

Applying for a Tennessee Pharmacy or Manufacturer/Wholesale/Distributor License

For Resident and Non-Resident Applicants

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Definitions and Rules

- Rule 1140-01-.01

- (26) “Pharmacy practice site” means any place within this state where prescription drugs or prescription devices are dispensed and where pharmaceutical care is provided, and any place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.

- Rule 1140-09-.01

- (1) *Manufacturers and Wholesaler/Distributors* – Every manufacturer or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter.

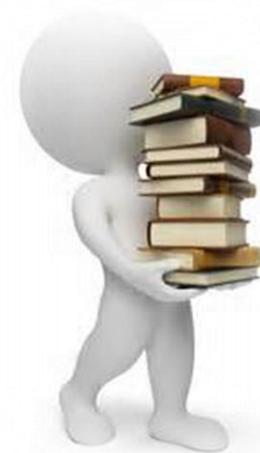
Definitions and Rules (cont'd)

□ Rule 1140-01-.01

- (33) “Sterile product” means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.
- (34) “Sterile manufacturing” means the production, propagation, processing, pooling, or repackaging of sterile products for wholesale or any other form of distribution, not pursuant to a prescription or medical order.

□ Rule 1140-11-.01

- (e) “Controlled substance(s)” means a drug, substance, or immediate precursor in Schedules I through VI as defined or listed in the Tennessee Drug Control Act, compiled in T.C.A., Title 39, Chapter 17, part 4;



Registration Fees

Pharmacy License

- Application Fee
 - ▣ \$300.00
- State Regulatory Fee
 - ▣ \$10.00

Manufacturer/Wholesale/Distributor License

- Application Fee
 - ▣ \$525.00
- State Regulatory Fee
 - ▣ \$10.00

New fee structure effective January 31, 2014

All fees are NON-REFUNDABLE

License Modifier Fees

- **Controlled Substance Modifier - \$40.00**
 - **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.

- **Sterile Compounding Modifier - \$250.00**
 - **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 other wise distributed in or from this state without first obtaining a sterile compounding modifier form the Board of Pharmacy.

Sending Applications and Documents

Please send all fees, applications, and supporting documents to:

Office of Health Related Boards

Tennessee Board of Pharmacy

665 Mainstream Drive

Nashville, TN 37243

(Courier services use 37228)

Note: Sending applications and/or documents by special courier services will not appreciably reduce the time it takes to process an application. ***It takes approximately eight (8) weeks for a license to be issued.***

Understanding the Licensure Process

Application Arrival

- Please allow ten (10) business days for information to be received.
- Once an application has been entered in our records, please allow up to 48 hours for an application status to update online.

Application Review

- Applications will undergo a preliminary review by a member of the administrative staff.
- Notification of application deficiencies will be provided via regular or electronic mail.

Inspections

- Resident facilities must satisfactorily pass an inspection conducted by a Board of Pharmacy investigator.
- Non-resident facilities must show proof of inspection by the state licensing agency.
- T.C.A. §63-10-216 requires compounding pharmacies to submit an inspection report issued within the previous twelve(12) months.

License Issuance

- Upon receipt of all required documents, including proof of a satisfactory inspection, all applications will undergo a final review.
- Upon approval, a license will be issued and mailed to the address provided. Please allow 7-14 business days for receipt of the license certificate.

Verifying a License Status

Please limit phone calls and/or emails to the board office regarding the status of an application.

You may verify license statuses here:

http://health.state.tn.us/HCF/Facilities_Listings/facilities.htm

Useful Links

- [Application for Pharmacy Business](#)
- [Application for Manufacturer/Wholesale/Distributor License](#)
- [Board of Pharmacy Rules](#)
- [Controlled Substance Monitoring Database \(CSMD\)](#)
- [Dispenser Exemption or Waiver Request form](#)
- [Automation of Reports & Consolidated Order System \(ARCOS\) Reporting](#)
- [National Association of Boards of Pharmacy \(NABP\)](#)
- [United States Drug Enforcement Agency \(DEA\)](#)
- [U.S. Food & Drug Administration \(FDA\)](#)
- [License Status Verification](#)

Contacting the Board of Pharmacy

Have questions or need assistance?

Contact the Board of Pharmacy

Phone: (615) 741-2718

Fax: (615) 741-2722

