OKLAHOMA PHARMACY LAW BOOK

2017

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
September 2017
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].


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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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“This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website.” [74 O.S. § 3105 and 65 O.S. § 3-114]
Directory

[Pharmacy related addresses and numbers. This list is not intended to be exclusive or exhaustive.]

ACPE, Accreditation Council for Pharmacy Education.......................................................... 312-664-3575
135 S LaSalle St, Ste 4100 ................................................................................................... fax 312-664-4652
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 202-783-2351
Washington, DC 20037 ..................................................................................................... e-mail: infocenter@aphanet.org / www.pharmacist.com

ASCP, American Society of Consultant Pharmacists......................................................... 800-355-2727
1321 Duke Street ................................................................................................................ 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 847-391-4502
Mount Prospect, IL 60056 ............................................................................................... e-mail: custserv@nabp.net / www.nabp.net

NACDS, National Association of Chain Drug Stores ....................................................... 703-549-3001
1776 Wilson Blvd, Ste 200 ............................................................................................... fax 703-836-4869
Arlington, VA 22209 ......................................................................................................... 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
3000 E. Memorial Rd...405-528-3338
Edmond, OK 73013...www.opha.com

**OPHP**, Oklahoma Pharmacists Helping Pharmacists
3000 E. Memorial Rd...800-260-7574 x5773
Edmond, OK 73013...www.opha.com/?page=OPHP

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

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

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

**Oklahoma Numbers**

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

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

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

**Dentistry Board**
2920 Lincoln Blvd, Ste B...405-522-4844
Oklahoma City, OK 73105...e-mail: dentist@oklaosf.state.ok.us / www.ok.gov/dentistry

**Health Care Authority (OHCA)**
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 ............................................................................................................................ 405-521-3160
2501 N Lincoln Blvd ....................................................................................................................... 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 .............................................................................................................. e-mail: info@okvetboard.com / www.okvetboard.com
Pharmacy Laws and Rules:
Oklahoma State Board of Pharmacy ................................................................. 405-521-3815
2920 Lincoln Blvd, Ste A .................................................................................. fax 405-521-3758
Oklahoma City, OK 73105 ............................................................................. www.pharmacy.ok.gov

Narcotics Rules:
Oklahoma Bureau of Narcotics & Dangerous Drugs Control .................... 800-522-8031
419 NE 38th Terr .............................................................................................. 405-521-2885
Oklahoma City, OK 73105 ............................................................................. www.ok.gov/obnnd
Prescription Monitoring Program (PMP) Help Line ..................................... 877-627-2674

AHFS Drug Information (the “Big Red Book”):
ASHP Customer Service
7272 Wisconsin Ave ......................................................................................... 866-279-0681
Bethesda, MD 20814-4820 ............................................................................. www.ashp.org


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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Title 535. Oklahoma State Board of Pharmacy

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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 filled prescription 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);
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. "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;
20. "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;
21. "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;
22. "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, or
   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;
23. "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;

24. "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;

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

26. "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;

27. "Medical gas supplier" means a person who dispenses medical gases on drug orders only to a patient or ultimate user;

28. "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;

29. "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.;

30. "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;

31. "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;

32. "Person" means an individual, partnership, limited liability company, corporation or association, unless the context otherwise requires;

33. "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;

34. "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;

35. "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;

36. "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;

37. "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;

38. "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;

39. "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;

40. "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 practitioner

   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;

41. "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;

42. "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;

43. "Sterile drug" means a drug that is intended for parental administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under state and federal law;

44. "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;

45. "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;

46. "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; and

47. "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.

353.1a. Prescribing Authority.
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.

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.

353.1b. 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 perinasthetical 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 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.

353.6. Meetings of Applicants for Licensing – Notice of Time and Place.
Meetings for the examination of applicants for licensing and granting of certificates shall be held at least one time each year at a time and place to be fixed by the State Board of Pharmacy. At least ten (10) days’ notice shall be publicly given of the time and place of each meeting at which there is an examination of candidates for licensure.

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, repackers, outsourcing facilities, wholesale distributors, third-party logistics providers, pharmacies, and other dispensers, medical gas suppliers, and medical gas distributors;
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 to carry out the provisions of the Oklahoma Pharmacy Act at an annual salary to be fixed by the Board, and to authorize necessary expenses. Such inspectors shall have the same powers and authority as that granted to peace
officers by the laws of this state for the purpose of enforcing the Oklahoma Pharmacy Act. 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 or take other disciplinary action and/or levy fines not to exceed Three Thousand Dollars ($3,000.00) for each count for which any holder of a certificate, license or permit has been convicted in Board hearings. 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 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; and

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.

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 of good moral character;
2. 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 FPGECE equivalency certification by the National Association of Boards of Pharmacy; and

3. 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.


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 prescription 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.

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 not 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. 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.


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. 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.

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.

353.22. – 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 who 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 under Medicare and/or Medicaid for End State Renal Disease (ESRD) may be delivered or shipped to a prescriber’s clinic for administration or final delivery to the patient, or
e. patient-specific filled prescriptions for radiopharmaceuticals may be delivered or shipped to a prescriber’s clinic for administration or pick-up.

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 Substances 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;

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 Substances 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.
   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.

A. The State Board of Pharmacy may:
   1. Revoke permanently or suspend any certificate, license or permit issued pursuant to the Oklahoma Pharmacy Act or reprimand or place on probation any holder of a certificate, license, or permit who:
      a. violates any provision of the Oklahoma Pharmacy Act or any other applicable state or federal law,
      b. violates any of the provisions of the Uniform Controlled Dangerous Substances Act,
      c. has been convicted of a felony or has pleaded guilty or no contest to a felony,
      d. engages in the practice of pharmacy while incapacitated or abuses intoxicating liquors or other chemical substances,
      e. conducts himself or herself in a manner likely to lower public esteem for the profession of pharmacy,
      f. has been disciplined by another State Board of Pharmacy or by another state or federal entity,
      g. has been legally adjudged to be not mentally competent, or
      h. exercises conduct and habits inconsistent with the rules of professional conduct established by the Board; and
   2. Levy administrative fines not to exceed Three Thousand Dollars ($3,000.00) for each count of which any holder of a certificate, license, or permit has been convicted in Board hearings.
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.

Pharmacists may dispense prescriptions for dangerous drugs and controlled dangerous substances specified in Section 581 of Title 59 of the Oklahoma Statutes for the treatment of ocular abnormalities, provided that such prescriptions are written by optometrists licensed by the State Board of Examiners in Optometry. Prescriptions issued by licensed optometrists shall include the optometrist's license number. Prescriptions for controlled dangerous substances shall include the optometrist's license 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 immunizations and therapeutic injections on orders from an osteopathic physician or allopathic physician.

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.

356. - Pharmacy Audit Integrity Act – Short Title.
   This act shall be known and may be cited as the “Pharmacy Audit Integrity 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 describe the audit procedures in the pharmacy contract. Unless otherwise agreed to in contract by both parties, 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. For an on-site audit, give the pharmacy written notice, including identification of prescription numbers to be audited, at least two (2) weeks prior to conducting the on-site audit. 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. For an on-site audit, 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 regarding a required document or record; however, such errors may be subject to recoupment. The pharmacy shall have the right to submit amended claims to correct clerical or record-keeping errors in lieu of recoupment, provided that the prescription was dispensed according to prescription documentation requirements set forth by the Oklahoma Pharmacy Act. 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 or such error results in actual financial harm to the pharmacy benefits manager, a health insurance plan managed by the pharmacy benefits manager or a consumer. 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. Base a finding of an overpayment or underpayment on a projection based on the number of patients served having similar diagnoses or on the number of similar orders or refills for similar drugs; provided, recoupment of claims shall be based on the actual overpayment or underpayment of each identified claim. A projection for overpayment or underpayment may be used to determine recoupment as part of a settlement as agreed to by the pharmacy;

8. Not include the dispensing fee amount in a finding of an overpayment unless a prescription was not actually dispensed or a physician denied authorization or as otherwise agreed to by contract;

9. Audit each pharmacy under the same standards and parameters as other similarly situated pharmacies audited by the entity;

10. Not exceed two (2) years 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;

11. Not schedule or initiate an audit during the first seven (7) calendar days of any month due to the high volume of prescriptions filled in the pharmacy during that time unless otherwise consented to by the pharmacy; and

12. Disclose to any plan sponsor whose claims were included in the audit any money recouped in the audit.

B. A pharmacy may 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.

C. The entity conducting the audit shall not audit more than seventy-five (75) prescriptions per initial audit.

D. 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.

E. The entity conducting the audit shall provide the pharmacy with a written report of the audit and shall:

1. Deliver a preliminary audit report to the pharmacy within ninety (90) calendar days after conclusion of the audit;
2. Allow the pharmacy at least sixty (60) calendar days following receipt of the preliminary audit 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 sixty (60) calendar days;

3. Deliver a final audit report to the pharmacy signed by the auditor within one hundred twenty (120) calendar days after receipt of the preliminary audit report or final appeal, as provided for in Section 356.3 of this title, whichever is later;

4. Recoup any disputed funds after final internal disposition of the audit, including the appeals process as provided for in Section 356.3 of this title. Unless otherwise agreed by the parties, future payments to the pharmacy may be withheld pending finalization of the audit should the identified discrepancy exceed Twenty-five Thousand Dollars ($25,000.00); and

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

F. 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.

G. 1. The full amount of any recoupment on an on-site 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.

H. 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 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 suspected or alleged 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.

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.
   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.
    Unless otherwise provided by contract, 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:
       1. Include in such contracts the 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, or has an "NR" or "NA" rating or a similar rating by a
          nationally recognized reference, 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 or a
          provider's representative to contest reimbursement amounts within ten (10) business days of the
          final adjusted payment date. The pharmacy benefits manager must respond to a provider or
          provider’s representative who has contested a reimbursement amount through this procedure
          within ten (10) business days. If a price update is warranted, the pharmacy benefits manager shall
          make the change in the reimbursement amount, permit the challenging pharmacy to reverse and
          rebill the claim in question, and make the reimbursement amount change effective for each similarly
          contracted Oklahoma provider; and
5. If the reimbursement appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code number from national or regional wholesalers where the drug is generally available for purchase by pharmacies in the state at or below the PBM's reimbursement.

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

C. The pharmacy benefits manager shall not require accreditation or licensing of providers other than by the State Board of Pharmacy or other state or federal government entity.

364. Renewal Certification.

No annual renewal certificate shall be issued to a pharmacist until such pharmacist shall have submitted proof to the Board that he has participated in not less than fifteen (15) clock hours of continuing education obtained through the satisfactory completion of an accredited program of continuing professional education during the previous calendar year.

366. Alternative Methods of Meeting Requirements.

A. The State Board of Pharmacy may grant to a pharmacist who meets all the necessary requirements for licensure, except the continuing education requirements, alternate methods of obtaining continuing education hours.

B. 1. Any pharmacist who does not meet the requirement 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 Oklahoma.

3. The holder of an inactive renewal certificate of licensure shall apply to the State Board of Pharmacy to be removed from the inactive status.

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.

367.6. 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.

A. A pharmacy may maintain controlled dangerous substances in an emergency medication kit used at a facility. The controlled dangerous substances may be used only for the emergency medication needs of a resident at the facility. A pharmacy may maintain drugs in an emergency medication kit for any facility.

B. The State Board of Pharmacy shall promulgate rules relating to emergency medication kits, including, but not limited to:
   1. The amount and type of controlled dangerous substances that may be maintained in an emergency medication kit;
   2. Procedures regarding the use of drugs from an emergency medication kit;
   3. Recordkeeping requirements; and
   4. Security requirements.

C. 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.
OKLAHOMA ADMINISTRATIVE CODE (OAC)
TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY

Chapter 1. Administrative Operations ................................................................. 535:1-1-1
10. Pharmacists; and Interns, Preceptors and Training Areas ............................ 535:10-1-1
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20. Manufacturers, Repackagers, Outsourcing Facilities, Wholesalers, Third-Party Logistics Providers, and Medical Gas Suppliers and Distributors .................................................. 535:20-1-1
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CHAPTER 1. ADMINISTRATIVE OPERATIONS

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.

SUBCHAPTER 3. DESCRIPTION OF ORGANIZATION

Section 535:1-3-1. Creation 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

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, and at least one meeting for examinations 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]

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.

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.

SUBCHAPTER 7. INDIVIDUAL PROCEEDINGS

(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.

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.
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.

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

535:1-7-5. Subpoenas
(a) **Issuance; serving.** Subpoenas for the attendance of witnesses, and/or for the furnishing of information required by the Board, and/or for the production of evidence or records of any kind shall be issued by the Director or his designee. Subpoenas shall be served, and a return made in any manner prescribed by Oklahoma Administrative Procedures Act.

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

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

535:1-7-6. Hearing records and record maintenance
(a) **Recordings.** The Board’s hearings shall be electronically recorded.

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


535:1-9-1. 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]


In any rule-making action, the Board shall comply with the then current requirements in the
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

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

535:1-11-3. Practical experience licenses and certificates
Practical experience license and certificate fees, as set by the Board, shall be as follows:
(1) Intern certificate - $100
(2) Training area certificate - $25
(3) Training area renewal - $10
(4) Preceptor certificate - $25
(5) Preceptor renewal - $10

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

535:1-11-4. Other fees
(a) For all records required to be open by the Oklahoma Open Records Act, fees shall be charged for copying as specified in the open records act.
(b) Other fees shall be as follows:

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

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

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

535:1-11-5. Miscellaneous
Miscellaneous fees, as set by the Board, shall be as follows:
(1) Oklahoma Board 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
[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]

(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]

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

Subchapter 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

Section 535:10-1-1. Purpose

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.

(8) Knowingly billing or charging for quantities greater than delivered, or for a brand when a generic or a compounded product is dispensed.
(9) Submitting fraudulent billing or reports to a third party payor of prescription drugs.
(10) Refusing to answer reasonable questions or provide information about prescriptions dispensed by the pharmacy when requested by, or for, the patient and which would aid the patient’s health in the professional judgement of the pharmacist.
(11) Not attempting to resolve a possible prescription error; or situation of potential harm to the patient when apparent or should have been apparent to the pharmacist.
(12) Not attempting to address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that the patient may be dependent or addicted.
(13) The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.
(14) The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.
(15) Discriminating in any manner between patients or groups of patients for reasons of a particular disease, religion, race, creed, color, sex, age or national origin.
(16) Violating patient confidentiality. This does not prevent pharmacies from providing drug therapy information to prescribers for their patients, nor does it prevent the provision of information as required by law.
(17) Theft while practicing pharmacy.
(18) Knowingly dispensing prescription drug refills after the death of a prescriber. (A limited quantity may be allowed for the patient’s health and safety.)
(19) Failure to establish and maintain effective controls to prevent prescription errors or misfills.
(20) The misfilling of a prescription 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]

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.
(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]

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
535:10-5-1. 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]

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 2246, eff 7-11-10; Amended at 33 Ok Reg 1778, eff 9-11-16]

535:10-5-4. Intern practice requirements

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

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

(2) A ratio of one (1) faculty preceptor with up to two (2) interns will be allowed in 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
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)
(c) **Changes.** Changes of pharmacy location, name or ownership shall require a new training area certificate.

**535:10-5-11. Violations**

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

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

**535:10-5-13. Intern file destruction**

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

1. is dropped from a college of pharmacy;
2. becomes a licensed pharmacist in any state; or transfers by reciprocity or score transfer to another state; or,
3. license expires.

**SUBCHAPTER 7. PHARMACIST LICENSURE**

**Section 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.

**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.

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.

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.

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).

(f) Applicants may be required to take the Board approved law exam as described in 535:10-7-4(e).

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

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

[Source: Added at 18 Ok Reg 2732, eff 7-1-01; Amended at 27 Ok Reg 2246, eff 7-11-10; Amended at 33 OK Reg 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
[Source: Codified 6-25-93]

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]

(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]

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 ordered by a prescribing licensed practitioner.
(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]
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) A D.Ph. shall administer immunizations on the order of a prescribing licensed practitioner.

(c) The Board will maintain a register of those pharmacists who have been approved for immunizations.

(d) A D.Ph. with immunization registration must maintain ongoing competency through required training, including 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]

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 and 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 26 Ok Reg 2274, eff 7-1-09; 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
   (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]

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.

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:
   - Drugs have been kept under control of a health care professional
   - Drugs have been stored properly (e.g. heat, cold, moisture),
   - Drugs can be identified, and
   - 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:
   - Names of Consultant Pharmacist and Director of Nursing (D.O.N.) or designee, the nursing home and the name of the receiving pharmacy;
   - Name and strength of the eligible prescription drug (EPD);
   - Expiration date of the EPD;
   - 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.

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.

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.

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.

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.

535:12-1.2. 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.

535:12-1.2. 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
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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
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(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.

CHAPTER 13. EMERGENCY/ DISASTER PRESCRIPTION DRUG RULES

Section 535:13-1. Purpose
535:13-1.3. Declaration of emergency
535:13-1.4. Prescription Drug Emergency / Disaster Response
[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]
(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]
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. Definitions
535:15-3-2. Pharmacy responsibilities
535:15-3-3. Requirements for pharmacies employing assistant pharmacists
535:15-3-4. Physical requirements for pharmacies
535:15-3-4.1. Pharmacy licensing Requirement
535:15-3-4.2. Minimum required information for licensure
535:15-3-5. Lock out pharmacy or prescription department
535:15-3-6. Required library reference books or computer sources
535:15-3-7. Condemnation authority for open packages of drugs taken in thefts/burglaries
535:15-3-8. Closing a drug store; violation notice
535:15-3-9. Non-resident pharmacies
535:15-3-10. Inventory
535:15-3-11. Prescription drugs
535:15-3-12. Transfer of prescription refill information
535:15-3-12.1. Electronic transfer of prescription refill information
535:15-3-13. Pharmacist's responsibility in a pharmacy
535:15-3-14. Patient records
535:15-3-15. 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

535:15-3-1.1. 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.

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

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

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

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

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

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

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

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

(d) Responsibility for automated pharmacy systems. This subsection describes the responsibilities of the pharmacy and the PIC for automated pharmacy systems.
(1) Prior written notice must be provided to the Board of the installation or removal of automated pharmacy systems. Such notice must include, but is not limited to the:
   (A) name and address of the pharmacy,
   (B) name of PIC,
   (C) name of the manufacturer & model of system.
(2) The system being implemented should conform to Board automated pharmacy system guidelines.
(3) The pharmacy shall monitor the automated pharmacy system with a quality assurance program.
(4) The pharmacy, pharmacist, and/or PIC shall establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.
(5) The pharmacy, pharmacist and PIC are responsible for supervision of all employees as they relate to the practice of pharmacy regarding automation.

(e) Responsibilities for personnel identification. The PIC and the pharmacy are responsible to assure that the public is able to distinguish pharmacy technicians, auxiliary support personnel, and/or interns from any pharmacist in the pharmacy.
   (1) All pharmacy technicians, auxiliary support personnel, and/or interns must wear a designation tag and be distinctly identifiable from a practicing pharmacist.
   (2) Designation tags must be clear, readable and lettered with “Rx Tech”, “Tech”, “Clerk”, or “Intern”.
   (3) All pharmacy interns, technicians or clerks must identify themselves as such on any phone calls initiated or received while performing pharmacy functions.

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

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

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) Graduates. There shall be graduates scaled in both metric and apothecary measure sufficient in size and number to assure proper operation of the prescription department.
   (5) Spatulas. There shall be spatulas of sufficient size and number to assure its proper operation.
   (6) Mortars and pestles. There shall be mortars and pestles of sufficient size and number to assure its proper operation.
   (7) Library. There shall be the necessary library which has been prescribed and standardized by the Board in Section 535:15-3-6.
   (8) Refrigeration. There shall be sufficient refrigeration facilities to store all necessary biologicals,
injectables, suppositories and other products requiring refrigeration. This refrigerator shall be entirely separate from the storage of any food products in open packages.

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

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

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

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

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

[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]

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

(d) **Inspections.** Non-resident pharmacies are subject to inspection and investigation.

(1) 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.

(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.

[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]

535:15-3-10. **Inventory**

(a) **Change of ownership or pharmacy manager inventory.** When changing the owner or pharmacy manager, a controlled drug inventory must be taken and sent to the Board within ten (10) days. (It is recommended that both the out-going and in-coming managers sign the inventory). The inventory must indicate the new manager’s name and registration number. The inventory should indicate the former manager’s name, registration number and current employment, if known.
(b) **Inventory at renewal.** An inventory of all controlled dangerous substances (CDS) must be taken between May 1 and July 1 of each year. A copy of this inventory will be included with the pharmacy renewal application.

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

[Source: Added at Ok Reg 2593, eff 6-26-95; Amended at 26 Ok Reg 2274, eff 7-1-09]

**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 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.

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 32 Ok Reg 1229, eff 8-27-15]

**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.

2. The transfer 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]

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.

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.

(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.)

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

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

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

535:15-3-17. Pharmacy prescription records

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

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

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

[Source: Added at 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 9-11-16]

[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 (b)) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by them and is correct as shown.

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

(3) Refill reports. Any pharmacy using an automated data processing system to track refills shall be able to print such reports as required in CFR 1306.22 (b) et seq.

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

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

[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]

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 appropriate drug information resources;
(H) Establish and maintain hospital staff training and orientation to the remote medication order process;
(I) Establish and maintain a process that documents issues or problems which includes issue escalation and problem resolution to resolve such;
(J) Establish and maintain on-call assistance and communication between the hospital and remote site personnel;
(K) Establish and maintain internal quality assurance and medication error reporting systems;
(L) Clarification of medication orders;
(M) Establish and maintain access to either hard-copy or online references as described in 535:15-5-9 (1) (B) and 535:15-5-9 (1) (C).
(N) Establish and maintain access to Hospital policy resources, policies and procedures;
(O) Establish and maintain records and reports;
(P) 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;
   (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]

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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535:15-5-3. Applicability
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535:15-5-7.16. Monthly inspections  
535:15-5-7.17. Board inspections  
535:15-5-7.18. Drug rooms  
535:15-5-7.19. 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 perform operations or activities, relative to the storage, packaging, compounding, labeling, dispensing, administration, or distribution of medications, and which collects, controls, and maintains all transaction information.

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

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

"Certified pharmacy technician" means a pharmacy technician who has a current Board approved pharmacy technician certification in addition to a current Oklahoma pharmacy technician permit.

"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.

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.

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).

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 two pharmacy technicians to one supervising pharmacist.

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

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

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

[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 the 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) 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.
   (A) Pharmacy technicians may perform functions involving the:
   (i) reconstitution of single dosage units that are to be administered to a given patient as a unit; and/or
   (ii) addition of one manufacturer's prepared unit (whole or in part) to another manufacturer's prepared unit if the unit is to be administered as one dose to a patient.
   (B) Pharmacy technicians may add a single ingredient in preparing sterile compounded preparations.
   (C) Certified pharmacy technicians as defined in 535:15-5-2 may prepare chemotherapy and add multiple ingredients when preparing sterile products only following documented demonstration of appropriate competency to the Director of Pharmacy or his designated pharmacist on an annual basis.
(11) 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.
(12) select prepackaged and pre-labeled doses of medication from storage areas and place and
transport to the patient area such doses in containers bearing a patient's name in a unit dose distribution system or a modified unit dose distribution system if the pharmacist personally checks and verifies by signature or initial all patient medication before it is administered to the patient.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 32 Ok Reg 1229, eff 8-27-15]

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:
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.

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.
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
The Board's qualified designee shall inspect all aspects of the management and operation of all hospital pharmacies in the State of Oklahoma, to verify compliance with the law, the rules of this Title, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the facility serviced by the pharmacy are protected. Any discrepancies or deficiencies shall be corrected.

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

535:15-5-18. Drug rooms
(a) A drug room, as defined in 535:15-5-2, shall comply with all federal, state and local rules for drug rooms.
(b) At a minimum there shall be a consultant pharmacist on duty as required by the rules of the Oklahoma State Department of Health.
(c) The drugs dispensed from a drug room shall be for administration only to patients in the facility hospital.

[Source: Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2479, eff 1-1-04]

535:15-5-19. Remote medication order processing (RMOP)
(a) Hospitals, the pharmacist manager and the director of pharmacy at the hospital that allow remote medication order processing shall establish and maintain policies and procedures related to remote medication order processing.

1. Such registrants remain responsible to assure the hospital pharmacy meets requirements under Oklahoma laws and rules.
2. Such registrants shall be responsible to assure RMOP, if used, is reviewed at least annually and that proper credentialing, review and that oversight is established, maintained and exercised.
(b) Prior to implementation of RMOP services, training shall be provided by the hospital, and the relevant portions of the hospital pharmacy's policy and procedure manual shall be established and maintained on RMOP; and such shall be reviewed by the Pharmacist providing RMOP entry services at least annually.
(c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:

1. Pharmacists performing RMOP entry must be licensed by the Board.
2. Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1.1(6) and 535:10-3-1.2(a)(16)).
3. The hospital shall ensure the pharmacist performing remote medication order processing has individual, pharmacist-specific access to the hospital pharmacy's patient information system and to other electronic systems that on-site pharmacists have access to during the hours of operation of the hospital pharmacy.
(d) The hospital will make available to the pharmacist(s) performing RMOP entry, access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).
(e) The hospital's computer system shall have the ability to audit the activities of each pharmacist(s) remotely processing the RMOP orders.

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

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

1. Availability of internet, phone, and scan or fax access to the hospital.
2. Ability to access the hospital facility via the hospital's information system.
3. To the extent possible, have redundant systems in place to ensure remote medication order processing service availability (e.g. internet connectivity, other information systems used to facilitate remote medication order processing).
4. Have secure electronic access to the hospital's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open.
5. Use of a computer workstation e.g. with passwords, firewalls and encryption.

(h) The record of each patient-specific RMOP drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the review and verification of the order.

(i) Remote medication order processing by a pharmacist shall not relieve the hospital pharmacy from employing or contracting with pharmacist(s) to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed or additional pharmacist assistance is needed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist(s).

(j) Pharmacists performing remote medication order processing shall not be included in the ratio of the pharmacist and technician as outlined in 535:15-5-7.2.(e).

(k) A pharmacist employed by or contracting with a hospital pharmacy for on-site services may also provide remote medication order processing services when the hospital pharmacy is closed or additional pharmacist assistance is needed through a remote medication order processing pharmacy.

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

SUBCHAPTER 6. HOSPITAL DRUG ROOM

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) Visits in any calendar month shall be no less than 2.

(C) 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.

(D) 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]

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. The other professional staff of the hospital facility shall cooperate with the PIC in meeting this responsibility. The PIC shall be responsible for, at a minimum, the following:

(1) Competency education and training of nursing personnel concerning admixture of sterile compounded preparations, and incompatibility and provision of proper incompatibility information.
(2) Prepackaging and/or preparing of drug products including certification of unit dose.
(3) Establishing of specifications for procurement of all materials, including drugs, chemicals, and biologicals used within the hospital system, subject to approval of the appropriate committee of the hospital system.
(4) Participating in the development and maintenance of a formulary for use within the hospital facility.
(5) Maintaining and making available a sufficient inventory of medicines, including antidotes and other emergency drugs, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.
(6) Reviewing records of all transactions of the hospital drug room required by applicable local, state, and federal law, necessary to maintain accurate control and accountability for all medicine materials.
(7) Participating in those aspects of the hospital facility’s patient care evaluation programs that relate
to drug utilization and effectiveness.

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

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

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

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

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

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

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

(2) Labeling for use outside the hospital facility. All drugs labeled by the pharmacist or licensed practitioner for after hours dispensing to 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:

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

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

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

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

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

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

(h) Records and reports. The PIC shall develop a mechanism for maintaining and submitting as appropriate, such records and reports as are required to insure patient health, safety, and welfare. These should include the following:

1. Adverse drug reaction reports,
2. Floor stock inventories of night cabinets and emergency boxes,
3. Drug list or formulary of the hospital drug room as required by state health department rules,
4. Controlled substance inventory,
5. Ethyl alcohol inventory,
6. Pharmacy and therapeutics committee minutes; and
7. Reports and records as may be required by law, and the rules of this chapter.

[Source: Added at 20 Ok Reg 2479, eff 1‐1‐04; Amended at 32 Ok Reg 1229, eff 8‐27‐15]

### 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):
   1. Codeine/acetaminophen combination [one]
   2. Tramadol [one]
   3. 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, to verify compliance with the law, the rules of this Title, and such other
standards as may be appropriate to insure that the health, safety and welfare of patients of the facility serviced by the hospital drug room are protected.

(b) 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]

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, or controlled dangerous substances, PGP or a compounded preparation to a wholesaler, manufacturer or repackager, outsourcing pharmacy or logistics provider. Return of a drug to the wholesaler from whom it was purchased is allowed.
(b) This restriction does not apply to packaging services provided to a pharmacy where the ownership of the pharmacy’s drug does not change hands.

535:15-7-4. Sterile compounding pharmacy
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.

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.

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.

**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.

**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.

**535:15-9-6. Sterile compounding preparation pharmacy physical requirements**
(a) Pharmacies who engage in non-sterile or sterile compounding are responsible for complying with all aspects of USP Compounding Standards and these rules.
(b) **Reference materials.**
   (1) The sterile compounding preparation pharmacy shall have, in addition to the library reference material required for retail licensure, one or more reference materials from the following list:
      (A) Handbook of Injectable Drugs
      (B) King’s Guide to Parenteral Admixtures
      (C) MicroMedex
      (D) Lexicomp
      (E) Applicable USP standards
   (2) Electronic versions are acceptable.

**535:15-9-7. 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.

**535:15-9-8. Pharmacist accessibility**
Each sterile compounding pharmacy and pharmacy manager shall assure that a qualified pharmacist
is accessible and available to respond to patients and healthcare professional questions and needs at all
times. A 24-hour telephone number shall be provided.
[Source: Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-9. Drug distribution and control
(a) Labeling. Each preparation dispensed to patients by a sterile compounding preparation pharmacy shall
be labeled with the following information with a permanent label:
   (1) Name, address, and telephone number of the pharmacy;
   (2) Date and prescription number;
   (3) Patient's name;
   (4) Name, strength, and amount of each drug;
   (5) Directions for use, including infusion rate where applicable;
   (6) Prescriber's name;
   (7) Required controlled substance transfer warnings, where applicable;
   (8) Date of compounding;
   (9) Expiration date and time;
   (10) Identity of pharmacist compounding and dispensing;
   (11) Storage requirements;
   (12) Auxiliary labels, where applicable;
   (13) Hazardous drug auxiliary labels, where applicable.
(b) Delivery service. The pharmacy manager shall assure the environmental control of all products shipped.
Therefore, any compounded, sterile preparation or pharmaceutical must be shipped in appropriate
containers to insure minimal temperature fluctuation (as defined by USP standards), and stored
appropriately in the patient's home. Chain of possession for the delivery of Schedule II controlled substances
via courier must be documented.
(c) Disposal of infectious waste. The pharmacy manager is responsible for assuring that there is a system
for the disposal of infectious waste in a manner so as not to endanger the public health.
[Source: Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-10. Cytotoxic or Hazardous drugs
Pharmacies who engage in non-sterile or sterile compounding are responsible for complying with all
aspects of USP Compounding Standards and these rules.
[Source: Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-9-11. Quality assurance
Pharmacies who engage in non-sterile or sterile compounding are responsible for complying with all
aspects of USP Compounding Standards and these rules.
[Source: Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 32 Ok Reg 1229, eff 8-27-15]

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

PART 1. GOOD COMPOUNDING PRACTICES FOR NON-SterILE PRODUCTS

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PART 1. GOOD COMPOUNDING PRACTICES FOR NON-SterILE PRODUCTS

535:15-10-1. Purpose

The rules of this subchapter describe the requirements of minimum current good compounding practices for the compounding of drug preparations by Oklahoma licensed pharmacies for dispensing and/or administration to humans or animals.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 32 Ok Reg 1229, eff 8-27-15]
535:15-10-2. Definitions
The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

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

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

"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 microbiologically 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.

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

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

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

"USP" means "United States Pharmacopeia"

[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]

535:15-10-3. 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) Every pharmacist engaging in drug compounding shall be familiar with all details of USP Compounding Standards 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) Integrity of the container, including visual defects
      (vii) Proper storage
      (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 these regulations and contained in the regulations set forth in USP standards.
   (1) Competency shall be demonstrated prior to preparing any products for patient use, and
   (2) Whenever the quality assurance program yields unacceptable results, and
   (3) Whenever unacceptable or questionable techniques are observed, and
   (4) Evaluated at least annually.
(e) Pharmacist requirements. Any pharmacist in charge who performs or supervises the preparation of compounded medications shall:
   (1) Have available written policies and procedures for all steps in the compounding of preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, quality assurance, expiration dating, and other procedures as needed.
   (2) Certify that all participating pharmacists, interns and technicians have completed training and testing program in product preparation. Documentation of training and testing shall be available for review.
   (3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians.
(f) Staff will be trained and evaluated accordingly as follows:
   (1) Training is required for any individual who prepares compounded preparations. This training must be completed before such individual is allowed to compound preparations.
(2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards.

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

(4) Testing will be conducted annually for every individual involved in compounding preparations. Compounding personnel who fail written tests shall be immediately re instructed 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 who engage in non-sterile compounding are responsible for complying with all aspects of USP Compounding Standards and these rules.

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

535:15-10-4. Drug compounding facilities

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

(b) The area used for the compounding of non-sterile compounded preparations shall be in an area separate and distinct from the area used for the compounding and aseptic processing of sterile preparations.

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

(d) Hazardous drugs shall be prepared within a certified Biological Safety Cabinet (Powder Containment hood). Hazardous drug compounding shall be prepared in compliance with applicable USP standards. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. Do not use a ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatize while they are being handled or after they are captured by the HEPA filter.

(e) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area, under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers). Bulk drugs shall also be stored such that they are protected from contamination.

(f) Adequate lighting and ventilation shall be provided in all compounding areas.

(g) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug preparation.

(h) Purified water must be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water.

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.

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.

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:
   (1) For Non-aqueous liquids and solid formulations
      (A) Where the manufactured drug product is the source of active Ingredient - The BUD is not later than 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.
      (B) Where a USP of NF substance is the source of active ingredient - the BUD is not later than 6 months for
         (i) Water-containing oral formulations (prepared from ingredients in solid form) - the BUD is not later than 14 days for liquid preparations when stored at cold temperatures between 2° and 8°C (36° and 46° F).
         (ii) All other formulations - The BUD is not later than the intended duration of therapy or 30 days, whichever is earlier.
   (2) The USP-NF standards listed above may be exceeded when there is supporting scientific stability information that is directly applicable to the specific preparation (e.g., the same drug concentration range, pH, excipients, vehicle, water content, etc.)
   (3) Information to be considered when assigning a BUD includes chemical, physical and microbiological stability; nature of the drug, its chemical degradation mechanism, the container in which it is packaged, expected storage conditions, and the intended duration of therapy.

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 USP Compounding Standards shall be retained for the same period of time as required for retention of prescription records; and copies of such records, shall be readily available for authorized inspection.

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

(c) Adequate records must be kept of controlled dangerous substances (Scheduled drugs) used in compounding.

[Source: Added at 17 Ok Reg 2633, eff 7-1-00; Amended at 26 Ok Reg 2282, eff 7-1-09]

535:15-10-11. Pharmacy generated product requirements

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

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

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

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

(e) Compounded PGPs must be labeled in compliance with FDA OTC labeling regulations.
535:15-10-13. 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.

535:15-10-14. Compounding of non-sterile hazardous drugs
Pharmacies engaging in compounding of hazardous drugs shall be responsible for meeting the following criteria:
(1) Non-sterile hazardous drugs shall include the NIOSH list of hazardous drugs as well as any individual products named per each individual pharmacy by referencing MSDS sheets or any other reference relating to above definition.
(2) Exposure control shall begin when hazardous drugs enter the facility. The PIC shall be responsible to confirm that medical products have labeling on the outer container that can be understood by all workers who will be separating hazardous from nonhazardous drugs.
(3) All individuals must wear PPE when opening containers to unpack hazardous drugs. Individuals must also wear chemotherapy gloves to prevent contamination when transporting the drug to the work area.
(4) Hazardous drugs must be stored separately from other drugs, as recommended by current ASHP guidelines on handling hazardous drugs. Hazardous drugs must be stored and transported in closed containers that minimize the risk of breakage.
(5) Pharmacies and pharmacist shall make sure the storage area has sufficient general exhaust ventilation to dilute and remove any airborne contaminants. Use a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. Do not use a ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatize while they are being handled or after they are captured by the HEPA filter.
(6) Staff should be fully trained and procedures established for their particular equipment and unique workplace setting.
(7) All staff shall wear PPE while working with hazardous drugs.
(8) Mix, prepare, and otherwise manipulate, count, crush, compound powders, or pour liquid hazardous drugs inside a ventilated cabinet designed to prevent hazardous drugs from being released into the work environment.
(9) Do not use supplemental engineering or process controls (such as needleless systems, glove bags and closed-system drug transfer devices) as a substitution for ventilated cabinets, even though such controls may reduce the potential for exposure when preparing and administering hazardous drugs.
(10) Use a high-efficiency particulate air filter (HEPA filter) for the exhaust from these controls.
(11) When drug preparation is complete, seal the final product in a plastic bag or other sealable container for transport before taking it out of the ventilated cabinet.
(12) Wash hands with soap and water immediately before donning and after removing gloves.
(13) Develop a written safety plan for all routine maintenance activities performed on equipment that could be contaminated with hazardous drugs.
(14) Manage hazardous drug spills according to policies and procedures for each workplace according to size of spill, possible spreading etc. Locate spill kits and other cleanup materials in the immediate area where exposures may occur.

(15) Consider a medical surveillance program or allow workers to have routine medical care.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-15. Compounding of non-sterile radiopharmaceuticals
(a) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.
(b) Radiopharmaceuticals prepared for oral administration shall be designated as, and conform to, the standards for non-sterile preparations. Any variation in certain chapter standards may be required to meet radiation safety concerns to operators and shall be documented with supporting evidence upon request.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09]

535:15-10-16. Violations
It shall be a violation to fail to comply with all aspects of USP compounding standards and these rules.

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

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PRODUCTS

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 microbiologically 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 other shipping container. The term 'label' designates that part of the labeling on the immediate container.

"LAFW" means "Laminar Airflow Workbench".
"Manufacturing" means manufacturing as defined in 59 O.S. Section 353.1.
"MDV" means 'Multiple Dose Vial'.

"Media-Fill Test" means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

"Multiple-Dose Container" means a multiple-unit container for articles or preparations intended for sterile compounded preparations administration only and usually containing antimicrobial preservatives.

"Negative Pressure Room" means a room that is at a lower pressure than the adjacent spaces and therefore, the net flow of air is into the room.

"National Safety Foundation" or "NSF" means the foundation that certifies that Biological or Class II safety cabinets meet NSF Standard 49.

"NIOSH" means "National Institute for Occupational Safety and Health"
"PEC" means "Primary Engineering Control".
"PET" means "Positron Emission Tomography".
"Personal Protective Equipment (PPE)" means items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

"Primary Engineering Control (PEC)" means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

"Preparation" means an article compounded in a licensed pharmacy pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

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

"Positive Pressure Room" means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

"Single-dose container" means a single-dose, or a single-unit, container for articles or preparations intended for sterile compounded preparations administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

"Segregated Compounding Area" means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

"Terminal Sterilization" means the application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than $10^{-6}$, or a probability of less than one in one million of a non-sterile unit.

"Unidirectional Flow" means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

"USP" means "United States Pharmacopeia".

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-52. Pharmacist responsibilities
(a) All Pharmacists who engage in drug compounding, shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.
(b) Every pharmacist engaging in drug compounding must be familiar with all details of USP Compounding Standards.
(c) The pharmacist has the responsibility to:
(1) ensure the validity of all prescriptions
(2) certify all prescriptions.
(3) approve or reject all components, drug product containers, closures, in-process materials, and labeling.
(4) ensure preparations are of acceptable strength, quality, and purity.
(5) verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation.
(6) prepare and review all compounding records to ensure that no errors have occurred in the compounding process.
(7) ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.
(8) ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and,

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(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) Integrity of the container, including visual defects
   (vii) Proper storage
   (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 these regulations and contained in the regulations set forth in USP standards.

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

(2) Whenever the quality assurance program yields unacceptable results, and

(3) Whenever unacceptable or questionable techniques are observed, and

(4) Evaluated at least annually.

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

   (1) Have available written policies and procedures for all steps in the compounding of preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.
   (2) Certify that all participating pharmacists, interns and technicians have completed training and testing program in sterile product preparation. Documentation of training and testing shall be available for review.
   (3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.

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

   (1) Training is required for any individual who compounds sterile preparations. This training must be completed before the individual is allowed to compound sterile preparations.
   (2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards,
   (3) A written test shall be administered and passed based on the material referenced above upon initial hire or prior to assignment to compound sterile preparations.
   (4) Media-fill challenge tests will be used to evaluate sterile technique.
   (5) Results of the media challenge tests shall be documented and logged.
   (6) End product testing that results in a failure, will result in a review of the aseptic technique of the individual involved.
(7) Testing involving media challenge tests will be conducted annually for every individual involved in sterile preparation compounding. Semiannual testing will be conducted for personnel involved in high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re 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 USP Compounding Standards and these rules.

(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]

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 to 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.
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.

Compounding personnel are improperly garbed and gloved as outlined by USP.

Sterile water-containing preparations are stored for more than 6 hours before being sterilized.

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.

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.

1. Administration begins not later than 1 hour following the start of the preparation of the CSP.
2. 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.
3. If administration has not begun within 1 hour following the start of preparing the CSP; the CSP shall be promptly, properly, and safely discarded.

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.

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.
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

(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 gowns, 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]

535:15-10-55. Drug compounding facilities
(a) Pharmacies engaging in compounding shall have a specifically designated and adequate space for the orderly compounding of prescriptions, including the placement and storage of equipment and materials.
(b) The aseptic processing for sterile preparations shall be in an area separate and distinct from the area used for the compounding of non-sterile drug preparations. If sterile compounded preparations are being compounded, the rules in OAC 535:15-10-3.1 should be met. A primary engineering control (PEC), (laminar airflow workbench (LAFW), biological safety cabinet (BSC), compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)) will be used to prepare all sterile preparations, except those compounded for Immediate Use.
(c) The area(s) used for the compounding of drugs shall be maintained in a good state of repair. These area(s) shall also be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided and sewage, trash and other refuse in the compounding area is to be disposed of in a safe, sanitary, and timely manner.
(d) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers.) Bulk drugs shall also be stored such that they are protected from contamination.
(e) Adequate lighting and ventilation shall be provided in all compounding areas.
(f) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug preparation.

(g) Work area and equipment. Any pharmacy dispensing compounded sterile preparations shall meet or exceed the following requirements:

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

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

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

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

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

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

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

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

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

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

11. Daily procedures must be established for cleaning the compounding area. The pharmacy must keep cleaning logs consistent with the minimum cleaning frequency as outlined in USP 797 standards:
Minimum frequency of cleaning and disinfecting compounding areas (USP 797), site and minimum frequency are listed below:

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

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

(C) Floors shall be cleaned and disinfected daily.

(D) Walls shall be cleaned and disinfected monthly.

(E) Ceilings shall be cleaned and disinfected monthly.

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

535:15-10-56. 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.

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.

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.

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:
Based on published data, 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]

535:15-10-65. 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.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]
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 intradermal or subcutaneous injections that are prepared by specially trained physicians and pharmacy personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met:

1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).

2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Non-preserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.

3. Before beginning compounding activities, personnel perform a thorough hand cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either non-antimicrobial or antimicrobial soap and water.

4. Compounding personnel don hair covers, facial hair covers, gowns, and face masks.

5. Compounding personnel perform antiseptic hand cleansing with an alcohol based surgical hand scrub with persistent activity.

6. Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.

7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.

8. Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.

9. The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other non-sterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).

10. The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers’ recommendations or peer-reviewed publications.

11. Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

(b) Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for CSP Microbial Contamination Risk Levels. Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected intradermally or subcutaneously, these risks are substantially greater if the extract is inadvertently injected intravenously.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09; Amended at 32 Ok Reg 1229, eff 8-27-15]

535:15-10-68. Violations

It shall be a violation to fail to comply with all aspects of USP compounding standards and these rules.

[Source: Added at 32 Ok Reg 1229, eff 8-27-15]
Appendix B USP <797> Beyond-Use Date Limits Chart

<table>
<thead>
<tr>
<th>USP &lt;797&gt; Risk Level</th>
<th>Room Temperature</th>
<th>Refrigerated</th>
<th>Freezer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Use</td>
<td>1 hour</td>
<td>1 hour</td>
<td>N/A</td>
</tr>
<tr>
<td>Low Risk</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Low Risk with 12 hour or less BUD</td>
<td>12 hours or less</td>
<td>12 hours or less</td>
<td>N/A</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>30 hours</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High Risk</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

[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.
[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]

**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 353.29.
[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]

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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.
   “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]

535:15-13-4. Pharmacy technician qualifications and training
   (a) A pharmacy technician must have completed a high school education or G.E.D. equivalence, be of good
   moral character, be non-impaired (e.g. alcohol or drugs) and have adequate education to perform assigned
   duties.
   (b) A pharmacy manager employing a currently permitted technician must document training of that
   technician within 10 days of hire.
   (c) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job
   training (OJT) program described in 535:15-13-13.
   (d) To be eligible for a pharmacy technician permit, an applicant must maintain compliance with the
   requirements in this Title, 535.25 and 535:15.
   [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]

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
      rules.
      (2) An intern cannot supervise a technician.
      (3) Failure to adequately supervise a pharmacy technician is a violation of these rules by the
      pharmacist, pharmacy and pharmacist manager.
   (b) A pharmacy technician may perform certain non-judgmental functions of dispensing as enumerated in
   this Subchapter, provided that whenever the pharmacist leaves the prescription department, other than for
   in-pharmacy counseling of a patient, all dispensing functions listed shall cease.
   (c) A ratio of no more than two pharmacy technicians per supervising pharmacist on duty shall be
   maintained.
   (d) A pharmacy intern working in the pharmacy will not affect or change this ratio.
(e) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. An intern cannot certify the completion of a technician filled prescription.

535:15-13-6. Duties

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

1. 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. functions involving reconstitution of single dose units of sterile compounded preparations that are to be administered to a given patient as a unit, and functions involving the addition of one manufacturer's prepared unit (whole or in part) to another manufacturer's prepared unit if the unit is to be administered as one dose to a patient. The pharmacist must establish the procedures for compounding sterile preparations and certify the ingredients, label and finished preparation;
8. any duties auxiliary personnel are allowed to perform;
9. assist the pharmacist in the annual CDS inventory. The pharmacist remains responsible for completeness and accuracy; and,
10. 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.

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 prepare multi-ingredient, non-repetitive, cytotoxic or experimental drug I.V.'s, enteral or other sterile multi-ingredient medications; and the pharmacist shall be responsible
for weighing, measuring and calculating ingredients for sterile compounded preparations.

(6) 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.

(7) The pharmacist must provide patient counseling or drug information as necessary.

(8) 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]

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.

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.

535:15-13-11. Multiple locations of employment
(a) A pharmacy technician may work in multiple pharmacies providing:
   (1) The technician has been properly trained for each location (see 535:15-13-13(d)); and,
   (2) The training is documented in each pharmacy.
(b) A technician working in multiple locations regularly or on an emergency relief basis may be issued a duplicate permit on request.
   (1) A written request indicating the need for such duplicate shall be sent to the Board by the technician.
   (2) A duplicate fee of ten dollars $10 shall accompany each individual duplicate request.
   (3) Current and in good standing technicians who have renewed online for the current period may print a duplicate permit online at no additional charge.

535:15-13-12. Work schedule display
(a) A work schedule shall be conspicuously displayed in the pharmacy when both a tech and an auxiliary supportive person are working. The schedule shall indicate who is working as a tech and hours worked and who is working as an auxiliary supportive person and hours worked.
(b) The schedule shall indicate the proper ratio of technician to supervising pharmacist.
(c) If a supportive person is found to be performing duties not listed on the schedule (e.g. an auxiliary supportive person working as a technician), the auxiliary supportive person, the technician, the pharmacy, and the supervising pharmacist will be considered to be in violation of this Chapter.

535:15-13-13. Pharmacy technician training
(a) The pharmacy manager shall be responsible for the development and/or implementation of a pharmacy technician training program.
   (1) The instructional text of the training program shall be kept in the pharmacy and only upon request submitted to the Board for approval.
   (2) The program shall be designed to train personnel to perform allowed 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
535:15-15-3. 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.

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.

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 (DSW)
   B. dextrose 5% in normal saline solution (DSS)
   C. lactated ringers solution
   D. normal saline solution; and
8. legend medicated dressings.

535:15-16. 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. Drug categories allowed in emergency medication kits
535:15-16-7. Violations

[Source: Added at 12 Ok Reg 2593, eff 6-26-95; Amended at 13 Ok Reg 2807, eff 6-27-96]
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 facility remote site for an annual fee 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.
[Source: Added at 29 Ok Reg 1641, eff 7-12-12]

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 50 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 50 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 an authorized licensed or permitted 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, agent of the Oklahoma licensed pharmacy, licensed or permitted 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 which facilities the Oklahoma licensed pharmacy provides emergency medications for;
   (2) A log of medications stored 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 or permitted 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]

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, authorized licensed or permitted employee of the Oklahoma licensed pharmacy.
(g) Access to non-controlled drugs in the emergency medication kit shall be limited to a licensed nurse, agent of the Oklahoma licensed pharmacy, licensed or permitted employee of the Oklahoma licensed pharmacy.

[Source: Added at 29 Ok Reg 1641, eff 7-12-12]

535:15-16-6. Drug categories 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. The drugs listed below are to ensure that such drugs are available to each resident of a facility in need of emergency medications.
(b) The following categories of drugs are acceptable for emergency medication kits in a facility:
   (1) Analgesic oral:
      (A) Non-CDS - Limit 2;
      (B) Plus CDS, (CII-CV) - Limit 4 medications; of which only 2 may be CII
         [Only if approved by Oklahoma Bureau of Narcotics (OBNDD) and the Federal Drug Enforcement Administration (DEA)]
   (2) Antipsychotic - Limit 4
   (3) Anti-epileptic - Limit 2
   (4) Anti-diarrheal - Limit 1
   (5) Antinauseant - Limit 2
   (6) Antibiotic
      (A) Oral - Limit 6
      (B) Injectable (IM or IV) - Limit 2
   (7) Antihistamine/allergic reactions - Limit 4
   (8) Anti-hypertensive - Limit 4 (may include nitroglycerin, clonidine, nifedipine)
   (9) Anti-asthmatic - Limit 2
   (10) Anti-anxiety - Limit 4 (scheduled and non scheduled, injectable and oral)
(11) Diabetic Medications - Limit 4 (may include medications for hypoglycemia)
(12) Diuretic - Limit 2
(13) Sterile compounded preparations intravenous fluid:
    (A) Isotonic - Limit 1 bag;
    (B) Hypotonic - Limit 1 bag; and,
    (C) Hypertonic solution - Limit 1 bag.
(14) Steroid - Limit 3
(15) Misc. non CDS medications - Limit 6
(c) Before placing miscellaneous non-controlled or CDS medications listed in b (1)-(15) above the Oklahoma licensed pharmacy and facility must have a written policy indicating what these drugs are; and the reason for their need. This written policy must be available for Board inspection. The Oklahoma licensed pharmacy must be in compliance 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.

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.

535:15-17. 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.
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) through (8) and (10) through (11).

(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]

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]

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. Repackers ........................................................................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.
The rules of this Chapter are necessary to protect the health, safety, and welfare of the public. 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;
      (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


(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]
Section 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

(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]
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.

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.

535:20-6.3. Outsourcing facility licensing requirement
(a) If Oklahoma is the state in which a prescription drug is compounded or is the state from which or into which a prescription drug of an outsourcing facility is shipped, this prescription drug may not be compounded in and/or shipped into or out of Oklahoma unless each facility of such outsourcing facility is licensed in Oklahoma. Such license shall be renewed annually by application and payment of renewal fees.
(b) An outsourcing facility shall also be licensed as an outsourcing facility by the Secretary of the U. S. Department of Health and Human Services, Food and Drug Administration.
(c) An outsourcing facility license is only valid for the name, ownership and location listed on the license. Changes of name, ownership or location require a new outsourcing facility license.
(d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.).
(e) When outsourcing facility operations are conducted at more than one location, each location shall be licensed by the Board.
(f) An outsourcing facility shall not operate from a place of residence.
(g) The outsourcing facility may be located in a facility where a retail pharmacy licensed by the Board is located.
(h) An outsourcing facility which receives patient specific prescriptions and fills the prescriptions in Oklahoma or ships the filled prescriptions into Oklahoma shall also have an Oklahoma pharmacy or non-resident pharmacy license.
(i) An outsourcing facility must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.

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.

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.

535:20-6-6. Personnel

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

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

(c) Each outsourcing facility shall designate, in writing on a Board-approved form, a person to serve as the PIC who is a pharmacist licensed by the Board. No pharmacist may serve as the PIC for more than one outsourcing facility and/or pharmacy at a time unless they are located at the same physical address and are dually licensed with the Board.
(d) No outsourcing facility shall have as an owner, designated representative, facility manager, or pharmacist-in-charge anyone convicted of any felony for conduct relating to compounding prescription drugs, any felony for violation of 21 U.S.C. § 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering. No outsourcing facility shall have as an owner, designated representative, facility manager or pharmacist-in-charge anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

[Source: Added at 32 Ok Reg 1233, eff 8-27-15; Amended at 34 Ok Reg 1887, eff 9-11-17]

535:20-6-7. Compliance with federal, state and local laws


(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.
[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.
(d) Changes in any information required for licensure must be reported to the Board, in writing, within ten (10) days (e.g. facility manager, designated representative, telephone number, etc.)
(e) When wholesale distributor operations are conducted at more than one location, each location shall be licensed by the Board.
(f) A wholesale distributor shall not operate from a place of residence.
(g) The wholesale distributing facility located in Oklahoma shall be located apart and separate from any retail pharmacy licensed by the Board.
(h) A wholesale distributor must publicly display all licenses and have readily available the most recent state and/or federal inspection reports.
[Source: Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 32 Ok Reg 1233, eff 8-27-15; Amended at 33 OK Reg 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 7-1-08; 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 licensees's 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]

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.
[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.

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.

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]

SUBCHARTER 9. MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

Section
535:20-9-1. Purpose
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535:20-9-3. Medical gas suppliers
535:20-9-4. Medical gas distributors
535:20-9-5. Violations and penalties
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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.

(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.

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.

(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.
   - Access from outside the premises shall be kept to a minimum and be well controlled.
   - The outside perimeter of the premises shall be well-lighted.
   - Entry into areas where drugs are held shall be limited to authorized personnel.
   - 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.
   - 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:
     - The medical gas distributor must not ship the customer's order if the order is confirmed as suspicious;
     - Each medical gas distributor shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,
     - 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).
   - 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.
   - 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.
   - 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.
   - 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.
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.

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.

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.
CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

535:25-1. Purpose

535:25-1-1. 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.

535:25-1-1. 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.

535:25-3. 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.

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.

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) All changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. for businesses the address, manager, contact person, phone, etc. and/or for individuals name, address, etc.)
Address change requires a new license prior to drugs being moved or stored at the new address, see (1) above.

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

335:25-3-8. 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.

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

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.

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.

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.

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.
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-MILITARY SERVICE APPLICANTS

Section
535:25-5-3. Post-Military service applicants

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 Reserve 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.
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.

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.

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.

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. Misfill or incorrect fill of a prescription or drug order
535:25-9-10. Patient health and safety
535:25-9-11. Arrangements
535:25-9-12. Professional fee

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.

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.

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.
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. Misfill or incorrect fill of a prescription or drug order
The incorrect fill or misfill of a prescription or drug order 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]

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]

A registrant shall not do auto refills of a prescription unless authorized to do so by the patient or the patient's agent.
[Source: Added at 32 Ok Reg 1261, eff 8-27-15]
Appendix A

Oklahoma Administrative Code (OAC)
Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control
[Selected portions of Chapters 20, 25, 30, 40, 45 and 55 are included for use by Oklahoma licensed pharmacies and facilities]

*UNOFFICIAL*

and

OBN Effect of HIPAA on State Law

and

Acceptable ID for PSE and CDS purchases

For a complete copy of the unofficial Title 475 rules or interpretation of these rules, contact the Oklahoma Bureau of Narcotics:
(405) 521-2885
www.ok.gov/obndd

*Official copies of the rules in Title 475 may be obtained from the Oklahoma Secretary of State, Office of Administrative Rules.*
475:20-1. Purpose
The rules of this Chapter mandate the security requirements for OBN registrants and other individuals in possession of controlled dangerous substances.

475:20-1-2. General security requirements
(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled dangerous substances. In order to determine whether a registrant has provided effective controls against diversion, the Director shall require adherence to the security requirements as set forth generally in the Uniform Controlled Dangerous Substances Act, and specifically by this Chapter, as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in 475:20-1-4 and 475:20-1-6 may be used in lieu of the materials and construction described in those Sections.
(b) Substantial compliance with the standards set forth in 475:20-1-3 through 475:20-1-7 may be deemed sufficient by the Director after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Director may consider any of the following factors as he/she may deem relevant to the need for strict compliance with security requirements:
   (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.).
   (2) The type and form of controlled dangerous substances handled (e.g., bulk liquids or dosage units, usable or non-usable powders).
   (3) The quantity of controlled dangerous substances handled.
   (4) The location of the premises and the relationship such location bears on security needs.
   (5) The type of building construction comprising the facility and the general characteristics of the building(s).
   (6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used.
   (7) The type of closures on vaults, safes and secure enclosures.
   (8) The adequacy of key control systems and/or combination lock control systems.
   (9) The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources.
   (10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any.
   (11) The adequacy of supervision over employees having access to manufacturing and storage areas.
   (12) The procedures for handling business guests, visitors, maintenance personnel and non-employee service personnel.
   (13) The availability of local police protection or of the registrant's or applicant's security personnel.
   (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of controlled dangerous substances in its operations.
(c) When physical security controls become inadequate as a result of a controlled dangerous substance being transferred to a different schedule, or as a result of a non-controlled dangerous substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled dangerous substances in the possession of the registrant during normal business operations, the physical security
controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in 475:20-1-3 through 475:20-1-7 when the need for such controls, as determined by the Director, decreases as a result of a controlled dangerous substance being transferred to a different schedule, or as a result of a controlled dangerous substance being moved from control, or as a result of a significant decrease in the quantity of controlled dangerous substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in 475:20-1-3 through 475:20-1-7, may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

475:20-1-3. Physical security controls for nonpractitioners; storage areas

Physical security controls for nonpractitioners and storage areas shall comply with Title 21 Code of Federal Regulations §1301.72

475:20-1-4. Physical security controls for nonpractitioners; manufacturing areas

Physical security controls for nonpractitioners and manufacturing areas shall be in compliance with Title 21 Code of Federal Regulations §1301.73.

475:20-1-5. Other security controls for nonpractitioner registrants

(a) Before distributing a controlled dangerous substance to any person whom the registrant does not know to be registered to possess the controlled dangerous substance, the registrant shall make a good-faith inquiry either with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or with the Drug Enforcement Administration to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled dangerous substances. The registrant shall inform the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) All registrants shall notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of any theft or significant loss of any controlled dangerous substances upon discovery of such theft or loss. Notification shall be made in writing and shall contain a list of the substances stolen or diverted by their trade name, quantities, descriptions, amount lost or stolen, and any cost code marks utilized. Thefts must be reported whether or not the controlled dangerous substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) No person acting as an agent of a registered controlled dangerous substances manufacturer or distributor (i.e., detailman, salesman, etc.) shall distribute samples of controlled dangerous substances to a practitioner without first having been registered (no fee required) with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

(1) To register with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control to distribute samples of controlled dangerous substances a form must be filled out and submitted to the Registration Department. Such forms may be obtained through the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control website or by calling the Registration Department.

(2) A new form shall be completed and submitted to the registration department each time the list of items to be distributed changes.

(3) A copy of the form submitted to the Oklahoma State Bureau of Narcotics shall be retained by the distributor.

(4) The practitioner receiving the samples shall keep a record each time he/she receives or distributes samples of controlled dangerous substances.
(e) When shipping controlled dangerous substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled dangerous substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled dangerous substances in a public warehouse which complies with the requirements set forth in this Chapter. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled dangerous substances) to guard against storage or in-transit losses and comply with all current Federal regulations. Reporting the loss of in-transit shipments is the responsibility of the registrant shipping the controlled dangerous substances.

(f) When distributing controlled dangerous substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the controlled dangerous substances are being stored or handled by the agent(s).

(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.

(h) The registrant shall immediately notify OBN and seek authorization to employ any individual as specified above.

[Source: Amended at 12 Ok Reg 2841, eff 7-15-95; Amended at 24 Ok Reg 2737, eff 8-11-07; Amended at 29 Ok Reg 1317, eff 6-25-12; Amended at 31 Ok Reg 2110, eff 9-12-14]

475:20-1-6. Physical security controls for practitioners

Physical security controls for practitioners shall be as follows:

(1) Controlled dangerous substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(2) Controlled dangerous substances listed in Schedules II, III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of non-controlled dangerous substances in such a manner as to obstruct the theft or diversion of the controlled dangerous substance.

475:20-1-7. Physical security controls for drug canine handlers

Physical security controls for drug canine handlers shall be as follows:

(1) Controlled dangerous substances stored at a registration location shall be in a securely locked, substantially constructed cabinet and/or may be stored in a safe deposit box maintained by a financial institution.

(2) Controlled dangerous substances transported in a vehicle must be maintained in a locked container inside the vehicle.

475:20-1-8. Other security controls for registrants

(a) All registrants shall immediately notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of any theft or significant loss of any state or federal registration certificates, D.E.A. Form 222 order blanks, prescription blanks or other materials used in purchasing, distributing, prescribing or transferring controlled dangerous substances.

(b) All registrants shall immediately notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or the local law enforcement agency having jurisdiction of any information the registrant receives
concerning any violations of the Oklahoma Controlled Dangerous Substances Act and/or federal statutes and regulations related to controlled dangerous substances.

Chapter 25 - Records and Reports of Registrants

475:25-1-1. Purpose

The rules of this Chapter list and describe the types of records that must be maintained regarding the lawful possession of controlled dangerous substances, and also state how long said records must be available for inspection.

475:25-1-2. General information

Registrants shall be required to maintain records, reports and inventory in accordance with this Chapter and pursuant to Title 21 Code of Federal Regulations, and Title 63 Okl.St.Ann. §2-307.

475:25-1-3. Persons required to keep records and file reports

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this Chapter, except as exempted by this Section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities pursuant to 475:10-1-7 shall maintain the records and inventories and shall file the reports required for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled dangerous substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled dangerous substances used in any activity. Also, the Director does not wish to require separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he/she must keep a record of the quantity manufactured; when he/she distributes a quantity of the item, he/she must use and keep invoices or order forms as required by Title 21 Code of Federal Regulations, to document the transfer. When substances are used in chemical analysis, he/she need not keep a record of this because such record would not be required of him/her under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his/her controlled items in one place and every two (2) years take inventory of all items on hand, regardless of whether the substances were manufactured by him/her, purchased domestically by him/her, or whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis. This may be accomplished by keeping a log for administering similar to that kept for dispensing.

(b) A registered individual practitioner is required to keep readily-retrievable records with respect to all controlled dangerous substances listed in Schedules II through V which he/she prescribes, administers or dispenses in the lawful course of his/her professional practice. Practitioners shall keep a suitable book, file or record in which information pertaining to controlled dangerous substances dispensed by the practitioner shall be preserved for a period of at least two (2) years and be available to designated law enforcement officers for their inspection and copying. These records will be maintained separate and apart from all other records.

(c) A registered individual practitioner is required to maintain patient records for any individual receiving controlled dangerous substances whether by prescribing, administering or dispensing. Such record will contain as a minimum the patient’s full legal name, date of birth, residence address, last physician seen and when, and notations of date, amount and type of controlled dangerous substance for each occasion the patient receives a controlled dangerous substance. Such records should contain additional identifying information when possible, including, but not limited to, social security number or driver’s license number, telephone number, next-of-kin and general physical description of the patient. This includes authorization of refills and the number of refills authorized on the original prescription.
(d) A registered person using any controlled dangerous substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records, unless so ordered by the Director for cause, if he/she notifies the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of the name, address and registration number of the establishment maintaining such records.

475:25-1-4. Maintenance of records and inventories
(a) Every inventory and other record required to be kept by the Uniform Controlled Dangerous Substances Act and this Chapter shall be kept by the registrant and be available for at least two (2) years from the date of such inventory or record, for inspecting and copying by authorized peace officers or officers of agencies specifically directed to enforce the State of Oklahoma or the United States controlled dangerous substances laws, pursuant to and in the manner prescribed by Title 63 Okl.St.Ann. § 2-502, Title 21 Code of Federal Regulations § 1304.04, and this Chapter.
(b) Each registered manufacturer and distributor shall maintain inventories and records of controlled substances as follows:
   (1) Inventories and records of controlled dangerous substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.
   (2) Inventories and records of controlled dangerous substances listed in Schedules III, IV and V shall be maintained separately from all other records of the registrant as of November 1, 1990.
(c) Each registered individual practitioner required to keep records and institutional practitioners required to keep records shall maintain inventories and records of controlled dangerous substances in the manner prescribed in (b) of this Section.
(d) Each registered pharmacy shall maintain the inventories and records of controlled dangerous substances as follows:
   (1) Inventories, records, invoices and purchase records of all controlled dangerous substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file and be readily retrievable.
   (2) Inventories, records, invoices and purchase records of controlled dangerous substances listed in Schedules III, IV and V shall be maintained separately from all other records of the pharmacy and be readily retrievable. Prescriptions for such substances shall be maintained in separate prescription files for controlled dangerous substances listed in Schedules III, IV and V and shall be readily retrievable from the other prescription records of the pharmacy.

475:25-1-5. General requirements for inventories
(a) Each inventory shall contain a complete accurate record of all controlled dangerous substances on hand on the date the inventory is taken. Controlled dangerous substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.
(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled dangerous substances in the possession or under the control of the registrant are at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.
(c) A separate inventory shall be made by a registrant for each independent activity for which he/she is registered.
(d) A registrant may take an inventory on a date that is within four (4) days of this biennial inventory date pursuant to 475:25-1-7 if he/she notifies in advance the Oklahoma State Bureau of Narcotics and
Dangerous Drugs Control of the date on which he/she will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken. The inventory shall be signed by the person taking said inventory.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

475:25-1-7. Biennial inventory date
   Every two (2) years following the date on which the initial inventory is taken by a registrant, the registrant shall take a new inventory of all stocks of controlled dangerous substances on hand. The biennial inventory may be taken:
   (1) on the day of the year on which the initial inventory was taken; or
   (2) on the registrant’s regular general physical inventory date, as long as the date chosen does not exceed two (2) years from the last inventory date.

475:25-1-8. Inventory date for newly-controlled dangerous substances
   Every registrant required to keep records who possesses a substance which has been added to any schedule of controlled dangerous substances shall take an inventory of all stocks of the newly-scheduled substance on hand. Thereafter, such substances shall be included in each inventory made by the registrant pursuant to 475:25-1-7.

475:25-1-9. Inventories of manufacturers
   Inventories of manufacturers of controlled dangerous substances shall conform to Title 21 Code of Federal Regulations, §1304.11.

475:25-1-10. Inventories of distributors
   Each person registered or otherwise authorized to distribute controlled dangerous substances shall include in his/her inventory the same information required of a manufacturer pursuant to Title 21 Code of Federal Regulations, §1304.11.

475:25-1-11. Accounting requirements
   In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the registrant shall make an accurate count or measure of all controlled dangerous substances in schedules I, II, III, IV, or V.

   (a) Every registrant required to keep records shall maintain on a current basis a complete and accurate record of each such substance manufactured, received, sold, delivered or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.
   (b) Separate records shall be maintained by a registrant for each registered location or except as otherwise provided independent activity for which he/she is registered.
   (c) In recording dates of receipt, distribution or other transfers, the date on which the controlled dangerous substances are actually received, distributed or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

475:25-1-14. Records for manufacturers
   Records for manufacturers of controlled dangerous substances shall conform to Title 21 Code of Federal Regulations, §1304.22.

475:25-1-15. Records for distributors
   Each person registered or otherwise authorized to distribute controlled dangerous substances shall maintain records with the following information for each controlled dangerous substance:
(1) The name of the substance.
(2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
(3) The number of commercial containers of each such finished form received from other persons, including the date and number of containers in each receipt and the name, address and Federal Drug Enforcement Administration registration number of the person from whom the containers were received.
(4) The number of commercial containers of each such finished form imported directly by the person, including the date of, the number of commercial containers in, and the import permit or declaration number for each importation.
(5) The number of commercial containers of each such finished form distributed to other persons, including the date and number of containers in each distribution and the name, address and Federal Drug Enforcement Administration registration number of the person to whom the containers were distributed.
(6) The number of commercial containers of each such finished form exported directly by the person, including the date of, the number of commercial containers in, and the export permit or declaration number for each exportation.
(7) The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the person (e.g., by distribution as complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and the Federal Drug Enforcement Administration registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed.

475:25-1-17. Records of scientific analyst

(a) Each person registered or otherwise authorized to conduct scientific analysis with controlled dangerous substances shall maintain records with the following information to the extent known and reasonably ascertainable by him/her for each controlled dangerous substance:
   (1) The name of the substance.
   (2) The form or forms in which the substance is received, imported or manufactured by the registrant (e.g., powder, granulation, tablet, capsule or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.D., 10-milligram tablet or 10-milligram concentration per milli-liter).
   (3) The total number of the forms received, imported or manufactured (e.g., 100 tablets, 30 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation or manufacture and the name, address and Federal Drug Enforcement Administration registration number, if any, of the person from whom the substance was received.
   (4) The quantity distributed or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution or destruction and the name, address and Federal Drug Enforcement Administration registration number, if any, of each person to whom the substance was distributed.

(b) Records of controlled dangerous substances used in chemical analysis or other laboratory work are not required.

(c) Records relating to known or suspected controlled dangerous substances received as evidentiary material for analysis are not required under (a) of this Section.

(d) Each person registered as a scientific analyst conducting scientific analysis of anonymous samples of suspected controlled dangerous substances shall maintain records containing the following information (to the extent known and reasonably ascertainable by him/her):
   (1) Laboratory identification number.
(2) Date the sample received.
(3) Purported contents and actual identification.
(4) Quantity received.
(5) Form of sample (i.e., powder, liquid, tablets, etc.).
(6) Description of sample.
(7) Quantity utilized in analysis.
(8) Disposition of sample.
(9) Street price, if known.
(10) Method shipment is received.
(11) Each laboratory shall submit to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control a quarterly report containing at least the following information:
   (A) Actual content of drug analyzed.
   (B) Alleged content of drug analyzed.
   (C) Description of sample.
   (D) Origin of sample.
   (E) Street price, if known.

(e) Quantitative analysis may be conducted of anonymous samples. However, to prevent the possibility of illegal drug traffickers utilizing these laboratories as quality control, only qualitative results may be given to the donor. Analysis should be sufficient to determine if the strength is so great that use would be harmful to the user. In these cases, the submitter can only be told what the drug was and that use would be dangerous.

(1) Security of standards and samples shall be in accordance with 475:20-1-6 and 475:20-1-7, with the exception that all standards and samples must be treated as Schedules I and II.
(2) Any unused portion of a submitted anonymous sample shall be disposed of in accordance with 475:35-1-4.
(3) All controlled dangerous substances distributed to canine handler registrants and scientific research registrants shall be analyzed quantitatively, and a record of such analysis shall be maintained prior to distribution. Oklahoma State Bureau of Investigation has discretion to refuse to distribute any controlled dangerous substances. Each such registrant shall receive a copy of the quantitative analysis.

475:25-1-18. Records of medical institutions

Each registered medical institution licensed by the Oklahoma State Department of Health or the Oklahoma State Department of Human Services as a hospital or otherwise authorized to professionally handle controlled dangerous substances shall maintain records with the following information for each controlled dangerous substance:

(1) Each such registered or otherwise authorized hospital shall issue a specific internal code number for each resident or staff practitioner required within the scope of his or her employment to administer, dispense or prescribe controlled dangerous substances within the hospital. The code number shall consist of numbers, letters, or a combination thereof, and shall be a suffix to the hospital's Federal Drug Enforcement Administration registration number, preceded by a hyphen (e.g., AB1234567-12 or AB1234567-A12).

   (A) If the hospital has a graduate intern training program authorized by the Oklahoma State Board of Medical Licensure and Supervision, the hospital may authorize such interns, required within the scope of his or her employment, to administer, dispense or prescribe controlled dangerous substances within the hospital, in accordance with 475:10-1-5.
   (B) A current list of the internal code numbers of each hospital and the corresponding authorized individual resident, staff practitioner or intern shall be kept by the hospital pharmacist and will be made available at all times to other registrants and properly designated law
enforcement agencies upon request, for the purpose of verifying the prescribing individual practitioner.

(2) Controlled dangerous substances records for accountability in a registered medical institution are required for all substances listed in Schedules II through V of the Oklahoma Uniform Controlled Dangerous Substances Act. These records shall include and provide at least:

(A) The number of doses of controlled dangerous substances purchased.
(B) The number of doses dispensed to individual patients or distributed to nursing stations.
(C) The number of doses administered.
(D) A biennial physical inventory and reconciliation of any discrepancies.

(3) Where a controlled dangerous substance is not dispensed to an individual patient, the following are required:

(A) Controlled dangerous substances records for those substances in Schedules II through V.
(B) Distribution of a controlled dangerous substance to a nursing station shall not exceed twenty-five (25) doses per container.
(C) A distribution record for each multiple of twenty-five (25) or fewer doses shall be used to account for delivery to a nursing station. The record shall include the name and dose of the controlled dangerous substance, quantity, date, location of the nursing station, and names of the person from the pharmacy or drug department distributing and the person on the nursing station receiving the substance.
(D) A proof-of-use record to account for all doses of a substance administered, including the name of the substance, dose administered, time administered, name of the patient and signature of the person who administered the dose.

(4) A controlled dangerous substance maintained at a nursing station shall be stored in a securely-locked cabinet or medication cart accessible only to persons responsible for administration or distribution of the substance.

(5) Completed controlled dangerous substances records shall be maintained or controlled by the pharmacy or drug department official for two (2) years.

(6) When a dose is destroyed, a witness shall countersign on the proper accountability record, record the disposition, and explain the destruction of the dose.

(7) The patient's chart shall constitute the medication record.

475:25-1-19. Order forms

Procedures governing the issuance, use and preservation of order forms regarding controlled dangerous substances shall be maintained pursuant to Title 21 Code of Federal Regulations §1305 in accordance with Title 63 Okl.St.Ann. §2-308.

Chapter 30 - Labeling Requirements

475:30-1-1. Purpose

The rules of this Chapter describe the procedures to be followed for issuance of a valid prescription, and the information required to be placed on labels for controlled dangerous substances.

475:30-1-2. Persons entitled to issue prescriptions

Only a registered individual practitioner may issue a prescription for a Schedule II, III, IV and V controlled dangerous substance. An individual practitioner, an authorized employee of the practitioner, or an authorized employee of the facility at which the practitioner works may communicate by telephone an oral prescription for any controlled dangerous substance in Schedules III, IV or V being prescribed by the individual practitioner. It remains the responsibility of the practitioner to guard against the diversion of CDS by employees authorized by him/her to call in such prescriptions.

475:30-1-3. Purpose of issuance of prescriptions

(a) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate
medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription, as the filling of a prescription is not incumbent on the pharmacy. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Title 63 Okl.St.Ann. §§ 2-309 and 2-312, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

(b) A prescription may not be issued in order for a registered or otherwise authorized individual practitioner to obtain controlled dangerous substances to stock or re-supply his/her office or medical bag for the purpose of general dispensing to patients. Such orders for stock or re-supply must be made by invoice for schedules III, IV, and V, or by DEA-222 order form for schedules I and II.

(c) A prescription may not be issued for the dispensing of a controlled dangerous substance listed in any schedule to a drug dependent person for the sole purpose of continuing his/her dependence upon such drugs. This prohibition applies to the use of gradually diminished doses for the purpose of tapering the person's dependence. This section does not apply to a properly licensed and registered narcotic treatment program.

(d) A practitioner may not distribute, dispense, sell, give, prescribe or administer any controlled substances in Schedules I through V for the practitioner's personal use, or for an immediate family member. Provided that this paragraph shall not apply to family members outside the second degree of consanguinity or affinity. Provided further that this paragraph shall not apply to medical emergencies when no other medical doctor is available to respond to the emergency.

475:30-1-4. Manner of issuance of prescriptions
(a) The practitioner shall sign a written prescription in the same manner as he/she would sign a check or legal document and shall also type, stamp or print the practitioner's name on the face of each prescription. Where an oral order is not permitted, prescriptions shall be written with ink. All written prescriptions shall be manually signed by the practitioner. The prescriptions may be prepared by an agent for the signature of a practitioner, but the prescribing practitioner is responsible in the event the prescription does not conform in all essential respects to the Uniform Controlled Dangerous Substances Act and this Chapter.

(b) A resident or staff practitioner, an intern of a teaching hospital, or a limited institutional practitioner of a federal, state or local government hospital or institution, exempted from registration or registered in fee-exempt status with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, shall include on all prescriptions issued by him/her the hospital or institutional Federal Drug Enforcement Administration registration number with the special internal code number assigned by the hospital or other institution; or include on all prescriptions he/she issues his/her personal Federal Drug Enforcement Administration registration number. Such prescriptions issued by interns of a teaching hospital, if for outpatients, must be countersigned by a practitioner licensed by the practitioner's appropriate State of Oklahoma licensing board.

(c) A practitioner must state on a written prescription for any controlled dangerous substance the name, address and Federal Drug Enforcement Administration registration number of the practitioner; the date of delivery of the prescription; the name, dosage and strength per dosage unit of the controlled dangerous substance; the name and address of the patient, or if it is a veterinary prescription, the species of the animal and the name and address of the owner; the directions for use and any cautionary statements required; and if allowable, the number of times to be refilled.

(1) The face of a prescription must not be materially altered; if an error is made in filling out the prescription, a new prescription must be written by the prescribing practitioner.
(A) A pharmacist may add to the prescription the patient’s address or age, the prescribing practitioner’s federal DEA number, or the generic drug name if used.
(B) After confirming with the prescribing practitioner, the pharmacist may add information indicating the strength, whether tablet or capsule form, and whether it is compounded if such additions would not materially alter the prescription.
(C) If omitted, the directions (Sig) or the quantity, may be added by the pharmacist after confirming with the prescribing practitioner.
(D) Documentation of contacting the prescribing practitioner will be noted on the back of the prescription regarding (B) and (C) above.
(2) A written prescription for a controlled dangerous substance in Schedule II becomes invalid thirty (30) days after the date of issuance, with day one (1) of the thirty (30) day period being the first day after the date of issuance.
(3) Each scheduled drug shall be written on a single prescription form, and no other prescriptions (controlled or non-controlled) shall be written on the same prescription form.
(d) Upon receiving an oral prescription, the pharmacist must reduce the oral prescription to the form specified in (c) of this Section, including the typewritten name of the prescribing practitioner. The pharmacist filling any prescription for any controlled dangerous substance must enter the date of filling and handwrite the initials of the pharmacist on the prescription. If the practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that the oral authorization came from a registered practitioner.
(e) Upon receiving an oral prescription, the pharmacist may use a computer printout label if the label meets all requirements for a prescription as set out by the Uniform Controlled Dangerous Substances Act and this Chapter. On computer labeling for oral prescriptions, it is not necessary that the Drug Enforcement Administration registration number be on the label used as an oral prescription, but it must be recorded on the document prepared by the pharmacist.
(f) Written prescriptions may be transmitted by a practitioner to a dispensing pharmacy by facsimile. In such cases, the prescribing practitioner shall print "FAXED" on the face of the prescription, and the facsimile received must be on non-fading standard paper. Thermographic paper is not acceptable for any prescriptions for drugs in any Schedule.
(1) For drugs in Schedules III, IV, and V, a facsimile of a written, signed prescription transmitted directly by the prescribing practitioner to the pharmacy can serve as an original prescription.
(2) For drugs in Schedule II, the original written prescription must still be presented and verified against the facsimile at the time the substance is actually dispensed and the original document must be properly annotated and retained for filing subject to the exceptions listed in (3) below.
(3) Exception to (2): A facsimile copy of a prescription for a Schedule II drug when sent by facsimile by the prescribing practitioner:
   (A) To a Home Infusion Pharmacy.
   (B) When the prescription is for a patient in a Long Term Care Facility.
   (C) When the prescription is for a patient in a Hospice program certified by Medicare under Title XVIII or licensed by the state.
   (D) If the facsimile is sent from a LTCF or hospice instead of the prescribing practitioner's office, the original must be presented at the time any CDS is dispensed.
(g) The pharmacist still bears the responsibility for ensuring that prescriptions for controlled substances have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. This responsibility applies equally to an order transmitted by facsimile. Measures to be considered in authenticating prescriptions sent by facsimile equipment would include maintenance of a practitioner’s facsimile number reference file, verification of the telephone number of the originating facsimile equipment and/or telephone verification with the practitioner’s office that the
prescription was both written by the practitioner and transmitted by the practitioner or the practitioner's agent.

(h) Electronic prescriptions are permitted as provided by 21 CFR §§ 1311 et. seq.

475:30-1-5. Dispensing of narcotic drugs during scientific research
(a) The administering or dispensing directly (but not prescribing) of narcotic drugs in any schedule to a narcotic drug dependent person for the purpose of continuing his/her dependence upon such drugs in the course of conducting an authorized clinical scientific research in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his/her professional practice or research"; PROVIDED that approval is obtained prior to the initiation of such a program by submission of a protocol submitted to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and the State of Oklahoma Drug Treatment Rehabilitation Authority. It will be reviewed by the State of Oklahoma Drug Treatment Rehabilitation Authority and the Mental Health Department for scientific merit and qualifications and by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control for controlled dangerous substances requirements as provided by the Uniform Controlled Dangerous Substances Act and this Chapter.
(b) Nothing in this Title shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms, when necessary, while arrangements are being made for referral for treatment. Not more than one (1) day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three (3) days and may not be renewed or extended.

475:30-1-6. Requirements of prescriptions for controlled dangerous substances listed in Schedule II
(a) A pharmacy may dispense directly a controlled dangerous substance listed in Schedule II which is a prescription drug as determined under the Uniform Controlled Dangerous Substances Act, only pursuant to a written prescription or as otherwise provided for in this Title.
(b) A registered individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedule II in the course of his/her professional practice without a prescription, subject to 475:30-1-5.
(c) An institutional physician limited in practice by the individual's appropriate Oklahoma state licensing board, other than those registered in a fee-exempt status with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, may administer or dispense directly (but not prescribe) a controlled dangerous substance listed in Schedule II, only pursuant to a written prescription signed by the "Limited Institutional Practitioner's" supervising chief medical practitioner or to an order for medication made by an individual supervising chief medical practitioner which is dispensed for immediate administration to the ultimate user.
(d) In case of an emergency situation, as defined by the Oklahoma State Board of Pharmacy pursuant to Title 63 Okl.St.Ann. §2-309, and Title 21 Code of Federal Regulations, §1306.11, the pharmacist of a registered or otherwise authorized pharmacy may dispense a controlled dangerous substance listed in Schedule II upon receiving oral authorization of a prescribing registered individual; PROVIDED that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing registered individual practitioner).
2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Title 63 Okl.St.Ann. §2-309 and OAC 475, except for the signature of the prescribing registered individual practitioner.
3. If the prescribing registered individual practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that oral authorization came from a registered individual practitioner, which may include a callback to the prescribing registered individual practitioner.
practitioner, using his/her phone number as listed in the telephone directory and/or good faith effort to ensure his/her identity.

(4) In emergency situations, reasonable effort must be made to determine the identity of the person picking up the prescription if that person is not known to the pharmacist.

(5) Within seventy-two (72) hours after authorizing an emergency oral prescription, the prescribing registered individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Title 63 Okl.St.Ann. §2-309(F), the prescription shall have written on its face "Authorization for Emergency Dispensing", and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacy shall notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control if the prescribing registered individual practitioner fails to deliver to him/her a written prescription; failure of the pharmacy to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing registered individual practitioner.

475:30-1-7. Partial filling of Schedule II prescriptions
(a) The partial filling of a prescription for a controlled dangerous substance listed in Schedule II is permissible if the pharmacy is unable to supply the full quantity called for in a written or emergency oral prescription. A notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription) is required. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling if the initial partial filling occurred within thirty (30) days of the issuance of the prescription. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacy shall so notify the prescribing registered individual practitioner. No further quantity may be supplied beyond the seventy-two (72) hours without the issuance of a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient". A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Uniform Controlled Dangerous Substances Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

475:30-1-10. Requirements of prescriptions for controlled dangerous substances listed in Schedules III and IV
(a) A pharmacy may dispense controlled dangerous substances listed in Schedules III or IV only pursuant to either a written prescription signed by a registered or otherwise authorized individual practitioner or an oral prescription made by a prescribing registered or otherwise authorized individual practitioner and promptly reduced to writing by the pharmacist, containing all the information required by Title 63
Okl.St.Ann. §§2-309 and 2-314, and this Chapter, or pursuant to an electronic prescription in compliance with the terms of 21 CFR §§ 1311 et. seq. Computer labels meeting these requirements are acceptable.

(b) A registered or otherwise authorized individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedule III or IV in the course of his/her professional practice without a prescription, subject to 475:30-1-5.

(c) An institutional practitioner limited in practice by the individual's appropriate State of Oklahoma professional licensing board, other than those registered as fee-exempt by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, may administer or dispense directly (but not prescribe) a controlled dangerous substance listed in Schedule III or IV pursuant to a written prescription signed by the "Limited Institutional Practitioner's" supervising chief medical practitioner, or pursuant to oral prescription made by the "Limited Institutional Practitioner's" supervising chief medical practitioner and promptly reduced to writing by the pharmacist containing all information required by 475:30-1-4, except for the signature of the "Limited Institutional Practitioner's" supervising chief medical practitioner or pursuant to an order for medication made by an individual supervising chief medical practitioner which is dispensed for immediate administration to the ultimate user, subject to 475:30-1-5.

475:30-1-11. Refilling of prescriptions

(a) No prescription for a controlled dangerous substance in Schedules III or IV shall be filled or refilled more than six (6) months after the date such prescription was issued, and no such prescription authorized to be refilled may be refilled more than five (5) times. Each refilling of a prescription shall be maintained by the pharmacy, which indicated by the number of the prescription the following information: the name and dosage form of the controlled dangerous substance; the date of each refilling; the quantity dispensed; the identity or initials of the dispensing pharmacist in each refilling; and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription, he/she shall be deemed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled dangerous substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new and separate prescription. Refills shall not be obtained at the same time as the initial filling of the prescription and only one (1) refill shall be obtained at any one time. A new prescription for a specific CDS voids any existing refills or other prescriptions for the same drug.

(b) A pharmacy registrant may elect to use an automated data processing system to maintain prescription files; however, if such a system is used, there must also be written files kept which meet the requirements of Title 59 Okl.St.Ann. § 353.20, OAC 535:15-3-21 and 21 CFR § 1306.22.

(c) Prescriptions for hydrocodone containing products may not be refilled.

475:30-1-12. Partial filling of Schedules III, IV and V prescriptions

The partial filling of a prescription for a controlled dangerous substance listed in Schedules III, IV or V is permissible; PROVIDED that:

(1) Each partial filling is recorded in the same manner as a refilling.
(2) The total quantity dispensed does not exceed the total quantity prescribed.
(3) No dispensing occurs after six (6) months after the date on which the prescription was issued.
(4) Prescriptions for hydrocodone containing products are partially filled pursuant to 475:30-1-7.

475:30-1-13. Requirements of prescriptions for controlled dangerous substances listed in Schedule V

(a) A pharmacist of a registered or otherwise authorized pharmacy may dispense directly a controlled dangerous substance listed in Schedule V pursuant to a prescription as required for controlled dangerous substances listed in Schedules III and IV. A prescription for a controlled dangerous substance listed in Schedule V may be refilled only the number of times expressly authorized by the prescribing registered individual practitioner on the face of the prescription, and such prescription may not be refilled more than six (6) months after the date of issuance. If no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance and
file the prescription.
(b) A registered individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedule V, in the course of his/her professional practice, without a prescription.
(c) An institutional physician limited in practice by the individual's appropriate State of Oklahoma professional licensing board, other than those registered as fee-exempt with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, may administer or dispense directly (but not prescribe) a controlled dangerous substance listed in Schedule V only pursuant to a written prescription signed by the "Limited Institutional Practitioner's" supervising chief medical practitioner, or pursuant to an oral prescription made by a "Limited Institutional Practitioner's" supervising chief medical practitioner and promptly reduced to writing by the pharmacist (containing all information required in 475:30-1-4, except for the signature of the "Limited Institutional Practitioner's" supervising practitioner), or pursuant to an order for medication made by a "Limited Institutional Practitioner's" supervising chief medical practitioner which is dispensed for immediate administration to the ultimate user.

475:30-1-14. Dispensing, prescribing, administering or distributing without prescription

A controlled dangerous substance listed in Schedule V which is not a prescription drug as determined by the Oklahoma State Board of Pharmacy and/or the Federal Food and Drug Administration, may be dispensed by a pharmacy without a prescription to a purchaser at retail level; PROVIDED that:

(1) Such dispensing is made only by a pharmacist that has been licensed by the Oklahoma State Board of Pharmacy to dispense controlled dangerous substances and not by a non-pharmacist employee, even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his/her professional and legal responsibilities set forth in this Section, the actual cash, credit transaction or delivery may be completed by a non-pharmacist).
(2) No person shall dispense, prescribe, administer or distribute to any one person, for the use of any one person or animal, any preparation(s) included in Title 63 Okl.St.Ann. § 2-313(B)(1), when the dispensing, prescribing, administering or distributing person knows, or can by reasonable diligence ascertain, that such dispensing, prescribing, administering or distributing will provide the person to whom or for whose use, or the owner of the animal for the use of which, such preparation is prescribed, administered, dispensed or distributed, within any forty-eight (48) consecutive hours, with more than 320 milligrams of opium, or more than 40 milligrams of morphine or any of its salts, or more than 160 milligrams of codeine or any of its salts, or will provide such person or the owner of such animal, within forty-eight (48) consecutive hours, more than one preparation exempted by Title 63 Okl.St.Ann. § 2-313.
(3) Except as otherwise authorized by the Act, OAC 475:30-1-14 shall not apply to the following cases:

(A) Prescribing, administering, dispensing or selling at retail not more than one of any of the following medicinal preparations that contain in thirty (30) milliliters or if a solid or semi-solid preparation, in one (1) avoirdupois ounce:
   (i) Not more than one hundred sixty (160) milligrams of opium.
   (ii) Not more than twenty (20) milligrams of morphine or any of its salts.
   (iii) Not more than eighty (80) milligrams of codeine or any of its salts.
(B) Prescribing, administering, dispensing or selling at retail of liniments, ointments and other preparations that are susceptible of external use only and that contain narcotic drugs in such combinations as to prevent their being readily extracted from such liniments, ointments or preparations, except that this shall apply to all liniments, ointments and other preparations that contain coca leaves in any quantity or combination.
(C) Any compound, mixture or preparation which contains not more than one drachma of paregoric per thirty (30) milliliters.
(D) The labeling requirements set forth in this Chapter shall not apply to medicinal preparations
excepted by Title 63 Okl.St.Ann. § 2-313, and OAC 475.

(4) The medicinal preparation or the liniment, ointment or other preparation susceptible of external use only, prescribed, administered, dispensed or distributed shall contain, in addition to the narcotic drug therein, some drug or drugs conferring upon it medicinal qualities other than those possessed by the narcotic drug alone. Such preparation shall be prescribed, administered, dispensed and distributed in good faith as a medicine and not for the purpose of evading the provisions of the Uniform Controlled Dangerous Substances Act and this Chapter.

(5) The pharmacy, through its agent who is duly licensed by the Oklahoma State Board of Pharmacy, shall not dispense to persons under eighteen (18) years of age.

(6) The pharmacy requires every purchaser of controlled dangerous substances under this Chapter not known to him/her to furnish suitable identification (including proof of age where appropriate).

(7) A bound record book for dispensing controlled dangerous substances under this Section is maintained by the pharmacy, which book shall contain the name and address of the purchaser, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record-keeping requirements of 475:25-1-4).

(8) The pharmacy agent dispensing controlled dangerous substances listed in Schedule V shall, pursuant to Title 63 Okl.St.Ann. § 2-314(B), affix to the package a label showing the prescription number, if any, the date dispensed, the purchaser's name, the name of the prescribing physician, if any, name and address of the pharmacy, if the patient or ultimate user is an animal, the name of the owner of the animal and the words "for veterinary use only".

475:30-1-15. Identification requirement
Pharmacists are required to obtain valid identification as required by Title 63 § 2-309C if they are unsure of the identity of a person picking up a prescription for any controlled dangerous substance.

Chapter 35 - Transfer and Disposal of Controlled Dangerous Drugs

475:35-1-1. Purpose
The rules of this Chapter describe the methods of acceptable transfer of controlled dangerous substances other than by prescription.

475:35-1-2. Distribution by a registered practitioner or pharmacy to another registered practitioner or pharmacy
(a) A practitioner or pharmacy who is registered to dispense a controlled dangerous substance may distribute (without being registered to distribute) a quantity of such substance to another registered practitioner or pharmacy for the purpose of general dispensing by the practitioner or pharmacy to his/her or its patients; PROVIDED that:

(1) The practitioner or pharmacy to whom the controlled dangerous substance is to be distributed is registered under the Uniform Controlled Dangerous Substances Act to dispense that controlled dangerous substance.

(2) The distribution is recorded by the distributing practitioner or pharmacy and by the receiving practitioner or pharmacy in accordance with Chapter 25 of this Title. If the substance is listed in Schedule I or II, an order form is used, as required by Title 21 Code of Federal Regulations, §1305, and pursuant to Title 63 Okl.St.Ann. §2-308.

(3) The total number of dosage units of all controlled dangerous substances distributed by the practitioner pursuant to this Section during the 12-month period in which the practitioner or pharmacy is registered to dispense does not exceed five percent (5%) of the total number of dosage units of all controlled dangerous substances distributed and dispensed by the practitioner during the 12-month period.

(b) If, at any time during the 12-month period during which the practitioner or pharmacy is registered to
dispense, the practitioner or pharmacy has reason to believe that the total number of dosage units of all controlled dangerous substances which will be distributed by him/her pursuant to this Section will exceed five percent (5%) of the total number of dosage units of all controlled dangerous substances distributed and dispensed by him/her during the 12-month period, the practitioner or pharmacy shall obtain a registration to distribute controlled dangerous substances.

475:35-1-3. Distribution upon discontinuance or transfer of business
(a) Any registrant desiring to discontinue business activities altogether or with respect to controlled dangerous substances (without transferring such business activities to another person) shall return for cancellation of his/her Certificate of Registration. Any controlled dangerous substances in his/her possession may be disposed of in accordance with Title 21 Code of Federal Regulations, § 1307.21.
(b) Any registrant desiring to discontinue business activities altogether or with respect to controlled dangerous substances (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control at least fourteen (14) days in advance of the date of the proposed transfer (unless the Director waives this time limitation in individual instances), the following information:
   (1) The name, address, registration number and authorized business activity of the registrant discontinuing the business (registrant-transferor).
   (2) The name, address, registration number and authorized business activity of the person acquiring the business (registrant-transferee).
   (3) Whether the business activities will be continued at the location registered by the person discontinuing the business or moved to another location (if the latter, the address of the new location should be listed).
   (4) Whether the registrant-transferor has a quota to manufacture or procure any controlled dangerous substance listed in Schedule I or II (if so, the basic class or classes of the substance should be indicated).
   (5) The date on which the transfer of controlled dangerous substances will occur.
(c) Unless the registrant-transferor is informed by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled dangerous substances in his/her possession to the registrant-transferee in accordance with the following:
   (1) On the date of transfer of the controlled dangerous substances, a complete inventory of all controlled dangerous substances being transferred shall be taken in accordance with 475:25-1-5 through 475:25-1-12. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control unless requested by the Director. Transfers of any substances listed in Schedule I or II requires the use of order forms in accordance with Title 21 Code of Federal Regulations, § 1305.
   (2) On the date of transfer of the controlled dangerous substances, all records required to be kept by the registrant-transferor with reference to the controlled dangerous substances being transferred, pursuant to this Chapter and Title 21 Code of Federal Regulations, § 1304, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

475:35-1-4. Procedure for disposing of controlled dangerous substances
Any registrant in possession of any controlled dangerous substances and desiring or required to dispose of such substances shall obtain appropriate forms from the Oklahoma State Bureau of Investigation Laboratory in Oklahoma City, Oklahoma. The drugs must be inventoried and submitted pursuant to Title 63 Okl.St.Ann. §2-315. Registrants may alternatively request the Regional Director of the Drug Enforcement
Administration in the region in which the person is located for authority and instructions to dispose of such substances pursuant to Title 21 Code of Federal Regulations, §1307.21.

475:35-1-5. Procedure for disposing of controlled dangerous substances in bankruptcy proceeding
At no time shall a representative who is not duly registered with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control be in possession of any controlled dangerous substances awarded out of a bankruptcy proceeding.

Chapter 40 - Enforcement and Administrative Inspections

475:40-1-1. Purpose
The rules of this Chapter set out the authority for administrative inspections of OBN registrants to validate compliance with rules and statutes.

475:40-1-2. Authority to make inspections
Administrative inspections of OBN registrants shall include, but not be limited to, the following:
1. Inspecting, copying and verifying the correctness of records, reports or other documents required to be kept or made, including, but not limited to, inventory and other records required to be kept pursuant to the Uniform Controlled Dangerous Substances Act, this Title, and the Code of Federal Regulations governing controlled dangerous substances; order form records required to be kept pursuant to Title 63 Okl.St.Ann. § 2-308; prescriptions and distribution records required to be kept pursuant to Title 63 Okl.St.Ann. § 2-307; shipping records identifying the name of each carrier used; and the date and quantity of each storage.
2. Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled dangerous substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Uniform Controlled Dangerous Substances Act and this Title.
3. Making a physical inventory of all controlled dangerous substances on hand at the premises.
4. Collecting samples of controlled dangerous substances or precursors (in the event any samples are collected during an inspection, the peace officer or officer so authorized shall issue a receipt for such samples to the owner, operator or agent in charge of the premises).

475:40-1-3. Entry
A peace officer of the State of Oklahoma, upon stating his/her purpose and presenting to the owner, operator or agent in charge of the premises to be inspected his/her appropriate credentials, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

Chapter 45 - Oklahoma Control Reporting Requirements

475:45-1-1. Purpose
The rules of this Chapter delineate the requirement of pharmacies or dispensing (but not administering) practitioners to report certain information upon filling any prescription for any controlled dangerous substance in schedules II, III, IV or V.

475:45-1-2. Required reporting of certain information
(a) Every pharmacy or dispensing practitioner filling any schedule II, III, IV or V prescriptions must report the following information to a central repository maintained by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN). The information must include, but not be limited to, the following:
1. Recipient's name;
2. Recipient's identification number;
3. National Drug Code number of the substance dispensed,
4. Date of the dispensation;
(5) Quantity of the substance dispensed;
(6) Prescriber's U.S. Drug Enforcement Agency registration number; and,
(7) Dispenser's registration number and location.
(b) The term “recipient” is also intended to include reporting the required information concerning the recipient’s agent as defined by 63 O.S. §2-309B.

475:45-1-3. Method of reporting
Each pharmacy or dispensing practitioner must transmit the information required in 475:45-1-2 in the following manner: On an electronic device which is compatible with the receiving device of the central repository.

475:45-1-4. Waiver of electronic submissions
(a) The Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN) may waive the requirement to submit prescription data in an electronic format, and allow a pharmacy filling a prescription of a Schedule II, III, IV or V Controlled Dangerous Substance to submit prescription data in a paper format if the dispenser has an appropriate hardship.
(b) A formal request for this waiver must be made in writing to the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN) and must clearly state (1) the nature and extent of the hardship; and, (2) a proposed time-line for the waiver.
(c) Any such hardship granted by the Director of OBN will be reviewed every thirty (30) days following the granting of a waiver to determine whether or not the hardship will be extended.

475:45-1-5. Time limit for reporting
The information required by this section must be reported to the central repository within five (5) minutes of the time that the controlled dangerous substance was dispensed.

475:45-1-6. Failure to report
Failure to accurately report the required information according to the rules set forth in this Chapter may result in administrative action against the registration of the pharmacy or dispensing practitioner, including, but not limited to, fines not to exceed Two Thousand Dollars ($2000) per violation.

Chapter 55 - Pseudoephedrine Control

475:55-1-1. Purpose
(a) The Oklahoma Bureau of Narcotics and Dangerous Drugs Control has been granted statutory authority by 63 O.S., 2-301 to "promulgate rules and regulations relating to the registration and control of the manufacture, distribution, dispensing, prescribing, administering or use for scientific purposes of controlled dangerous substances within this state." Furthermore, 63 O.S., 2-212 authorizes the Oklahoma Bureau of Narcotics and Dangerous Drugs Control to promulgate rules specifically for Schedule V pseudoephedrine products. These statutes, as well as the entire Oklahoma Uniform Controlled Dangerous Substances Act, O.S. 63 Chapter 2, and the Oklahoma Administrative Code Title 475, are used as guiding authorities for the specific points of these rules and regulations.
(b) The rules of this Chapter specify the requirements for pseudoephedrine control in Oklahoma. Included in this Chapter are characteristics of exempt pseudoephedrine products, pharmacy requirements, dispensing pseudoephedrine products, thirty-day requirement, special registration for distribution centers, lawful possession of Schedule V pseudoephedrine products, records and invoices, labeling, prescriptions, distributor and warehouse storage of Schedule V pseudoephedrine, and criteria for exemption.

475:55-1-3. Pharmacy requirements
(a) Schedule V pseudoephedrine substances may be sold only in licensed pharmacies that are registered with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control. These substances, as a special class of Schedule V controlled substances, shall be kept in a locked environment (shelving unit, safe, cabinet, etc.) that is within view of the pharmacy, or behind the pharmacy counter. As specified in 63 OS, 2-303 (1),
2-304 (A)-4, and OAC 475:20-1-2, the pharmacist and those with access to pseudoephedrine products will have an affirmative duty to guard against the theft and diversion of these products.

(b) Pharmacies that sell, distribute or otherwise deliver Schedule V pseudoephedrine substances must post a sign, provided by the Oklahoma Bureau of Narcotics, in a conspicuous area in or around the pharmacy, to inform persons obtaining pseudoephedrine about the provisions of the Oklahoma Methamphetamine Offender Registry Act, 63 O.S. §2-701, that prohibit any person who, after November 1, 2010, that has been convicted, pled guilty or no contest, or otherwise on that date was serving any sentence for a methamphetamine related offense, from purchasing or possessing a product containing any amount of pseudoephedrine. Alternatively, the above notification may be presented to the purchaser by electronic means. A purchaser must attest, by signature, in written or electronic form, that they are not subject to the Oklahoma Methamphetamine Offender Registry Act, as summarized above, prior to purchase of any pseudoephedrine products. The pharmacy must maintain those signatures for a period of two (2) years from the date of signature.

475:55-1-5. Electronic Reporting
Pharmacists or other authorized persons who sell Schedule V pseudoephedrine products shall exercise reasonable care in assuring that the purchaser has not exceeded the three and six-tenths (3.6) gram limit per day, the seven and two-tenths (7.2) gram limit for a thirty (30) day period or the sixty (60) gram limit for a twelve (12) month period. The pharmacist or other authorized person must utilize the real-time electronic pseudoephedrine tracking system as set forth pursuant to 63 O.S. §2-341 and the Methamphetamine Registry as set forth pursuant to 63 O.S. §2-701. The following provisions are necessary for compliance with this system:

1. All pseudoephedrine transactions regulated by Oklahoma law must be approved through submitting the request to the electronic log and Methamphetamine Registry;
2. Pseudoephedrine products regulated by Oklahoma law will only be sold to customers who present a valid form of identification and who attest that they are not subject to the Oklahoma Methamphetamine Offender Registry Act;
3. The customer information must be the same as that on the presented identification, and shall include the following information (fields that are required for submitting information as required by Oklahoma law):
   (A) Pharmacy identification;
   (B) Identification number;
   (C) Last name;
   (D) First name;
   (E) Purchase quantity (in grams);
   (F) Initials of the pharmacist or other authorized person conducting the transaction;
   (G) Product name;
   (H) Form of pseudoephedrine if it is liquid or gel-caps;
   (I) Customer’s street address;
   (J) Customer’s current city, state, and zip code; and
   (K) Date of birth.
4. If at any time a pharmacist or other authorized person discovers that the electronic log is unavailable or that the information submitted to the electronic log is inaccurate, the authorized person may continue regulated transactions for twenty-four (24) hours, provided that all sales are manually recorded. The authorized person shall suspend all sales if the reporting problem is not corrected within twenty-four (24) hours of discovery. Regulated sales may be resumed only when the reporting problem is corrected and all manually recorded sales are correctly submitted to the electronic log.
475:55-1-6. Special registration for distribution centers

Wholesale distribution centers located in Oklahoma that are engaged in interstate business to states in which Schedule V pseudoephedrine products may be sold legally can apply for and be granted a limited Schedule V pseudoephedrine pharmacy distributor license from the Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Eligibility for this registration shall be subject to the applicant's meeting the following conditions:

1. Applicant is actively engaged in the interstate sale of grocery or pharmaceutical items;
2. Applicant's sales are not limited to pseudoephedrine items alone, or to pseudoephedrine items in conjunction with other items associated with the illegal manufacture of methamphetamine or other controlled drugs;
3. Applicant does not have a history of association with the diversion of pseudoephedrine, or of having failed to guard against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs;
4. Applicant provides a list of customers, and they do not have a history of association with the diversion of pseudoephedrine, or of having failed to guard against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs;
5. Applicant meets the security conditions determined by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control in 475:20 of this code. However, the security for pseudoephedrine shall be less restrictive than for other pharmaceutical Schedule V controlled drugs and shall be held to a level commensurate with the nature of wholesale distribution;
6. Other conditions, as determined on a case-by-case basis by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control.

475:55-1-7. Lawful possession of Schedule V pseudoephedrine

(a) The following persons are allowed to lawfully possess Schedule V pseudoephedrine while in the course of legitimate business:

1. Any Schedule V pseudoephedrine-only limited pharmaceutical distributor, or its agents, licensed by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
2. Any wholesale drug distributor, or its agents, licensed by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
3. Any manufacturer of controlled drugs, or its agents, licensed by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
4. A pharmacy licensed by the Oklahoma State Board of Pharmacy; and
5. A physician, certified registered nurse anesthetist, advance practice nurse, physician's assistant, or other person, registered with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control.

(b) These individuals will be required to guard against the diversion of controlled drugs and are subject to the rules and regulations pertaining to registrants handling, reporting, dispensing controlled dangerous drugs, and submission to inspections by peace officers as set forth in 63 O.S. and OAC 475.

475:55-1-9. Labeling

Schedule V pseudoephedrine products shall be exempt from the labeling requirements of other Schedule V controlled drugs. Pseudoephedrine products that are obtained pursuant to a valid prescription and exempt from Schedule V classification must have an attached pharmacy label consistent with other non-scheduled drugs obtained by prescription.

475:55-1-10. Prescriptions

The threshold limits set forth in Oklahoma Statutes, Title 63 §2-212 shall not apply to Schedule V pseudoephedrine products that are dispensed pursuant to a valid prescription.

475:55-1-11. Distributor and Warehouse Storage of Schedule V Pseudoephedrine Products

Scheduled pseudoephedrine products shall be stored in a locked area that is monitored; however, they
will not be required to be kept in a special locked cage. Pharmaceutical distributors and warehouses are responsible for establishing security measures to guard against diversion as specified in Chapter 20 of this code.

475:55-1-12. Criteria for exemption
(a) Any person may request an exemption or conditional exemption of Schedule V classification for a specific product. The decision of whether to grant an exemption shall be made by the Director of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, who will take the following into consideration:
   (1) Ease with which the product can be converted to methamphetamine;
   (2) Ease with which pseudoephedrine is extracted from the substance and whether it forms an emulsion, salt, or other form;
   (3) Whether the product contains a "molecular lock" that renders it incapable of being converted into methamphetamine;
   (4) Presence of other ingredients that render the product less likely to be used in the manufacture of methamphetamine; and,
   (5) Any pertinent data that can be used to determine the risks of the substance being used in the illegal manufacture of methamphetamine or any other controlled substance.
(b) The burden of proof for exemption shall be upon the person requesting the exemption. The petitioner shall provide the Oklahoma Bureau of Narcotics and Dangerous Drugs Control with evidence that the product has been formulated in such a way as to serve as an effective general deterrent to the conversion of pseudoephedrine into methamphetamine. Such evidence shall include the furnishing of a valid scientific study, conducted by a professional laboratory and evincing professional quality chemical analysis, which is in accordance with uniform parameters set forth in writing by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. This report shall include documentable and reviewable data and a clear delineation of methodology.
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 a valid passport, military identification card, driver license, or identification card issued to a recipient pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the recipient is not a resident of the State of Oklahoma, or, if the recipient is less than eighteen (18) years old and has no such identification, the unique number contained on a valid passport, military identification card, driver license, or identification card issued to the recipient’s parent or guardian pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the parent or guardian is not a resident of the State of Oklahoma, or, if the controlled dangerous substance is obtained for an animal, the unique number contained on the animal owner’s valid driver license or identification card issued pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the owner is not a resident of the State of Oklahoma. Nonresident drug outlets registered pursuant to the Oklahoma Pharmacy Act and resident drug outlets defined in Section 353.1 of Title 59 of the Oklahoma Statutes are exempt from the picture identification requirement if the nonresident and resident drug outlets have obtained the identification of the patient through the prescription benefit plan of the patient;

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 at least three weeks prior to the effective date.
B. The pharmacy should notify the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) and the Federal Drug Enforcement Agency (DEA) in writing at least fourteen (14) days in advance.
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 ClI’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 B
APPENDIX C - DEA Form 222

For information concerning DEA Form 222, see the following:

http://www.deadiversion.usdoj.gov/faq/dea222.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:

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.
Appendix E

Oklahoma Mid-Level Practitioner Prescribing Summary

This summary dated March 2016 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).

Only Oklahoma licensed mid-level practitioners supervised by Oklahoma licensed physicians may prescribe and issue valid OK scripts:

- 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 Physician Assistants and Advance Practice Nurses.
- PA's, Advanced Practice Nurses and Optometrists may receive and distribute drug samples of drugs they may prescribe.
- They may NOT dispense.
- They may NOT prescribe CDS for themselves nor for their immediate family members [see OBN rules 475:30-1-3(d)].

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 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.

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 perinatal periods. CRNA’s may select, order, obtain and administer drugs including C-II thru C-V (with OBND 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.

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 E
Appendix F

**Consanguinity / Affinity Table**
*(Blood / Marriage)*

Showing Degrees of Relationships
PERSON
(Practitioner)

<table>
<thead>
<tr>
<th>Degrees</th>
<th>1st *</th>
<th>2nd *</th>
<th>3rd **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spouse</td>
<td>Parents</td>
<td>Grandchildren</td>
<td>Great Grandparents</td>
</tr>
<tr>
<td>Parents</td>
<td>Grandchildren</td>
<td>Great Grandchildren</td>
<td>Great Grandparents</td>
</tr>
</tbody>
</table>
| Children | Grandparents | Great Grandparents | **A practitioner MAY prescribe for the 3rd degree and below.**

* 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.