TEXAS PHARMACY LICENSE APPLICATION

Non-Resident Pharmacy Engaged in Sterile Compounding (Class E-S) License

PLEASE READ CAREFULLY: Pharmacy application 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.
  - 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 where it was formed.
  - Certificate of Good Standing/Existence/Status/Authorization issued by the Secretary of State to which the pharmacy is doing business.
  - 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.
  - *IF* the entity is also registered with Texas, provide documentation from the Texas Comptroller that shows the entity has an ACTIVE Franchise Tax Account Status. Texas Comptroller,
  - 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: property deed), including the pharmacy floor plan.
- ☐ Letter of Credit Worthiness – 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 Texas Department of State Health Services (DSHS) and be for the specific pharmacy and/or for the pharmacy owner. NOTE: this document will be verified via phone call/email to drug distributor and/or wholesaler listed on letter.
- ☐ 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 one of the three Board approved vendors AFTER the pharmacy was in operation for a minimum of 30 days. Approved Inspectors & Vendors.
- ☐ License Verifications: Submit written verification from the resident Board of Pharmacy that verifies the licenses of BOTH the Texas licensed Pharmacist-in-Charge and the Pharmacy. Printed online verifications from the resident board of pharmacy are acceptable.

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.

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue Suite 13.100 ✯ Austin, TX 78701
(512) 305-9127 ✯ www.pharmacy.texas.gov

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 supplemental documentation electronically, avoid using zip files, pdf attachments are preferred.

☐ 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 officer), provide a copy of the regulatory citation from the resident state that authorizes compounding for practitioner office use.

☐ FDA Inspection – Provide a statement which must include the date of the FDA Inspection IF the pharmacy has been inspected by the FDA.

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

FOR TSBP USE ONLY			
File #	App #	Entity #	Trans Code#
			1044
Amount Rcv'd	License #	AFL Date	

1	This application MUST be submitted with a check or money order made payable to the Texas State Board of Pharmacy.	Pharmacy Application Fee $ 611.00

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.

Print or Type

Clear Form

2 Pharmacy (Facility) Information

Pharmacy Name: _____ Resident Pharmacy License # _____
Pharmacy Name – Name listed on the prescription labels/signage

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

_____ _____ _____
City *State* *ZIP Code*

Pharmacy Phone: _____ Pharmacy Email: _____

Pharmacy Fax Number: _____ Web Address: _____

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 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.

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

_____ _____ _____
Signature of Pharmacist in Charge Date Notary Public Signature

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TEXAS PHARMACY LICENSE APPLICATION
Non-Resident Sterile Compounding Pharmacy (Class E-S) Information Form, continued

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

If licensed as a pharmacist or technician, provide the TX license number, if not licensed by TX, leave blank

Name of Staff RPh or Technician	License/Registration #	Name of Staff RPh or Technician	License/Registration #

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 Pharmacy Located	Expiration Date

10. The Owner or One of the Managing Officer 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? (Check all that apply) ☐ Yes ☐ No

☐ 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 fulfil 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 fulfil 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

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

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

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TEXAS PHARMACY LICENSE APPLICATION
Ownership Information Form

1 Pharmacy (Facility) Information

a. Pharmacy Name: _____
Pharmacy Name – Name listed on the prescription labels/signage

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

_____ _____ _____
City *State* *Zip Code*

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

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

c. Direct Owner of Pharmacy (i.e., Corp, Inc, LLC, LP, PA, LTD, etc.)

_____

d. Corporate Mailing Address for Owner

_____ _____
Street Address *Suite/Unit #*

_____ _____ _____
City *State* *Zip/Code*

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:

Subscribed and sworn to before me this

_____ _____
Signature of Owner/Managing Officer Date _____ Day Of _____ ,20 _____

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

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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 fulfil 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 fulfil 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 serve 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, including the pharmacy floor plan
- Articles of Incorporation/Organization
- Certificate of Good Standing/Existence/Status/Authorization
- 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

IMPORTANT - Pharmacy application 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.