

# OKLAHOMA State Board of Pharmacy

2920 N Lincoln Blvd, Suite A • Oklahoma City, OK 73105 <u>pharmacy@pharmacy.ok.gov</u> • <u>www.pharmacy.ok.gov</u> Marty Hendrick, Pharm.D., D.Ph., Executive Director Phone: 405.521.3815 • Fax: 405.900.8365

# **In-State Pharmacy Application Guidelines**

## **A.** LICENSURE:

**1**. The physical street address of the pharmacy must be listed on the application. A post office box mailing address may also be included, but it cannot be the sole address of the pharmacy.

**2**. If you are not ready for inspection at the time the application is submitted, please notate on the application. Otherwise OSBP will assume you are ready, will process the application, and it will be submitted to an Inspector who will contact the PIC listed to schedule the inspection.

**3**. If OSBP requires any further information/clarification to process the application, an email will be sent to the PIC/designated contact person listed on the application.

4. Please allow a minimum of <u>14-21 DAYS</u> for processing, and be aware that if an application is incomplete it could further delay this timeline. After processing, you may obtain your license number by checking the Board website at <u>www.pharmacy.ok.gov</u> under "*License Verification*" but note that your license is not yet valid if it reflects "In-Process."

5. You will receive your pharmacy license from the Board Inspector at the time of inspection.

6. The pharmacy must pass final inspection within ninety (90) days of application or the pharmacy must resubmit the application and fees. Fees will not be refunded.

**B.** All **PHYSICAL REQUIREMENTS FOR PHARMACIES** must be in place at the inspection site at the scheduled inspection time and date:

1. The required sanitary facilities, consisting of a lavatory located in the prescription area with properly connected hot/cold water, must be in place and operating at the time of the inspection. A bathroom is not considered a part of a pharmacy area.

2. Under NO circumstances will legend drugs and/or controlled substances be at a NEW site where the pharmacy has no current pharmacy license. Any and all legend drugs and/or controlled substances at an unlicensed location may be seized by the Inspector.

**3**. Required library reference books or computer sources are expected to be in place.

**C.** An Oklahoma licensed pharmacist must be present during the inspection to represent the applicant.

**D.** If the site should fail to meet inspection requirements for licensure, the Inspector will re-inspect the site ONLY at the convenience of the Board, which may delay licensure.



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**E.** Please contact the following for the appropriate applications: *(applications are available on-line)* 

### Oklahoma Bureau of Narcotics & Dangerous Drugs (OBNDD)

419 NE 38th Terrace Oklahoma City, OK 73105 Registration Phone: (405) 521-2885 http://www.ok.gov/obndd/OBN\_Registration\_Forms/index.html

National Council for Prescription Drug Programs (NCPDP) - issues NABP #'s

9240 E Raintree Dr Scottsdale, AZ 85260 Phone: (480) 477-1000 http://www.ncpdp.org

### Drug Enforcement Administration (DEA)

901 NE 122<sup>nd</sup> Street, Ste. #210 Oklahoma City, OK 73114 Phone: (405) 475-7500 http://www.deadiversion.usdoj.gov/index.html

**F.** The following **ADDITIONAL PERMIT APPLICATIONS (if applicable)** may also be submitted with your pharmacy application:

**1. Training Area Permit** - A Training Area Permit is an additional specialized permit issued to Oklahoma resident pharmacies which desire approval for the training of pharmacy interns (i.e. a student currently enrolled in an accredited college of pharmacy) [OAC 535:10-5-9]

**2. Drug Supplier Permit** - A Drug Supplier Permit is an additional specialized permit issued to Oklahoma resident Retail pharmacies which "supply legend drugs to licensed practitioners for their office administration and/or to hospitals and other licensed pharmacies for their dispensing." [OAC 535:15-7-1]

**3.** Sterile Compounding Permit - A Sterile Compounding Permit allows the "compounding and dispensing of sterile preparations by an Oklahoma licensed pharmacist pursuant to a prescription order." [OAC 535:15-9-2]

### OAC TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY

#### 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.

(14) **E-Prescribing of Controlled Substances (EPCS).** Any pharmacy that dispenses controlled dangerous substances shall have computer software that supports EPCS by January 1, 2019.

[Source: Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 27 Ok Reg 2249, eff 7-11-10; Amended at 32 Ok Reg 1229, eff 8-27-15; Added at 35 OK Reg 1920, eff 9-14-18]

#### 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]