe covers or dedicated shoes, gloving with chemotherapy gloves; and compliance with manufacturers' recommendations when using a CACI.

(j) All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous drugs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. The training shall include at least the following:

- (1) safe aseptic manipulation practices;
- (2) negative pressure techniques when utilizing a BSC, powder containment hood or CACI;
- (3) correct use of CSTD devices;
- (4) containment, cleanup, and disposal procedures for breakages and spills; and (5) treatment of personnel contact and inhalation exposure.

(k) Consider a medical surveillance program or allow workers to have routine medical care.

(l) Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

(m) Pharmacies engaging in compounding of hazardous drugs shall be responsible to manage hazardous drug spills according to policies and procedures for each workplace.

(n) Pharmacies engaging in compounding of hazardous drugs shall locate spill kits and other cleanup materials in the immediate area where exposures may occur.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-10-66. Compounding of sterile radiopharmaceuticals

(a) In the case of production of radiopharmaceuticals for positron emission tomography (PET), the USP general test chapter *Radiopharmaceuticals for Positron Emission Tomography—Compounding* <823> supersedes this part 3 of Subchapter 10 or applicable federal manufacturing regulations. Upon release of a PET radiopharmaceutical as a finished drug product from a production facility, the further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.

(b) For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as, and conform to, the standards for 'Low-Risk Level CSPs'

(c) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. An integrated approach which addresses both aseptic and radiation safety techniques is necessary. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.

(d) These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to

permit compliance with applicable state and federal regulations.

(e) Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

(f) Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 or cleaner air environment.

(g) Direct visual inspection of radiopharmaceutical CSPs shall be conducted in accordance with ALARA.

(h) The handling of radiopharmaceuticals is controlled through the licensing of ‘Authorized Users’ by the Oklahoma Department of Environmental Quality. As such, limited numbers of distribution channels exist to obtain radiopharmaceuticals. It is recognized that there is a special population that is outside the daily distribution range of a commercial nuclear pharmacy and that radiopharmaceuticals are not reasonably available. For these facilities, if the PEC is a CAI, CACI, a LAFW or a BSC that cannot be located within an ISO Class 8 or better buffer area, then only low-risk CSPs pursuant to a physician’s order may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers’ package insert, whichever is less. These Low-risk level radiopharmaceutical CSPs with a 12-hour or less BUD shall be prepared in PECs (LAFWs, BSCs, CAIs, CACIs), which shall be certified and maintain ISO Class 5 and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment areas must be cleaned before being brought into controlled compounding area. Other requirements as dictated by Low-Risk Radiopharmaceuticals shall be followed as described in this chapter.

(i) Preparation of radiopharmaceuticals for Immediate-Use category is reserved for radiopharmaceuticals needed for emergency or immediate patient care. Radiopharmaceuticals under this exemption shall apply only to diagnostic radiopharmaceuticals and administration must begin no later than one hour following the start of preparing the CSP. Certain preparations may necessitate more than two punctures into the same septum, i.e. Technetium 99mTc-Red Blood Cell labeling.

(j) Preparation of radio-labeled leukocytes or blood products requires the procedure be performed in an ISO Class 5 PEC that is located in an ISO Class 8 or cleaner air environment. Blood manipulations shall be clearly separated from routine procedures and have specific standard operating procedures to avoid cross contamination.

(k) Labeling requirements for this chapter do not supersede the labeling requirements of 535:15-17-5.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-67. Compounding of sterile allergen extracts

(a) Allergen extracts as CSPs are single-dose and multiple-dose *intra*dermal or *subcutaneous injections* that are prepared by specially trained physicians and pharmacy personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all *CSP Microbial Contamination Risk Levels* in this chapter only when all of the following criteria are met:

(1) The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).

(2) All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Non-preserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.

(3) Before beginning compounding activities, personnel perform a thorough hand cleansing procedure

by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either non-antimicrobial or antimicrobial soap and water.

(4) Compounding personnel don hair covers, facial hair covers, gowns, and face masks.

(5) Compounding personnel perform antiseptic hand cleansing with an alcohol based surgical hand scrub with persistent activity.

(6) Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.

(7) Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.

(8) Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.

(9) The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other non-sterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).

(10) The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.

(11) Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

(b) Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for CSP Microbial Contamination Risk Levels. Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected intradermally or subcutaneously, these risks are substantially greater if the extract is inadvertently injected intravenously.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-68. Violations

It shall be a violation to fail to comply with State Board of Pharmacy regulations.

[Source: Added at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2454, eff 9-11-21]

Appendix B USP <797> Beyond-Use Date Limits Chart

USP <797> Risk Level	Room Temperature	Refrigerated	Freezer
Immediate Use	1 hour	1 hour	N/A
Low Risk	48 hours	14 days	45 days
Low Risk with 12 hour or less BUD	12 hours or less	12 hours or less	N/A
Medium Risk	30 hours	9 days	45 days
High Risk	24 hours	3 days	45 days

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

SUBCHAPTER 11. CHARITABLE CLINIC PHARMACIES

Section

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

[Source: Codified 6-25-93]

535:15-11-1. Charitable clinic pharmacy license

- (a) A charitable clinic pharmacy license may be issued by the Board to clinics operating on a non-profit basis to furnish medical care to poor and underprivileged persons and in which drugs are dispensed or administered without charge to such persons on orders or prescriptions of prescribers authorized by law to prescribe or administer said drugs.
- (b) Charitable clinic pharmacies must assure that the pharmacy area be secured during the pharmacist's absence.
- (c) The minimum of (40) hours for a lock out pharmacy shall not apply to charitable clinic pharmacies.
- (d) All dangerous drugs for patients shall be on an individual prescription basis, and the pharmacist shall dispense drugs properly labeled, and adhere to the requirements for proper storage, safeguarding, preparation and recordkeeping for prescription drugs.
- (e) Before a charitable clinic pharmacy license is issued, all pharmacy policies and procedures must first be approved by the Board.
- (f) A charitable clinic pharmacy can be part of a medical clinic that utilizes a mobile clinic to provide medical services to indigent patients provided that;
 - (1) The charitable clinic pharmacy has a permanent location where all dangerous drugs and records are stored,
 - (2) All dangerous drugs are returned to the permanent location each day and stored there,
 - (3) The permanent location is the address of record for the pharmacy, and
 - (4) A charitable clinic that utilizes mobile clinics shall not have controlled dangerous substances (CDS). No CDS are allowed in mobile clinics.

[Source: Added at 10 Ok Reg 3171, eff 6-25-93; Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2456, eff 9-11-21]

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. Pharmacy technician qualifications and training

535:15-13-5. Supervision of pharmacy technicians

535:15-13-6. Duties

535:15-13-7. Prohibited duties

535:15-13-8. Technician annual permit requirement

535:15-13-9. Technician permit display

535:15-13-10. Technician address and employment change, and training at change of employment

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

[Source: Codified 6-27-94]

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 353.18A.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2454, eff 7-1-04]; Amended at 38 OK

535:15-13-2. Hospital pharmacy technician definitions and duties

Hospital pharmacy technician definitions and duties are enumerated in OAC 535:15-5.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94]

535:15-13-3. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

“**Auxiliary supportive personnel**” or “auxiliary supportive person” means all persons, other than pharmacists, interns and techs, who are regularly paid employees of the pharmacy and who work or perform tasks in the pharmacy that do not require a permit or license (e.g. clerk, typist, delivery or data entry person, etc.).

“**Certify a prescription**” means the confirmation by the supervising pharmacist of the accuracy and completeness of the acts, tasks or functions undertaken by supportive personnel to assist the pharmacist in the practice of pharmacy. This process shall be completed before the prescription is given to the patient.

“**Pharmacy technician**”, “**Technician**”, or “**Rx Tech**” means a person who has been issued a permit by the Board to assist the pharmacist and perform nonjudgmental, technical, manipulative, non-discretionary functions in the prescription department under the pharmacist's immediate and direct supervision.

“**Significant compounding**” means compounding activity which equals at least ten percent (10%) of the prescription volume of the pharmacy.

“**Supportive personnel**” means supportive personnel as defined in 59 O.S. Section 353.1 et seq.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2456, eff 9-11-21]

535:15-13-4. Pharmacy technician qualifications and training

(a) A pharmacy technician must have satisfactorily completed a high school education, HiSet Examination, or G.E.D. equivalence, and shall be of good moral character, be non-impaired (e.g. alcohol or drugs) and have adequate education to perform assigned duties.

(b) A pharmacy manager employing a currently permitted technician must document training of that technician within 10 days of hire.

(c) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job training (OJT) program described in 535:15-13-13.

(d) To be eligible for a pharmacy technician permit, an applicant must maintain compliance with the requirements in this Title, 535.25 and 535:15.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-13-5. Supervision of pharmacy technicians

(a) All tasks performed by pharmacy technicians must be in a licensed pharmacy located in Oklahoma and must be accomplished under the immediate and direct supervision of a pharmacist who is currently licensed by the Board.

(1) Failure by the licensed pharmacy and pharmacist manager (PIC) to provide adequate supervision; and/or failure of a pharmacist to adequately supervise a technician is a violation of these State Board of Pharmacy regulations.

(2) An intern cannot supervise a technician.

(3) Failure to adequately supervise a pharmacy technician is a violation of these State Board of Pharmacy regulations by the pharmacist, pharmacy and pharmacist manager.

- (b) A pharmacy technician may perform certain non-judgmental functions of dispensing as enumerated in this Subchapter, provided that whenever the pharmacist leaves the prescription department, other than for in-pharmacy counseling of a patient, all dispensing functions listed shall cease.
- (c) A ratio of no more than two pharmacy technicians per supervising pharmacist on duty shall be maintained.
- (d) A licensed pharmacy that conducts significant compounding may utilize up to two pharmacy technicians specifically trained in compounding who shall, only while performing compounding duties, not be counted for the purposes of the pharmacy technician to pharmacist ratio of two pharmacy technicians to one supervising pharmacist.
- (e) A pharmacy intern working in the pharmacy will not affect or change this ratio.
- (f) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. An intern cannot certify the completion of a technician filled prescription.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15]; Amended at 38 OK Reg 2456, eff 9-11-21]

535:15-13-6. Duties

- (a) The following tasks may be performed by auxiliary supportive personnel:
 - (1) retrieval tasks such as retrieving prescriptions or files as necessary;
 - (2) clerical tasks such as data entry, typing labels and maintaining patient profiles;
 - (3) secretarial tasks such as telephoning, filing, and typing;
 - (4) accounting tasks such as record keeping, maintaining accounts receivables, third party billing and posting;
 - (5) inventory control tasks including monitoring, pricing, dating, invoicing, stocking pharmacy, and preparation of purchase orders; and
 - (6) help maintain a clean and orderly pharmacy.
- (b) The following tasks may be performed by pharmacy technicians:
 - (1) count and/or pour medications;
 - (2) prepackage (e.g. unit dose) and properly label medications;
 - (3) affix the prescription label to the proper container;
 - (4) affix auxiliary labels to the container as directed by the pharmacist;
 - (5) reconstitution of medications (i.e. liquid antibiotics);
 - (6) bulk compounding, including such items as non-sterile topical compounds, sterile bulk solutions for small volume injectables, sterile irrigation solutions and products prepared in relatively large volume for internal or external use. Documentation of a system of in-process and final checks and controls must be developed or approved by the certifying pharmacist and carefully and systematically enforced;
 - (7) Technician training and requirements for technician participation in non-sterile compounding is described in 535:15-10-3 (a) – (h).
 - (8) Technician training and requirements for technician participation in sterile compounding is described in 535:15-10-52 (a) – (h).
 - (9) Any duties auxiliary personnel are allowed to perform;
 - (10) Assist the pharmacist in the annual CDS inventory. The pharmacist remains responsible for completeness and accuracy; and,
 - (11) Take verbal authorizations from licensed prescriber or licensed prescriber’s authorized agent (when-allowed) for refill of non-controlled prescriptions with no changes to strength or directions

and,

(12) fill "Modified unit dose distribution systems", "Automated dispensing systems" and/or "Unit dose distribution systems".

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 33 OK Reg 1785, eff 9-11-16; Amended at 34 Ok Reg 1885, eff 9-11-17; Amended at 37 Ok Reg 2048, eff 9-11-20]; Amended at 38 OK Reg 2456, eff 9-11-21; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-13-7. Prohibited duties

These duties shall not be performed by supportive personnel:

- (1) The pharmacist must interpret the original prescription.
- (2) The pharmacist must perform the prospective drug utilization review and determine action to be taken when there is an indication of a drug interaction.
- (3) The pharmacist must receive new orally communicated prescriptions from prescribers or their agents.
- (4) The pharmacist must determine product selection if substitution is requested or approved.
- (5) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. This process shall be completed before the prescription is given to the patient.
- (6) The pharmacist must provide patient counseling or drug information as necessary.
- (7) The pharmacist must take verbal authorizations from licensed prescriber or licensed prescriber's authorized agent (when allowed) for any refill of a controlled substance or any non-controlled prescription that has changes to strength or directions.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 37 Ok Reg 2048, eff 9-11-20]

535:15-13-8. Technician annual permit requirement

(a) Each pharmacy technician in Oklahoma shall obtain a permit annually before practicing as such. A pharmacy technician must be employed in a licensed pharmacy located in Oklahoma to be eligible to renew his pharmacy technician permit.

- (1) Upon meeting the qualifications listed in 535:15-13-4 and 535:25, applicants shall apply for a pharmacy technician permit on the form provided by the Board. Such application shall be returned accompanied by the fee authorized by the legislature and in the agency fee schedule.
- (2) After the pharmacy technician has completed his portion of the application, he must submit it to the pharmacy manager or designated pharmacist who has conducted the technician training for review and signature.
- (3) The pharmacy manager or designated pharmacist must first verify the applicant's completion of Phase I of the Board approved pharmacy technician training program. The signature by the pharmacist verifying technician training indicates that there is written training verification in the pharmacy available for Board inspection.
- (4) Each pharmacy technician who desires to continue to work as a tech shall annually, on or before the last day of the registrants' birth month, send to the Board the fee authorized by the legislature and in the agency fee schedule, with a completed Board renewal application signed by the supervising pharmacist and the technician. Renewal notice will be sent to the technician's address on file in the Board office either electronically or by mail.

(b) The technician applicant is required to report and the Board shall, at a minimum, consider the following factors in reviewing qualifications of persons who apply for a pharmacy technician permit within the state:

- (1) any arrest, charge, plea of nolo contendere, or conviction, or deferred sentence, for any

- misdemeanor or felony offense of the applicant under any federal, state, or local laws;
- (2) the furnishing of any false or fraudulent material in any application made to the Board;
- (3) suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant;
- (4) compliance with permitting requirements under previously granted permits, if any;
- (5) any abuse of alcohol or habit-forming drugs or use of an illegal CDS substance or a positive drug screen for such illegal substance or its metabolite; and,
- (6) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(c) The Board shall have the right to deny a permit to an applicant if it determines that the granting of such a permit would not be consistent with the public health and safety.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 33 OK Reg 1785, eff 9-11-16]

535:15-13-9. Technician permit display

(a) Each pharmacy technician shall conspicuously display a current original permit issued by the Board in the pharmacy where the tech is actively engaged as a pharmacy technician.

(b) A current 2 x 2 photo shall be attached in the upper right hand corner of the permit while on display in the pharmacy.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-13-10. Technician address and employment change, and training at change of employment

(a) A pharmacy technician must notify the Board, in writing, within ten days of change of employment.

(b) A pharmacy manager employing a currently permitted technician must document training of that technician at the new pharmacy as required in 535:15-13-13 (d).

(c) A pharmacy shall notify the Board, in writing, within ten days of the employment termination of a pharmacy technician. The pharmacist must share any concern about public safety relating to the technician with the Board. (No Board action shall be taken without due process.)

(d) A pharmacy technician must notify the Board, in writing, within ten days, of a change of address.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-13-11. Multiple locations of employment

(a) A pharmacy technician may work in multiple pharmacies providing:

- (1) The technician has been properly trained for each location (see 535:15-13-13(d)); and,
- (2) The training is documented in each pharmacy.

A technician working in multiple locations regularly or on an emergency relief basis may be issued a duplicate permit on request.

(3) A written request indicating the need for such duplicate shall be sent to the Board by the technician.

(4) A duplicate fee of ten dollars \$10 shall accompany each individual duplicate request.

(5) Current and in good standing technicians who have renewed online for the current period may print a duplicate permit online at no additional charge.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 19 Ok Reg 1796, eff 7-1-02; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-13-12. Work schedule display

(a) A work schedule shall be conspicuously displayed in the pharmacy when both a tech and an auxiliary supportive person are working. The schedule shall indicate who is working as a tech and hours worked and who is working as an auxiliary supportive person and hours worked.

(b) The schedule shall indicate the proper ratio of 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.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982 eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-13-13. Pharmacy technician training

(a) The pharmacy manager shall be responsible for the development and/or implementation of a pharmacy technician training program.

(1) The instructional text of the training program shall be kept in the pharmacy and only upon request submitted to the Board for approval.

(2) The program shall be designed to train personnel to perform allowed nonprofessional functions, as described in OAC 535:15-5 and 535:15-13.

(3) Minimum standards for technician training programs shall be those set out in the Board approved "Pharmacy Technician Training Guidelines".

(A) Pharmacy technician applicants shall complete Phase I training before they may apply for an Oklahoma Pharmacy Technician permit. A pharmacy technician permit must be received before performing any of the duties of pharmacy technicians authorized in OAC 535:15-5 and 535:15-13.

(B) A technician has not met Board requirements until he has successfully completed Phase II of pharmacy technician training.

(C) A pharmacy technician must complete Phase II within ninety (90) days after issuance of a pharmacy technician permit.

(D) Pharmacy technician applicants shall not have fully received their permits until they have completed Phase II of pharmacy technician training.

(E) If the pharmacy technician fails to complete Phase II within 90 days, the pharmacist manager shall notify the Board in writing,

(i) If the pharmacy technician fails to complete Phase II within 90 days,

(I) the pharmacy technician permit is automatically void; and,

(II) the pharmacy technician shall return such permit to the Board.

(ii) Such pharmacy technician may apply for a new pharmacy technician permit when he has again satisfactorily completed Phase I training with an employing pharmacy, provided the provisions of these rules have not been violated by the pharmacy technician.

(b) The pharmacist manager, or another pharmacist in the pharmacy whom the pharmacist manager may designate, shall conduct the training and attest to its successful completion.

(c) The pharmacist manager shall assure that the pharmacy technician remains competent through annual continuing on-the-job training. The pharmacist manager must document such training in the pharmacy and provide it at inspection.

(d) A pharmacy manager employing a currently permitted technician must document training of that technician within 10 days of hire at such pharmacy. Documentation of this training must be kept in the pharmacy and be available for Board inspection.

(e) The pharmacist manager shall be responsible for assuring proof of annual technician training is maintained in the pharmacy and such proof is available for Board inspection.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-13-14. Pharmacy technician identification

The pharmacy technician must be identified as set out in 535:15-3-2 (e).

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 14 Ok Reg 3024, eff 7-11-97; Amended at 17 Ok Reg 2626, eff 7-1-00]

SUBCHAPTER 15. HOME CARE AGENCY PHARMACY AGREEMENTS

Section

535:15-15-1. Definitions

535:15-15-2. Pharmacy agreements with Home Health Care Agencies (HCA's)

535:15-15-3. Home Care Agency protocol

535:15-15-4. Drug formulary

[Source: Codified 6-26-95]

535:15-15-1. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Administer Drugs" means the direct application of a drug as defined in Title 59, O.S., Section 353.1.

"Authorized Employee" means any employee of a Home Care Agency who in the course of their duties, is licensed by their appropriate Board to administer legend or dangerous drugs.

"Home Care Agency" or **"HCA"** means an entity required to license under the 1992 Home Care Act with the Oklahoma State Department of Health.

"Pharmacy manager" or **"PIC"** means the PIC as described in 535:15-3-2.

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 34 Ok Reg 1886, eff 9-11-17]

535:15-15-2. Pharmacy agreements with Home Care Agencies (HCA's)

(a) Pharmacies will be allowed to place certain drugs with HCA's for the betterment of public health.

(b) The pharmacy shall remain the legal owner of the drugs.

(c) A written agreement between the pharmacy and the HCA shall document the protocol for handling and storage of these drugs by authorized employees and shall be approved by the pharmacy manager.

(d) The pharmacy manager shall review the protocol to assure safe, secure and accountable handling of the dangerous drugs is maintained under the protocol. The protocol should stress the use of these drugs should not be for routine use, but for emergency use and the need of the patient.

(e) The pharmacy manager or a designated pharmacist shall physically inspect and review the drug storage and handling at the HCA at a minimum of every four months.

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96; Amended at 14 Ok Reg 3024, eff 7-1-97]

535:15-15-3. Home Care Agency protocol

Home Care Agency protocol will include, but not be limited to, the following:

(1) safe and secure storage of drugs;

(2) access to drugs limited to authorized employees;

(3) records of drugs checked out to authorized employees and records of drugs, amounts, to whom and by whom administered;

(4) prompt notification of the pharmacy when a drug is used, including the prescriber, patient, drug, dosage form, directions for use, etc.;

(5) billing information;

(6) procedures for handling drugs beyond expiration date (outdated drugs shall be returned to the pharmacy, quarantined and destroyed in a reasonable time frame); and,

(7) inventory control.

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96]

535:15-15-4. Drug formulary

The following legend or dangerous drugs will be allowed under these agreements:

- (1) sterile water for injection or irrigation;
- (2) sterile saline solution for injection or irrigation;
- (3) acetic acid for irrigation;
- (4) heparin flush solution or kits;
- (5) diphenhydramine injectable;
- (6) epinephrine injectable;
- (7) four (4) I.V. solutions
 - (A) dextrose 5% in water (D5W)
 - (B) dextrose 5% in normal saline solution (D5S)
 - (C) lactated ringers solution
 - (D) normal saline solution; and
- (8) legend medicated dressings.

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96]

SUBCHAPTER 16. PHARMACY EMERGENCY MEDICATION KITS FOR USE IN A FACILITY

Section

535:15-16-1. Purpose

535:15-16-2. Definitions

535:15-16-3. Licensing requirements

535:15-16-4. Policies and procedures for use of emergency medication kit drugs

535:15-16-5. Security

535:15-16-6. Drugs allowed in emergency medication kits

535:15-16-7. Violations

[Source: Codified 7-12-12]

535:15-16-1. Purpose

- (a) This subchapter establishes rules regarding drugs that an Oklahoma licensed pharmacy may maintain in an emergency medication kit, as authorized under Title 59 O.S. Section 367.8.
- (b) The purpose of these Oklahoma licensed pharmacy emergency medication kits for use in a facility is not to relieve a pharmacist or an Oklahoma licensed pharmacy of the responsibility for timely provision of a facility resident's routine drug needs; but to ensure that an emergency medication kit is available to facility residents in need of urgent or emergency medications.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12]

535:15-16-2. Definitions

The following words or terms, when used in this chapter, shall have the following meaning, unless the context clearly indicates otherwise:

“Emergency medication kits”, “Emergency medication boxes”, or “Emergency medication carts”, “emergency kits”, “kits”, “boxes” or “carts” means those drugs which are allowed under these rules that may be required to meet the immediate emergency therapeutic needs of facility residents; and which are not available from any other authorized source in sufficient time to prevent risk of harm or death to residents.

“Facility” or “Institution” means a facility as defined by the Nursing Home Care Act or an Assisted Living Center as defined by the Continuum of Care and Assisted Living Act. [59 O.S. § 367.8 (C)]

“Remote site” means a facility location where a Oklahoma licensed pharmacy has placed an emergency medication kit.

“Resident” means a patient residing at the facility.

“Single dose injectable medication” means any injectable medication vial in the emergency medication kit.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12]

[Agency Note: Facility defined in 59 OS Section 367.8 (C) included in rules for reference.]

535:15-16-3. Licensing requirements

(a) The Oklahoma licensed pharmacy shall maintain a separate pharmacy emergency medication kit permit for each emergency medication kit maintained at each facility remote site for an annual fee for each set by the Board.

(b) The Oklahoma licensed pharmacy shall contact DEA and OBN and comply with any registration or requirements for each remote site prior to providing a controlled dangerous substance in the emergency medication kit.

(c) The permit for the medication kit will expire at the same time as the license of the pharmacy.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-16-4. Policies and procedures for use of emergency medication kit drugs

(a) The drugs in the emergency medication kits shall remain the property of an Oklahoma licensed pharmacy.

(b) Only one Oklahoma licensed pharmacy may provide emergency medication kits to each facility.

(c) Emergency medication kits maintained by an Oklahoma licensed pharmacy within the facility shall be approved by the medical director of the facility and the facility’s consultant pharmacist on at least an annual basis.

(d) Medications may be administered from the facility’s emergency medication kit only upon a prescriber’s order for the emergency medication; and must be administered by a licensed nurse, physician, or physician’s assistant.

(e) The facility licensed nurse shall

(1) verbally transmit the order for an emergency drug requiring access to the emergency medication kit to an Oklahoma licensed pharmacist who is an employee of the Oklahoma licensed pharmacy and is physically located within the United States at the time the order is transmitted prior to the removal of a medication from the emergency medication kit,

(2) or may electronically transmit the order to an Oklahoma licensed pharmacy and located within the United States following all federal and state regulations and rules only if the Oklahoma licensed pharmacy is utilizing technology which requires the Oklahoma licensed pharmacist to release the medication from the emergency medication kit by electronic means.

(f) The facility and Oklahoma licensed pharmacy shall have a written agreement that clearly states these drugs should not be used for routine use, but for emergency use and the need of the patient for urgent care.

(1) This written agreement shall contain a policy for record keeping of medications removed from the emergency medication kit.

(2) The Oklahoma licensed pharmacy shall require the facility to maintain a readily retrievable log of usage from the emergency medication kit which shall include for each dose administered from the emergency medication kit, at a minimum:

(A) Name of ordering prescriber,

(B) Date and time of order,

(C) Facility resident’s name,

(D) Medication name and strength,

(E) Name of person administering medication, and date and time administered,

(F) Such log shall be maintained in the facility and the Oklahoma licensed pharmacy and shall be available for Board inspection.

- (3) The facility and Oklahoma licensed pharmacy shall document the nature of the emergency.
- (4) Name of person verbally notifying the Oklahoma licensed pharmacy shall be recorded by the Oklahoma licensed pharmacy,
- (5) The agreement shall document the protocol for handling and storage of these drugs by authorized employees and shall be approved by the Oklahoma licensed pharmacy manager.
- (6) The Oklahoma licensed pharmacy shall review the agreement, recordkeeping and drug storage and handling at a minimum of annually.
- (7) The facility and Oklahoma licensed pharmacy shall have a policy on replacement of medication in a timely manner.

(A) Replacement of controlled dangerous substances (CDS) in the emergency medication kit in a facility may be done by a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy.

(B) Replacement of the non-controlled drugs from the licensed Oklahoma pharmacy in the emergency medication kit may be done by a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy.

(g) The Oklahoma licensed pharmacy shall maintain the following records for each facility remote site where an emergency medication kit is maintained:

- (1) A log of facilities for which the Oklahoma licensed pharmacy provides emergency medication kits;
- (2) A log of medications stored in each emergency kit at each facility;
- (3) The Oklahoma licensed pharmacy shall require the facility to maintain a log of usage from the emergency medication kit; and
- (4) The log of usage from the emergency medication kit shall be auditable and maintained in a readily retrievable manner by the facility.

(h) Expired medications shall be removed from emergency supply by a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy; and shall not be dispensed or administered.

(i) Controlled Dangerous Substances (CDS) may be maintained only in a medication kit that is separate from non-controlled dangerous substances or within an electronic medication dispensing machine, if allowed, in accordance with Oklahoma Bureau of Narcotics and the federal Drug Enforcement Administration laws and rules.

(j) Emergency medication kits that do not contain controlled dangerous substances may be maintained in an electronic system or in a secure emergency medication kit. A list of drugs in the emergency medication kit shall be attached to the same.

(k) A record of transactions involving the controlled substance emergency medication kit shall be maintained for two (2) years in a readily retrievable manner by the Oklahoma licensed pharmacy and facility. This transaction record is separate from the prescription record which must be maintained for a minimum of 5 years.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 30 Ok Reg 2010, eff 7-25-13; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-16-5. Security

(a) Emergency medication kits shall have adequate security and procedures to:

- (1) Prohibit unauthorized access;
- (2) Comply with federal and state law and regulations; and
- (3) Maintain patient confidentiality.

(b) The emergency medication kit shall be sealed with a tamper-evident seal; or,

- (1) It shall be locked or sealed in a manner that obviously reveals when the kit has been opened or

tampered with; or,

(2) An electronic system may be used, which notifies the Oklahoma licensed pharmacy when the kit has been accessed.

(3) Paper or tape seals are unacceptable.

(c) If an electronic system is utilized, the Oklahoma licensed pharmacy and facility must maintain a written procedure for how the kit can be accessed in the event of downtime.

(d) The emergency medication kit shall be properly sealed, stored, and accessible only to authorized personnel.

(e) The emergency medication kit shall be securely locked in a sufficiently well-constructed cabinet or cart maintained in the medication room, and access to the cabinet or cart shall be available only to the nurse or nurses as determined by the pharmaceutical services committee or its equivalent.

(f) Access to the controlled substances in the emergency medication kit shall be limited to a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy.

(g) Access to non-controlled drugs in the emergency medication kit shall be limited to a licensed nurse employed at the facility or an employee of the Oklahoma licensed pharmacy.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-16-6. Drugs allowed in emergency medication kits

(a) An Oklahoma licensed pharmacy and its pharmacists shall be responsible for timely provision of a facility resident's routine drug needs.

(b) The drugs allowed in the emergency medication kit, both Controlled Dangerous Substances (CDS) and Non-Controlled dangerous substances (Non-CDS) shall be determined by the medical director of the facility and an Oklahoma licensed pharmacist employed by the Oklahoma licensed pharmacy providing the kit.

(1) The quantity of each Non-CDS drug shall be of sufficient quantity to meet the needs of the patients in that facility.

(2) The quantity of each CDS drug shall not exceed the limit allowed in 59 O.S. Section 367.8 (D) (1).

(c) Before placing Non-CDS or CDS medications in an emergency medication kit the Oklahoma licensed pharmacy and facility must have a written policy indicating what drugs are included, and the reason for their need. This written policy must be available for Board inspection. The Oklahoma licensed pharmacy and the facility must comply with the rules and laws of the Oklahoma Bureau of Narcotics and the Federal Drug Enforcement Administration.

(d) All injectable medications shall be considered a single dose vial; any remainder shall be destroyed as required under Oklahoma or federal law and rules.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-16-7. Violations

(a) Theft or diversion of prescription drugs is a violation of state law and these rules.

(1) Violation by a licensed nursing home or licensed Assisted Living Center of these rules will be referred to the Oklahoma State Health Department and/or other proper authorities for possible action.

(2) Violation by a registrant of the Board may result in action under 59 O.S. Section 353.26 and/or other proper authorities for possible action.

(b) Violation of this subchapter by an Oklahoma licensed pharmacy or a facility may result in loss of the ability to have or use emergency medication kits as authorized under these rules.

(c) Violation(s) may be referred for criminal prosecution where appropriate.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12; Amended at 32 Ok Reg 1229, eff 8-27-15]

SUBCHAPTER 17. NUCLEAR PHARMACY

Section

535:15-17-1. Purpose

535:15-17-3. Definitions

535:15-17-5. General requirements

535:15-17-7. Minimum equipment

535:15-17-9. Library reference books or computer sources

[Source: Codified 7-11-91]

535:15-17-1. Purpose

The rules of this Subchapter are to accomplish the purposes of the Oklahoma Pharmacy Act, as specified in 59 O.S., Section 353.18 (A) thereof, by implementing rules of a licensed nuclear pharmacy. Nuclear pharmacy is hereby recognized as a specialty of pharmacy practice. As such, the following rules address those areas specific or unique to this specialty practice. These regulations are intended to supplement the regulations of other state and federal agencies.

[Source: Added at 14 Ok Reg 3027, eff 7-11-97]

535:15-17-3. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

“Authentication of Product History” means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

“Nuclear Pharmacy” means a pharmacy which provides radiopharmaceutical services and shall be licensed by the Board as a retail pharmacy.

“Practice of Nuclear Pharmacy” means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and related drugs.

“Qualified Nuclear Pharmacist” means a pharmacist who holds a current license issued by the Board, and who is either listed as an authorized user on a radioactive material users license or certified as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties or satisfies each of the following requirements:

(A) Meets minimal standards of training for status as an Authorized Nuclear Pharmacist (ANP), as specified by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency.

(B) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy, or other training program recognized by the Nuclear Regulatory Commission, with the following subjects covered:

- (i) radiation physics and instrumentation,
- (ii) radiation protection,
- (iii) mathematics pertaining to the use and measurement of radioactivity,
- (iv) radiation biology,
- (v) radiopharmaceutical chemistry;

(C) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas, as described in the current American Pharmaceutical Association (APhA) Nuclear Pharmacy Practice Standards:

- (i) procuring radioactive materials,
- (ii) compounding radiopharmaceuticals,
- (iii) performing routine quality control procedures,
- (iv) dispensing radiopharmaceuticals,
- (v) distributing radiopharmaceuticals,
- (vi) implementing basic radiation protection procedures,

(vii) consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public;

(D) Keeps documentation of experience and training available in the pharmacy for Board review.

“Quality Assurance Procedures” means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

“Quality Control Testing” means the performance of appropriate chemical and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

“Radiopharmaceutical Services” means, the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

“Radiopharmaceutical” means any substance which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term “radiopharmaceutical” also includes any product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

[Source: Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 24 Ok Reg 2262, eff 7-1-07]

535:15-17-5. General requirements

(a) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The nuclear pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The permit to operate a nuclear pharmacy is effective only so long as the pharmacy also holds a current Radioactive Material License issued by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency. Copies of inspection reports from Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency shall be available for Board inspection.

(c) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping / receiving area; radioactive material storage area; and radioactive waste decay area.

(d) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and must be totally enclosed and lockable.

(e) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with Board and Nuclear Regulatory Commission statutes and regulations.

(f) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted

standards of radiopharmaceutical quality assurance, including compounded sterile products. The Board recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(g) A radiopharmaceutical shall be dispensed only to a licensed prescriber authorized by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission or appropriate agreement state nuclear regulatory agency to possess, use and administer such drug. A

radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed prescriber. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications as described in 535:15-17-5 subsection (k) below. Separate records will be kept for these transfers and sales, see drug supplier permit rules in 535:15-7.

(h) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(1) This writing or record shall contain at least the following:

- (A) the name of the institution and prescriber, or prescribers' agent;
- (B) the date of dispensing (or calibration) and the calibration time of the radiopharmaceutical;
- (C) the name of the procedure;
- (D) the name of the radiopharmaceutical;
- (E) the dose or quantity of the radiopharmaceutical;
- (F) the serial number assigned to the order for the radiopharmaceutical;
- (G) any specific instructions; and
- (H) the initials of the pharmacist who dispensed the order.

(2) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

(i)

(1) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

- (A) the name and address of the pharmacy;
- (B) the name of the prescriber;
- (C) the date of dispensing (or calibration);
- (D) the serial number assigned to the order for the radiopharmaceutical;
- (E) the standard radiation symbol;
- (F) the words "Caution Radioactive Material";
- (G) the name of the procedure;
- (H) the radionuclide and chemical form;
- (I) the amount of radioactivity and the calibration date and time;
- (J) if a liquid, the volume;
- (K) if a solid, the number of items or weight;
- (L) if a gas, the number of ampules or vials;
- (M) the BUD and time; and,
- (N) the name of the patient or the words e.g. "Per Physician's Orders" in the absence of a patient name.

(2) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this sub-section shall be met when the name of the patient is readily retrievable from the physician upon demand.

(j) The inner container label of a radiopharmaceutical to be dispensed shall be labeled with, but not limited to:

- (1) the standard radiation symbol;
- (2) the identity of the radionuclide;
- (3) the amount of radioactivity and the calibration date and time;
- (4) the name of the procedure; and
- (5) serial number of the radiopharmaceutical.

(k) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the institutional radiation safety committee or equivalent radioactive use oversight committee approval, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(l) Each nuclear pharmacy shall have an adequate library and a current copy of state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

[Source: Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 15 Ok Reg 3272, eff 7-13-98; Amended at 24 Ok Reg 2262, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 34 Ok Reg 1886, eff 9-11-17]

535:15-17-7. Minimum equipment

(a) A nuclear pharmacy shall be exempt from the physical requirements in Section 535:15-3-4, Subsections (3), (6) and (7).

(b) The professional area of the pharmacy shall have at least the following equipment:

- (1) Radionuclide Dose Calibrator;
- (2) Refrigerator;
- (3) Single or multiple channel scintillation counter with solid state detector (e.g. NaI (Tl) or Ge(Li));
- (4) Radiochemical fume hood and filter system with suitable air sampling equipment when dispensing or preparing volatile radiopharmaceuticals;
- (5) Area survey meter;
- (6) At least two GM survey meters (including one high-range meter);
- (7) Microscope and hemacytometer, when dispensing or preparing particle size dependent radiopharmaceuticals;
- (8) Laminar airflow hood and appropriate supplies to ensure sterile practices for sterile compounded preparation solutions;
- (9) Syringe and vial radiation shields;
- (10) Appropriate shielded drawing station;
- (11) Decontamination supplies;
- (12) Appropriate supplies to perform quality assurance testing;
- (13) Appropriate transport shields for syringes and vials; and
- (14) Transport containers which meet the U.S. Department of Transportation regulations, and other labels and supplies for shipping radioactive materials.

[Source: Added at 14 Ok Reg 3027, eff 7-11-97; Amended at 24 Ok Reg 2262, eff 7-1-07; Amended at 32 Ok Reg 1229, eff 8-27-15; Amended at 39 Ok Reg 2057, eff 9-11-22]

535:15-17-9. Library reference books or computer sources

A pharmacy library shall contain the following current reference books or computer sources:

(1) **Oklahoma law books.** The latest copy of the Oklahoma State Board of Pharmacy, Laws and Rules and

Regulations Pertaining to the Practice of Pharmacy and a recent copy of the Oklahoma State Bureau of Narcotics & Dangerous Drug Control's Rules and Regulations.

(2) Reference compendia necessary to practice Nuclear Pharmacy safely within federal and state requirements.

[Source: Added at 14 Ok Reg 3027, eff 7-11-97]

SUBCHAPTER 18. CUSTOMIZED ADHERENCE MEDICATION PACKAGE (CAMP)

Section

535:15-18-1. Purpose

535:15-18-2. Definitions

535:15-18-3. Packaging requirements

535:15-18-4. Labeling

[Source: Codified at 35 OK Reg 1923, eff 9-14-18]

535:15-18-1. Purpose.

The rules of this Subchapter are to provide standards for the preparation and labeling of customized adherence medication packaging by licensed pharmacies, pursuant to orders or prescriptions. Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the requirements of this subchapter.

535:15-18-2. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the content clearly indicates otherwise:

“**Customized Adherence Medication Package**” or “**CAMP**” means packaging for dispensed drugs that is comprised of units containing two or more medications and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

“**USER**” means patient or caregiver.

535:15-18-3. Packaging requirements

Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the following requirements:

(1) In place of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient’s caregiver, or a prescriber, provide a CAMP. The CAMP is designed and labeled to indicate the day and time or period of time that the contents within each CAMP are to be taken. The dispensing pharmacy shall instruct the patient or caregiver on the use of the CAMP.

(2) In the absence of more stringent packaging requirements for any of the drug products contained in the CAMP, each CAMP shall be in compliance with the United States Pharmacopeia (USP) and National Formulary (NF). Each container shall be designed as to show evidence of tampering. CAMP packaging shall comply with all provisions of the poison prevention packaging act.

(3) When preparing a CAMP, the dispenser shall take into account any applicable USP Compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may affect the simultaneous administration of the medications. Medications shall not be dispensed in CAMP in any of the following situations:

(A) The USP monograph or official labeling of a medication requires dispensing in the original container

(B) The drugs or dosage forms are incompatible with packaging components or each other.

(C) The drugs are therapeutically incompatible when administered simultaneously.

(4) If two medications have physical characteristics that make them indistinguishable from each other, then the medication shall not be packaged together in the same CAMP.

(5) Medications that have been dispensed in CAMP may not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in the CAMP

is changed, then a new appropriately labeled CAMP may be prepared for the patient. Medications that have been dispensed in CAMP are not eligible for donation under the Utilization of Unused Prescription Medications Act.

535:15-18-4. Labeling

(a) Packaging must bear, at a minimum, the labeling requirements as stated in Title 59, Section 353.20.1(B); and,

- (1) Physical description of medication (i.e. imprint, description) or be separately packaged;
- (2) Expiration date;
- (3) Lot number(s), if required;
- (4) Date and time to be given

(b) If packaging is detachable into individual units of administration time, each individual unit must bear:

- (1) The name of patient;
- (2) The name and strength of the medication(s); and
- (3) Date and time to be given.

[Source: Added at 35 OK Reg 1923, eff 9-14-18; Amended at 37 Ok Reg 2048, eff9-11-20]

SUBCHAPTER 19. AUTOMATION RULES

Section

535:15-19-1. Purpose

535:15-19-2. Definitions

535:15-19-3- Medication Stocking

535:15-19-4. Pharmacist Verification

535:15-19-5. Policies and Procedures

535:15-19-6. Recordkeeping

535:15-19-7. Prepacking by automation

[Source: Added at 35 OK Reg 1924, eff 9-14-18]

535:15-19-1. Purpose

The rules of this Subchapter are to establish standards for automated dispensing systems by licensed pharmacies. Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the rules of this subchapter.

[Source: Added at 35 OK Reg 1924, eff 9-14-18]

535:15-19-2. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the content clearly indicates otherwise:

"Automated dispensing system" means an automated system used by a pharmacy licensed by the state of Oklahoma to assist in dispensing a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated dispensing system" does not include automated devices used solely to count medication that is then subject to final product check by a pharmacist prior to dispensing, vacuum tube drug delivery systems, or automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient.

"Electronic verification system" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated dispensing system.

"Manufacturer's unit of use package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

"Prepacked" for the purposes of this chapter means any drug that has been removed from the original packaging of the manufacturer or an FDA repackager and is placed in a properly labeled dispensing container by a pharmacy for the purpose of dispensing to the ultimate user from the pharmacy in which the prepacking occurred.

[Source: Added at 35 OK Reg 1924, eff 9-14-18]

535:15-19-3. Medication stocking

Automated dispensing systems may be stocked or loaded by a pharmacist, or by an intern or pharmacy technician under the direct supervision of a pharmacist.

[Source: Added at 35 OK Reg 1924, eff 9-14-18]

535:15-19-4. Pharmacist verification

- a) A licensed pharmacist shall inspect and verify the accuracy of the contents of any final dispensing container filled or packaged by an automated dispensing system, and any label affixed there to, prior to dispensing.
- b) The pharmacist verification requirements of Subsection (a) shall be deemed satisfied if:
 - (1) Individual unit-dose, bar-coded medications are employed by the automated system, and
 - (2) The process of filling / loading the system includes bar-code verification to prevent errors, and
 - (3) The process included a pharmacist verification step either prior to or after loading the automated System.

[Source: Added at 38 OK Reg 1924, eff 9-11-21]; Amended at 38 OK Reg 2456, eff 9-11-21]

535:15-19-5. Policies and procedures

(a) Written policies and procedures shall be established by and reviewed annually by the pharmacist-in-charge, be maintained in the pharmacy, and be available for review upon inspection.

(b) At a minimum, the pharmacy and pharmacy personnel shall establish and follow policies and procedures for the following:

- (1) accurate filling, loading, and stocking of the system;
- (2) sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;
- (3) investigating and addressing dispensing errors and system malfunctions;
- (4) tracking and documenting prescription errors related to the system that are not corrected prior to dispensing to the patient;
- (5) testing the proper function of the system and any accompanying electronic verification system; at a minimum, the system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification system that changes or alters the dispensing or electronic verification process;
- (6) written documentation of training persons authorized to access, stock, or load the system in equipment use and operations which shall be maintained in the pharmacy and be available for inspection;
- (7) preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;
- (8) identifying and recording persons responsible for stocking, loading, and filling the system
- (9) conducting routine and preventive maintenance and, if applicable, calibration;
- (10) removing expired, adulterated, misbranded, or recalled drugs;

(11) ensuring proper drug storage within the system, consistent with the manufacturer's specifications and the USP;

(12) maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification system to ensure proper and accurate functioning; and

(13) ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements.

[Source: Added at 35 OK Reg 1924, eff 9-14-18]

535:15-19-6. Recordkeeping

Records and documentation required by this chapter shall be maintained in the pharmacy's records electronically or in writing for a minimum of two (2) years. Records shall be made readily available for inspection and produced to the board inspector upon request.

[Source: Added at 35 OK Reg 1924, eff 9-14-18]

535:15-19-7. Prepacking by automation

A pharmacist, or an intern or pharmacy technician under the direct supervision of a licensed pharmacist, may prepack drugs for other than immediate dispensing purposes provided that the following conditions are met:

(1) prepacking occurs at the licensed pharmacy utilizing the system;

(2) only products which will be dispensed directly to the patient may be prepacked;

(3) containers utilized for prepacking shall meet standards specified by the USP, which has been incorporated herein by reference (e.g. preservation, packaging, storage and labeling section of the general notices and requirements); and where needed, light resistant containers shall be used;

(4) any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, quantity, NDC number, the expiration date and lot number, and the date prepacked; and

(5) a record of drugs prepacked must be kept, and include the following: the name and strength of the drug, lot number, NDC number, expiration date, date of prepacking, total number of dosage units (tabs, caps) prepacked, quantity per prepacked container, initials of packer and of pharmacist performing verification of prepack.

[Source: Added at 35 OK Reg 1924, eff 9-14-18]

CHAPTER 20. MANUFACTURERS, REPACKAGERS, OUTSOURCING FACILITIES, WHOLESALERS, THIRD-PARTY LOGISTICS PROVIDERS, AND MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

Subchapter	Section
1. General Purpose	535:20-1-1
3. Manufacturers	535:20-3-1
5. Repackagers	535:20-5-1
6. Outsourcing Facilities.....	535:20-6-1
7. Wholesale Distributor Rules.....	535:20-7-1
8. Third-Party Logistics Providers.....	535:20-8-1
9. Medical Gas Suppliers and Distributors	535:20-9-1

[Authority: 59 O.S., §§ 353.7, 353.13(G), 353.13A, 353.17, 353.18, 353.20, 353.22, and 353.24 through 353.26]

[Source: Codified 12-31-91]

SUBCHAPTER 1. GENERAL PURPOSE

Section

535:20-1-1. Purpose

535:20-1-1. Purpose

- (a) The rules in this Chapter regulate the manufacture, repackaging, distribution, compounding and sale or storage of drugs, medicines, chemicals and poisons and the dispensing of drugs and medicines in all places where drugs and medicines are compounded, dispensed or stored. The rules regulate any and all places, including premises, vehicles, equipment, contents and records, where drugs, medicines, chemicals or poisons are sold, stored, vended, given away, compounded, dispensed, manufactured, repackaged or distributed.
- (b) The rules in this Chapter further concern the Board's authority and duty to confiscate all drugs, medicines, chemicals or poisons found to be sold, stored, vended, given away, compounded, dispensed, manufactured, repackaged or distributed contrary to the provisions of 59 O.S. Section 353 et seq.
- (c) The rules in this Chapter prescribe minimum standards, for the issuance of new or renewal licenses, with respect to floor space and other physical characteristics necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public.
- (d) The rules of this Chapter are necessary to protect the health, safety, and welfare of the public.
- (e) The rules in this Chapter implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[Source: Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 3. MANUFACTURERS

Section

535:20-3-1.1. Purpose

535:20-3-1.2. Definitions

535:20-3-3. Manufacturer licensing requirements

535:20-3-4. Minimum required information for licensure

535:20-3-4.1. Minimum qualifications

535:20-3-5.1. Personnel

535:20-3-6. Minimum requirements for Rx Only drug storage, handling, maintenance and records

[REVOKED]

535:20-3-6.10. Compliance with federal, state and local laws

535:20-3-7. Compressed medical gases

535:20-3-9. Prohibited conduct

535:20-3-10. Violations and penalties

[Source: Codified 6-11-92]

535:20-3-1.1. Purpose

- (a) The rules in this Subchapter set out the minimum requirements for licensure as a manufacturer.
- (b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[Source: Reserved at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-1.2. Definitions

The words or terms defined in 59 O.S. Section 353.1 and in 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[Source: Reserved at 26 Ok Reg 2296, eff 7-1-09; Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1786, eff 9-11-16]

535:20-3-3. Manufacturer licensing requirements

- (a) If Oklahoma is the state in which a prescription drug is manufactured or is the state from which or into which a prescription drug of a manufacturer is shipped, this prescription drug may not be manufactured in and/or shipped into or out of Oklahoma unless each facility of such manufacturer is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
- (b) A manufacturer shall also be licensed as a manufacturer by the Secretary of the U.S. Department of Health and Human Services, Food and Drug Administration.
- (c) A manufacturer license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new manufacturer license.
- (d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).
- (e) When manufacturer operations are conducted at more than one location, each location shall be licensed by the Board.
- (f) A manufacturer shall not operate from a place of residence.
- (g) The manufacturing facility shall be located apart and separate from any retail pharmacy licensed by the Board.
- (h) A manufacturer must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[Source: Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-4. Minimum required information for licensure

- (a) A manufacturer applicant must submit a satisfactorily completed Board-approved application together with the required fee.
 - (1) New applicants shall provide, at least, the following:
 - (A) Applicant's full name, all trade or business names used, full business address and telephone number;
 - (B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;
 - (C) Name(s) of the owner(s) of the applicant, including:
 - (i) if a person, the name, address, Social Security number and date of birth;
 - (ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;
 - (iii) if a corporation, the State of incorporation; and
 - (iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.
 - (D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and dates of birth;
 - (E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;

(F) Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration, and, if applicable, by the state where the applicant is located (home state); and,
(G) Upon the Board's written request, a list of all manufacturers, wholesale distributors, third-party logistics providers and dispensers for whom the manufacturer provides services at such facility.

(2) Renewal applicants shall provide those items listed above.

(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy (NABP), at its discretion, to inspect manufacturers.

[Source: Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 25 Ok Reg 1772, eff 5-12-08 (emergency); Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-4.1. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of manufacturers:

(1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;

(2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;

(3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;

(4) The furnishing by the applicant of false or fraudulent material in any application;

(5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by manufacturers;

(6) Any licensee who has no record of manufacturing prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and

(7) Any other factors or qualifications that the Board considers relevant to and consistent with the public health and safety.

(b) A manufacturer shall have and follow a diversion detection and prevention plan that includes all prescription drugs.

(c) The Board shall have the right to deny a license to an applicant if it determines that granting such a license would not be consistent with the public health and safety.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-5.1. Personnel

(a) Manufacturers shall establish and maintain for Board inspection a list of each partner, limited liability company member or corporate officer and corporate director, as well as designated representatives and facility managers, including a description of their duties and a summary of their qualifications.

(b) Each manufacturer shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the manufacturer for each location licensed. The facility manager is responsible for all aspects of the operation of the manufacturer.

(c) No manufacturer shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to manufacturing prescription drugs, any felony for violation of 21 U.S.C. § 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering. No manufacturer

shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-6.10. Compliance with federal, state and local laws

(a) A manufacturer shall operate in compliance with the Federal Food, Drug, and Cosmetic Act Good Manufacturing Practices, 21 U.S.C. §§ 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. §§ 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211.

(b) A manufacturer shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's Rules, OAC 535.

(c) A manufacturer shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.

(d) A manufacturer shall only ship to the address listed on the licensee's license.

[Source: Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-7. Compressed medical gases

Manufacturers of multiple products that include medical gases shall comply with the requirements in 535:20-9 for medical gas distributors.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01]

535:20-3-9. Prohibited conduct

(a) The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.

(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

[Source: Added at 25 Ok Reg 1772, eff 5-12-08 (emergency); Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-3-10. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.

(b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 5. REPACKAGERS

Section

535:20-5-1.1. Purpose

535:20-5-2.1. Definitions

535:20-5-3.1. Repackager licensing requirement

535:20-5-4.1. Minimum required information for licensure

535:20-5-4.2. Minimum qualifications

535:20-5-5.1. Personnel

535:20-5-6.10. Compliance with federal, state and local laws

535:20-5-7. Compressed medical gases

535:20-5-9. Prohibited conduct

535:20-5-1.1. Purpose

- (a) The rules in this Subchapter set the minimum requirements for licensure as a repackager.
- (b) The rules of this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[Source: Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-2.1. Definitions

The words or terms defined in 59 O.S. Section 353.1 and 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-3.1. Repackager licensing requirement

- (a) If Oklahoma is the state in which a prescription drug is repackaged or is the state from which or into which a prescription drug of a repackager is shipped, this prescription drug may not be repackaged and/or shipped into or out of Oklahoma unless each facility of such repackager is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
- (b) A repackager shall also be licensed as a repackager by the Secretary of the U.S. Department of Health and Human Services, Food and Drug Administration.
- (c) A repackager license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new repackager license.
- (d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).
- (e) When repackager operations are conducted at more than one location, each location shall be licensed by the Board.
- (f) A repackager shall not operate from a place of residence.
- (g) The repackaging facility shall be located apart and separate from any retail pharmacy licensed by the Board.
- (h) A repackager must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-4.1. Minimum required information for licensure

- (a) A repackager applicant must submit a satisfactorily completed Board-approved application together with the required fee.
 - (1) New applicants shall provide, at least, the following:
 - (A) Applicant's full name, all trade or business names used, full business address and telephone number;
 - (B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;
 - (C) Name(s) of the owner(s) of the applicant, including:
 - (i) if a person, the name, address, Social Security number and date of birth;
 - (ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;
 - (iii) if a corporation, the State of incorporation; and

(iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.

(D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and dates of birth;

(E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;

(F) Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration, and, if applicable, by the state where the applicant is located (home state); and,

(G) Upon the Board's written request, a list of all manufacturers, wholesale distributors, third-party logistics providers and dispensers for whom the repackager provides services at such facility.

(2) Renewal applicants shall provide those items listed above.

(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy, (NABP), at its discretion, to inspect repackagers.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-4.2. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of repackagers:

(1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;

(2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;

(3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;

(4) The furnishing by the applicant of false or fraudulent material in any application;

(5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by repackagers;

(6) Any licensee who has no record of repackaging prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and,

(7) Any other factors or qualifications that the Board considers relevant to and consistent with the public health and safety.

(b) A repackager shall have and follow diversion detection and prevention plan that includes all prescription drugs.

(c) The Board shall have the right to deny a license to an applicant if it determines that granting such a license would not be consistent with the public health and safety.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-5.5.1. Personnel

(a) Repackagers shall establish and maintain for Board inspection a list of each partner, limited liability company member or corporate officer and corporate director, as well as designated representatives and facility managers, including a description of their duties and a summary of their qualifications.

(b) Each repackager shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the repackager for each location licensed. The facility manager is responsible for all aspects of the operation of the repackager.

(c) No repackager shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to repackaging prescription drugs, any felony for violation of 21 U.S.C. § 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering. No repackager shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-6.10. Compliance with federal, state and local laws

(a) A repackager shall operate in compliance with the Federal Food, Drug, and Cosmetic Act Good Manufacturing Practices, 21 U.S.C. §§ 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. §§ 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211.

(b) A repackager shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's Rules, OAC 535.

(c) A repackager shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.

(d) A repackager shall ship only to the address listed on the licensee's license.

[Source: Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-7. Compressed medical gases

Packager of multiple products that include medical gases shall comply with the requirements in 535:20-9 for medical gas distributors.

[Source: Added at 9 Ok Reg 2145, eff 6-11-92; Revoked at 10 Ok Reg 3175, eff 6-25-93; Added at 18 Ok Reg 2749, eff 7-1-01]

535:20-5-9. Prohibited conduct

(a) The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.

(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

[Source: Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-5-10 Violations and Penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.

(b) Rules of conduct, violations of the rules of conduct and other requirements of applicants can be found in 535:25.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 6. OUTSOURCING FACILITIES

Section

535:20-6-1. Purpose

535:20-6-2. Definitions

- 535:20-6-3. Outsourcing facility licensing requirement
- 535:20-6-4. Minimum required information for licensure
- 535:20-6-5. Minimum qualifications
- 535:20-6-6. Personnel
- 535:20-6-7. Compliance with federal, state and local laws
- 535:20-6-8. Prohibited conduct
- 535:20-6-9. Violations and penalties

535:20-6-1. Purpose

- (a) The rules in this Subchapter set out the minimum requirements for licensure as an outsourcing facility.
- (b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-2. Definitions

The words or terms defined in 59 O.S. Section 353.1 shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1786, eff 9-11-16]

535:20-6-3. Outsourcing facility licensing requirement

- a) If Oklahoma is the state in which a prescription drug is compounded or is the state from which or into which a prescription drug of an outsourcing facility is shipped, this prescription drug may not be compounded in and/or shipped into or out of Oklahoma unless each facility of such outsourcing facility is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
- b) An outsourcing facility shall also be licensed as an outsourcing facility by the Secretary of the U. S. Department of Health and Human Services, Food and Drug Administration.
- c) An outsourcing facility license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new outsourcing facility license.
 - a. Changes in any information required for licensure must be reported to the Board, in writing, within ten
- d) days (e.g. facility manager, designated representative, telephone number, etc.).
- e) When outsourcing facility operations are conducted at more than one location, each location shall be licensed by the Board.
- f) An outsourcing facility shall not operate from a place of residence.
- g) The outsourcing facility may be located in a facility where a retail pharmacy licensed by the Board is located.
- h) An outsourcing facility which receives patient specific prescriptions and fills the prescriptions in Oklahoma or ships the filled prescriptions into Oklahoma shall also have an Oklahoma pharmacy or non-resident pharmacy license.
- i) An outsourcing facility must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-4. Minimum required information for licensure

- (a) An outsourcing facility applicant must submit a satisfactorily completed Board-approved application together with the required fee.

- (1) New applicants shall provide, at least, the following:

- (A) Applicant's full name, all trade or business names used, full business address, telephone number and unique facility identifier;
- (B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;
- (C) Name(s) of the owner(s) of the applicant, including:
 - (i) if a person, the name, address, Social Security number and date of birth;
 - (ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;
 - (iii) if a corporation, the State of incorporation; and
 - (iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.
- (D) Names of designated representatives, facility managers, and, if applicable, pharmacist-in-charge of the applicant, their Social Security numbers and dates of birth;
- (E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;
- (F) Proof of licensure by the U.S. Secretary of Health and Human Services, Food and Drug Administration, and, if applicable, by the state where the applicant is located (home state); and
- (G) Upon the Board's written request, a list of all dispensers for whom the outsourcing facility provides services at such facility.

(2) Renewal applicants shall provide those items listed above.

(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy (NABP), at its discretion, to inspect outsourcing facilities.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-5. Minimum qualifications

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of outsourcing facilities:

- (1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws or foreign laws;
- (2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;
- (3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;
- (4) The furnishing by the applicant of false or fraudulent material in any application;
- (5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by outsourcing facilities;
- (6) Any licensee who has no record of compounding prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and
- (7) Any other factors or qualifications that the Board considers relevant to and consistent with the public health and safety.

(b) An outsourcing facility shall have and follow a diversion detection and prevention plan that includes all prescription drugs.

(c) The Board shall have the right to deny a license to an applicant if it determines that granting such a license would not be consistent with the public health and safety.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-6. Personnel

(a) Outsourcing facilities shall establish and maintain for Board inspection a list of each partner, limited liability company member or corporate officer and corporate director, as well as designated representatives and facility managers, including a description of their duties and a summary of their qualifications.

(b) Each outsourcing facility shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the outsourcing facility for each location licensed.

(c) Each outsourcing facility shall designate, in writing on a Board-approved form, a person to serve as the PIC who is a pharmacist licensed by the Board. No pharmacist may serve as the PIC for more than one outsourcing facility and/or pharmacy at a time unless they are located at the same physical address and are dually licensed with the Board.

(d) No pharmacist may serve as the PIC for more than one outsourcing facility and/or pharmacy at a time unless they are located at the same physical address and are dually licensed with the Board.

(e) The PIC shall be present and practicing at the outsourcing facility for which he holds the PIC position no less than 20 hours per week during the outsourcing facility's ordinary course of business. In the event the outsourcing facility's normal hours of business are less than 40 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.

(f) A PIC shall work sufficient hours in the outsourcing facility to exercise control and meet the responsibilities of the PIC.

(g) A non-resident outsourcing facility registrant may request, in writing, that the Board allow additional time for a new pharmacist-in-charge to obtain an Oklahoma license in emergency or urgent situations. If the Board determines circumstances warrant it, the Board may grant up to a 90-day extension.

(h) No outsourcing facility shall have as an owner, designated representative, facility manager, or pharmacist-in-charge anyone convicted of any felony for conduct relating to compounding prescription drugs, any felony for violation of 21 U.S.C. § 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering.

(i) No outsourcing facility shall have as an owner, designated representative, facility manager or pharmacist-in-charge anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[Source: Added at 38 Ok Reg 1233, eff 9-11-21; Amended at 38 OK Reg 2458, eff 9-11-21; Amended at 39 Ok Reg 2067, eff 9-11-22]

535:20-6-7. Compliance with federal, state and local laws

(a) An outsourcing facility shall operate in compliance with the Federal Food, Drug, and Cosmetic Act Good Manufacturing Practices, 21 U.S.C. §§ 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. §§ 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211: and meet the requirements of Current Good Manufacturing Practice - Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act or any revision to the document as finalized.

(b) An outsourcing facility shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's Rules, OAC 535.

(c) An outsourcing facility shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.

(d) When shipping to licensees, an outsourcing facility shall ship only to the address listed on the licensee's license.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-8. Prohibited conduct

The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Drug Quality and Security Act of 2013 and rules promulgated thereunder, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-6-9. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.

(b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 7. WHOLESALE DISTRIBUTOR RULES

Section

535:20-7-1. Purpose

535:20-7-2. Definitions

535:20-7-3. Wholesale distributor licensing requirement

535:20-7-4. Minimum required information for licensure

535:20-7-5. Minimum qualifications

535:20-7-6. Personnel

535:20-7-7.10. Compliance with federal, state and local laws

535:20-7-8. Compressed medical gases

535:20-7-9.1. Prohibited conduct

535:20-7-10. Violations and penalties

535:20-7-1. Purpose

(a) The rules in this Subchapter set out the minimum requirements for licensure as a wholesaler distributor.

(b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Supply Chain Security Act of 2013, 21 U.S.C. § 360eee, et seq., 21 C.F.R. Part 205, other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[Source: Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-2. Definitions

The words or terms defined in 59 O.S. Section 353.1 and 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[Source: Amended at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1787, eff 9-11-16]

535:20-7-3. Wholesale distributor licensing requirement

(a) If Oklahoma is the state in which a prescription drug is distributed or is the state from which or into which a prescription drug is distributed by a wholesale distributor, that wholesale distributor may not distribute in or into or out of Oklahoma unless each facility of such wholesale distributor is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.

(b) If Oklahoma is the state into which a prescription drug is shipped by a wholesale distributor, that wholesale distributor shall also be licensed as a wholesale distributor by the state from which that wholesale distributor ships.

- (c) A wholesaler distributor license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new wholesale distributor license. Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.)
- (d) When wholesale distributor operations are conducted at more than one location, each location shall be licensed by the Board.
- (e) A wholesale distributor shall not operate from a place of residence.
- (f) The wholesale distributing facility located in Oklahoma shall be located apart and separate from any retail pharmacy licensed by the Board.
- (g) A wholesale distributor must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[Source: Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1787, eff 9-11-16]

535:20-7-4. Minimum required information for license

- (a) A wholesale distributor applicant must submit a satisfactorily completed Board-approved application together with the required fee.
 - (1) New applicants shall provide at least, the following:
 - (A) Applicant's full name, all trade or business names used, full business address and telephone number;
 - (B) Type of ownership, e.g. individual, partnership or corporation;
 - (C) Name(s) of the owner(s) of the applicant including:
 - (i) if a person; the name, address, social security number and date of birth;
 - (ii) if other than a person; the name, address, and social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director, and the federal employer identification number;
 - (iii) if a corporation, the State of incorporation; and,
 - (iv) if a publicly traded corporation, the information in ((a)(1)(C)(ii) is not required for corporate officers and corporate directors.
 - (D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and date of birth;
 - (E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and all of applicant's designated facility managers;
 - (F) Proof of licensure by the state where the applicant is located (home state) and, if applicable, by the U.S. Secretary of Health and Human Services, Food and Drug Administration;
 - (G) Submission of a surety bond meeting the requirements of the Drug Supply Chain Security Act of 2013, et seq. and the rules promulgated thereunder; and,
 - (H) Upon the Board's written request, a list of all manufacturers, wholesale distributors and dispensers for whom the wholesale distributor provides services at such facility.
 - (2) Renewal applicants shall provide those items listed above.
 - (3) Any other information the Board deems necessary to protect the public health and safety.
- (b) The Board may use an outside agency, such as the National Association of Boards of Pharmacy (NABP) program, at its discretion, to inspect wholesale distributors.

[Source: Amended at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-5. Minimum qualifications

- (a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of wholesale distributors:
- (1) Any findings by a law enforcement or regulatory agency that the applicant or any of its owners has violated any federal, state, or local laws;
 - (2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state, local, or federal laws;
 - (3) Any finding that the applicant or any of its owners is guilty of or pleaded nolo contendere to violating federal, state, or local laws;
 - (4) The furnishing by the applicant of false or fraudulent material in any application;
 - (5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors;
 - (6) Any licensee who has no record of providing wholesaler distributions during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require registrant appearance before the Board; and,
 - (7) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.
- (b) A wholesale distributor shall have and follow a diversion detection and prevention plan that includes all prescription drugs.
- (c) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

[Source: Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1787, eff 9-11-16]

535:20-7-6. Personnel

- (a) Wholesale distributors shall establish and maintain for Board inspection a list of each partner, corporate officer and corporate director or limited liability company member and facility manager, including a description of their duties and a summary of their qualifications.
- (b) Each wholesale distributor shall designate, in writing on a Board-approved form, a person to serve as the facility manager of the wholesale distributor for each location licensed. The facility manager is responsible for all aspects of the operation of the wholesale distributor.
- (c) No wholesale distributor shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to providing wholesale distribution of prescription drugs, any felony for violating 21 U.S.C. Section 331(i) or (k) or any felony for violation of 18 U.S.C. Section 1365 relating to product tampering. No wholesale distributor shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirement for licensure that presents a threat of serious adverse health consequences or death to humans.

[Source: Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08¹; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-7.10. Compliance with federal, state and local laws

- (a) A wholesale distributor shall operate in compliance with applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Supply Chain Security Act of 2013 and the rules promulgated thereunder and the Act, 59 O.S. Section 353 et seq., and the Board rules, OAC 535. A wholesale distributor shall comply with 21 C.F.R. Part 205, e.g. facilities, security, storage and written policies and procedures.
- (b) A wholesale distributor shall allow the Board and authorized federal, state, and local law enforcement

officials to enter and inspect their premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate records to the extent authorized by law or rules.

(c) A wholesaler distributor shall ship only to the address listed on the license.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15]; Amended at 38 OK Reg 2458, eff 9-11-21]

535:20-7-8. Compressed medical gases

Wholesalers of multiple products that include medical gases shall comply with the requirements in 535:20-9 for medical gas distributors.

[Source: Revoked at 10 Ok Reg 3175, eff 6-25-93; Added at 18 Ok Reg 2749, eff 7-1-01]

535:20-7-9.1. Prohibited Conduct

The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including but not limited to, the Drug Supply Chain Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and Board rules, OAC 535.

[Source: Added at 24 Ok Reg 2906, eff 8-1-07 (emergency); Added at 25 Ok Reg 1976, eff 7-1-08; Amended at 27 Ok Reg 2261, eff 7-11-10; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-7-10. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.

(b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 8. THIRD-PARTY LOGISTICS PROVIDERS

Section

535:20-8-1. Purpose

535:20-8-2. Definitions

535:20-8-3. Third-party logistics provider licensing requirement

535:20-8-4. Minimum required information for licensure

535:20-8-5. Minimum qualifications

535:20-8-6. Personnel

535:20-8-7. Compliance with federal, state and local laws

535:20-8-8. Prohibited conduct

535:20-8-9. Violations and penalties

535:20-8-1. Purpose

(a) The rules in this Subchapter set out the minimum requirements for licensure as a third-party logistics provider.

(b) The rules in this Subchapter are to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Supply Chain Security Act of 2013, 21 U.S.C. § 360eee, et seq., other applicable federal statutes and rules and the Act, 59 O.S. Section 353 et seq. and the Board's Rules, OAC 535.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-2. Definitions

The words or terms defined in 59 O.S. Section 353.1 and 21 U.S.C. § 360eee shall have the same meaning when used in this Subchapter as defined in these statutes, unless the context clearly indicates otherwise.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1787, eff 9-11-16]

535:20-8-3. Third-party logistics provider licensing requirement

- a) If Oklahoma is the state in which a prescription drug is shipped or is the state from which or into which a prescription drug is shipped by a third-party logistics provider, that third-party logistics provider may not ship in, into or out of Oklahoma unless each facility of such third-party logistics provider is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
- b) If Oklahoma is the state into which a prescription drug is shipped by a third-party logistics provider, that third-party logistics provider shall also be licensed as a third-party logistics provider by the state from which that third-party logistics provider ships.
- c) A third-party logistics provider license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new third-party logistics provider license.
- d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).
- e) When third-party logistics provider operations are conducted at more than one location, each location shall be licensed by the Board.
- f) A third-party logistics provider shall not operate from a place of residence.
- g) The third-party logistics provider facility shall be located apart and separate from any retail pharmacy licensed by the Board.
- h) A third-party logistics provider must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-4. Minimum required information for licensure

- (a) A third-party logistics provider applicant must submit a satisfactorily completed Board-approved application together with the required fee.
 - (1) New applicants shall provide, at least, the following:
 - (A) Applicant's full name, all trade or business names used, full business address and telephone number;
 - (B) Type of ownership, e.g. individual, partnership, limited liability company or corporation;
 - (C) Name(s) of the owner(s) of the applicant, including:
 - (i) if a person, the name, address, Social Security number and date of birth;
 - (ii) if other than a person, the name, address, and Social Security number and date of birth of each partner, limited liability company member or corporate officer and corporate director and the federal employer identification number;
 - (iii) if a corporation, the State of incorporation; and
 - (iv) if a publicly traded corporation, the information in (a)(1)(C)(ii) is not required for corporate officers and corporate directors.
 - (D) Names of designated representatives and facility managers of the applicant, their Social Security numbers and dates of birth;
 - (E) Evidence of criminal background checks and fingerprinting of the applicant, if a person, and of all of applicant's designated representatives and facility managers;
 - (F) Proof of licensure by the state where the applicant is located (home state) and/or, if applicable, by the U.S. Secretary of Health and Human Services, Food and Drug Administration; and
 - (G) Upon the Board's written request, a list of all manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility.

(2) Renewal applicants shall provide those items listed above.

(3) Any other information the Board deems necessary to protect the public health and safety.

(b) The Board may use an outside agency, such as a National Association of Boards of Pharmacy (NABP), at its discretion, to inspect third-party logistics providers.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-5. Minimum qualifications

- a) The Board shall consider, at a minimum, the following factors in determining the eligibility for and renewal of licensure of third-party logistics providers:
- (1) Any finding by a law enforcement agency or regulatory agency that the applicant or any of its owners have violated any federal, state, or local laws;
 - (2) Suspension, revocation or any other sanction against a license currently or previously held by the applicant or any of its owners for violations of state or federal laws;
 - (3) Any finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local criminal laws;
 - (4) The furnishing by the applicant of false or fraudulent material in any application;
 - (5) Failure to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by third-party logistics providers;
 - (6) Any licensee who has no record of providing third-party logistics services involving prescription drugs during routine inspection may have its subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require the licensee to appear before the Board; and
 - (7) Any other factors or qualifications that the Board considers relevant to and consistent with the public health and safety.
- b) A third-party logistics provider shall have and follow a diversion detection and prevention plan that includes all prescription drugs.
- c) The Board shall have the right to deny a license to an applicant if it determines that granting such a license would not be consistent with the public health and safety.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-6. Personnel

- a) Third-party logistics providers shall establish and maintain for Board inspection a list of each partner, limited liability company member or corporate officer and corporate director, as well as designated representatives and facility managers, including a description of their duties and a summary of their qualifications.
- b) Each third-party logistics provider shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the third-party logistics provider for each location licensed. The facility manager is responsible for all aspects of the operation of the third-party logistics provider.
- c) No third-party logistics provider shall have as an owner, designated representative or facility manager anyone convicted of any felony for conduct relating to providing third-party logistics services involving prescription drugs, any felony for violation of 21 U.S.C. § 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering. No third-party logistics provider shall have as an owner, designated representative or facility manager anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-7. Compliance with federal, state and local laws

- a) A third-party logistics provider shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Supply Chain Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535. A third-party logistics provider shall comply with the storage practices set out in 21 U.S.C. § 360eee-3(d)(2)(C).
- b) A third-party logistics provider shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.
- c) When shipping to licensees, a third-party logistics provider shall ship only to the address listed on the licensee's license.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-8. Prohibited conduct

- a) A third-party logistics provider shall operate in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, the Drug Supply Chain Security Act of 2013 and rules promulgated thereunder and the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535. A third-party logistics provider shall comply with the storage practices set out in 21 U.S.C. § 360eee-3(d)(2)(C).
- b) A third-party logistics provider shall allow the Board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law or rules.
- c) When shipping to licensees, a third-party logistics provider shall ship only to the address listed on the licensee's license.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

535:20-8-9. Violations and penalties

- (a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.
- (b) Rules of conduct, violations of the rules of conduct and other requirements of all applicants can be found in 535:25.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15]

SUBCHAPTER 9. MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

Section

535:20-9-1. Purpose

535:20-9-2. Definitions

535:20-9-3. Medical gas suppliers

535:20-9-4. Medical gas distributors

535:20-9-5. Violations and penalties

535:20-9-6. Prohibited conduct

535:20-9-1. Purpose

This subchapter is to establish rules specific to medical gases due to the fact that its labeling, packaging, distribution and handling is unique.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93]

535:20-9-2. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Drug order" means a prescription drug order issued by a licensed prescriber for medical gas.

"Medical gas" means those gases and liquid oxygen upon which the manufacturer or distributor has, in compliance with federal law and regulations, placed one of several cautions, such as: "RX Only" that replaces "Caution - Federal Law prohibits dispensing without prescription".

"Medical gas distributor" means a person licensed to distribute medical gases on drug orders and to suppliers or other entities licensed to use, administer, or distribute medical gases.

"Medical gas supplier" means a person licensed to supply medical gases only on drug orders.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-9-3. Medical gas suppliers

(a) **Licensing requirement.** Before conducting interstate and/or intrastate transactions in Oklahoma, a medical gas supplier shall register annually with the Board.

(1) A medical gas supplier license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location shall require a new medical gas supplier license.

(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas supplier license. A medical gas supplier license entitles the license holder to store and supply medical gas (prescription drugs) at the licensed location.

(4) A medical gas supplier shall not operate from a place of residence.

(5) A medical gas supplier shall not operate from a storage unit.

(b) **License issuance.** Licenses shall be issued only to those medical gas suppliers who satisfy the provisions of: 59 O.S. Section 353.18 (B)(1)(2) et seq., and the requirements under the Act, this Title and the rules in 535:25 for applicants.

(c) **Compliance with federal requirements.** Medical gas supplier applicants and registrants shall meet the federal requirements to handle medical gas, the Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.), and/or any other applicable federal, state, or local laws and regulations. Medical gas supplier applicants and registrants shall be registered with the federal Food and Drug Administration (FDA), if required.

(d) **Minimum required information for licensure.** The minimum required information for medical gas supplier licensure shall be as follows, Medical gas supplier applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

(1) The name, full business address, and telephone number;

(2) All trade or business names used by the manufacturer applicant;

(3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;

(4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the manufacturer applicant; and

(6) Any other information the Board deems necessary to protect the public health.

(e) **Minimum qualifications.** Medical gas suppliers must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(1) Medical gas suppliers must conform to all applicable federal, state or local laws and regulations.

(2) The minimum qualifications shall be the same as those set forth in 535:25 and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in the supplying of medical gases:

- (A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;
- (B) Any felony convictions of the applicant under federal, state, or local laws;
- (C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;
- (D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;
- (E) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;
- (F) Compliance with licensing requirements under previously granted licenses, if any;
- (G) Compliance with requirements to maintain and/or make available to the State Board or to federal, state, or local law enforcement officials those records required under this section; and,
- (H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

(f) **Personnel.** Personnel employed by medical gas suppliers shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

(g) **Minimum requirements for storage, handling, and records.** Medical gas suppliers must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

(1) The following shall describe the minimum requirements for the storage and handling of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.

(A) All medical gas suppliers of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.

(B) All medical gas suppliers shall conform to the Act and the rules of this Title.

(C) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(i) Be licensed by the Board;

(ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(iv) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(v) Be maintained in a clean and orderly condition; and,

(vi) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Medical gases housed by a medical gas supplier shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

- (h) **Prescription requirement.** Medical gas suppliers shall not supply medical gas without a drug order.
- (1) An original or copy of a prescription drug order must be kept at the licensed location supplying the medical gas.
 - (2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.
- (i) **Minimum requirements for storage, handling, and records for medical gas.** The following shall describe the minimum requirements for the storage and handling of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.
- (1) **Security.** Each facility used for medical gases shall be secure from unauthorized entry.
 - (A) Access from outside the premises shall be kept to a minimum and be well controlled.
 - (B) The outside perimeter of the premises shall be well-lighted.
 - (C) Entry into areas where drugs are held shall be limited to authorized personnel.
 - (D) All medical gas suppliers shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - (E) All medical gas suppliers shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:
 - (i) The medical gas supplier must not ship the customer's order if the order is confirmed as suspicious;
 - (ii) Each medical gas supplier shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,
 - (iii) Medical gas suppliers shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.
 - (2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia / National Formulary (USP/NF).
 - (A) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
 - (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.
 - (C) The recordkeeping requirement in this Chapter for medical gas suppliers shall be followed for all stored drugs.
 - (3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.

(4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas supplier shall consider, among other things:

- (i) The conditions under which the drug has been held, stored or shipped before or during its return; and,
- (ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(B) The recordkeeping requirements for medical gas suppliers in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

(5) **Recordkeeping.** Medical gas suppliers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(C) Each medical gas supplier should maintain an ongoing list of persons with whom they do business.

(6) **Written policies and procedures.** Medical gas suppliers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas suppliers shall include in their written policies and procedures the following; A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

- (i) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board;
- (ii) Voluntary action by the medical gas supplier to remove defective or potentially defective drugs from the market; or
- (iii) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(B) A procedure to ensure that medical gas suppliers prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(i) This procedure shall provide for written documentation of the disposition of outdated drugs.

(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(7) **Responsible persons.** Medical gas suppliers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(8) **Compliance with federal, state and local laws.** Medical gas suppliers shall operate in compliance with applicable federal, state, and local laws and regulations.

(A) Medical gas suppliers shall permit the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(B) Medical gas suppliers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.

(9) **Salvaging and reprocessing.** Medical gas suppliers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-11-10; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1788, eff 9-11-16; Added at 35 OK Reg 1925, eff 9-14-18]

535:20-9-4. Medical gas distributors

(a) **Licensing requirement.** Before conducting interstate and or intrastate transactions in Oklahoma, a medical gas distributor shall register annually with the Board.

(1) A medical gas distributor license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location shall require a new medical gas distributor license.

(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas distributor license. Medical gas distributor license entitles the holder to store and distribute medical gas (prescription drugs) at the licensed location.

(4) A medical gas distributor shall not operate from a place of residence.

(5) A medical gas distributor shall not operate from a storage unit.

(b) **License issuance.** Licenses shall be issued only to those medical gas distributors who satisfy the provisions of: 59, O.S. Section 353.18 (B)(1)(2) et seq., and the requirements under the Act, this Title and the rules in 535:25 for applicants.

(c) **Compliance with federal requirements.** Medical gas distributor applicants and registrants shall meet the federal requirements to handle medical gas, the Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or any other applicable federal, state, or local laws and regulations. Medical gas distributor applicants and registrants shall be registered with the federal Food and Drug Administration (FDA), if

required.

(d) **Minimum required information for licensure.** The minimum required information for medical gas distributors licensure shall be as follows, Medical gas distributor applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

- (1) The name, full business address, and telephone number;
- (2) All trade or business names used by the manufacturer applicant;
- (3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;
- (4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);
- (5) The name(s) of the owner and/or operator of the manufacturer applicant; and
- (6) Any other information the Board deems necessary to protect the public health.

(e) **Minimum qualifications.** Medical gas distributors must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(1) Medical gas distributors must conform to all applicable federal, state or local laws and regulations.

(2) The minimum qualifications shall be the same as those set forth in 535:25 and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in medical gas distribution:

- (A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;
- (B) Any felony convictions of the applicant under federal, state, or local laws;
- (C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;
- (D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;
- (E) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;
- (F) Compliance with licensing requirements under previously granted licenses, if any;
- (G) Compliance with requirements to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required under this section; and,
- (H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

(f) **Personnel.** Personnel employed by medical gas distributors shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

(g) **Minimum requirements.** Medical gas distributors must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

(1) The following shall describe the minimum requirements for the storage and handling of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas

distributors and their officers, agents, representatives, and employees.

(A) All medical gas distributors of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.

(B) All medical gas distributors shall conform to the Act and the rules of this Title.

(C) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(i) Be licensed by the Board;

(ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(iv) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(v) Be maintained in a clean and orderly condition; and,

(vi) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Medical gases housed by a medical gas distributor shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(h) **Prescription requirements.** Medical gas distributors shall distribute only to an entity licensed to receive medical gas or upon a prescriber's drug order. A pharmacy, dentist, or licensed prescriber's license verifies their authority to receive Rx Only medical gases.

(1) An original or copy of a prescription drug order must be kept at the licensed location distributing the medical gas.

(2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.

(3) Distributors that sell to licensed medical gas suppliers must keep an updated copy of each supplier's license on file.

(i) **Minimum requirements for storage, handling and records for medical gas Rx Only drugs.** The following shall describe the minimum requirements for the storage and handling of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas distributors and their officers, agents, representatives, and employees.

(1) Security. Each facility used for medical gases shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

(B) The outside perimeter of the premises shall be well-lighted.

(C) Entry into areas where drugs are held shall be limited to authorized personnel.

(D) All medical gas distributors shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All medical gas distributors shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:

(i) The medical gas distributor must not ship the customer's order if the order is confirmed as suspicious;

- (ii) Each medical gas distributor shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,
 - (iii) Medical gas distributors shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.
- (2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
 - (A) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
 - (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.
 - (C) The recordkeeping requirement in this Chapter for medical gas distributors shall be followed for all stored drugs.
- (3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.
 - (B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.
- (4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.
 - (A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas distributors shall consider, among other things:
 - (i) The conditions under which the drug has been held, stored or shipped before or during its return; and,
 - (ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
 - (B) The recordkeeping requirements for medical gas distributors in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.
- (5) **Recordkeeping.** Medical gas distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.
 - (A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years

following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(C) Each medical gas distributor should maintain an ongoing list of persons with whom they do business.

(6) **Written policies and procedures.** Medical gas distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas distributors shall include in their written policies and procedures the following; A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(i) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board;

(ii) Voluntary action by the medical gas distributor to remove defective or potentially defective drugs from the market; or

(iii) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(B) A procedure to ensure that medical gas distributors prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(i) This procedure shall provide for written documentation of the disposition of outdated drugs.

(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(7) **Responsible persons.** Medical gas distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(8) **Compliance with federal, state and local laws.** Medical gas distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(A) Medical gas distributors shall permit the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(B) Medical gas distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.

(9) **Salvaging and reprocessing.** Medical gas distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-11-10; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1792, eff 9-11-16]

535:20-9-5. Violations and penalties

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in 59 O.S. Section 353, et seq.

(b) Rules of conduct, violations of the rules of conduct and other requirements of applicants can be found in 535:25.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 32 Ok Reg 1233, eff 8-27-15]

535:20-9-6. Prohibited conduct

(a) The following shall be considered prohibited conduct and be a violation of these rules: Failure to follow all applicable requirements of state and federal statutes and regulations, including, but not limited to, the Act, 59 O.S. Section 353, et seq. and the Board's rules, OAC 535.

(1) Engaging in medical gas distributing of drugs

(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate record, when required;

(B) destroying, altering, concealing, or failing to maintain complete and accurate records for any drug packaging, when required;

(C) knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, or,

(D) selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s).

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or the commission of any other act with respect to a drug; that results in the drug being misbranded.

(4) supplying, packaging, purchasing, selling, delivering or bringing into the state contraband drug(s), or anyone who illegally possesses any amount of contraband drug(s); or,

(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

[Source: Added at 26 Ok Reg 2296, eff 7-1-09; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 1793, eff 9-11-16]

CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

Subchapter	Section
1. General Requirements	535:25-1-1
3. Applicants, Registrants, and Applications	535:25-3-1

5. General Requirements or Procedures	535:25-5-1
6. Post and Active Duty Military Service and their Spouse Applicants	535:25-6-1
7. Rules of Registrant Conduct.....	535:25-7-1
9. Violations of the Rules of Registrant Conduct	535:25-9-1

[Authority: 59 O.S., §§ 353.7, 353.9, 353.11, 353.13A, 353.16A, 353.17, 353.18, 353.20, 353.22, and 353.24 through 353.26 and 354.]

[Source: Codified 12-31-91]

SUBCHAPTER 1. GENERAL REQUIREMENTS

Section

535:25-1-1. Purpose

535:25-1-1.1. Definitions

535:25-1-1. Purpose

- (a) The rules of this Chapter regulate the sale of drugs, medicines, chemicals and poisons in order to prevent illegal diversion of dangerous drugs.
- (b) The rules of this Chapter describe requirements applicable to various registrants.
- (c) The rules of this Chapter describe an inspector's notice to registrants to correct deficiencies and give notice of compliance.
- (d) The rules of this Chapter describe minimum qualifications and requirements for all applicants and registrants.
- (e) The rules of this Chapter describe registrant conduct and violations of registrant conduct.

[Source: Amended at 9 Ok Reg 2147, eff 6-11-92; Amended at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-1-1.1. Definitions

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Applicant" means a "person" as defined in Title 59, O.S., Section 353.1 who is making application for any registration, certificate, license or permit or renewal of the same.

"License" means any license, permit, registration or certificate.

"Registrant" means any holder of registration, certificate, license or permit that is regulated by the Board.

[Source: Amended at 17 Ok Reg 2636, eff 7-1-00; Amended at 18 Ok Reg 2757, eff 7-1-01]

SUBCHAPTER 3. APPLICANTS, REGISTRANTS, AND APPLICATIONS

Section

535:25-3-3. Qualifications and requirements for registrant applicants

535:25-3-4. Requirements for applicants or registrants who have had Board action taken against any license, permit or certificate

535:25-3-5. Multiple licenses/permits

535:25-3-6. Individual address change

535:25-3-7. Change requirements and notification

[535:25-3-8. Requirements for Licensees

[Source: Codified 7-1-00]

535:25-3-3. Qualifications and requirements for registrant applicants

- (a) The Board shall consider at least the following factors in reviewing the qualifications of registrants or applicants for licensure e.g.:

- (1) Any charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under any federal, state, or local laws relating to drug samples, drug distribution, or distribution of controlled substances;

- (2) Any felony charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under federal, state, or local laws;
- (3) The applicant's or registrant's past experience with prescription drugs, including controlled substances;
- (4) The furnishing by the applicant or registrant of fictitious, false, misleading, or fraudulent material in any application (original, new or renewal) or failing to provide information relevant to this application;
- (5) The suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant or registrant;
- (6) Compliance with licensing requirements under previously granted licenses, if any;
- (7) Compliance with requirements to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required by rule and law;
- (8) Abuse of alcohol or habit-forming drugs, or use of illegal CDS drugs or positive drug screen for such illegal substance or its metabolite;
- (9) Practicing as a registrant without reasonable skill and safety by reason of use and/or abuse of drugs, narcotics, chemicals or any other type of material, or as a result of any mental or physical condition; and,
- (10) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The applicant shall be forthright and open in the provision of information to the Board in the application process. No license, permit or certificate shall be awarded to an applicant who does not provide the Board with complete open and honest responses to all requests for information.

(c) The applicant shall be candid in regards to providing information related to any academic misconduct, malpractice, legal, or disciplinary action.

(d) The applicant shall fully and completely disclose ownership of any pharmacy, wholesaler, distributor, manufacturer, repackager, third-party logistics provider, outsourcing facility, medical gas supplier or medical gas distributor or any other person licensed by the Board.

(e) The Board shall have the right to deny a license to an applicant or registrant if it determines that the granting of such a license would not be consistent with the public health and safety.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 18 Ok Reg 2757, eff 7-1-01; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 21 Ok Reg 2460, eff 7-1-04; Amended at 24 Ok Reg 2265, eff 7-1-07; Amended at 27 Ok Reg 2269, eff 7-11-10; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-3-4. Requirements for applicants or registrants who have had Board action taken against any license, permit or certificate

(a) If the Board approves an application of an applicant or registrant who has had a previous registration, license, permit, or certificate which was revoked or subject to Board action the applicant shall be subject to the following terms: any specific requirements placed on the applicant by the Board based on the previous action, or pending action, and applicant's or registrant's current status.

(b) Any subsequent violations by the applicant or registrant shall subject the applicant or registrant to cumulative action based on previous violation on the previous license and the current violation.

(c) Failure of the applicant or registrant to meet any terms or requirements of the Board shall subject the applicant or registrant to Board action.

(d) The Board shall have the right to order any additional terms or conditions that it determines are required to protect the public health and safety.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 26 Ok Reg 2310, eff 7-1-09; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 33 OK Reg 1794, eff 9-11-16]

535:25-3-5. Multiple licenses/permits

- (a) **Pharmacy, Manufacturer, Repackager, Wholesaler, Distributor or Third-party logistics provider.** A pharmacy located in Oklahoma shall not be licensed in the same location as a manufacturer, repackager, wholesale distributor or third party logistics provider.
- (b) **Pharmacy/Pharmacy.** No more than one pharmacy license will be allowed in one location.
- (c) **Wholesaler/Wholesaler.** No more than one wholesale distributor license will be allowed in one location.
- (d) **Wholesaler/Repackager.** The licensing of a wholesaler distributor and a repackager in the same location will be allowed.
- (e) **Pharmacy/Drug Supplier.** The licensing of a pharmacy license and pharmacy drug supplier permit in the same location will be allowed.
- (f) **Pharmacy/Outsourcing Facility.** The licensing of a pharmacy and an outsourcing facility will be allowed when state and federal requirements are met.
- (g) **Pharmacy/Sterile compounding.** The licensing of a pharmacy and a sterile compounding pharmacy in the same location will be allowed.
- (h) **Intern/Technician.** Applicants may not hold an intern license and a technician permit at the same time.
- (i) **Pharmacist/Technician.** Applicants may not hold a pharmacist license and a technician permit at the same time. A pharmacist who has had Board action taken against his pharmacist license for whatever reason and no longer holds a current pharmacist license is not eligible for a technician permit.
- (j) **Medical Gas Supplier.** No more than one medical gas supplier license will be allowed in one location.
- (k) **Medical Gas Distributor.** No more than one medical gas distributor license will be allowed in one location.
- (l) **Medical Gas Distributor/Medical Gas Supplier.** A medical gas supplier located in Oklahoma shall not be allowed in the same location as a medical gas distributor.

[Source: Amended and renumbered from 535:25-1-2 at 17 Ok Reg 2636, eff 7-1-00; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 33 OK Reg 1794, eff 9-11-16; Added at 35 OK Reg 1931 eff 9-14-18]

535:25-3-6. Individual address change

Every individual applicant and/or registrant (e.g.: pharmacist, intern, technician, etc.) shall notify the Board in writing within 10 days of an address change.

[Source: Added at 18 Ok Reg 2757, eff 7-1-01]

535:25-3-7. Change requirements and notification

(a) Change of name, ownership, and/or location shall require a new license for all business permits, certificates or licenses (e.g. pharmacy, wholesale distributor, repackager, manufacturer, outsourcing facility, third-party logistics provider, medical gas supplier and distributor, training areas, sterile compounding, drug supplier, etc.)

(1) A change of ownership occurs when:

(A) a change of 20% or more of the ownership of the entity owning the license, permit or certificate occurs (for example, when the corporation owning the license, permit or certificate sells 20% or more of the stock); or

(B) a change of ownership form occurs (for example, from a sole proprietor ownership to a partnership, limited liability company or corporation).

(2) Any ownership change not reported as a change of ownership because it involves a transfer of less than 20% of the ownership of the entity owning the license, permit or certificate must be reported at the next renewal of the entity license, permit or certificate.

(3) For publicly traded corporations, a routine sale of stock is not a change of ownership. (Note: a publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.)

(b) Changes:

- (1) Changes of ownership, name, and/or location require a new license, special inspection and special inspection fee.
- (2) The following changes in information must be reported to the Board within ten (10) days: manager, representative, contact person, officer(s), phone number, email address, and hours of operation.
- (3) Address change requires a new license prior to drugs being moved or stored at the new address, see (1) above.

(c) Every applicant for change or renewal of license, permit or certificate shall meet the requirements in 535:25 at a minimum.

[Source: Added at 18 Ok Reg 2757, eff 7-1-01; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 24 Ok Reg 2265, eff 7-1-07; Amended at 32 Ok Reg 1261, eff 8-27-15]; Amended at 38 OK Reg 2459, eff 9-11-21]

535:25-3-8. Requirements for Licensees

- (a) Licensees shall sell, ship, deliver, etc. only to the address listed on the receiving licensee's license.
- (b) Licensees that store, ship, sell, deliver, or handle drugs shall not operate from a place of residence
- (c) Licensees shall not receive drugs at other than the address listed on their license.
- (d) A licensee representative shall sign the Pharmacy Board inspection report upon completion. The licensee representative shall be responsible to assure that issues noted, if any, are resolved.

[Source: Added at 32 Ok Reg 1261, eff 8-27-15; Amended at 39 Ok Reg 2068, eff 9-11-22]

SUBCHAPTER 5. GENERAL REQUIREMENTS OR PROCEDURES

Section

535:25-5-1. Inspector's warning notice

535:25-5-2. Procedure to return a restricted license to good standing

535:25-5-3. Drug Screening

535:25-5-4. Board order(s) due date

535:25-5-5. Prescription drug (Rx only) purchases and record requirements

[Source: Codified 7-1-00]

535:25-5-1. Inspector's warning notice

- (a) Purpose. An inspector's warning notice protects public health by allowing registrants to expeditiously correct violations of laws and rules, and report these corrections to the Board in writing.
- (b) Recipient. A warning notice may be issued to any registrant found to be violating the rules of this Title (OAC 535), 59 O.S. Section 353 et seq., and/or any federal, state or local laws and rules.
- (c) Issuance. An inspector may issue a warning notice at the time a violation is found.
- (d) Failure to respond. A recipient's failure to satisfactorily respond within ten days to a warning notice may be referred by the Director to the Board for review or complaint and hearing.
- (e) Board review of warning notices. Any registrant receiving a warning notice may be referred by the Director to the Board for review or complaint and hearing.

[Source: Amended and renumbered from 535:25-1-3 at 17 Ok Reg 2636, eff 7-1-00; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-5-2. Procedure to return a restricted license to good standing

- (a) Upon the expiration date of a restriction, the registrant must request in writing that the Board return the license to good standing.
- (b) The registrant may be requested to appear before the Board prior to any action being taken on the request.

[Source: Renumbered from 535:25-1-4 at 17 Ok Reg 2636, eff 7-1-00]

535:25-5-3. Drug Screening

- (a) Any individual registrant who is suspended and/or placed on probation may be required to submit to

random drug screening.

(b) Random drug screening required by the Board shall be done at the registrant's expense.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-5-4. Board order(s) due date

Any fine(s) ordered or agreed to in a Final Order, Agreed Order, or any other Order of the Board is due and payable upon receipt of such Order by the registrant; unless otherwise stated in the Order.

[Source: Added at 18 Ok Reg 2757, eff 7-1-01]

535:25-5-5. Prescription drug (Rx only) purchases and record requirements

(a) All registrants shall keep adequate records to assure that prescription drugs are legally received and/or distributed or dispensed, as appropriate. Such records shall include, but not be limited to, all prescription drug purchase (e.g. invoices, etc.) and inventory records and shall be maintained and be readily retrievable for a period of at least 2 years.

(b) Prescription drug purchases may only be made from entities licensed to sell prescription drugs. A registrant shall exercise professional judgment regarding the purchase of prescription drugs in order to assure a safe, sanitary and legal prescription drug supply is maintained.

[Source: Added at 24 Ok Reg 2265, eff 7-1-07; Amended at 32 Ok Reg 1261, eff 8-27-15]

SUBCHAPTER 6. POST AND ACTIVE DUTY MILITARY SERVICE AND THEIR SPOUSE APPLICANTS

Section

535:25-5-3. Post and Active Duty Military service and their Spouse applicants

535:25-6-1. Purpose

The purpose of this subchapter is to implement 59 O.S. Section 4100.5 -4100.8 regarding active duty military personnel who receive notice or orders for military transfer or honorable discharge to this state, and their spouse.

[Source: added at 38 OK Reg 2459, eff 9-11-21]

535:25-6-2. Active duty military and their spouse requirements

(a) Active duty military personnel and their spouse licensed as a pharmacist or permitted as a pharmacy technician in another state, upon receiving notice or orders for military transfer or honorable discharge to Oklahoma are eligible for expedited pharmacist reciprocity license or initial technician permit.

(b) Active duty military personnel and their spouse shall provide copies of military notice or orders as indicated in (a) and complete the required application. Such applicant shall present satisfactory evidence of education, training and experience of such valid license or certificate from another state.

(c) Not required for active duty military personnel who are performing their duties only on the premises of an assigned military base pursuant to federal or military law or rule.

(d) Upon receipt of the completed application and when the required documentation from the other state is found to be in good standing and reasonably equivalent to the requirements in this state, the Board shall issue such licenses or permits within 30 days.

(e) The Board shall waive the fee for active duty military and their spouse described in (a) above for the first period of issuance for such pharmacist reciprocity license or technician permit.

[Source: added at 38 OK Reg 2459, eff 9-11-21]

535:25-6-3. Post-Military service applicants

a) The Board shall consider the equivalent education, training and experience completed by an applicant for licensure while the applicant was a member of the United States Armed Forces or Reserves, National Guard of any state, the Military Reserves of any state, or the Naval militias of any state, and apply it in the manner most favorable toward satisfying the qualifications for issuance of a license or approval for license

examination.

- b) The Board shall expedite the process of licensure by reciprocity for applicants whose spouse is an active duty member of the Armed Forces of the United States if:
- 1) the military service member is on active duty within Oklahoma or claims permanent residency within Oklahoma for the six (6) months prior to assignment to active duty or during the period of active duty; and,
 - 2) the applicant left employment in another state to accompany the military service member spouse to Oklahoma.

[Source: Added at 32 Ok Reg 1261, eff 8-27-15]

SUBCHAPTER 7. RULES OF REGISTRANT CONDUCT

Section

535:25-7-1. Scope and purpose

535:25-7-2. Definitions

535:25-7-3. Registrant conduct

535:25-7-4. Confidentiality

535:25-7-5. Practice of medicine

535:25-7-6. Governing body

[Source: Codified 7-1-00]

535:25-7-1. Scope and purpose

The rules of this subchapter provide standards of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-7-2. Definitions

The definitions of this subchapter shall be the same as those set out in 535:25-1-1.1.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-7-3. Registrant conduct

- (a) Registrants shall conduct business in conformity with all federal, state and municipal laws at all times.
- (b) Registrants shall conduct themselves at all times in a manner that will entitle them to the respect and confidence of the community in which they practice.
- (c) Abuse of alcohol or drugs, use of an illegal controlled dangerous substance (CDS), or testing positive for such substance or its metabolite is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 21 Ok Reg 2460, eff 7-1-04; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 33 OK Reg 1794, eff 9-11-16]

535:25-7-4. Confidentiality

A registrant shall hold the health and safety of his patrons as his first consideration and will not divulge the nature of the patrons' problems or ailments or any confidence entrusted to him in his licensed capacity except in response to legal requirements or in the best interest of the patron.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-7-5. Practice of medicine

Registrants will refrain from any attempt at diagnosis or treatment that is the legally constituted right or obligation of any licensed practitioner or mid-level practitioner.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-7-6. Governing body

- (a) A registrant will recognize the Board as the governing body in the State of Oklahoma and report to them any violation of pharmacy laws or regulations that may come to his attention.

(b) A registrant who fails to report such violations will be subject to Board action against his license, permit or certificate.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 20 Ok Reg 2488, eff 7-11-03; Amended at 32 Ok Reg 1261, eff 8-27-15]

SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT

Section

535:25-9-1. Scope and purpose

535:25-9-2. Violating confidentiality

535:25-9-3. Violating laws or rules

535:25-9-4. False report or record, billing incorrectly, fraudulent billing or reports

535:25-9-5. Conducting business without reasonable skill and safety

535:25-9-6. Discrimination

535:25-9-7. Theft

535:25-9-8. Failure to establish and maintain effective controls

535:25-9-9. Prescription or drug order error

535:25-9-10. Patient health and safety

535:25-9-11. Arrangements

535:25-9-12. Professional fee

535:25-9-13. Auto refills

[Source: Codified 7-1-00]

535:25-9-1. Scope and purpose

The rules of this subchapter describe some violations of the rules of registrant conduct. Violations of registrant conduct include, but are not limited to, those violations described in this subchapter.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-2. Violating confidentiality

A registrant shall not violate patron confidentiality. This does not prevent pharmacies from providing drug therapy information to physicians for their patients, nor does it prevent the provision of information as required by law.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-9-3. Violating laws or rules

A registrant shall not violate directly, (or indirectly, through actions of another), assist or abet in the violation of, or conspire to violate, any provision of the Oklahoma Pharmacy Act, 59, O.S. Section 353 et seq., the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, the Prescription Drug Marketing Act (21 U.S.C., Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C., Sec. 13 et seq.), or federal, state and local laws and rules.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 21 Ok Reg 2460, eff 7-1-04; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-4. False report or record, billing incorrectly, fraudulent billing or reports

The following are violations of registrant conduct:

- (1) Making or filing a report or record which a registrant knows or should have known to be false, intentionally or negligently failing to file a report or record required by federal, state or local laws or rules, willfully impeding or obstructing such filing, or inducing another person to violate this rule. Such reports or records include only those which the registrant is required to make or file in his capacity as a registrant;
- (2) Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed;
- (3) Fraudulent billing or submitting false reports to a third party payer of prescription drugs.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-5. Conducting business without reasonable skill and safety

Conducting business in a registrant's capacity without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-9-6. Discrimination

Discriminating in any manner between patients or groups of patients for reasons of a particular disease, religion, race, creed, color, sex, age or national origin is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

535:25-9-7. Theft

Theft while working as a registrant is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 25 Ok Reg 1984, eff 7-1-08]

535:25-9-8. Failure to establish and maintain effective controls

The following are violations of registrant conduct:

- 1) Failure to establish and maintain effective controls to prevent prescription errors;
- 2) Failure to establish and maintain effective controls against the diversion of prescription drugs and/or controlled dangerous drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules;
- 3) The sale of dangerous drugs to a person or entity not eligible to receive such drugs;
- 4) The purchase of dangerous drugs from a person or entity not eligible to possess such drugs;
- 5) Failure to establish and maintain suspicious order monitoring records in a suspicious order monitoring program; and failure to notify the Board of confirmed suspicious orders; .
- 6) Shipping orders that are confirmed as suspicious; and,
- 7) Shipping to other than the licensees address on the license.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 26 Ok Reg 2310, eff 7-1-09; Amended at 27 Ok Reg 2269, eff 7-11-10; Amended at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-9. Prescription or drug order error

A prescription or drug order error which departs from the standards of care ordinarily exercised by a registrant with proof of actual injury not having to be established is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 32 Ok Reg 1261, eff 8-27-15; Amended at 34 Ok Reg 1888 , eff 9-11-17]; [Source: added at 38 OK Reg 2459, eff 9-11-21]

535:25-9-10. Patient health and safety

The health and safety of patients shall be a registrant's first consideration.

[Source: Added at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-11. Arrangements

Registrants shall oppose any arrangements inimical to public health. Such an arrangement could include, but is not limited to, an arrangement between a registrant and a prescriber or any practitioner of the healing arts whereby fees are divided or in which private formulas are concerned.

[Source: Added at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-12. Professional fee

A registrant's fee for professional services shall be fair, equitable, and commensurate with the knowledge and skill required to compound and dispense prescriptions and/or to render other professional services.

[Source: Added at 32 Ok Reg 1261, eff 8-27-15]

535:25-9-13. Auto refills

A registrant shall not do auto refills of a prescription unless authorized to do so by the patient or the patient's

agent. The registrant shall document the authorization to do auto refills of a prescription.

[Source: Added at 32 Ok Reg 1261, eff 8-27-15; Amended at 39 Ok Reg 2068, eff 9-11-22]

Appendix A

Oklahoma Administrative Code (OAC)

OBN Rules and Regulations link:

<https://www.obnnd.ok.gov/about-us/rules-regulations>

OBN Effect of HIPAA on State Law

and

Acceptable ID for PSE and CDS purchases

Oklahoma Bureau of Narcotics & Dangerous Drug Control:
(405) 521-2885
www.obnnd.ok.gov

The Effect of HIPAA on State Law

Oklahoma State Law authorizes the Oklahoma State Bureau of Narcotics (OBN) to perform administrative inspections of pharmacies and other registrants without a subpoena. This authority to make public health investigations is derived from Title 63. Public Health and Safety. HIPAA does not prevent OBN from performing this duty, nor does it require a subpoena for this information. The following section of HIPAA, in pertinent part, makes this clear:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) Standard: uses and disclosures required by law.

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) Standard: uses and disclosures for public health activities.

(1) Permitted disclosures. A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

This section does not require a subpoena. In fact, requiring a subpoena would invalidate the authority and duty of OBN to make administrative inspections which never required a subpoena.

It is a privilege to have an OBN narcotic registration. This privilege may be revoked for failing to provide records required to be kept by the Rules of OBN and Title 63. It is also a crime to interfere with an investigation of an OBN Agent.

If you have any questions or concerns, please contact the OBNDD at 405-521-2885.

Acceptable ID for PSE and CDS purchases

[O.S. Title 63 § 2-309B (7) and (9)]

7. "Recipient's identification number" and "recipient's agent's identification number" means the unique number contained on forms of identification listed in 8 CFR 274a.2(b)(1)(v)(A) and (B).

9. "State" means any state, territory, or possession of the United States, the District of Columbia, or foreign nation.

If you have any questions or concerns, please contact the OBNDD at 405-521-2885.

Appendix B

PHARMACY CHANGE OF OWNERSHIP, NAME AND/OR LOCATION

- A. An Oklahoma State Board of Pharmacy application for pharmacy license should be completed and sent to the Board office within 30 days after the effective date. (Non-Resident Pharmacies & Facilities must have updated license & inspection report before eligible for updated Oklahoma license)
- B. The pharmacy should notify the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBND) and the Federal Drug Enforcement Agency (DEA) in writing within fourteen (14) days of the change.
- C. In the case of a change of ownership, dangerous drugs, controlled dangerous substances and prescription files may be transferred to the new owner. An inventory of all controlled dangerous substances (CDS) must be taken on the date of the transfer and a copy sent to the Board of Pharmacy. The pharmacy inventory copy shall serve as the final inventory of the previous owner and the initial inventory of the new owner and must be maintained in the pharmacy.
- D. No inventory is required if there is a change of location or name with no change of ownership.

CLOSING A PHARMACY (*in-state*)

- A. Perform a final CDS inventory.
- B. Return the following to the Board:
 - 1. Pharmacy license
 - 2. A copy of final CDS inventory
 - 3. Letter stating the date of closing and the disposition of pharmacy records and "Rx Only" drugs.
- C. "RX Only" drugs may be sold to another licensed pharmacy, returned to the wholesaler or destroyed.
- D. CIII-V's must be invoiced and CII's require DEA 222 for transfer.
- E. "Rx Only" drugs may NOT be kept in an unlicensed location.
- F. All outdated or unwanted CDS drugs must be destroyed in accordance with State law.
- G. Prescription records may be sold or kept. However, they must be maintained and accessible for inspection for a period of five (5) years.
- H. Return DEA license and blank 222 forms to DEA. Contact DEA for any further requirements at (405) 475-7500.
- I. Return OBN license to OBN with a letter that the pharmacy is closing. Contact OBN for further requirements at (405) 530-3120.
- J. Remove all signs stating "pharmacy" "drug store", etc. unless another pharmacy will be replacing the closed pharmacy.

Appendix C - D

APPENDIX C - DEA Form 222

For information concerning DEA Form 222, see the following:

https://www.deadiversion.usdoj.gov/faq/form_222_faq.htm

Questions concerning DEA Form 222 may be directed to the OKC DEA at 405-475-7500.

APPENDIX D - DEA Form 106 (Report Lost / Stolen CDS)

1. Upon a loss or theft of controlled dangerous substances (CDS) a pharmacy must fill out a DEA Form 106:
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html
2. Copies of the completed DEA 106 may be sent to:

OBN, Oklahoma Bureau of Narcotics
419 NE 38th Terr
Oklahoma City, OK 73105

OSBP, Oklahoma State Board of Pharmacy
2920 N. Lincoln Blvd, Ste A
Oklahoma City, OK 73105
3. Keep a copy of the completed Form 106 in your files.
4. If a crime was committed (i.e. robbery or burglary), a police report must be filed. In the case of a loss of a controlled dangerous substance pharmacists must use their professional judgment, as it may not be necessary to file a police report.
5. Questions may be directed to the OKC DEA at 405-475-7500 or to OBN at 800-522-8031 or 405-521-2885.
6. Theft or any violation of the Oklahoma Controlled Substance Act by a Pharmacist, Technician, Intern, or other registrant must be reported to the Oklahoma State Board of Pharmacy.

21 CFR § 1301.76 (b)

The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or

significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances lost;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known;
5. Whether the specific controlled substances are likely candidates for diversion;
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

Appendix E

Oklahoma Mid-Level Practitioner Prescribing Summary

This summary dated November 2018 is subject to change. For specific information, contact the appropriate practice boards, the OK Bureau of Narcotics (OBN) and/or the Drug Enforcement Agency (DEA).

As of November 1, 2018, Oklahoma licensed Pharmacies can fill non CDS prescriptions from out of state Advanced Practice Registered Nurses (APRN's), Physician Assistants (PA's), and Optometrists.

Only Oklahoma licensed mid-level practitioners supervised by Oklahoma licensed physicians may prescribe and issue valid Oklahoma CDS prescriptions.

- They must obtain a mid-level DEA and OBN license to prescribe controlled dangerous substances.
- The name of the prescriber must be placed on the prescription label.
- The supervising physician's name must be on the prescription blank for Oklahoma licensed Physician Assistants and Advance Practice Nurses.
- PA's, Advanced Practice Nurses and Optometrists may receive and distribute samples of drugs they can prescribe.
- Optometrists can dispense medications to patients to treat ocular abnormalities.
- PA's and Advance Practice Nurses may NOT dispense.
- They may NOT prescribe CDS for themselves nor for their immediate family members [see OBN rules 475:30-1-3(d)].

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- ❖ **OKLAHOMA LICENSED PHYSICIAN ASSISTANTS (PA's)** have prescribing authority under the direction of a supervising physician. They must prescribe within the Medical Board's adopted Drug Formulary.
 - **C-II's** are limited to orders for immediate or ongoing administration on-site pursuant to an Oklahoma supervising physician and on-site facility approved written protocol.
 - **C-III thru C-V** prescriptions are limited to a 30-day supply as an individual prescription. No refills are allowed on controlled substances.
 - **Non-controlled drugs prescribed for a new diagnosis** for a patient are limited to a 30-day supply with two (2) refills.
 - **Non-controlled drugs prescribed for an established diagnosis** are permitted up to a 90-day supply with three (3) refills.
 - A PA may not issue prescriptions for drugs that the supervising physician is not permitted to prescribe.For licensure status and formulary information, contact the Medical Board at 405-962-1400 or access their website at www.okmedicalboard.org.
 - ❖ The following **OKLAHOMA LICENSED ADVANCED PRACTICE NURSES (APN's)** may apply for authority from the Oklahoma Board of Nursing to prescribe drugs subject to supervision by a physician: **Advanced Registered Nurse Practitioners, Clinical Nurse Specialists, Certified Nurse Midwives**. Parameters of prescribing include: the prescribed drug must be within the APN's specialty area of practice; prescribing includes C-III thru C-V limited to a 30-day supply (the 30 days supply may be a combination of the initial fill and a number of refills which add up to the 30 days supply); and prescribing is subject to an Exclusionary Formulary [list of drugs which may NOT be prescribed]. The Exclusionary Formulary is available at www.ok.gov/nursing/prac-exclusfrm.pdf.
 - ❖ **OKLAHOMA LICENSED CERTIFIED REGISTERED NURSE ANESTHETISTS (CRNA's)** authorized by the Oklahoma Board of Nursing may select, order, obtain and administer drugs only in the perioperative and periparturient periods. CRNA's may select, order, obtain and administer drugs including C-II thru C-V (with OBNDD and DEA registrations) from an Inclusionary Formulary [list of drugs which MAY be prescribed]. The Inclusionary Formulary is available at www.ok.gov/nursing/prac-crnafrm.pdf. CRNA's may NOT write outpatient prescriptions. Verification of licensure/advanced practice prescriptive authority is available from the Nursing Board's website at www.ok.gov/nursing or by contacting the Nursing Board at 405-962-1800.
 - ❖ **OKLAHOMA LICENSED OPTOMETRISTS** certified by the Oklahoma Optometry Board to prescribe may prescribe C-III thru C-V limited to a 7-day supply (no refills without a follow-up examination). Optometrists may prescribe up to a 5-day supply of Hydrocodone-containing drugs. Drugs prescribed have to be for abnormalities of the eye. For licensure status and formulary information, contact the Optometry Board at 405-733-7836 or visit their website at www.optometry.ok.gov.

Language is included in the statutes of the professions above to require their prescriptions be filled by a pharmacist for added patient protection. Pharmacists are responsible for the dosage and drug utilization review.

Appendix F

Consanguinity / Affinity Table

(Blood / Marriage)

Showing Degrees of Relationships

PERSON

(Practitioner)

1st *	Spouse	Parents	Children	
2nd *	Brothers Sisters	Grandchildren	Grandparents	
3rd **	Nieces Nephews	Great Grandchildren	Aunts Uncles	Great Grandparents

* A practitioner may NOT prescribe a Controlled Dangerous Substance (CDS) for a patient related within the first or second degree, whether by blood or marriage.

** A practitioner MAY prescribe for the 3rd degree and below.

[see Bureau of Narcotics Rule 475:30-1-3 and the appropriate professional licensure Board rules]

Appendix G

Waiver Requirements

All registrants of the Oklahoma Bureau of Narcotics and the Drug Enforcement Administration should review the waiver requirements for persons who will have access to controlled dangerous substances in their working environment. Regulations require that the registrant (pharmacy, hospital, drug room, wholesaler, manufacturer, etc.) obtain a waiver from the appropriate agency or agencies PRIOR to the employment of a person who “has been convicted of a misdemeanor or felony relating to any controlled dangerous substances.” Due diligence on the part of registrants may include a nationwide background check prior to employment to determine employment eligibility. As waiver requirements vary significantly from state to state, the eligibility of a person to work in an environment with access to controlled dangerous substances may be different. A review of the person’s background is important whether the person is a new hire, or a transfer, especially if the transfer is from another state.

Waiver References:

- **Oklahoma Bureau of Narcotics:** OAC 475:20-1-5(g) No registrant shall knowingly employ as an agent or employee any person who will have access to controlled dangerous substances if such person has been convicted, pled guilty or nolo contendere or otherwise ordered to complete a period of probation or supervision for a misdemeanor or felony relating to any controlled dangerous substances as defined by the Uniform Controlled Dangerous Substances Act in this state, any other state, or the United States, or any person convicted, pled guilty or nolo contendere or otherwise ordered to complete a period of probation or supervision for any felony of this state, any other state, or the United States, unless, after full review of the circumstances, the Director waives this requirement in writing with respect to each person on a case-by-case basis.
- **DEA:** 21 CFR 1301.76(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term “for cause” means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual’s handling of controlled substances.

Appendix H

Oklahoma Pharmacists Helping Pharmacists

- Oklahoma Pharmacists Helping Pharmacists (OPHP) is a not-for-profit, volunteer organization composed of pharmacists and college of pharmacy faculty dedicated to identification, intervention and retention of chemically-dependent or recovering pharmacists/student pharmacists.
- The goals and objectives of OPHP are to eliminate alcohol and drug abuse among pharmacists and student pharmacists through education about chemical dependency as a disease.
- OPHP is organized as a ten member Board of Directors to oversee the work of a full time Executive Director who is responsible for the day-to-day operation of OPHP. Pharmacist interveners are in place across the state and have received professional training in confronting their impaired colleagues.
- OPHP's decisions and actions are not reported to the Oklahoma State Board of Pharmacy when the impaired pharmacist/student pharmacist cooperates.
- Assistance may be obtained by calling the **OPHP "Helpline" (1-800-260-7574 x 5773) 24 hours a day**. A taped message may be left and calls will be returned as soon as possible. If immediate assistance is needed, a phone number is available for immediate response. All calls are kept confidential. However, the caller must identify him or herself and give specific reasons for suspecting impairment exists.
- Calls for assistance may come from several sources. A call may be made by the impaired pharmacist or student pharmacist who realizes he/she has a chemical dependency, mental or physical impairment and is seeking help. He/she will remain anonymous to the profession and the Oklahoma State Board of Pharmacy. In these instances, an appointment will be made for the impaired individual at an OPHP approved evaluation/referral center. If the pharmacist or student pharmacist desires, the Executive Director will assist in making arrangements to receive the appropriate treatment. After treatment, OPHP will monitor progress in recovery thus assisting in re-entry into the profession or school.
- If the pharmacist or student pharmacist denies any illness and refuses to seek an evaluation or treatment, or after acknowledging impairment the pharmacist or student pharmacist fails to comply with the evaluation and recommended treatment, the Executive Director will make every effort to encourage the pharmacist/student pharmacist to comply. If the impaired person refuses, the OPHP Board of Directors will direct the Executive Director to issue a report to the Oklahoma State Board of Pharmacy. If there is imminent peril to the public, impaired person, or the Executive Director, a directive from the OPHP Board of Directors can be waived and an immediate report issued.
- If an impaired pharmacist or student pharmacist refers themselves to OPHP, the Oklahoma State Board of Pharmacy is not notified unless that person fails to comply with OPHP recommendations. However, there are circumstances where the Oklahoma State Board of Pharmacy requires participation in OPHP based on a Board-ordered contract.