



## 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 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](http://www.pharmacy.texas.gov/rules).



## TEXAS PHARMACY LICENSE APPLICATION CHECKLIST

### Documents Required to Apply for a Non-Resident Pharmacies Engaged in Compounding Sterile Preparations (Class E-S) Pharmacies

**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. **IMPORTANT:** If applying for a **Change of Ownership**, refer to the [Change of Ownership Instructions](#) for the additional items required. **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.

- Application** - The Non-Resident Pharmacy Engaged in Compounding Sterile Preparations (Class E-S) Information Form ([LIC-Class E-S](#)).
- Fee** - 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 Secretary of State (SOS)
  - For Foreign Entities ONLY: Formation Documents from Jurisdiction of Formation
  - Verification from the [Texas Comptroller](#), if entity is also registered with [Texas SOS](#). Provide verification 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.
- Sworn Disclosure Statement** - Each applicant must submit a completed Sworn Disclosure Statement ([LIC-005](#)), 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.
- Managing Officer Forms** - 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.  
\*Further managing officer information, including the definition, can be found by reading [Rule 291.1](#).
- Lease Agreement** or Proof of Property Ownership
- Inspection Report** - Attach a copy of the pharmacy inspection report issued within the **last two years** before the date the license application is received. Approved inspectors can be found by going to the following link: [Approved Inspectors & Vendors](#)
- License Verification** - Written license verification for Pharmacy and Pharmacist-in-Charge (printed online verifications from the resident board of pharmacy are acceptable)
- Proof of Credit Worthiness** - Letter of Credit Worthiness from your primary drug wholesaler
- Supplemental Documents** - Pharmacy Supplemental Documents for Sterile Compounding see detailed instructions on the next page.



**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](mailto: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.