

TEXAS PHARMACY LICENSE APPLICATION

Non-Resident Pharmacy Engaged in Sterile Compounding (Class E-S) License Information Change of Ownership Form

PLEASE READ CAREFULLY: Pharmacy applications status – allow 10 business days before contacting TSBP regarding the application status. Completed applications *may* take approximately 90 days for a license to be issued.

Failure to submit all required documentation will result in a delay of licensure. Questions regarding the application can be directed to the Pharmacy Licensing Specialist either by email to nonresphcy@pharmacy.texas.gov or by phone at (512) 305-9127.

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 [Non-Resident Pharmacy-Class E-S Information Form](#) (LIC-Class_ES) see form included below.
- [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 Form](#)– Form included below. TSBP requires the direct owner of the pharmacy to be listed. If you choose to also provide the parent company, you can submit separate ownership forms for each.
 - Copy of the entity's Certificate of Formation, 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 [Texas Comptroller](#), if entity is registered with Texas. If the entity is formed in another state, provide the verification showing the entity is still active and in good standing.
 - [Sworn Disclosure Statement Form \(LIC-005\)](#) – See form for additional instruction and to verify if applicable. Organizational chart – provide an organization chart that shows multi-levels of ownership and relation to the pharmacy.
- [Managing Officer Forms for each officer \(LIC-021\)](#) (attach a separate page if listing more than four officers). *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.”
 - Copy of each Officers' State Issue Photo ID. Acceptable Photo IDs are: Current Driver's License, State Issued Identification Card or US Passport.
 - Verification of each Officers' Social Security Number – Submit a copy of the individual's Social Security Card OR a copy of the individual's W2, that shows the full SSN and Name of the individual, with all financial information redacted.
- [Lease Agreement or Proof of Property Ownership](#) (ex: Sublease & master lease, property deed, etc.)
- [Bill of Sale](#) (or legal document which transfers Ownership) Including Records & Drugs statement.
- [Letter of Credit Worthiness](#) – Letter of Credit Worthiness from your primary drug wholesaler
- [Inspection Report](#): Attach a copy of the most recent pharmacy inspection report dated no more than **two years** prior to the date of this application. The inspection must have been conducted by the regulatory or licensing agency of the resident state AFTER the pharmacy was in operation for a minimum of 30 days. [Approved Inspectors & Vendors](#).
- [License Verifications](#): Written license verification for Pharmacy and Pharmacist-in-Charge (printed online verifications from the resident board of pharmacy are acceptable).
- [Description of Services](#): Attach a detailed written description of services that the pharmacy plans to offer Texas Residents upon licensure.

NOTE: TSBP may request additional documentation to confirm or substantiate information submitted on the application.



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.

Sterile Compounding Supplemental Documentation

All Class E-S Applicants must provide the following items electronically to complete their application, by emailing nonresphcy@pharmacy.texas.gov. Failure to submit all required documentation will result in a delay of licensure. Documents submitted with a separate or similar 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. **When sending the supplemental documentation electronically, avoid using zip files.**

- Labeled Pharmacy Blueprints or Floor Plans:** Provide labeled blueprints or floorplans for the pharmacy, including the floor plan or design plan of the controlled environment for compounding sterile preparations
- Photographs of the Controlled Environment for Compounding Sterile Preparations:** submit a minimum of 10 clearly labeled color photographs, including equipment used for compounding sterile preparations. These photos should provide a 360-degree view of the sterile compounding area.
- Photographs of the Pharmacy Business Location:** submit a minimum of 10 clearly labeled color photographs showing the pharmacy business location (e.g. pharmacy building showing neighboring business). These photos should include areas facing the rear and sides of the building.
- Table of Contents of the Pharmacy's Standard Operating Procedures (SOPs) for Compounding Sterile Preparations:** Provide a copy of the complete listing of the Table of Contents for the Pharmacy's Standard Operating Procedures (SOPs) for compounding Sterile Preparations.
- Documentation of Sterile Compounding Training or Special Education –** Provide documentation of Training or Special Education for ALL pharmacy personnel who compound sterile preparations or supervise the compounding of sterile preparations at the pharmacy, as specified in Board Rule §291.133. Include written record of initial and in-service training, education, as well as the results of the written and practical testing, and the media-fill testing of pharmacy personnel.
- List of ALL Sterile Preparations compounded by the pharmacy:** Provide a list of ALL Sterile Preparations that are compounded by the pharmacy
- List of ALL pharmacy personnel who engage in Sterile Preparations compounded by the pharmacy:** Provide a list of ALL pharmacy personnel who engage in Sterile Preparations. All Members must meet the training requirements per Board Rule §291.133.
- FOR PHARMACIES COMPOUNDING FOR OFFICE USE:** If the Pharmacy is compounding sterile preparations for distribution or delivery to practitioners for office-use/office-stock (e.g. for administration to patients in the practitioner's office), provide a copy of the regulatory citation from the resident state that authorizes compounding for practitioner office use.
- FOR PHARMACIES COMPOUNDING HIGH-RISK STERILE PREPARATIONS:** Attach documentation that shows the pharmacy is routinely conducting the following tests of compounded sterile preparations: sterility, fungal, and endotoxin.
- FDA Inspection –** Provide a statement which must include the date of the FDA Inspection IF the pharmacy has been inspected by the FDA.



TEXAS PHARMACY LICENSE APPLICATION
Non-Resident Sterile Compounding Pharmacy (Class ES) Information Change of Ownership Form

Current Pharmacy License #	
Previous Pharmacy owner (entity name):	
Effective Date of Change:	

FOR TSBP USE ONLY			
File #	App #	Entity #	Trans Code#
			3044
Amount Rcv'd	License #	AFL Date	

Print or Type

1	This application MUST be submitted with a check or money order made payable to the Texas State Board of Pharmacy. Use the column to the right to calculate the fee for the application.	Pharmacy Application Fee	\$ 516.00
		Number of Balances/Scales	X \$25.00 ea \$
			Total DUE \$

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.

2 Pharmacy (Facility) Information

Pharmacy Name: _____
(dba) – Name listed on the prescription labels/signage

Pharmacy Address: _____
Street Address (Inspectable Location) Suite/Unit #

City State ZIP Code

Pharmacy Phone: _____ Pharmacy Fax Number: _____

Pharmacy Toll-Free: _____ Website Address: _____

Pharmacy Email: _____

Pharmacy Hours: Mon-Fri: _____ Sat: _____ Sun: _____

3 Type of Ownership

- Sole Proprietorship/Individual
 Corporation (Includes Non-Profit)
 Government
 Partnership
 Limited Liability Company
 Other (specify) _____

4 Type of Pharmacy

- Community Independent
 Community Multi/Chain (5 or more)
 Other (Specify): _____

5 Services Provided by Pharmacy (check all that apply)

- 24 Hour Service
 Compounding, Non-Sterile
 Pharmacist Admin. Immunizations
 503b Outsourcing Facility
 Compounding, Office Use
 Shipping Prescriptions Out-of-State
 Closed Door
 Home Delivery
 Veterinary Prescriptions
 Compounding Sterile, LOW Risk
 Infusion
 Other (Specify): _____
 Compounding Sterile, MED Risk
 Nuclear
 Compounding Sterile, HIGH Risk
 Outpatient Prescriptions

6 Texas Pharmacist-in-Charge Attestation

By my signature, I acknowledge that I am employed by the pharmacy listed above and that I am the Pharmacist-in-Charge of this pharmacy. I attest that I have read and understand the laws and rules relating to this class of pharmacy. **THIS SIGNATURE MUST BE NOTARIZED.**

Print or Type Name of Pharmacist in Charge	TX License #	Subscribed and sworn to before me this	
_____	_____	Day Of _____	,20 _____
Signature of Pharmacist in Charge	Date	Notary Public	
_____	_____	_____	



TEXAS PHARMACY LICENSE APPLICATION

Non-Resident Sterile Compounding Pharmacy (Class E-S) Information Change of Ownership Form, continued

7 List of Staff Pharmacists and Pharmacy Technicians (Attach a list if additional room is needed)

If licensed as a Rph or Technician, provide the Texas license number, if not licensed in Texas, leave blank

Name of Staff RPh or Technician	TX Lic/Reg #	Name of Staff RPh or Technician	TX Lic/Reg #

8 Pharmacy Inspection Information

NABP e-Profile #: _____ **Last Inspection Date:** _____ **FDA Inspection Date (if applicable)** _____

The pharmacy must be inspected by ONE of the three vendors below. Select the vendor provider used for the inspection.

- National Association of Boards of Pharmacy (NABP) Superior Laboratory Services, Inc (SLSI)
 Accreditation Commission for Health Care, Inc. (ACHC)

9 Other Pharmacy Licenses Held

Provide a list of ALL States/Territories in which the facility is currently licensed in or has been licensed in as a pharmacy. Attach a separate list with the information indicated, if necessary. If the facility does not hold any other licenses indicate "N/A" in the space below.

Name of Pharmacy	Pharmacy License #	State Located	Expiration Date

10 The Owner or One of the Managing Officers MUST Answer the Following Questions:

- a. Has the pharmacy or the corporation, partnership, or other entity that owns the pharmacy been the subject of **ANY** professional disciplinary action or are any such actions pending against this entity by a regulatory authority? (e.g., surrender, revocation, reinstatement, suspension, fine, probation, restriction.) Include such information for **all** states, including Texas, and for all regulated professions. Yes No
- b. Has the pharmacy or the corporation, partnership, or other entity that owns the pharmacy been subject to court ordered probation as related to any offense? Yes No
If you answered "YES" to Question 1 and/or Question 2, include the name of the Board, licensing or disciplinary authority, and the date of the order, and, if applicable, the date of the termination of the conditions and/or probation:
- c. Are the customer service areas of the pharmacy accessible to disabled persons, as defined by federal law? Yes No
- d. Does the pharmacy provide translating services for customers, including translating services for a person with impairment of hearing? **If yes, what type of translating services does the pharmacy provide?** Yes No
(Check all that apply)
 Spanish American Sign Language
 Vietnamese AT&T Translating Service
 Telecommunication Device for the Deaf (TDD) Other: _____
- e. Does this Pharmacy participate in the Texas Medicaid Program? Yes No

Owner/Managing Officer Attestation

Attest: I hereby attest that the foregoing statements on this form or those on any attachment(s) to this form are to the best of my knowledge true and correct and that they are all given of my free will. I agree that any misstatement(s) or omission(s) as to material facts will constitute violation of and subject me to the penalties set forth in the Texas Pharmacy Act and Rules. I agree to comply with the Texas Pharmacy Act and Rules.

This pharmacy (check all that apply):

- engages in compounding sterile preparations
 delivers or ships sterile compounded preparations to Texas residents;
 delivers or ships sterile compounded preparations to Texas practitioners.
 fulfills a purchase order or initiative from a Texas practitioner for sterile compounded preparations to be used as office drug supplies by the practitioner for administration to the practitioner's patients.

This pharmacy will NOT:

- obtain sterile compounded preparations from a separate pharmacy, whether there is an affiliation or not, and use the sterile compounded preparations to fulfill a prescription drug order for a Texas resident, or to fulfill a purchase order or initiative from a Texas practitioner for sterile compounded preparations to be used as office drug supplies by the practitioner for administration to the practitioner's patients.
 obtain non-sterile compounded preparations from a separate pharmacy, whether there is an affiliation or not, and use the non-sterile compounded preparations to fulfill a prescription drug order for a Texas resident, or to fulfill a purchase order or initiative from a Texas practitioner for non-sterile compounded preparations to be used as office drug supplies by the practitioner for administration to the practitioner's patients.

THIS SIGNATURE MUST BE NOTARIZED

Signature of Owner/Managing Officer _____ Date _____ Subscribed and sworn before me this _____ Day Of _____, 20 _____

Owner/Managing Officer's Name (Type or Print) _____ Notary Public _____



TEXAS PHARMACY LICENSE APPLICATION
Ownership Information Form

1 Pharmacy (Facility) Information	
a.	Pharmacy Name: _____ <i>Doing business as (dba) – Name listed on the prescription labels/signage</i>
b.	Pharmacy Address: _____ <i>Street Address (Inspectable Location) Suite/Unit #</i>
	_____ <i>City State Zip Code</i>
2 Designated Person of Contact for Pharmacy Person Authorized by Owner/Officer to Discuss Application Material with TSBP Staff	
Full Name: _____ Title: _____	
Contact Phone: _____ Contact Email: _____	
3 OWNERSHIP INFORMATION The below information should match all Secretary of State, Comptroller, and IRS Filings.	
a. Entity's Federal Employer ID Number (FEIN)	b. Type of Ownership <input type="checkbox"/> Sole Proprietorship/Individual <input type="checkbox"/> Corporation (Includes Non-Profit) <input type="checkbox"/> Partnership <input type="checkbox"/> Government <input type="checkbox"/> Limited Liability Company <input type="checkbox"/> Other (specify) _____
c. Direct Owner of Pharmacy (i.e., Corp, Inc, LLC, LP, PA, LTD, etc.)	
d. Corporate Mailing Address for Owner	
_____ <i>Street Address Suite/Unit #</i>	
_____ <i>City State Zip/Postal Code</i>	

ATTEST: I hereby attest that the foregoing statements or those on any attachment(s) to this form are to the best of my knowledge true and correct and that they are all given of my free will. I agree that any misstatement(s) or omission(s) as to material facts will constitute violation of and subject me to the penalties set forth in the Texas Pharmacy Act. I agree to comply with the Texas Pharmacy Act and Rules. ***THIS SIGNATURE MUST BE NOTARIZED:***

Signature of Owner / Managing Officer _____ Date

Owner / Managing Officer's Name (Type or Print)

Subscribed and sworn to before me this _____ day of _____, 20__

Notary Public



Important Information regarding Non-Resident Pharmacies Engaged in Compounding Sterile Preparations (Class E-S) Pharmacies

Read all the below information thoroughly before applying for a Non-Resident or Out-Of-State Pharmacy Engaged in Compounding Sterile Preparations (Class E-S) Pharmacy License.

Operational Requirements:

Class E-S Pharmacy Applicants may be authorized to:

- engage in compounding sterile preparations
- delivers or ships sterile compounded preparations to Texas residents;
- delivers or ships sterile compounded preparations to Texas practitioners.
- fulfills a purchase order or initiative from a Texas practitioner for sterile compounded preparations to be used as office drug supplies by the practitioner for administration to the practitioner's patients.

Class E-S Pharmacy Applicants can NOT:

- obtain sterile compounded preparations from a separate pharmacy, whether there is an affiliation or not, and use the sterile compounded preparations to fulfill a prescription drug order for a Texas resident, or to fulfill a purchase order or initiative from a Texas practitioner for sterile compounded preparations to be used as office drug supplies by the practitioner for administration to the practitioner's patients.
- obtain non-sterile compounded preparations from a separate pharmacy, whether there is an affiliation or not, and use the non-sterile compounded preparations to fulfill a prescription drug order for a Texas resident, or to fulfill a purchase order or initiative from a Texas practitioner for non-sterile compounded preparations to be used as office drug supplies by the practitioner for administration to the practitioner's patients.

Pharmacist-in-Charge Requirements:

Per Rule 291.103, A Class E-S pharmacy must designate a Pharmacist to service as the Pharmacist-in-Charge for the pharmacy. This pharmacist must be licensed to practice pharmacy by the regulatory or licensing agency in the resident state AND must be licensed as a pharmacist in Texas.

Applications without a Texas licensed Pharmacist-in-Charge listed will be considered incomplete and not reviewed.

Additional Requirements:

All Requirements for Non-Resident (or Out-of-State) Pharmacy may be found in the Texas Pharmacy Laws and Rules by going to the following website at:

www.pharmacy.texas.gov/rules

THE FOLLOWING MUST BE SUBMITTED WITH THIS APPLICATION:

- [Managing Officer Form\(s\) \(LIC-021\)](#) for each Officer
- Lease Agreement or Property Deed
- Articles of Incorporation/Organization
- Certificate of Good Standing
- Organization Chart
- [Sworn Disclosure Statement Form \(LIC-005\)](#)
- Proof of Credit Worthiness from your Primary Wholesaler
- Written letter(s) of License Verification for the Pharmacy and the Pharmacist-in-Charge
- Inspection Report within the last two years by approved vendor
- Description of Services
- Bill of Sale