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 <u>Texas Occupations Code § 565.0551</u>, 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 <u>two years</u> 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. <u>Approved Inspectors & Vendors</u> .
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		Trans Code#	
				1044
	Amount Rcv'd	License #	Al	L Date
This application MUST be submitted with a check or money order made payable to the Texas State Board of Pharmacy.	Pharmacy Application Fee		\$ 583.00	

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

· ····································					
2 Pharmacy (Facili	ty) Information				
Pharmacy Name:	Resident Pharmacy License #				
Pharmacy Name: Pharmacy Name – Name listed on the prescription labels/signage Pharmacy Address: Resident Pharmacy License # 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 Ownersh	nin				
☐ Sole Proprietorship/Individual ☐ Corporation (Includ					
☐ Partnership ☐ Limited Liability Co					
4 Type of Pharmac					
☐ Community Independent ☐ Community Multi/C	Chain (5 or more)				
5 Services Provided by Pharmacy	(check all that apply)				
, ,	Non-Sterile Pharmacist Admin. Immunizations				
	Office Use Shipping Prescriptions Out-of-State				
☐ Closed Door ☐ Home Delivery					
☐ Compounding Sterile, LOW Risk ☐ Infusion	Other (Specify):				
☐ Compounding Sterile, MED Risk ☐ Nuclear					
☐ Compounding Sterile, HIGH Risk ☐ Outpatient Pres	criptions				
6 Pharmacist-in-Charge A					
By my signature, I acknowledge that I am employed by the pharm					
this pharmacy. I attest that I have read and understand the laws a THIS SIGNATURE MUST BE NOTARIZED.	and rules relating to this class of pharmacy.				
THIS SIGNATURE MOST 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 Pha	armacists and Pharmacy Te	echnicians (Attach a list if addition	nal 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 Technicia	an License/Registration #	Name of Staff RPh or Technician	License/Registration #					
8.		/ Inspection Information	D-4- (#					
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.	• , ,	narmacy Licenses Held						
		tly licensed in or has been licensed in as	a pharmacy. Attach a separate					
list with the information indicated, if		not hold any other licenses indicate "N/A"						
Name of Pharmacy	Pharmacy License #	State Pharmacy Located	Expiration Date					
10 The O	war or One of the Managi	ng Officer MUST Apower the Follo	wing Quastiana:					
		ng Officer MUST Answer the Follo other entity that owns the pharmacy l						
the subject of ANY profes entity by a regulatory auth	ssional disciplinary action or a hority? (e.g., surrender, revoc	are any such actions pending agains cation, reinstatement, suspension, fir states, including Texas, and for all	t this					
b. Has the pharmacy or the	corporation, partnership, or corobation as related to any of	other entity that owns the pharmacy lifense?	been Yes No					
licensing or disciplinary the termination of the co	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:							
federal law?	· · · · ·	ssible to disabled persons, as define						
	f hearing? <mark>If yes</mark> , what type o	stomers, including translating servic of translating services does the pharr						
☐ Spanish		☐ American Sign Language						
Vietnamese		☐ AT&T Translating Service						
☐ Telecommunication [Device for the Deaf (TDD)	Other:						
	cipate in the Texas Medicaid		 ☐ Yes ☐ No					
e. Bood that Harriday part	•		- 100 - 140					
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): ———————————————————————————————————								
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								
0: 1 (0)		Subscribed and sw	orn before me this					
Signature of Officer/Managing Office	cer Date	Day of	<u>,</u> 20					
Owner/Managing Officer's Name (Type or Print)		Notary Public Signature					

LIC-CLASS_ES (12/23)





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TEXAS PHARMACY LICENSE APPLICATION Ownership Information Form

1 Pharmacy (Facility	y) Information						
a. Pharmacy Name:	a. Pharmacy Name:						
b. Pharmacy Address	Pharmacy Name – Name listed on the prescription labels/signage						
b. Tharmacy Address		Street Address (Inspectable Location)		Suite/Unit #			
— Decimated Days	City Dho		State	Zip Code			
2 Designated Person Person Authorized by	on of Contact for Pha Owner/Officer to Discuss Ap	rmacy pplication Material with TSBF	P Staff				
Full Name:		Title:					
Contact Phone:		Contact Email:					
3 Ownership Information The below information	nation should match all Secretary	of State, Comptroller, and IF	RS Filinas				
Entity's Federal Emp							
ID Number (FEIN)	• •	rietorship/Individual Owner	□ Corporation	(Includes Non-Profit)			
	☐ Partnersh	•	Governmen	,			
		ability Company	☐ Other (spec				
				· · ·			
c. Direct Owner of Pha	armacy (i.e., Corp, Inc, LLo	C, LP, PA, LTD, etc.)					
d. Corporate Mailing A	Address for Owner						
d. Corporate Maning	rudicos foi O whoi						
Street Address			Suite/	/Unit #			
City		State	Zip/Code				
		ts or those on any attachmer of my free will. I agree that a					
material facts will constitute	e violation of and subject me	e to the penalties set forth in					
comply with the Texas Pha	armacy Act and Rules.						
THIS SIGNATURE MUS	T BE NOTARIZED:						
Subscribed and sworn to before me this							
Signature of Owner/Manag	ing Officer	Date Day Of	,20				
Owner/Managing Officer's	Name (Type or Print)	Notary Pul	olic Signature				

TEXAS STATE BOARD OF PHARMACY



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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.