STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
BOARD OF PHARMACY
665 MAINSTREAM DRIVE
NASHVILLE, TENNESSEE 37243
PHONE: (615) 741-2718 FAX: (615) 741-2722
http://tn.gov/health/topic/pharmacy-board

INSTRUCTIONS FOR A TENNESSEE PHARMACY LICENSE

By submitting an application, you indicate that your facility has met all the requirements necessary for licensure. You may access these rules 1140-01-.08 electronically at http://share.tn.gov/sos/rules/1140/1140.htm

Pursuant to board rule 1140-01-.08 (8) Designate a pharmacist in charge who shall be responsible for compliance with the provisions in this section, and who shall hold a current Tennessee pharmacist license.

If you are not applying for the controlled substance qualification, please submit the "Dispenser Exemption or Waiver Request Form available online at: https://health.state.tn.us/boards/Controlledsubstance/PDFs/PH-4138.pdf

At least thirty (30) days prior to the scheduled opening of a pharmacy practice site, an application for license shall be submitted to the office of the board. If the application is not complete upon receipt by the Board's Administrative Office, a deficiency letter will be sent by mail or by email.

NOTE: **A new application must be submitted to the Tennessee Board of Pharmacy, along with the required application fee(s), anytime there is a Name, Location, or Ownership change.**

ALL APPLICANTS

All documentation required to be submitted by you must be mailed directly to:

Tennessee Board of Pharmacy
665 Mainstream Drive
Nashville, TN 37243
(zip code 37228 for courier service only)

All application fees are Non-Refundable. Attach a check or money order made payable to the Tennessee Board of Pharmacy. **NOTE**: Please see the rules below to determine if the facility is required to also register for controlled substance and/or sterile compounding.

Registration Fee (required)	$300.00
State Regulatory Fee (required)	$10.00
*Controlled Substance Fee	$40.00
**Sterile Compounding Fee	$250.00

***Pursuant to Rule 1140-01-.11:** No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board.

****Pursuant to Rule 1140-01-.12 (1):** No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.

- Submit a list of owners, partners, board of directors or corporate officer.
- List the Tennessee Pharmacist in Charge
- List hours of operation
- List Reference books
- Compounding Survey

NON RESIDENT PHARMACY LICENSE

In addition to the items required for all applicants, out of state applicants must also provide the following:

- A copy of the latest home state inspection (if applying for sterile compounding modifier the inspection report must be date within the last 12 months)
- A copy of the home state pharmacy license
- A copy of the DEA certificate (if applicable)

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APPLICATION FOR PHARMACY BUSINESS

Application applying for:
__ New Business
__ Name Change
__ Location Change
__ Ownership Change

Please check type of application
__ Resident
__ Non-Resident
__ Charitable Clinic Pharmacy

Effective Date of Opening or Change: _____ TN License Number (if applicable): _____

Type of Practice:
__ Community:
  __ Independent 3 or Less
  __ Non-Independent 4 or More
__ Hospital/Institutional
__ Nursing Home
__ Home Health Care
__ Medical Gases
__ Nuclear
__ Mail Order
__ Other: _____

Is this a dispensing pharmacy? Yes ____No ____

Does this pharmacy produce compound sterile? Yes ____ No ____

Does this pharmacy produce non-sterile products? Yes ____ No ____

If yes, please submit a copy of an inspection report issued within the past 12 months. If no, you are required to immediately report to the board, any changes to the business model.

DEA Number: _____

Name of Pharmacy			
Street Address			Telephone No.
City	State	Zip Code	Pharmacist in Charge (include TN License Number)

MAILING ADDRESS

Company Name		
Street Address		Telephone No.
City	State	Zip Code

Do you wish to receive notifications, including renewal notification, from Department of Health via email? Please note, by opting in, all correspondence from the Department of Health will be delivered to the email address on file for you. You will no longer receive physical mail from our office. _____ Yes _____ No

Check type ownership: ❑ PROPRIETORSHIP ❑ PARTNERSHIP ❑ CORPORATION ❑ LLC

Name of Owners: _____

Address of Owner(s): _____

_____

_____

City State Zip Code

NOTE: Application CANNOT be processed unless you have a Pharmacist- In- Charge licensed in Tennessee.

TO BE COMPLETED BY PHARMACIST IN CHARGE (Cannot be executed by a pharmacist who is presently registered as a pharmacist- in- charge, except a part-time institutional pharmacist.

I, under oath, confirm that in the event the application for a license to conduct a pharmacy at the address stated therein is granted; that I will have supervision over the conduct of such pharmacy; that I will be in actual attendance at the same at least _____ hours of each business week; and furthermore, this pharmacy will be under the direct supervision of a pharmacist at all times as established by Tennessee Code Annotated.

NOTE: If there is any change in status of this pharmacy, owner and pharmacist are both required to notify the Board.

*If ownership change, the former owner must complete and sign in space indicated on this form.

This application is completed by: ☐OWNER ☐OFFICER OF CORP. ☐ADMINISTRATOR ☐PHARMACIST IN CHARGE

Does the Owner, Officer of Corporation or Administrator have any charges involving moral turpitude or violation of pharmacy law, or any other laws pending against the them? ☐ **Yes** ☐ **No** (If yes, please explain such charges or violations in detail; even to reporting minor infractions of pharmacy laws, liquor or narcotic laws regulations, including dates.)

Attach a list of the owners, officers or directors to this application.

AFFIDAVIT AND RELEASE

I, _____, of _____
(Applicant's Name) *(City)* *(State)*
affirm that the pharmacist in charge holds a valid and current license to practice pharmacy in Tennessee and that there is a supervising pharmacist for the pharmacy practice site listed in this application.

I affirm that the pharmacist in charge will be accountable to the Board of Pharmacy for this practice site's compliance with all state statutes and regulations governing the practice of pharmacy in Tennessee.

I affirm that before engaging in the practice of pharmacy in Tennessee, the pharmacy must obtain a valid license from the Tennessee Board of Pharmacy.

I hereby certify under oath that the pharmacy for which this application is made complies with requirements set forth in Tennessee laws and regulations and that said pharmacy is equipped with proper equipment, adequate lighting, and refrigeration; and that this business will be kept in a clean and sanitary condition at all times

I affirm that no pharmacy services shall be provided without the responsible supervision of Tennessee licensed pharmacist as the pharmacist in charge.

THIS CERTIFIES THAT THE INFORMATION SUBMITTED BY ME IN THIS APPLICATION IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

_____ _____
SIGNATURE **DATE**

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Attn: Pharmacist-in-Charge

To ensure compliance with state rules regarding sterile compounding, the Board of Pharmacy voted at the November 2012 meeting to survey Pharmacists-in-Charge about their pharmacy's compounding practices. Please answer the questions below and return to the board office via fax (615-741-2722) or scan and email to Pharmacyhealth@tn.gov . The request to complete and return this survey is considered a lawful order of the Board under Tennessee Code Annotated 63-10-305(8). Response is required before a license will be issued.

Name of Pharmacy _____

Pharmacy Address _____

City, State, _____

Provide the email address where you would like to receive information from the Board in the future.

_____ Phone Number_____

1. At any time in the past 18 months, has your pharmacy compounded products? ___ Yes ___ No

   If yes, is the pharmacy continuing to offer compounding services? ___ Yes ___ No

   If a new pharmacy, will your pharmacy compound products? ___ Yes ___ No
   (If no, please proceed to the PIC information at the end of the survey.)

2. At any time in the past 18 months, has your pharmacy compounded **sterile** products? ___Yes ___No

   If yes, is the pharmacy continuing to offer sterile compounding services? ___ Yes ___ No

   If a new pharmacy, will your pharmacy compound **sterile** products? ___ Yes ___ No
   (If no, please proceed to the PIC information at the end of the survey.)

   a. Approximately how many sterile compounded products does your pharmacy dispense per day?
      i. ____ 1-20 prescriptions per day
      ii. ____ 21-50 prescriptions per day
      iii. ____ 51-100 prescriptions per day
      iv. ____ More than 100 prescriptions per day

3. What types of compounded products does, or will, your pharmacy prepare? (Check all that apply)

a. ____IV
b. ____Intrathecal
c. ____TPN
d. ____Parenteral
e. ____Cardioplegia solution
f. ____Enteral
g. ____Irrigation
h. ____Ophthalmic
i. ____Oncology
j. ____Veterinary
k. ____Serum, toxins, vaccines and similar biologics
l. ____Radiopharmaceuticals
m. ____Other: _____

4. List any current accreditation (and expiration date) or pending application for accreditation related to compounding. _____

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5. If your pharmacy is domiciled outside of Tennessee, does your pharmacy dispense compounded sterile products to Tennessee residents? ___Yes ___No

6. If located in Tennessee, does your pharmacy dispense compounded product to other states? ___Yes ___No If yes, to what states do you dispense? _____

_____

_____

7. Does your pharmacy have a Policy & Procedure manual addressing compounding? ___Yes ___No
   a. Are you compliant? ___Yes ___No

8. If domiciled outside of Tennessee, does your state require USP 797? ___Yes ___No

9. Does your pharmacy hold a manufacturer's license in Tennessee or any other state? ___Yes ___No

   If yes, in what states? _____

_____

_____

_____

10. Have you or your pharmacy's license ever been disciplined by any licensing agency? ___Yes ___No

    If yes, please provide documentation/records of the action taken._____

_____

I, the undersigned, do hereby swear and affirm that all the answers provided pursuant to this survey are, to the best of my knowledge, accurate, complete, and true statements. I understand that by knowingly or purposefully making a false, fictitious, or inaccurate statement, or by making any omission to that effect, that I may be subject to discipline under T.C.A. 63-10-305(6). Furthermore, I understand that the responses contained herein establish an on-going obligation of accuracy. As such, should any information on this form change, I will update the Board immediately.

PIC Name_____ Date_____

PIC Signature_____