

**TITLE 535: OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 1. ADMINISTRATIVE OPERATIONS**

SUBCHAPTER 11. FEES

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

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

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

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

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

SUBCHAPTER 3. PHARMACIES

535:15-3-4.1. Pharmacy licensing requirement

(a) Every pharmacy conducting intrastate transactions in Oklahoma shall be licensed as required under Title 59, O.S., Section 353.18 (A). Every pharmacy shall also be licensed as required by Title 59 O.S. Section 353.18(A) if Oklahoma is the state from which it or to which it delivers, distributes, or dispenses or offers to sale, deliver, distribute, or dispense dangerous drugs, medicines, chemicals or poisons for the treatment or prevention of diseases, excluding agricultural chemicals and drugs.

~~(b) Every pharmacy shall list the corporate registered agent and address as required on their new and/or renewal application.~~

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

[Source: Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 24 Ok Reg 2259, eff 7-1-07; Amended at 26 Ok Reg 2274, eff 7-1-09]

535:15-3-17. Pharmacy prescription records

(a) The original ~~or an electronic copy of the~~ prescription [as defined in 353.1(29)] 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).

Agency 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.

[Source: Added at 12 Ok Reg 3024, eff 7-11-97; Amended at 17 Ok Reg 2626, eff 7-1-00]

SUBCHAPTER 6. HOSPITAL DRUG ROOM

535:15-6-9. Emergency room pre-packaged medications formulary

(a) Each hospital drug room may choose the medicines to be included in their emergency room (ER) pre-packaged medications formulary within the requirements and limits listed below. This formulary shall be included within the policies and procedures of the hospital drug room. These pre-packaged medications shall be administered only as allowed in 535:15-6-8 for a maximum of a 72-hour supply.

(b) Type of Medication defined or parameters for choice [Limits]

(1) Controlled Dangerous Substances (CDS):

(A) Hydrocodone / acetaminophen combination [one]

(B) Codeine/acetaminophen combination [one]

(C) ~~Propoxyphene/acetaminophen~~ Hydrocodone/ibuprofen combination [one]

(D) Hydrocodone 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] 110
- (18) Steroid: per ER formulary [three]

[Source: Added at 20 Ok Reg 2482, eff 1-1-04; Amended at 24 Ok Reg 2261, eff 7-1-07]

SUBCHAPTER 16. PHARMACY EMERGENCY MEDICATION KITS FOR USE IN A FACILITY **[NEW]**

535:15-16-1. Purpose [NEW]

(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.

535:15-16-2. Definitions [NEW]

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.

"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.

"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.

535:15-16-4. Policies and procedures for use of emergency medication kit drugs [NEW]

(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 medications 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 physician'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 physician or practitioner,

(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 drug 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.

535:15-16-5. Security [NEW]

(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.

535:15-16-6. Drug categories allowed in emergency medication kits [NEW]

(a) A 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;

(2) Antipsychotic - Limit 4 [Only if approved by OBN & DEA].

(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) Parenteral 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 [NEW]

(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 Title 59 O.S. Section 353.26 and/or other proper authorities for possible action.

(b) Violation of this subchapter by a 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.