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.

CE: According to Texas Occupations Code § 565.0551, the Executive Director of the Texas State 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. 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.
Bill of Sale (or legal document which transfers Ownership) MUST include the Records & Drugs statement
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-vears 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

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

verifications from the resident board of pharmacy are acceptable.

TEXAS STATE BOARD OF PHARMACY



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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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LIC-CLASS_ES_CHOW (12/23)





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TEXAS PHARMACY LICENSE APPLICATION

Non-Resident Sterile Compounding Pharmacy (Class ES) Information Change of Ownership Form

Current Pharmacy License #		FOR TSBP USE ONLY			
•		File #	App #	Entity #	Trans Code#
Previous Pharmacy owner (entity name)					3044
Effective Date of Change:		Amount Rcv'd	License #	AFL Date	
Enocavo Bato of change.					

Print or Type

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
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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.

of Frialmacy may require a license noider to sub-	•	
	cy (Facility) Information	
Pharmacy Name: Pharmacy Name – Name listed on	the prescription labels/signage	
Pharmacy Address:	the presemption labels signage	
Street Address (Inspectable Loc	ation)	Suite/Unit #
		<u> </u>
City	State	ZIP Code
Pharmacy Phone:	Pharmacy Email	<u>:</u>
Pharmacy Fax Number:	Web Address:	
Pharmacy Hours: Mon-Fri:		Sun:
3 Type of	Ownership	
☐ Sole Proprietorship/Individual ☐ Corporat	ion (Includes Non-Profit)] Government
☐ Partnership ☐ Limited L	Liability Company □	Other (specify)
4 Type of	Pharmacy	7 Oth (Cuif-)
☐ Community Independent ☐ Commun	nity Multi/Chain (5 or more)	Other (Specify):
5 Services Provided by P	harmacy (check all that app	lv)
•		harmacist Admin. Immunizations
	<u> </u>	hipping Prescriptions Out-of-State
	•	eterinary Prescriptions
☐ Compounding Sterile, LOW Risk ☐ Infusion		other (Specify):
☐ Compounding Sterile, MED Risk ☐ Nucle		
☐ Compounding Sterile, HIGH Risk ☐ Outpa		
	Pharmacist-in-Charge Atte	station
By my signature, I acknowledge that I am employed by		
this pharmacy. I attest that I have read and understand	I the laws and rules relating to th	is class of pharmacy.
THIS SIGNATURE MUST BE NOTARIZED.		
	Su	bscribed and sworn to before me this
Print or Type Name of Pharmacist in Charge	TX RPh License #	oay Of,20
Signature of Pharmacist in Charge	Date N	lotary Public Signature
3	•	,



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TEXAS PHARMACY LICENSE APPLICATION

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

	armacists and Pharmacy Te	echnicians (Attach a list if addition	nal room is needed)				
•		ide the TX license number, if not l					
Name of Staff RPh or Technici	an License/Registration #	Name of Staff RPh or Technician	License/Registration #				
0	4: 4:						
	ection Information						
NABP e-Profile #:	Last Inspection Date:	FDA Inspection	Date (if applicable)				
	ected by ONE of the three ve oards of Pharmacy (NABP)	endors below. Select the vendor prov					
☐ Accreditation Commission	n for Health Care, Inc. (ACHC)						
9. Other Pharmac	y Licenses Held						
		tly licensed in or has been licensed in as					
Name of Pharmacy	Pharmacy License #	not hold any other licenses indicate "N/A" State Pharmacy Located	Expiration Date				
Name of Filannacy	Filalillacy Licerise #	State Filannacy Located	Expiration Date				
10. The Owner or C	One of the Managing Office	r MUST Answer the Following Que	estions:				
		other entity that owns the pharmacy l					
entity by a regulatory aut	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						
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				
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					
person with impairment o	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)						
☐ Spanish							
☐ Vietnamese		☐ AT&T Translating Service					
☐ Telecommunication I	Device for the Deaf (TDD)	☐ Other:					
	, ,		 ☐ Yes ☐ No				
e. Does this Pharmacy participate in the Texas Medicaid Program?							
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							
Signature of Officer/Managing Officer	cer Date	Subscribed and sw	orn before me this				
Signature of Onicer/Managing Office	oei Date	Day of	<u>,2</u> 0				
Owner/Managing Officer's Name (Type or Print)		Notary Public Signature				





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TEXAS PHARMACY LICENSE APPLICATION Ownership Information Form

1 Pharmacy (Facili	ty) Information				
a. Pharmacy Name:					
b. Pharmacy Address	Pharmacy Name – N	Pharmacy Name – Name listed on the prescription labels/signage			
b. Tharmacy Address	Street Address (Inspe	ectable Location)		Suite/Unit	#
Designated Pers	City	or Pharmacy	Sta	te Zip (Code
Person Authorized by	Owner/Officer to Dis	scuss Application Materia	al with TSBP Staff		
Full Name:			Title:		
Contact Phone:	act Phone: Contact Email:				
3 Ownership Information The below information	mation n should match all Se	ecretary of State, Compt	roller, and IRS Fili	ngs	
Entity's <u>Federal En</u>	polover	pe of Ownership			
a. <u>ID Number (FEIN)</u>		ole Proprietorship/Individ	ual Owner 🗆	Corporation (Incl	udes Non-Profit)
		artnership		Government	ddes Non-i Tolitj
		mited Liability Company		Other (specify)	
				_	
c. Direct Owner of Pl	narmacy (i.e., Corp,	Inc, LLC, LP, PA, LTD	, etc.)		
d. Corporate Mailing	Address for Owner	•			
a. Corporate Maning	ridaress for 5 when				
01				0.70.701.70	
Street Address				Suite/Unit	#
City		State	Zip/0	Code	
ATTEST: I hereby attes knowledge true and corre					
material facts will constitu	ite violation of and su	bject me to the penalties			
comply with the Texas Ph	narmacy Act and Rule	es.			
THIS SIGNATURE MU	ST BE NOTARIZE	D:			
			Subscribed and	d sworn to before n	ne this
Signature of Owner/Mana	ging Officer	Date	Day Of	,20	
Owner/Managing Officer'	s Name (Type or Prir	nt)	Notary Public Si	gnature	
Owner/Managing Officer	s Name (Type or Prir	nt)	Notary Public Si	gnature	

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
- Description of Services
- Bill of Sale a copy of the purchase contract or mutual agreement between the buyer and seller.

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