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: 12-12-23
Rule ID(s): 9981-9982
File Date: 12/15/2023
Effective Date: 3/14/2024

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

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

Revision Type (check all that apply):

X Amendment
X New
___ Repeal

___ Content based on previous emergency rule filed on _____
___ Content is identical to the emergency rule

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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

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. §§ 63-10-308, 63-10-310 and 63-10-312.

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). All reasonable 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. § 63-10-308.

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, 63-10-224, and 63-10-308.

New Rule

Rule 1140-03-.18 Provision of Ivermectin is a new rule.

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(s).

(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 with 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; and

3. Adverse reactions as listed in the FDA factsheet.

(4) A 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) A 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) A 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 (10) 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 another pharmacy that may dispense ivermectin.

Authority: T.C.A. §§ 63-10-217, 63-10-224, and 63-10-308.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Pharmacy on 05/08/2023, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *03/01/2023*

Rulemaking Hearing(s) Conducted on: (add more dates). *05/08/2023*

Date: November 27, 2023

Signature:

Name of Officer: Matthew Gibbs

Title of Officer: Deputy General Counsel, Department of Health

Agency/Board/Commission: Board of Pharmacy

Rule Chapter Number(s): 1140-01 and 1140-03.

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Jonathan Skrmetti
Attorney General and Reporter

Dec. 13, 2023
Date

Department of State Use Only

RECEIVED
Dec 15 2023, 3:14 pm
Secretary of State
Division of Publications

Filed with the Department of State on: 12/15/2023

Effective on: 3/14/2024

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

Oral Comments:

Mark Binkley, Health & Wellness Compounding Pharmacy

> Provision of Ivermectin - Dr. Binkley raised a concern regarding the retention of ivermectin records for ten years when all other pharmacy records are maintained for two years pursuant to the Board's rules. The Board stated the ten-year requirement is consistent other collaborative pharmacy practice agreement rules as found in Tenn. Comp. R. and Regs. 1140-03-.17(5)(c) and (g).

Written Comments:

Tennessee Pharmacists Association ("TPA")

> Provision of Ivermectin – TPA suggested the creation and adoption of a standardized screening risk assessment tool which is made available to participating pharmacies. TPA opposed proposed rule 1140-03-.18(7) (as contained in the Notice of Rulemaking) because the referral clause seemed unclear and redundant. The Board denied all of the suggested changes pertaining to the provision of Ivermectin. For the screening risk assessment tool, the Board determined this suggestion is not required by statute. The Board declined to adopt changes related to the referral process and stated the referral language as written in the proposed rules is consistent with other Board rule language and the proposed rule language takes into consideration pharmacists who do not work at a dispensing pharmacy.

Dan Dillon, legislative chair, Tennessee Council for the Blind

> Accessible Prescription Labels – Mr. Dillon stated assurance is needed from the Board for visually impaired and print disabled patients that all relevant prescription information will be conveyed in an accessible format to the patient. The Board noted the comment because, as the Board observed, there were no specific changes requested or a request to describe the principal reasons for action.

Sharla Glass, public policy and community outreach liaison, En-Vision America

> Accessible prescription labels – Ms. Glass writes En-Vision supports the idea of the proposed rule change to make accessible prescription labels available but indicated the proposed rule may not fulfill the intent of the statutory language which specified access to prescription labels and medication guides (bag tags and medical guides). Ms. Glass also notes the proposed rule provides little guidance to pharmacies on what services qualify as accommodations. In response to this comment, and in an effort to strengthen the accommodation requirement, the Board voted to add the word "[a]ll reasonable" before "accommodations" in the proposed rule language.

James Brown, president, National Federation of the Blind TN

> Accessible prescription labels – Mr. Brown alleged a lack of specificity in the proposed rule language and suggested an enforcement clause inside the proposed rule language. The Board declined to place an enforcement clause directly inside the proposed rule language. The Board stated disciplinary actions for any violation, including a rule-based violation, are already included (as a basis for enforcement) in the Pharmacy Practice Act of 1996.

Honorable Susan Lynn, state representative

> Provision of Ivermectin – In a suggested edit, Representative Lynn proposed a change to the referral process by requiring pharmacists who are not participating in the provision of ivermectin to refer an eligible patient to a pharmacy that is participating or supply the patient with a website address, maintained by the Board, which lists names and locations of participating pharmacies. The Board declined to adopt this change and stated the referral language as written in the proposed rules is consistent with other Board rule language and the proposed rule language takes into consideration pharmacists who do not work at a dispensing pharmacy. The Board also stated

the creation and maintenance of a webpage dedicated to ivermectin is not required by Tenn. Code Ann. Section 63-10-224.

Bernadette Pajer

Provision of Ivermectin – Ms. Pajer proposed a change to the referral process by requiring, in a suggested edit, pharmacists who are not participating in the provision of ivermectin to refer an eligible patient to a pharmacy that is participating or supply the patient with a website address, maintained by the Board, which lists names and locations of participating pharmacies. The Board declined to adopt this change and stated the referral language as written in the proposed rules is consistent with other Board rule language and the proposed rule language takes into consideration pharmacists who do not work at a dispensing pharmacy. The Board also stated the creation and maintenance of a webpage dedicated to ivermectin is not required by Tenn. Code Ann. Section 63-10-224. Ms. Pajer also recommended removal of the word "comorbidities" from the screening risk assessment tool and removal of the recommendation, in the proposed rule language, to include additional information about the patient encounter in recordkeeping. The Board noted removal of comorbidities and additional patient encounter information would be the opposite of providing reasonable care as required by statute and, in turn, would be in conflict with providing reasonable care.

Bryant Cary, pharmacist

Provision of Ivermectin – In presenting opposition to the provision of ivermectin, Dr. Cary notes ivermectin is only approved for use in parasitic infections. Dr. Cary suggests adding language to the proposed rule to express the provision of ivermectin shall occur under a safe and recognized use by the United States Food and Drug Administration. In the alternative, Dr. Cary asks which standards will be applied to ensure a pharmacist is not dispensing a medication which lacks therapeutic value. The Board declined to adopt Dr. Cary's suggestion because off-label use of a prescription drug is already addressed (and allowed) in the Tennessee Code; Tennessee Code Ann. Section 63-10-224 requires rules to be promulgated for the provision of ivermectin, and, lastly, the suggested revision requests changes beyond what is required of the Board in statute.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

(1) **The extent to which the rule or rules may overlap, duplicate, or conflict with other federal, state, and local governmental rules.**

This amended rules do not overlap, duplicate, or conflict with other federal, state, and local government rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

The proposed rules are established with clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

The Board of Pharmacy may waive portions of the labeling requirements pursuant to current rule language. A licensee must request the wavier.

The portion of the rule packet relative to the provision of ivermectin is voluntary. If a pharmacist chooses to participate, the pharmacist shall comply with recordkeeping requirements, along with other standard procedures, as outline in the rule.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

The Board of Pharmacy may waive portions of the labeling requirements pursuant to current rule language. A licensee must request the wavier.

The portion of the rule packet relative to the provision of ivermectin is voluntary. If a pharmacist chooses to participate, the pharmacist shall comply with record-keeping requirements, along with other standard procedures, as outline in the rule.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

The requirements for the proposed rules cannot be consolidated or simplified. There is no other reasonable alternative than the proposed rules to ensure accommodations are made for visually impaired patients and standard procedures are followed for the provision of ivermectin.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These new rules do not establish performance standards for small businesses as opposed to design or operational standards required for the proposed rule.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

The Board of Pharmacy may waive portions of the labeling requirements pursuant to current rule language. A licensee must request the wavier.

The portion of the rule packet relative to the provision of ivermectin is voluntary. If a pharmacist chooses to participate, the pharmacist shall comply with record-keeping requirements, along with other standard procedures, as outline in the rule.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rule packet lowers the initial application fee for pharmacy technicians; mandates accommodations for visually impaired patients; and implements standard procedures for the provision of ivermectin by a pharmacist.

A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Tenn. Code Ann. Section 63-10-308 provides the Board the authority to promulgate rules. Tenn. Code Ann. Section 63-10-312(a) states "[t]he [B]oard may promulgate rules to establish licensure fees necessary to carry out parts 2-7 of this chapter."

On April 7, 2022, the General Assembly passed, and Governor Lee signed, 2022 Tenn. Pub. Acts 908, codified at Tenn. Code Ann. Section 63-10-224, which requires the Board to "adopt rules to establish standard procedures for the provision of ivermectin by pharmacists[.]" This rule packet implements the statutorily required provisions.

On April 21, 2022, the General Assembly passed, and Governor Lee signed, 2022 Tenn. Pub. Acts 1010, codified at Tenn. Code Ann. Section 63-10-308(c)(5), which requires the Board to "promulgate rules necessary to ensure that persons who are blind, visually impaired, or otherwise print disabled have appropriate access to prescription labels, bag tags, and medical guides."

The rules implement statutes.

Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Any person applying to the Board for licensure as a pharmacy technician is impacted positively by the rule change that lowers the initial application fee. Visually impaired patients are also impacted positively by the memorialization of accommodations for prescription labels. Pharmacist wishing to participate in the provision of ivermectin, along with patients seeking ivermectin, are impacted through the standardizing of procedures in the proposed rules.

Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

None.

An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

These rules should not impact revenues or expenditures.

Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Department of Health, Office of General Counsel, 665 Mainstream Drive, 2nd Floor, Nashville, TN 37243, 615-741-1611, Matthew.Gibbs@tn.gov

Any additional information relevant to the rule proposed for continuation that the committee requests;

None.

1140-01-.10 FEES

(1) An applicant for examination for a license as a pharmacist shall pay a fee of fifty dollars ($50.00) plus cost of the examination and materials.

(2) An applicant for a reciprocal license or NAPLEX score transfer shall pay a fee of three hundred dollars ($300.00).

(3) Each person becoming licensed as a pharmacist shall pay a registration fee of one-hundred twenty-five dollars ($125.00). Each person licensed as a pharmacist who desires to continue in the practice of pharmacy shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of one-hundred twenty-five dollars ($125.00). Each person licensed as a pharmacist and who wishes to obtain an inactive license shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of sixty-three dollars ($63.00).

(4) Each person becoming registered as a pharmacy technician shall pay a registration fee of ~~seventy-five~~fifty-five dollars ($55.00~~75.00~~). 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).

(5) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any establishment or institution where prescription drugs and devices and related materials are kept for the purpose of the compounding and dispensing of medical and prescription orders shall pay a registration fee of three-hundred dollars ($300.00) biennially. Any new pharmacy practice site to be opened or established, or any change in location, name or ownership of any existing pharmacy practice site, shall before active operation obtain a license from the Board of Pharmacy and shall pay a fee of three-hundred dollars ($300.00)

(6) All manufacturers, outsourcing facilities, oxygen suppliers, wholesalers/distributors, and 3PLs of prescription drugs and/or devices and related materials doing business in the state of Tennessee must be licensed by the Board of Pharmacy by paying a registration fee of five-hundred twenty-five dollars ($525.00), and thereafter a biennial renewal fee of five-hundred twenty-five dollars ($525.00).

(7) The fee for the Board of Pharmacy's publication of Pharmacy Drug Laws, Rules and Regulations shall be an amount which covers the cost of publication and shipping, as determined by the Board of Pharmacy. The Board may also publish Pharmacy Drug Laws, Rules and Regulations electronically, and may make an electronic publication freely available on the Board's website.

(8) The charge for a roster of Tennessee pharmacies, pharmacists and printing of mailing labels of Tennessee pharmacies and pharmacists shall be determined by the administration of the Department of Health.

(9) The fee for certification of license examination grades shall be twenty five dollars ($25.00).

(10) The fee for any duplicate or revised license, registration, modifier or license wall certificate shall be twenty five dollars ($25.00).

(11) If any person fails to renew a license, such license may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars ($10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event

such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.

(12) If any person fails to renew a license or registration certificate, such license or registration certificate may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars ($10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.

(13) A penalty of fifty dollars ($50.00) may, in the discretion of the board, attach to each failure of a licensee or registration certificate holder to provide any required notice to the director as may be required by the rules of the board.

(14) Any licensee who wishes to modify the terms or conditions of a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall file those modifications with a non-refundable fee of five dollars ($5.00).

(15) Any person who holds a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall pay a renewal fee of one-hundred dollars ($100.00) biennially from the date of issuance.

(16) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any other establishment licensed pursuant to this chapter, where sterile products are compounded, manufactured, prepared, propagated, repackaged, processed, stored, or distributed shall pay a registration fee of two-hundred and fifty dollars ($250.00), and thereafter a biennial renewal fee of two-hundred and fifty dollars ($250.00).

(17) Each automated dispensing system becoming registered with the Board shall pay a registration fee of three-hundred dollars ($300.00), and thereafter a biennial renewal fee of three-hundred dollars ($300.00).

(18) Each licensed practitioner, including pharmacy technicians, shall pay a fee of ten dollars ($10.00) in addition to any initial licensure or renewal fee. All fees collected pursuant to this paragraph shall be for the purpose of funding a peer assistance program.

(19) 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. §§ ~~4-5-202, 63-10-102(a), 63-10-204, 63-10-216, 63-10-301, 63-10-304, 63-10-306,~~ 63-10-308, ~~63-10-404(17), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508.~~63-10-310, and 63-10-312.

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-03
STANDARDS OF PRACTICE

TABLE OF CONTENTS

1140-03-.06 LABELING REQUIREMENTS

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). All reasonable 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. §~~§ 63-10-204, 63-10-304, 63-10-404(11), (15), and (19), and 63-10-504(b)(1) and (2)(j)~~63-10-308.

1140-03-.17 COLLABORATIVE PHARMACY PRACTICE

(1) Definitions-In addition to the definitions contained in Tenn. Code Ann. Title 63, Chapter 10, Part 2, the following definitions are applicable to collaborative pharmacy practice:

(a) "Active practice", for purposes of the qualifications of a pharmacist under (4)(b) of this rule, means engagement in paid, unpaid, or volunteer activity which requires a pharmacist's license under Tennessee law, for at least 2,000 hours within the 24-month period immediately preceding the date of the agreement. "Active practice" is not limited to direct patient care and includes supervisory, educational or consultative activities or responsibilities for the delivery of such services.

(b) "Agreement" means the collaborative pharmacy practice agreement.

(c) "Authorizing physician" means a medical doctor or osteopathic physician with an unencumbered Tennessee license who has a direct provider/patient relationship with the patients served under a collaborative pharmacy practice agreement or who is the supervising physician of an advanced practice nurse or physician assistant who has such direct relationship or who, in the case of a multi-specialty practice, is the representative or chief responsible for particular specialty care within that multi-specialty practice recognized and certified by the American Board of Medical Specialties (hereinafter "ABMS") or the American Osteopathic Association Bureau of Osteopathic Specialists (hereinafter "AOABOS").

(d) "Collaborating prescriber" means the physician, advanced practice nurse or physician assistant who is a party to a collaborative pharmacy practice agreement, who has a direct provider/patient relationship with the patient served by the agreement and who has prepared the patient specific, drug specific, disease or condition specific plan of care based on a physical examination of the patient where required under these rules.

(e) "Hospice patient" means an individual who has been diagnosed as terminally ill, has been certified in writing by a physician to have an anticipated life expectancy of six (6) months or less and who has voluntarily requested admission to, and been accepted by, a licensed hospice as defined in T.C.A. § 68-11-201.

(f) "Institutional-based pharmacy setting" means any institutional facility or long-term care facility, as defined in 1140-01-.01, or an academic health care institution, and where the pharmacist is responsible for the care of patients within that facility, including prescriptive practices, under the terms of a collaborative agreement.

(g) "Patient Care Services" means services rendered by physicians and members of the healthcare profession under their supervision, including advanced practice nurses, physician assistants and pharmacists for the benefit of the patient and which must be within the professional training and experience of the healthcare practitioner and be covered by the collaborative pharmacy practice agreement.

(h) "Routine scope of practice and services" means any patient care service provided by the authorizing physician and their practice in compliance with the respective applicable licensing board's laws, rules, policies and procedures. In addition, the services to be provided by the pharmacist shall be services that the authorizing physician generally provides to his or her patients in the normal course of his or her clinical medical practice. The pharmacist should only provide services to the patients whom the authorizing physician or collaborating prescriber routinely treats in the course of his or her clinical medical practice.

(i) "Unencumbered", for the purpose of this rule, means an active license that is not revoked, suspended or on probation at the time and is not subject to any conditions, restrictions, or limitations imposed by the applicable licensing board, which relate directly to the delivery of health care services. A condition, restriction or limitation directly relates to the delivery of health care services when it prevents a provider from treating certain types of patients or certain types of ailments or injuries, or otherwise limits a provider from fully engaging in the practice which would otherwise be authorized pursuant to his or her license.

(2) Physicians, advanced practice nurses and physician assistants may only engage in collaborative pharmacy practice agreements with pharmacists when an appropriately executed collaborative pharmacy practice agreement has been executed and a written attestation has been filed with the

licensing boards for all practitioners participating in the agreement notifying those boards of the existence of such agreement; and when the patient or the patient's authorized representative has signed a general consent that the patient is to receive services from a healthcare team, including a pharmacist. However, no such general consent shall be required in an institutional based pharmacy setting where consent to treatment has already been given. All consent given related to treatment at an institutional facility or to treatment under a collaborative pharmacy practice agreement is to be made part of the patient record.

(a) Any pharmacist who is a participant in a collaborative pharmacy practice agreement must be provided a copy of said agreement by the director of pharmacy, pharmacist-in-charge, or designated pharmacist in a group.

(b) The written attestation shall include the names of all signatories and practitioners participating in the collaborative pharmacy practice agreement, the date of the Agreement and a description of the scope of the services covered by the Agreement.

(c) In the event that an advanced practice nurse or physician assistant is a party to a collaborative pharmacy practice agreement, the physician with responsibility for supervision and control of that advanced practice nurse or physician assistant must approve and sign the Agreement.

(d) In addition, for those Agreements not involving the institutional-based pharmacy setting, the written attestation shall include a formulary of the categories of drugs and services authorized by the Agreement.

(e) The written attestation must be provided to the appropriate licensing boards of the signatories no later than thirty (30) days following the effective date of the Agreement.

(3) No physician, advanced practice nurse, physician assistant or pharmacist may engage in a collaborative pharmacy practice agreement unless each collaborating provider holds an active, unencumbered license in Tennessee and possesses at least one million dollars ($1,000,000) in professional liability insurance coverage per occurrence.

(4) In addition to the other requirements of these rules, a pharmacist must meet one of the following qualifications in order to engage in a collaborative pharmacy practice agreement:

(a) Has been awarded a doctor of pharmacy degree from a program accredited by the Accreditation Council for Pharmacy Education; or

(b) Has been awarded a bachelor of science in pharmacy and been in the active practice of pharmacy.

(5) Each collaborative pharmacy practice agreement ("Agreement") shall contain the following elements, at a minimum:

(a) Names and Titles of Collaborating Providers. The agreement must contain identification of all pharmacists and all physicians and other prescribers (collectively, "collaborating providers") who are parties to the Agreement. The Agreement shall state the procedure to be followed to indicate changes in the members of the group(s) participating in the Agreement. Unless expressly stated in the Agreement, changes to the list of collaborating providers bound by the Agreement shall not automatically void the Agreement. When the Agreement involves a group or groups of practitioners, the chief medical officer or medical

director, where applicable, and the director of pharmacy or pharmacist-in-charge shall sign the Agreement, and the Agreement shall identify all collaborating providers in one or more addendums. In the case of a healthcare institution with an organized medical staff or a multi-specialty group with more than one ABMS or AOABOS recognized physician specialty, the signature of the authorizing physician representing or responsible for that specialty unit will suffice. Nevertheless, each collaborating provider must affirm understanding and acceptance of the terms of the Agreement by signing an addendum to the Agreement within thirty (30) days of the effective date of the agreement (or within thirty days of employment or association with such multi-specialty group) and all members of the medical staff or group must be provided a copy of the collaborative agreement within fifteen (15) days of execution, with a copy also made available via online access. Signatures may be handwritten, electronic, or any other method authorized by the Board of Pharmacy and the respective licensing board of the signatory.

(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.

(c) Documentation and Communication. Any patient care services provided by a pharmacist or pharmacists pursuant to a collaborative pharmacy practice agreement shall be documented in a patient record accessible by the pharmacist(s) and the collaborating prescriber(s) or communicated in writing to the collaborating prescriber or prescribers within three (3) business days of the service. The Agreement shall describe the methods for maintenance and access to the records by the pharmacist(s) and the prescriber(s), for documentation of services performed pursuant to the Agreement and for communication and feedback between the pharmacist(s) and the collaborating prescriber(s). All such records shall be maintained by the collaborating prescriber(s) and pharmacist(s) for a period of not less than ten (10) years from the date of the last patient contact.

(d) Override Clause. A provision must be included in the Agreement allowing the collaborating prescriber to override the actions taken by the collaborating pharmacist specific to services provided under the Agreement if he or she determines that the override is essential to the optimal health outcomes of the patient, and stating how such overrides shall be documented and communicated to the collaborating pharmacist and the patient in a timely manner, as defined in the agreement.

(e) Expiration, Modification and Termination. The effective date of the Agreement shall be stated in the Agreement. Each agreement must contain a term or expiration date, upon which the agreement will expire if not renewed; however, in any event, all Agreements must be reviewed and updated at least every two (2) years as evidenced by signatures of the parties. Every Agreement must contain a provision stating the process for modification or termination of the agreement by either party. This process shall include written

notification to all affected parties when modification or termination is sought. An Agreement may be amended upon mutual approval by the collaborating prescriber, authorizing physician (where applicable) and pharmacist who have been duly authorized to execute, modify, or change the Agreement. Such amendments shall include, at a minimum, a description of the desired change and the effective date of the change. Additional prescriber(s) and additional pharmacist(s) may be added to an existing participating group through an addendum without affecting the effective date of the agreement. Any amendment executed shall not automatically void the terms and conditions of the existing Agreement unless expressly stated. Amendments to the authorized care and services not involving an institutional-based pharmacy setting which institute substantive additions or reductions to the scope of patient care services provided under the agreement including new therapeutic classes of drugs to the authorized formulary must be provided to the appropriate licensing boards no later than thirty (30) days from the effective date of the amendment. .

(f) Automatic Exclusions. A provision must be included in the Agreement which identifies any terms under which a provider will be automatically excluded from participation in the Agreement, which may include but need not be limited to death, suspension, surrender, revocation, or retirement of license; loss or restriction of prescriptive authority; the suspension or revocation of a Drug Enforcement Administration registration; exclusion from any federally-funded health programs, or the formal termination of the supervising relationship between an advanced nurse practitioner or physician assistant and his or her supervising physician. Any Agreement involving an advanced practice nurse or physician assistant participating in a collaborative pharmacy practice agreement shall contain a procedure for immediate notification to the collaborating pharmacist(s) if that supervisory relationship is terminated for any reason.

(g) Quality Assessment. The authorizing physician(s) and pharmacist(s) shall create written measurable and objective performance goals for evaluating the quality of care provided for the patients treated pursuant to the Agreement. The Agreement must provide for such goals and data as identified by the collaborating providers, to be aggregated and reviewed by the participants to the Agreement at least quarterly. Such quarterly review shall include consideration of any changes necessary to the Agreement, authorized formulary, and patient orders, in addition to strategies regarding patient education and medication adherence, increased or improved monitoring of side effects and the need for further screening/testing. The Agreement shall also provide at a minimum for monthly patient record review by the authorizing physician(s) of at least five per cent (5%) of the patients treated pursuant to the Agreement. The quality assessment review shall be properly documented, retained by the participating parties of the Agreement, and available for review by representatives of the various licensing boards for at least ten (10) years.

(6) The scope of a collaborative pharmacy practice agreement shall NOT include:

(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;

(b) The prescribing of controlled substances, except by a pharmacist practicing within an institutional-based pharmacy setting or for hospice patients.

(7) A copy of the Agreement, including any addendum, modification or termination shall be accessible at each practice site and shall be made available to the applicable regulatory board for review upon request.

(8) Pharmacists engaging in the collaborative pharmacy practice must utilize an area for in-person, telephonic or other approved consultations with patients that ensures the confidentiality of the communication.

(9) Physicians, advanced practice nurses and physician assistants engaged in a collaborative pharmacy practice agreement shall:

(a) Retain professional responsibility to his/her patients for the management of their drug therapy;

(b) Establish and maintain a physician-patient relationship with each patient subject to the collaborative pharmacy practice agreement;

(c) Be available at all times through direct telecommunication for consultation, assistance and direction, or shall make arrangements for a substitute physician to be available.

(10) Any pharmacist issuing a prescription order, as defined in T.C.A. § 63-10-204, or medical order, as defined in T.C.A. § 63-10-204, pursuant to an Agreement shall issue the prescription order or medical order in accordance with the requirements set forth in Tenn. Comp. Rules and Regs. 1140-03-.03 and within the terms set forth in the collaborative pharmacy practice agreement.

(11) All collaborative pharmacy practice agreements authorizing pharmacists to provide services and activities shall include language that ensures compliance with all applicable by-laws, policies, and procedures of that facility.

(12) For patient care services performed by a pharmacist and authorized only pursuant to a collaborative pharmacy practice agreement, the Board of Pharmacy expressly adopts the guidelines, rules, and standards of practice of the Board of Medical Examiners, Board of Osteopathic Examiners, or other Tennessee Health Related Boards, as applicable.

(13) Pharmacists engaged in the collaborative pharmacy practice are strongly encouraged to complete ten (10) hours of the biennially required thirty (30) hours of continuing education in topics related to the clinical practice of pharmacy.

(14) All signatories and other parties engaging in a collaborative pharmacy practice shall be subject to disciplinary action by their licensing boards if the licensee violates the terms of these rules or the terms of the collaborative pharmacy practice agreement. Each board with jurisdiction over any of the signatories to the agreement shall report to the other appropriate board any conduct which it believes to be in violation of any such agreement.

(15) Pharmacists who hold a current federal drug enforcement administration ("DEA") license must complete a minimum of two (2) hours biennially of continuing education related to controlled substance prescribing, which must include instruction in the Department's treatment guidelines on opioids and chronic pain and may include such other topics as medicine addiction, risk management tools, and other topics as approved by the Board of Pharmacy. Such continuing

education hours shall be counted toward the pharmacist's mandatory continuing education requirement.

Authority: T.C.A. §§ 63-10-217, 63-10-224, ~~63-10-304,~~ and 63-10-30~~6~~8.

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(s).

(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 with 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; and

3. Adverse reactions as listed in the FDA factsheet.

(4) A 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) A 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) A 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 (10) 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 another pharmacy that may dispense ivermectin.

Authority: T.C.A. §§ 63-10-217, 63-10-224, and 63-10-308.