Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-01-23
Notice ID(s): 3602-3603
File Date: 3/1/2023

Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Board of Pharmacy
Division:	
Contact Person:	Matthew Gibbs, Deputy General Counsel
Address:	665 Mainstream Drive, Nashville, TN 37243
Phone:	(615) 741-1611
Email:	Matthew.Gibbs@tn.gov

Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	ADA Coordinator
Address:	710 James Robertson Parkway, Andrew Johnson Building, 5th Floor, Nashville, Tennessee 37243
Phone:	(615) 741-6354
Email:	Marci.Martinez@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	Metro Center		
Address 2:	665 Mainstream Drive, Iris Conference Room		
City:	Nashville		
Zip:	37243		
Hearing Date:	05/08/2023		
Hearing Time:	9:30 A.M.	_X_CST/CDT ___EST/EDT	

Additional Hearing Information:

Revision Type (check all that apply):

X Amendment

X New

__ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart

below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1140-01	Introductory Rules
Rule Number	**Rule Title**
1140-01-.10	Fees

Chapter Number	**Chapter Title**
1140-03	Standards of Practice
Rule Number	**Rule Title**
1140-03-.06	Labeling Requirements
1140-03-.17	Collaborative Pharmacy Practice
1140-03-.18	Provision of Ivermectin

Chapter 1140-01
Introductory Rules

Amendments

Rule 1140-01-.10 Fees is amended by deleting paragraph (4) in its entirety and substituting instead the following language, so that as amended, the new paragraph shall read:

(4) Each person becoming registered as a pharmacy technician shall pay a registration fee of fifty-five dollars ($55.00). Each person who desires to continue to practice as a pharmacy technician shall biennially, on or before the last day of the month that the person's registration shall expire, pay a renewal fee of seventy-five dollars ($75.00).

Authority: T.C.A. §§ 63-10-304 and 63-10-308.

Chapter 1140-03
Standards of Practice

Amendments

Rule 1140-03-.06 Labeling Requirements is amended by deleting the rule in its entirety, but not the rule title, and substituting instead the following language, so that as amended, the new rule shall read:

The dispensing label for a medical or prescription order shall bear at least the following information: name and address and telephone number of pharmacy practice site; the medical or prescription order serial number, name of prescriber; name of patient; directions for use; date medical or prescription order originally dispensed, and/or refill date; "poison", "shake", "caution", or other appropriate advisory label; name of product (unless otherwise required by the prescriber); and expiration date of the product (if applicable). Accommodations for individuals who are blind, visually impaired, or otherwise print disabled shall be made. This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy or long-term care pharmacy for administration to inpatients of that institutional facility or long-term care facility, except when medications are dispensed to patients residing in assisted care living facilities. Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. § 63-10-304.

Rule 1140-03-.17 Collaborative Pharmacy Practice is amended by deleting subparagraphs (5)(b) and (6)(a) in their entirety and substituting instead the following language, so that as amended, the new subparagraphs shall read:

(5) (b) Authorized Care and Services. The Agreement must contain a provision defining the nature and scope of patient care services and activities, including screening, prevention, assessment, management, and care, authorized or restricted to be provided by the pharmacist(s) under the collaborative pharmacy practice agreement. All care and services authorized to be provided shall be within the routine scope of practice and services delivered by the authorizing physician and the advanced practice nurse or physician assistant, where applicable. All care and services provided, except immunizations, opioid antagonists, ivermectin, and preventive care, must be pursuant to a diagnosis appropriately made and documented by the physician, advanced practice nurse or physician assistant. An Agreement which grants the collaborating pharmacist prescriptive authority, including authority for initiation and discontinuance of drug therapy, must be specifically authorized in the authorized care and services portion of the Agreement and must contain a listing of the drugs or categories of drugs that may be prescribed by the collaborating pharmacist under the terms of the Agreement.

(6) (a) Any patient of the collaborating prescriber for whom such collaborating prescriber has not prepared a patient specific, drug specific, disease or condition specific plan of care based on a physical examination of the patient by the collaborating prescriber, with the exception of immunizations, dispensing of ivermectin, and screening/testing which do not require such patient-specific plans, as well as the

dispensing of opioid antagonists as defined in T.C.A. § 63-1-152, which require neither a physical examination nor a patient-specific plan;

Authority: T.C.A. §§ 63-10-217, 63-10-304, and 63-10-306.

New Rule

Rule 1140-03-.18 Provision of Ivermectin is a new rule. All subsequent rules, and references thereto, are renumbered accordingly.

1140-03-.18 Provision of Ivermectin

(1) A pharmacist may provide ivermectin under this rule to eligible individuals as identified in T.C.A. § 63-10-224 through a valid collaborative pharmacy practice agreement containing a non-patient-specific prescriptive order and standardized procedures developed and executed by one (1) or more authorized prescriber.

(a) The pharmacist shall maintain the collaborative pharmacy practice agreement in accordance with § 63-10-217 and shall comply with all requirements of Tenn. Comp. R. & Regs. 1140-03-.17 except for patient-specificity.

(b) Within 30 days from the effective date of a collaborative pharmacy practice agreement, the prescribing pharmacist shall submit written attestation to the Board for the purpose of notifying the Board of the collaborative agreement.

(2) A pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall provide the patient and review a screening risk assessment tool that screens for the following elements:

(a) Comorbidities;

(b) Contraindications; and

(c) Pregnancy.

(3) A pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall provide the patient with a standardized factsheet that includes at minimum the following elements:

(a) The statement “Off-label use is not prohibited by state or federal law. The FDA has not authorized or approved ivermectin for the treatment or prevention of COVID-19 in people or animals. Ivermectin has not gone through the new drug application process with the FDA for COVID-19.”

(b) FDA factsheet or at least the following elements:

1. Approved indications, dosage and administration as listed in the FDA factsheet

2. Contraindications, warnings, and precautions as listed in the FDA factsheet

3. Adverse reactions as listed in the FDA factsheet

(4) The pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall counsel the patient on matters contained in Tenn. Comp. R. & Regs. 1140-03-.01(1)(e)1 through 1140-03-.01(1)(e)8 at the time ivermectin is prescribed and dispensed.

(5) The pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall advise the patient to consult with the patient’s primary care practitioner if their symptoms seem to be worsening.

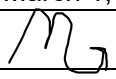
(6) The pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall document, at a minimum, the completed self-screening risk assessment and the medication and dosage prescribed to the patient by the pharmacist. While not required by this rule, the pharmacist is authorized to include additional information related to the patient encounter. These records shall be maintained by the pharmacy practice site for a period of ten years. Records regarding the dispensed ivermectin shall be maintained in accordance with Tenn. Comp. R. & Regs. 1140-03-.03.

(7) If the pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin determines that the patient is eligible to receive ivermectin, then, as soon as it is practicable, the collaborating pharmacist shall dispense ivermectin to the patient or refer the patient to a another pharmacy that may dispense ivermectin.

Authority: T.C.A. §§ 63-10-224 and 63-10-304.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: March 1, 2023

Signature: 

Name of Officer: Matthew Gibbs

Title of Officer: Deputy General Counsel, Department of Health

Department of State Use Only

Filed with the Department of State on: 3/1/2023

Tre Hargett
Secretary of State

RECEIVED

Mar 01 2023, 9:57 am

Secretary of State
Division of Publications