TEXAS STATE BOARD OF PHARMACY



333 Guadalupe Street Suite 3-500 ★ Austin, TX 78701 (512) 305-8000 ★ www.pharmacy.texas.gov

Important Information Regarding Clinic Pharmacies (Class D)

SPECIAL NOTE: Texas Pharmacy Rules & Regulations prohibit a Class D pharmacy from being placed in or issued to a physician's office setting.

<u>Texas Pharmacy Rule 291.91</u> defines Clinic Pharmacy (Class D) as "a facility/location other than a physician's office, where limited types of dangerous drugs or devices restricted to those listed in and approved for the clinic's formulary are stored, administered, provided, or dispensed to outpatients."

Examples of such settings include: rural health care clinics; school-based clinics; clinics for the homeless, indigent, or low-income; family planning clinics; TB, STD, or immunization clinics operated by state or local government; and onsite industrial clinics for company employee use.

A Class D pharmacy license is issued to a clinic with limited scope of services and authorizes the pharmacy to provide, supply, and/or administer a dangerous drug contained in the clinic's formulary, in accordance with a medical direction (e.g., standing practitioner orders, etc.), and with the objectives of the clinic. The Texas State Board of Pharmacy must review the clinic's services, formulary, and objectives.

A Class D Pharmacy Formulary is limited to the types of drugs and devices outlined in <u>Rule 291.93</u>. Currently these are limited to: anti-infective drugs, musculoskeletal drugs, vitamins, obstetrical and gynecological drugs, topical drugs, and serums, toxoids, and vaccines. A Class D Clinic may petition the board to operate with an expanded formulary by submitting the requirements outlined in <u>Rule 291.93</u>.

In a Class D pharmacy, the "provision" of unit-of-use packages of dangerous drugs at a Class D pharmacy site may be carried out by certain non-pharmacist personnel under the direct supervision of a pharmacist and shall be for the internal use of the clinic, in accordance with the Texas Pharmacy Rules. However, any "dispensing" (defined separately from "provision" and "administration") of a prescription drug order for a dangerous drug contained in the clinic's formulary must be performed by a licensed pharmacist in accordance with Class A regulations.

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TEXAS PHARMACY LICENSE APPLICATION CHECKLIST Documents Required to Apply for a Clinic Pharmacy (Class D) License

Instructions: Please use this page as both a checklist to ensure all documents are submitted and a coversheet for your pharmacy application. If an item is not applicable, put N/A in the space provided. Detailed instructions are provided on the following pages. Failure to submit the required documentation will result in a delay of licensure. **KEEP COPIES OF ALL ITEMS FOR YOUR OWN RECORDS.**

NOTICE: According to Texas Occupations Code § 565.0551, the Executive Director of the Texas State Board of Pharmacy may require a license holder to submit a surety bond to the board. ☐ The Clinic Pharmacy (Class D) Pharmacy Information Form (LIC-Class D). ☐ Check or Money Order for the Application Fee made payable to Texas State Board of Pharmacy. Fee calculation is provided in Box 1 on the Pharmacy Information Form. ☐ Ownership Information Ownership Information Form (LIC-004) Verification of the Owner's FEIN from the IRS Certificate of Formation/Application of Registration from Texas Secretary of State For Foreign Entities ONLY: Formation Documents from Jurisdiction of Formation Verification of Franchise Tax Account Status from Texas Comptroller ☐ Sworn Disclosure Statement (LIC-005) or submit one of the following: Page 1 of the company's 10-K SEC Filing Statement for Wholly Owned Retail Grocery Store Chain ☐ Managing Officer Forms for each officer (LIC-021) (attach a separate page if listing more than four officers). Name of Officer Name of Officer Name of Officer Name of Officer Copy of Photo ID Copy of Photo ID Copy of Photo ID Copy of Photo ID Verification of SSN Verification of SSN Verification of SSN Verification of SSN ☐ Lease Agreement or Proof of Property Ownership ☐ Minimum Infrastructure Attestation (LIC-018) ☐ Letter of Credit Worthiness from a licensed Drug Distributor and/or Manufacturer ☐ Policy and Procedure Manual ☐ Petition(s) for (circle one or both): Expanded Formulary Request and/or Alternative Visitation Schedule NOTE: TSBP may request additional documentation to confirm or substantiate information submitted on the

IMPORTANT: If applying for a Change of Ownership, refer to the Change of Ownership Instructions for the Change

of Ownership Checklist and additional items required.

application.



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TEXAS PHARMACY LICENSE APPLICATION Instructions on a Applying for a Clinic Pharmacy (Class D) License

Please carefully review and follow all the instructions below and any instructions on supplemental forms. Failure to submit all required documentation will result in a delay of licensure. Documents submitted with a separate or a previous application will NOT meet the requirements for completion of this application, nor will they be retrieved from the previous application to supplement this application.

Questions regarding the application can be directed to the Pharmacy Licensing Specialist either by email to pharmacy.texas.gov or by phone at (512) 305-8021.

Section 1: The Pharmacy Information Form. Submit <u>Clinic Pharmacy (Class D)</u> Pharmacy <u>Information Form (LIC-Class D)</u> to provide information for the pharmacy.

Important Information:

- ❖ The Name of the Pharmacy Owner is the Legal Name of the Pharmacy. This name should be the name of the direct owner legally responsible for the operation of the pharmacy, and it must match any and all Secretary of State and IRS filings.
- ❖ The Business Name of the Pharmacy is the name to be listed on all pharmacy signage, licenses from other regulatory agencies, advertisements, etc.

Section 2: Ownership Information Forms and Supplemental Documentation. Each applicant must submit the following forms to provide information about the pharmacy owner:

	Ownership Information Form. Submit the Ownership Information Form (LIC-004) to provide information regarding the owner entity.
	Verification of the Owner's Federal Employer Identification Number (FEIN) as assigned by the IRS. Provide a copy of the computer-generated notice that was issued by IRS that provides the FEIN for the entity.
is a Sc	olicants must also submit the next three items under this section, unless the ownership type (i.e., structure) ole Proprietorship, General Partnership, or a Government entity. Ownership Structure is be determined by ary of State and/or IRS Filings.
	Copy of the entity's Certificate of Formation as filed with the Texas Secretary of State. This may also be called the Articles of Incorporation, Articles of Organization, or Application of Registration depending on the type of entity and when it was formed.
	 Additionally, if the entity is a Foreign Entity (i.e., the entity was formed in another state), provide a copy of the formation documents as filed in the jurisdiction of formation.
	Verification of an ACTIVE Franchise Tax Account Status from the <u>Texas Comptroller</u> . Provide documentation from the Texas Comptroller that shows the entity has an ACTIVE Franchise Tax Account Status.
	Organizational Chart: Provide an organizational chart that shows multi-levels of ownership and relation to the pharmacy.
	n 3: Sworn Disclosure Statement: Each applicant must submit a completed Sworn Disclosure Statement (LIC-unless the pharmacy is:
	Operated by a Publicly Traded Company. Alternatively, provide a copy of page 1 of the company's 10-K SEC filing; or
	Wholly Owned by a Retail Grocery Store Chain. Alternatively, provide a written statement attesting to such.

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Section 4: Managing Officers Information: Submit an Officer Form (LIC-021) for each Individual Owner, General Partner, Managing Member, Managing Officer*, and/or Administrator to provide information regarding the "background" of the individual. Each officer form must be attached with the following:

□ Copy of the Officers' Photo ID. Acceptable Photo IDs are: Current Driver's License, State-Issued Identification Card, or US Passport.

☐ **Verification of the Officers' Social Security Number -** Submit a copy of the individual's Social Security Card OR a copy of the individual's W2 or Paystub, that shows the full SSN and Name of the individual, with all financial information redacted.

*Per Texas Pharmacy Rule 291.1 "Managing Officers are defined as the **top four executive officers**, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy."

Section 5: Lease Agreement or Proof of Property Ownership: Submit either a Lease Agreement or Proof of Property Ownership, if the pharmacy owner is not leasing the space but owns the premises.

Lease Agreement: If the pharmacy is leasing the space, submit a copy of the ENTIRE Lease Agreement. TSBP will review the lease agreement for the following items:

- ❖ The Tenant on the Lease Agreement must match the Pharmacy Owner
- The Lease Agreement must provide an address which must match the address on the Application. An amendment or a signed letter from the landlord will be required if the address does not match or is not provided in the lease.
- If you are subleasing the space or have been "assigned" the space, you must submit a copy of the Master Lease that allows the tenant to sublet or assign the property, or the Landlord must provide their consent on the signed sublease/assignment agreement or by providing a letter of consent

Proof of Property Ownership: If the owner of the pharmacy also owns the premises and is NOT leasing the space, submit either **ONE** of the following for proof of property ownership:

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☐ Verification of Property Ownership from the County Tax Appraisal District

If the document does NOT list the property address, provide a copy of the building permit, certificate of occupancy, or written verification of the address from the city or county.

Section 6: Minimum Infrastructure Attestation. Submit the <u>Minimum Infrastructure Attestation (LIC-018)</u> to attest that the pharmacy has the minimum infrastructure requirements needed to apply for a pharmacy license.

Section 7: Credit Worthiness Document: Submit a letter from the pharmacy's primary drug distributor and/or wholesaler that verifies the pharmacy applicant's credit worthiness. The letter must come from an entity that has an active license with HHSC and be for the specific pharmacy and/or for the pharmacy owner.

Section 8: Policy and Procedures Manual: Provide a copy of the complete policy and procedures manual for the facility. This must also include the clinic drug formulary and all information required under <u>Rule 291.93</u>. Additionally, if the pharmacy is requesting an Expanded Formulary or an Alternative Visitation Schedule, include the petition requests in accordance with <u>Rule 291.93</u>

If applying for a Change of Ownership, refer to the <u>Change of Ownership Instructions</u> for the additional items required.