TENNESSEE BOARD OF PHARMACY
665 Mainstream Dr
Nashville, TN 37243

BOARD MEMBER PRESENT
Richard Breeden, D.Ph., Vice President
Marlin Blane, D.Ph.
Adam Rodgers, D. Ph
Jake Bynum, Consumer Member
Shane McKinney, D.Ph.
Robert Harshbarger III, D.Ph.

BOARD MEMBER ABSENT
Melissa McCall, D.Ph., President

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STAFF PRESENT
Lucy A. Shell, Executive Director
Matthew Gibbs, Deputy General Counsel
Timothy Peters, Associate General Counsel
Rebecca Moak, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Derek Johnston, Pharmacy Investigator
Terry Grinder, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Patricia Beckham, Pharmacy Investigator
Rita Golden, Pharmacy Investigator
Shannon Kelly, Pharmacy Investigator
Richard Hadden, Pharmacy Investigator
Sheila Bush, Administrative Director

STAFF ABSENT
Larry Hill, Pharmacy Investigator

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May 8, 2023

The Tennessee Board of Pharmacy convened on Monday, May 8, 2023, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:33 a.m. with Dr. Breeden presiding. Dr. Breeden welcome Dr. Harshbarger III as the new board member.

Two separate rulemaking hearings occurred at this meeting. A summary of all oral and written comments discussed, the final rule language, and the final vote of the Board are captured in the information below.

Rulemaking Hearing – 22-0849 – Provision of Ivermectin, Accessible Prescription Labels, and Technician Fee Change

Oral Comments

Mark Binkley, Health & Wellness Compounding Pharmacy

> Provision of Ivermectin - Dr. Binkley raised a concern regarding the retention of ivermectin records for 10 years when all other pharmacy records are maintained for two years pursuant to the Board's rules. The Board stated the 10-year requirement is consistent other collaborative pharmacy practice agreement rules.

Written comments

Tennessee Pharmacists Association ("TPA")

Fees – TPA supports the Board's intent to lower the cost for pharmacy technicians to register with the Board.

Accessible prescription labels – TPA supports the Board's proposed rules pertaining to accessible prescription labels.

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 the referral language because the clause seemed unclear and redundant. The Board denied 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 referral language 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.

Pharmacy Technicians ratio – TPA opposes the proposed rule language as currently written which does not provide a cap on the number of technicians that a single pharmacist can supervise at one time. TPA suggested a maximum limit of six pharmacy technicians for each pharmacist on duty while preserving the authority of a pharmacist in charge to request a waiver from the 6:1 cap. The Board rejected TPA's suggestions after a lengthy discussion. The Board deferred to the pharmacy's pharmacist in charge to make the best determination for the ratio. The Board kept waiver language as it currently exists.

Dan Dillon, legislative chair, Tennessee Council for the Blind

Accessible Prescription Labels – Mr. Dillon noted 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.

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

Accessible prescription labels – Ms. Glass 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 to strengthen the accommodation requirement, the Board voted to add the word "reasonable" before "accommodations" in the proposed rule language as noted in section (a) under Changes, below.

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 and 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.

After consideration of all comments, all Board members present voted all in favor of the following language with Dr. Breeden, serving as Chair abstaining.

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-03
STANDARDS OF PRACTICE

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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,~~ and 63-10-308.~~, 63-10-404(17), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508.~~

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)~~.

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 patien'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, 63-10-304, and 63-10-306.

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 another pharmacy that may dispense ivermectin.

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

Rulemaking Hearing – 19-0259, Compounding Rules, Technician Ratio, Acceptable Inspections

Oral Comments

Mark Binkley, Health & Wellness Compounding Pharmacy

Compounding - Dr. Binkley asked if a United States Food and Drug Administration inspection would be acceptable for both an outsourcing pharmacy and a patient-specific sterile compounding pharmacy. The Board noted all inspections shall be evaluated for appropriateness.

Compounding – Dr. Binkley requested removal of the requirement to maintain, in a record, the name of the practitioner or health care entity who received the compounded drug product. The Board rejected this request and stated with the removal of the language specific to "compounding record" the rule as amended allows for information to be kept across a variety of records and pieced together for purposes of inspection.

Compounding – Dr. Binkley suggested the deletion of all language pertaining to simple compounding preparations. By majority vote, the Board rejected this comment.

Lindsay Adams / Nicole Wynne, Vanderbilt University Medical Center

Compounding – The proposed rule language regarding a final product label required recordation of the assigned lot and batch number. Dr. Adams requested a change in the proposed rule language to "internal identification number." The Board accepted this change as noted in section (c) under Changes, below.

Sheena Illarramendi, Vanderbilt University Medical Center

Pharmacy technician ratio – Ms. Illarramendi opposed to removal of a cap on the ratio of pharmacy technicians to pharmacist when all technicians beyond the 6:1 ratio are certified. The Board acknowledge the concern but decided, by majority vote, the pharmacist in charge shall be responsible for the ratio number.

Randy Davis, Designer Drugs

Compounding – Dr. Davis expressed concerns regarding nonsterile simple compounding preparations and the element of manipulation. The Board pointed to the description of manipulation in the proposed rule language and did not make any further amendments.

Out-of-state compounding pharmacy inspections – Dr. Davis raised concerns about language which appeared to require an inspection every twelve months for out-of-state compounding pharmacies. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Dr. Scott Denaburg, investigator – Tennessee Board of Pharmacy

Compounding – Dr. Denaburg asked for clarification regarding the types of quality assurance issues and events which require reporting. The Board voted to add clarity to the proposed rule by indicating events in addition to a corrective action preventative action event shall be reported as noted in section (j) under Changes, below.

Compounding – Dr. Denaburg urged the Board to adopt language which allows more than one designated person to perform a compounding task. The Board adopted this suggestion by making "person" plural inside the proposed rule language as noted in section (f) under Changes, below.

Written comments

Tennessee Pharmacists Association ("TPA")

Compounding - TPA supports removal of quarterly reporting requirements; supports a rule change which allows a waiver from the facility requirements of nonsterile simple compounded preparations; asked the Board to remove the requirement, in proposed rule language, to identify each person on the dispensing label who participated in the compounding process; and sought clarification from the Board regarding which rule chapter of the United States Pharmacopeia is applicable – does the rule pertain to officially adopted standards or draft standards. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below. The Board clarified the current compendially applicable standards are the standards of USP which apply.

Jay Phipps, president and chief executive officer, Phipps Pharmacy

Technician ratio – Dr. Phipps suggested increasing the pharmacy technician ratio to 10:1. The Board rejected this suggestion and noted there is flexibility allowed in the proposed rule for a ratio of greater than 6:1 if the additional technicians are certified. Moreover, the proposed rule language preserved the waiver authority for any pharmacist who seeks such waiver.

Compounding training – Dr. Phipps sought clarification regarding training under the proposed rules for compounded drug products. The Board stated training must occur in accordance with USP concepts. During this discussion, the Board deemed the proposed rule language too strict as only a designated pharmacist, but not other non-pharmacists, may accomplish various compounding tasks. This change is referenced in section (f) under Changes, below. Dr. Phipps asked the Board to remove the requirement, in proposed rule language, to identify each person on the dispensing label who participated in the compounding process. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below. Dr. Phipps suggested removal of the requirement to place the pharmacist who performed final verification from the dispensing label. The Board rejected this suggestion and determined the pharmacist who performed final verification is required information for a dispensing label.

Scott Brunner, chief executive officer, Alliance for Pharmacy Compounding

Compounding – Mr. Brunner broached concerns about the impetus for listing all personnel who participated in the compounding process on the dispensing label. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below.

Out-of-state compounding pharmacy inspections – Mr. Brunner asked the Board to provide a basis for requiring an inspection every twelve months. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Omar B. Hamid, pharmacist in charge, O'Brien Pharmacy

Compounding – Dr. Hamid asked the Board to strike proposed rule language which required listing all personnel who participated in the compounding process on the compounding label. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below.

Out-of-state compounding pharmacy inspections – Dr. Hamid stated an inspection every twelve months is unduly burdensome on a pharmacy and asked the Board to reject this proposed rule language. The Board clarified the inspections shall happen within twelve months of

renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Robert P. Nickell, pharmacist and chief executive officer, Pharmco, Inc.

Compounding – Dr. Nickell urged the Board to reject the proposed rule requirement to list all personnel who participated in compounding the anticipatory drug product on the dispensing label. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below.

Out-of-state compounding pharmacy inspections – Dr. Nickell asked the Board to strike proposed rule language which requires an inspection within 12 months of renewal or, in the alternative, to allow risk-based inspections. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Brad McCloskey, pharmacist and president/chief executive officer, University Compounding Pharmacy

Compounding – Dr. McCloskey asked the Board to strike the proposed rule requirement to list all personnel who participated in compounding the anticipatory drug product on the dispensing label. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below.

Out-of-state compounding pharmacy inspections – Dr. McCloskey asked the Board to strike proposed rule language which requires an inspection within twelve months of renewal. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Wayne Sartorio Sr, pharmacist and pharmacy director, Boothwyn Pharmacy

Compounding – Dr. Sartorio noted the proposed rule requirement to list all personnel who participated in the compounding process on the dispensing label creates a cluttered label with unnecessary information. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below.

Rodney Tubbs, pharmacist

Compounding – Dr. Tubbs ask the Board to consider only the dispensing pharmacist to be listed on the dispensing label. The Board accepted changes to the dispensing label as described in sections (g) and (h) under Changes, below.

Dan Lynch, pharmacist and director of regulatory services, Synchrony Pharmacy

Out-of-state compounding pharmacy inspections – Dr. Lynch asked the Board to consider inspections by affidavit, or, in the alternative, allowing inspections to occur every twenty-four months. The Board rejected the comment and clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Dr. Scott Denaburg, investigator – Tennessee Board of Pharmacy

Compounding – Dr. Denaburg suggested the addition of clarifying terms to the proposed rule language to note only the applicable chapters of USP to a given pharmacy's practice are required for compliance. In other words, if one or more USP chapters do not apply to the pharmacy practice site, the pharmacy practice site shall not be responsible for compliance with inapplicable chapters. The Board accepted changes to the applicability of USP to the pharmacy practice site as described in section (b) under Changes, below.

Compounding – Dr. Denaburg indicated the proposed rule language required record retention for three years. At the time of drafting, the proposed rule language mirrored USP requirements of three years for record retention. Subsequently, USP changed its recommendations from three years to two years. The Board adopted the change from three years to two years in the proposed rule language as noted in section (e) under Changes, below.

Compounding – Dr. Denaburg asked the Board to add clarifying language regarding the monitoring of pressure differentials. The Board accepted changes the monitoring of pressure differentials as described in section (i) under Changes, below.

Lindsay Ford, pharmacist, Vanderbilt University Medical Center

Compounding – Dr. Ford asked the Board to remove "the compounding record which shall contain the" from the proposed rules. The Board accepted removal of this term of art as described in section (c) under Changes, below.

Compounding – Dr. Ford retracted comments related to beyond use date because of changes made by the Board to the language of beyond use date as noted in section (d) under Changes, below.

Compounding – Dr. Ford requested the Board to make exception from the training requirement for certain personnel who have non-critical roles in the compounding process. The Board rejected this request and stated the proposed rules are consistent with currently effective rules regarding training. The Board desired to leave the training requirements unchanged.

Compounding – Dr. Ford sought clarification for reporting adverse events. The Board clarified the reporting events in proposed rule language as noted in section (j) under Changes, below.

Compounding – Dr. Ford ask the Board to clarify if both safety events and environmental events shall be reported. The clarified environmental events are not reported.

Cindy Brasher, pharmacist, St. Jude Children's Research Hospital

Compounding – Dr. Brasher sought clarification of "designated person." The Board accepted this change as noted in section (f) under Changes, below.

Compounding – Dr. Brasher inquired about the training requirement for the person(s) designated by the pharmacist in charge. The Board stated previous rule amendments regarding a designated person clarified the training requirements.

Compounding – Dr. Brasher asked if hazardous drug documents and the Gap analysis were no longer required. The Board confirmed neither the requirements for hazardous drug documents nor the Gap analysis were retained in the proposed rule language.

Compounding – Dr. Brasher asked for examples of nonsterile simple compounding. The Board stated Magic Mouthwash is an applicable nonsterile simple compounding preparation.

After consideration of all comments, the Board voted all in favor of the following language with Dr. Breeden, serving as Chair abstaining for rule 1140-01-.08, 1140-01-.09, 1140-07-.01, 1140-07-.02, 1140-07-.03, 1140-07-.04, 1140-07-.05, 1140-07-.06, 1140-07-.07, and 1140-07-.08.

After consideration of all comments, Dr. McKinney, Dr. Harshbarger, Dr. Rodgers, and Mr. Bynum voted in favor of rule 1140-02-.02, with Dr. Blane opposing, and Dr. Breeden, serving as Chair abstaining.

After consideration of all comments, Dr. McKinney, Dr. Blane, Dr. Rodgers, and Mr. Bynum voted in favor of rule 1140-07-.09, with Dr. Harshbarger opposing, and Dr. Breeden, serving as Chair abstaining.

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER, OUTSOURCING FACILITY, OXYGEN SUPPLIER AND WHOLESALER/DISTRIBUTOR LICENSES

(1) Application for a license to operate as a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to the scheduled opening date. No pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.

(2) An application for an existing pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor changes name, location or ownership.

(a) Transactions constituting a change of ownership include, but are not limited to, the following:

1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;

2. A partnership dissolves;

3. One partnership is replaced by another through the removal, addition or substitution of a partner;

4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and

5. Transfers between levels of government.

(b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives; and

3. Corporate stock transfers or sales, even when a controlling interest.

(3) No out-of-state pharmacy practice site, manufacturer outsourcing facility, oxygen supplier or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor physically located out-of-state the following standards must be met.

(a) Pharmacy practice site.

1. Submit an application for a license, which shall include the address of the pharmacy practice site, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation and names of all pharmacists who practice at the site, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license, including names of pharmacists practicing at the site.

2. Comply with all statutorily authorized directions and requests for information from the board.

3. Maintain at all times a current permit, license or registration to conduct the pharmacy practice site in compliance with the laws of the state in which the site is physically located.

4. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Thereafter, the pharmacy practice site shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the site is physically located.

(i) An out-of-state pharmacy practice site engaged in compounding must provide an inspection performed within the previous twelve (12) months.

(ii) An inspection completed by the United States Food and Drug Administration, or an inspection performed by the National Association of Boards of Pharmacy in lieu of an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located is acceptable.

5. Maintain records of prescription orders dispensed to and/or of medication assessments provided to persons residing in Tennessee.

6. All records of prescription orders prepared and dispensed to persons residing in Tennessee shall be readily retrievable from other records.

7. During regular hours of operation, but not less than six (6) days per week nor for a minimum of forty (40) hours per week provide access to a pharmacist by a toll-free telephone service. A toll-free number shall be placed on the label affixed to the dispensing container for each prescription dispensed to a person residing in Tennessee.

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.

9. All out-of-state pharmacy practice sites shall comply with the requirements for patient counseling, patient profiling, drug regimen review and pharmaceutical care as set forth at 1140-03-.01.

10. The board may require additional information before issuing or renewing a pharmacy license to ensure compliance with applicable laws of this state and rules of the board.

(b) Manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor.

1. Submit an application for a license, which shall include the address of the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.

2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located, or by the Food & Drug Administration. Thereafter, the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located, or by the FDA.

3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.

(4) Representatives of a manufacturer, outsourcing facility or wholesaler/distributor conducting business in the state of Tennessee and who possesses and distributes controlled substances shall obtain a controlled substance registration from the Board of Pharmacy.

(5) Any entity licensed as or applying for licensure as manufacturer or outsourcing facility conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic processing must register and possess a modifier as a sterile manufacturer with the Board of Pharmacy in accordance with this chapter. This section shall not apply to wholesalers/distributors of sterile products.

(6) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.

(7) In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:

(a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and

(b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.

(8) 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. §§ 53-11-301, 53-11-302, 53-14-104, 53-14-106, 53-14-107, ~~56-1-302(b)(1)(2), 63-10-101, 63-10-102(a),~~ 63-10-203, 63-10-204, 63-10-210, 63-10-216, 63-10-301, 63-10-304, 63-10-306, and 63-10-308~~, 63-10-404(18), (28), and (37), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508~~.

1140-01-.09 RENEWAL OF LICENSES

(1) All licenses and certificates of registration granted by the board shall be for a two (2) year period beginning on the date the license is initially granted. All licenses and certificates of registration shall be renewed on or before the last day of the two (2) year license cycle.

(2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.

(3) Prior to renewal of its license in this state, an out-of-state pharmacy practice site engaged in compounding must provide to the board the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, an inspection performed by the United States Food and Drug Administration, or an inspection performed by the National Association of Boards of Pharmacy, that must have been within the previous twelve (12) months.

(4)~~(3)~~ 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. §§ 53-11-301, 53-11-302~~, 56-1-302(b)(1)(2), 63-10-102(a)~~, 63-10-203, 63-10-204, 63-10-210, 63-10-216, 63-10-304, 63-10-306, 63-10-308, and ~~63-10-404(17), 63-10-504(1) and (2),~~ 63-10-304(b)(1).~~, and 63-10-508.~~

1140-02-.02 PHARMACY TECHNICIANS

(1) Any person acting as a pharmacy technician shall register with the Board by submitting a complete application on a form prescribed by the Board accompanied by the following:

(a) An affidavit signed by both the applicant and employer attesting that the applicant has read and understands the laws and rules relative to pharmacy technicians and the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the applicant's place of employment);

(b) Registration fee established in rule 1140-01-.10; and

(c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's registration application materials.

(d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for registration will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for registration and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.

(2) The following individuals are exempt from registration as a pharmacy technician:

(a) Any individual performing tasks that may be performed by a pharmacy technician who is classified by the employer as a probationary employee. The exemption shall not exceed ninety (90) days from the date of employment.

(b) A student enrolled in a formal pharmacy technician training program while performing experiential rotations as a part of the academic curriculum. The student shall wear a school-issued identification badge.

(3) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.

(4) A registered pharmacy technician may, under the supervision of a pharmacist, perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-02-.01(13) that must be personally performed by a pharmacist or pharmacy intern under the personal supervision and in the presence of a pharmacist.

(5) Certified pharmacy technicians may also:

(a) Receive new or transferred oral medical and prescription orders;

(b) Receive and transfer copies of oral medical and prescription orders between pharmacy practice sites; and

(c) Verify the contents of unit dose carts/automated dispensing systems prepared by other registered technicians when an additional verification by use of bar code technology or a licensed health care professional is performed prior to administration to the patient.

(6) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by a pharmacy technician.

(7) Pharmacy Technician to Pharmacist Ratio

(a) The pharmacy technician to pharmacist ratio shall not exceed 6~~2~~:1; however the ratio may be removed if ~~increased up to a maximum of 4:1 by the pharmacist in charge based upon public safety considerations but only if~~ the additional pharmacy technicians beyond the 6:1 ratio are certified pharmacy technicians. However, the pharmacist in charge may request a modification of the ratio from the Board in writing which addresses:

1. The pharmacy technician's experience, skill, knowledge and training; and

2. The workload at the practice site; and

3. Detailed information regarding the numbers of pharmacy technicians and the specific duties and responsibilities of each of the pharmacy technicians; and

4. Justification that patient safety and quality of pharmacy services and care can be maintained at the pharmacy.

(b) Requested modifications of the established ratios may not be implemented until the written request is considered and approved by the Board.

(8) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g. pharmacy technician, certified pharmacy technician).

(9) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions.

(10) A registered technician shall maintain his or her registration certificate at the pharmacy practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.

(11) All registered technicians shall immediately notify the board in writing of any change of address or employer.

(12) For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.

(13) 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. §§ 63-1-116, 63-10-204, 63-10-304, ~~63-10-304(b)(1), (e), and (j),~~ 63-10-306, ~~63-10-308, 63-10-404(30), 63-10-504(b)(1), 63-10-504(b)(1)(C), 63-10-506,~~ and 63-10-308~~63-10-508~~.

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-07
~~STERILE PRODUCT PREPARATION IN PHARMACY PRACTICE~~COMPOUNDING

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1140-07-.01 APPLICABILITY

(1) The provisions of this Chapter shall apply to all pharmacy practice sites and pharmacists, pharmacy interns, pharmacy technicians and supportive personnel involved in the compounding and dispensing of drug~~sterile~~ products.

(2) The provisions of this chapter relative to pharmacy practice sites shall be enforceable on January 1, 2024.

Authority: T.C.A. §§ ~~63-10-404(4), (11), (26), (28), (29), (30) and 63-10-504(b)(1), (2).~~63-10-216, 63-10-304, and 63-10-306.

1140-07-.02 STANDARDS

(1) ~~All sterile products shall be prepared in compliance with applicable USP standards for pharmaceutical compounding.~~The preparation, labeling, and dispensing of all compounded drug products shall comply with the standards established by United States Pharmacopeia ("USP") chapters 795, 797, 800, and 825, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

(2) The Board of Pharmacy, upon a showing of good cause and in the best interest of the public health, safety and welfare, may waive the requirements of any applicable portion of USP standards.

(a) All waiver requests submitted pursuant to this part shall be submitted in writing.

(b) The Board of Pharmacy may authorize the Executive Director to exercise some, or all, of its waiver authority under this part.

(3) Noncompliance by a licensee with applicable standards and guidelines, or any other violation of the provisions of this rule shall be considered unprofessional conduct within the meaning of T.C.A. § 63-10-305 and a violation of a duly promulgated rule of the Board of Pharmacy.

~~(4) Any licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of high risk or batch sterile products, as defined by USP standards, compounded and dispensed during the previous quarterly period and any other information as required by USP standards.~~

~~(a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.~~

~~(b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.~~

~~(c) The format for reports submitted pursuant to this paragraph shall be determined by the Board of Pharmacy through policy and made available to the public on the Board of Pharmacy's website.~~

(4)~~(5)~~ Any licensed pharmacy which compounds and dispenses ~~sterile~~ drug products shall provide at a minimum upon request of the Board of Pharmacy the following information for any ~~sterile~~ drug product compounded, dispensed, traded, sold, or otherwise distributed within the past two (2) years:

(a) Name, strength, and dosage form;

(b) Quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding ~~quarterly~~ period;

(c) ~~All components~~The source, lot number, expiration date and an accurate statement of the weight or measure of each component;

(d) ~~The beyond-use date~~The date, or hour and date, after which a compounded drug product must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded ("BUD");

(e) Storage requirements;

(f) Labels and labeling with appropriate BUD~~beyond-use date~~ and instructions for storage and use;~~.~~

(g) The names of all personnel who prepared the compounded drug product;

(h) The name of the pharmacist who approved the compounded drug product;

(i) The name of the patient, practitioner or healthcare entity who received the compounded drug product; and

(j) The results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any compounded drug products, compounded over the past two (2) years.

~~(6) Any licensed pharmacy which compounds and dispenses sterile products must ensure that the following information is on file at the practice site and readily accessible for sterile products:~~

~~(a) Documentation of the name and strength of all drug products compounded over the past two (2) years;~~

~~(b) The sources and lot numbers of the components used in those drug products;~~

~~(c) The total number of dosage units compounded over the past two (2) years;~~

~~(d) The name of the person who prepared the drug product;~~

~~(e) The name of the pharmacist who approved the drug product;~~

~~(f) The name of the practitioner or the name of the patient or healthcare entity who received the compounded drug product;~~

~~(g) The results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any sterile compounded products, as defined by chapter 1140-01, compounded over the past two (2) years.~~

(5)~~(7)~~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,~~ 63-10-216, ~~63-10-301,~~ 63-10-304, and 63-10-306.

1140-07-.03 PERSONNEL

(1) The pharmacist in charge or the person(s) designated by the pharmacist in charge ~~designee~~ shall be responsible for, at a minimum, the following:

(a) Procurement, storage, compounding, labeling, repackaging, dispensing, and distribution of all ~~prescription~~ drugs and devices and related materials necessary in compounding and dispensing compounded drug ~~sterile~~ products;

(b) Establishment of policies and procedures for the compounding and dispensing of compounded drug ~~sterile~~ products;

(c) Documentation of competency in proper~~aseptic~~ techniques of all pharmacists, pharmacy interns and pharmacy technicians. The proper~~aseptic~~ technique of each person compounding and dispensing compounded drug ~~sterile~~ products shall be observed and evaluated as satisfactory during orientation and training ~~and at least on an annual basis~~pursuant to standards established by USP chapters 795, 797, 800, and 825, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed or whenever unacceptable techniques are observed or detected;

(d) Establishment of a quality assurance program;

~~(e) Reviewing and updating annually all policies and procedures; and~~

~~(f) Provision of sterile products on a twenty four (24) hour a day basis.~~

(2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-2-.02 responsible for compounding or dispensing compounded drug ~~sterile~~ products shall:

(a) Obtain practical and/or academic training in the compounding and dispensing of compounded drug ~~sterile~~ products;

(b) Complete ~~annual continuing~~ education ~~related~~ pursuant to the standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed~~to sterile product compounding and dispensing and utilization~~; and

(c) Maintain, in the pharmacy practice site, documentation of completion of the required initial and subsequent training and competency evaluations for (2) years. A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site. These records shall contain the following information:~~continuing education.~~

1. Name of the person receiving the training or evaluation;

2. Date(s) of the training or evaluation;

3. General description of the topics covered; and

4. Signature of the person receiving the training or evaluation and the pharmacist in charge or the person(s) designated by the pharmacist in charge. The person receiving the training may not self-evaluate.

(d) Use proper ~~aseptic~~ technique in all ~~sterile~~drug product compounding as defined by the pharmacy practice site's policies and procedures and in compliance with standards established by USP chapters 795, 797, 800, and 825, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

(3)~~(4)~~ The pharmacist in charge shall be assisted by such additional pharmacists, pharmacy interns, pharmacy technicians as defined by 1140-2-.02 and supportive personnel necessary to operate the pharmacy practice site competently and safely and to provide services in a timely and appropriate manner.

(4)~~(5)~~ All pharmacists, pharmacy interns and pharmacy technicians must be qualified at least annually through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such pharmacists, interns and technicians will be assigned to use to compound and dispense ~~sterile~~compounded drug products.

~~(6) A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site and contain the following information:~~

~~(a) Name of the person receiving the training or evaluation;~~

~~(b) Date(s) of the training or evaluation;~~

~~(c) General description of the topics covered; and~~

~~(d) Signature of the person receiving the training or evaluation and the pharmacist in charge or pharmacist designee of the pharmacist in charge.~~

(5)~~(7)~~ 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. §§ 63-10-216~~63-10-204~~, 63-10-304, ~~63-10-404(4), (5), (8), (11), (14), (16), (26), (27), (29),~~ and 63-10-306~~(30), and 63-10-504(b)(1),(2)~~.

1140-07-.04 PHYSICAL REQUIREMENTS

(1) Any facility that compounds ~~sterile~~drug products shall comply with applicable USP standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

(2) 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,~~ 63-10-216, ~~63-10-301,~~ 63-10-304, and 63-10-306.

1140-07-.05 POLICY AND PROCEDURE MANUAL

(1) A policy and procedure manual related to drug~~sterile~~ product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for ~~sterile~~ compounding pursuant to USP standards, and shall, at a minimum, include:

(a) Security;

(b) Equipment;

(c) Sanitation;

(d) Reference materials;

(e) Prescription drug and device and related material storage;

(f) Prescription drug and device and related material compounding and dispensing;

(g) Prescription drug and device and related material labeling and relabeling;

(h) Prescription drug and device and related material destruction and returns;

(i) Dispensing of compounded drug~~sterile~~ products;

(j) Record keeping;

(k) Quality assurance;

(l) Quality control;

(m) Duties for pharmacist(s), pharmacy intern(s), pharmacy technician(s) and supportive personnel;

(n) Public safety relative to harmful compounded drug ~~sterile~~ products, including the active notification of patients if they may be affected by a product found to have a defect or an out-of-specification result including any recall policy and procedures;

(o) Attire;

(p) Pharmacist, pharmacy intern, and pharmacy technician training.

(q) Compliance with ~~all applicable USP standards~~the standards established by chapters 795, 797, 800, and 825, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed; and

(r) Response to adverse events, outbreaks, and other public health threats associated with products compounded, dispensed, manufactured, propagated, distributed, or otherwise processed at the facility, including procedures for the rapid compilation and dissemination of records to appropriate authorities.

(2) Any licensed facility which engages in drug product ~~sterile~~ compounding shall conduct an annual review of its policy and procedure manual, and shall update its policy and procedure manual as necessary.

(3) Failure by any licensee or registrant to comply with its policy and procedure manual, or any part of this rule shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T.C.A. §§ ~~63-10-204,~~ 63-10-216, ~~63-10-301,~~ 63-10-304, and 63-10-306~~, 63-10-404 (4), (8), (14), (26), (29), (30), and 63-10-504(b)(1),(2)~~.

1140-07-.06 LABELING

(1) At the time of ~~dispensing of~~ labeling the final ~~sterile~~ compounded drug product, the dispensing container must bear a label which contains the following information:

(a) Patient's name ~~(if for outpatient use)~~ or healthcare entity name;

(b) Prescriber~~–~~(s) name (if for outpatient use);

(c) Pharmacy practice site name, address, and phone number (if for outpatient use);

~~(d) Identification of the pharmacist who compounded the sterile product;~~

(d)~~(e)~~ ~~When applicable, identification of the pharmacy intern or pharmacy technician who assisted in the compounding of the sterile~~Identification of the pharmacist performing the final verification;

(e)~~(f)~~ Name and amount of drug added. Additional labels or other written/typed documentation may be given to the patient separately if there is not enough space on the label to accommodate all active ingredient(s), their amount(s), activity(ies), or concentration(s) as applicable;

(f)~~(g)~~ ~~Expiration date and, when applicable, expiration time, Beyond Use Dating (BUD)~~The date, or hour and date, after which a compounded drug product must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded ("BUD");

(g) Date of compounding;

(h) Date of dispensing;

(i) Appropriate auxiliary label(s);

(j) Assigned internal identification number; and

(k) Directions for use (if for outpatient), if applicable.

(2) At the time of labeling the anticipatory drug product, the container must bear a label which contains the following information:

(a) Identification of the pharmacist performing the final product verification;

(b) Name and amount of drug added;

(c) The date, or hour and date, after which a compounded drug product must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded. ("BUD");

(d) Date of compounding;

(e) Appropriate auxiliary label(s);

(f) Assigned lot and batch; and

(g) Storage requirements, if applicable.

(3)~~(2)~~ Original medical or prescription orders for sterile products shall comply with applicable state and federal laws and regulations.

Authority: T.C.A. §§ ~~63-10-204,~~ 63-10-216, ~~63-10-301,~~ 63-10-304, and 63-10-306~~, 63-10-404 (11), (14), (19), (26), (28), (29), (30), (32), (34), and 63-10-504(b)(1),(2)~~.

1140-07-.07 HAZARDOUS PRODUCTS

(1) Physical Requirements.

(a) If the pharmacy practice site is engaged in the compounding of hazardous ~~sterile~~drug products, a suitable facility to prepare such products and minimize the risk associated with such products shall be provided.

(b) Such pharmacy practice site shall be designed and equipped for storage and have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.

~~(1) A dedicated Class II, Type A contained vertical flow biohazard cabinet is the minimally acceptable compounding site for the routine compounding of hazardous sterile products.~~

~~(2) Hazardous sterile products shall be segregated within the pharmacy practice site and storage areas so identified.~~

(c) A device must be used to continuously monitor pressure differentials in all hazardous drug compounding areas and all hazardous drug storage areas that require negative pressure. The quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring.

(2) ~~Dispensing~~Compounding hazardous drug products shall comply with USP 800.

~~(a) Prepared doses of hazardous sterile products for patients shall be placed in an appropriate outer wrap to minimize the risk exposure in case of accidental rupture of the primary container.~~

~~(b) Reasonable effort shall be made to assure that all hazardous sterile product primary containers and waste are removed from the site of use and disposed of as hazardous waste in accordance with applicable state and federal laws.~~

~~(3) Training.~~

~~(a) As part of the training for all pharmacists, pharmacy interns and pharmacy technicians involved in compounding of hazardous sterile products, an annual certification must be made by each pharmacist, pharmacy intern and pharmacy technician and the pharmacist in charge that each has read and understands the latest editions of:~~

~~1. Work Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs (Occupational); and~~

~~2. The American Society of Health-System Pharmacists (ASHP) technical assistance bulletin on handling cytotoxic and hazardous substances.~~

~~(4) Hazardous sterile products dispensed shall bear a distinctive warning label with an appropriate caution statement thereon.~~

~~(5) Gloving and gowning shall be required in the compounding of hazardous sterile products. Gloves should be rinsed frequently with a sanitizing agent (e.g., seventy percent (70%) isopropyl alcohol) and shall be changed when the integrity of the gloves is compromised.~~

~~(6) In the compounding of hazardous sterile products, a protective disposable gown made of lint-free low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs with cuffs tucked under the gloves shall be worn. Gowns and gloves used in the compounding of hazardous sterile products shall not be worn outside the sterile product compounding area.~~

Authority: T.C.A. §§ ~~63-10-404(4), (11), (26), (27), (28), (29), (30) and 63-10-504(b)(1), (2).~~63-10-216, 63-10-304, and 63-10-306.

~~1140-07-.08 ATTIRE~~

~~(1) All pharmacists, pharmacy interns and pharmacy technicians shall wear applicable outer garments and shall use applicable respiratory precautions as set out in USP 797.~~

~~Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304, and 63-10-306. Administrative History: Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. Rule was previously numbered 1140-07-.07, but was renumbered to 1140-07-.08 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014.~~

1140-07-.08 QUALITY ASSURANCE

(1) There shall be a documented, ongoing quality assurance program that monitors process validation; pharmacist(s), pharmacy intern(s), and pharmacy technician(s) performance; equipment; and environment.

(2) The program shall be designed to assure that the pharmacy practice site is capable of consistently compounding quality compounded drug products.

(3) All quality assurance programs shall comply with the standards established by USP chapters 795, 797, 800,and/or 825, pursuant to the compounding pharmacy's site practice,including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

(4) Any recall or an event that results in the halting of compounding due to a quality assurance issue by a compounding facility, in addition to an event that resulted in a Corrective Action Preventative Action, shall be reported to the Board of Pharmacy immediately.

(5) Failure by any licensee or registrant to comply with its quality assurance program shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

~~1140-07-.09 QUALITY ASSURANCE~~

~~(1) There shall be a documented, ongoing quality assurance program that monitors process validation; pharmacist(s), pharmacy intern(s), and pharmacy technician(s) performance; equipment; and environment.~~

~~(2) The program shall be designed to assure that the pharmacy practice site is capable of consistently compounding quality sterile products.~~

~~(3) All quality assurance programs shall follow applicable USP standards.~~

~~(4) As part of its quality assurance program, any licensed facility which engages in sterile compounding shall perform a gap analysis pursuant to guidelines adopted by the Board of Pharmacy. Any exceptions or serious deficiencies noted in this analysis shall be reported to the Board of Pharmacy.~~

~~(5) Failure by any licensee or registrant to comply with its quality assurance program shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).~~

~~Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304, 63-10-306, 63-10-404(26), (28), (29), and (30), and 63-10-504(b)(1), (2). Administrative History: Original chapter filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. Rule was previously numbered 1140-07-.08, but was renumbered to 1140-07-.09 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014.~~

1140-07-.09 NONSTERILE SIMPLE COMPOUNDING PREPARATIONS

(1) The combining of commercially manufactured ready-to-use products shall be exempt from the 'Compounding Facilities' requirements in the USP 795 compounding standards if the following conditions are met:

(a) Commercially manufactured ready-to-use products (that have not been manipulated) are used. Manipulation occurs when a change of a commercially available drug product occurs for patient-specific needs beyond United States Food and Drug Administration approved labeling. Crushing, using a surfactant, diluting or using a dosage form that exists as a granule or powder is manipulating for the purpose of this section.

(b) Compounding is not prepared in anticipation of medication orders;

(c) Beyond Use Dates are assigned in accordance with the currently standards of USP 795;

(d) The label complies with the labeling requirements as set forth in Tenn. Comp. R. and Regs. 1140-07-.06.

(e) The compounding record complies with the requirements as set forth in Tenn. Comp. R. and Regs. 1140-07-.02.

(2) Solely adding flavoring to medications is not considered compounding.

(3) 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. §§ 63-10-216, 63-10-304, and 63-10-306.

The meeting adjourned at 5:05pm.

May 9, 2023

A quorum of the members being present, the meeting was called to order at 9:06 a.m. with Dr. Breeden presiding.

Mr. Bynum made the motion to approve the minutes from the March 14, 2023, board meeting as presented. Dr. Rodgers seconded the motion. The motion carried.

Dr. Shell presented amended May 10, 2022, board meeting minutes for review. Mr. Bynum made the motion to approve the amended minutes from the May 10, 2022, board meeting. Dr. McKinney seconded the motion. The motion carried.

Waivers

Board rule 1140-03-.14 (12)

Mr. Bynum made the motion to approve the waiver request for **Georgia Shuck, D.Ph.** to be the pharmacist in charge for Hancock County Hospital, Sneedville, TN and Hawkins County Memorial Hospital Rogersville, TN. Dr. Blane seconded the motion. The motion carried.

Dr. McKinney made the motion to approve the waiver request for **Aaron Logan Smith, Pharm. D.** to be the pharmacist in charge for NPS Pharmacy Direct and NPS Pharmacy at My House, Nashville, TN. Mr. Bynum seconded the motion. The motion carried.

Board rule 1140-04-.03 (1), (2) (a) & (b)

Dr. Rodgers made the motion to approve the waiver request for **Morristown West** for hot and cold running water, refrigeration and the 180 square footage. Dr. McKinney seconded the motion. The motion carried.

Mr. Bynum made the motion to approve the waiver request for **Town & County Drugs, Clarksville, TN** of the 180 square footage. Dr. McKinney seconded the motion. The motion carried. Dr. Blane was recused.

General Discussion

Mr. Bynum asked if the Executive Director could approve waivers for square footage, hot and cold running water and refrigeration without asking the applicants to appear. Mr. Bynum stated that it would be more efficient since the applicants are only before the board for a short period of time and the pharmacist investigators have already inspected the space. This request does not include the waiver for pharmacist in charge at two separate locations. The Board agreed to allow the Executive Director to present the waiver of refrigeration, hot and cold running water and square footage without the applicant appearing. The Executive Director must explain to the applicant that they can appear if they want just in case the Board has any questions or may have to appear at the next board meeting.

Appearance

Mary Garrett, RT

Ms. Garrett answered "yes" to the question that asked "Have you ever been convicted (including nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentenced was imposed or suspended. Documentation submitted indicates the Ms. Garrett pled guilty to domestic assault on 11/17/2021 and theft under $1000.00 on 1/10/2018. After discussion, Dr. Rodgers made the motion the to approve Ms. Garrett's application for registration as a pharmacy technician. Dr. Harshbarger seconded the motion. The motion carried.

Tennessee Pharmacist Association

Anthony Pudlo, PharmD., Executive Director of Tennessee Pharmacist Association (TPA) spoke to the board concerning drug donation depository program which has been renamed the Kevin Clauson Drug Repository Act. The Kevin Clauson Drug Repository Act will go into effect on January 1, 2024. The drug products and patient eligibility has been expanded under this act.

Dr. Pudlo spoke to the board about SB0753 which expanded the board from seven members to nine members. The new members will be a pharmacist and pharmacy technician. The service term has increased from 6 years to 7 years beginning with members appointed after July 1, 2023. The law will also allow the board to give advisory opinions affecting the licensee making the request.

Dr. Pudlo informed the board that TPA will be working on improving the collaborative practice agreement.

Dr. Olivia Welter, Director of Professional Affairs, informed the board that the Resolutions Committee with be presenting the following TPA policy statements for debate at the 2023 TPA Summer Meeting; 23.3: Management of medication for substance use disorder and 23.4 Modes of collaborative practice to increase patient access to healthcare. Dr. Welter stated that the Committee welcomes any feedback that the board may have.

Dr. Welter informed the board of the 2023 TPA Summer Meeting scheduled for June 22-25, 2023, in New Orleans, LA.

Appearance
Airgas

Stanley T Queener, CPS, Director of Compliance with Airgas Company, appeared before the board to ask for interpretation on Oxygen Supplier versus Wholesale/Distributor as it relates to Airgas' operations. The Board asked for a pharmacist investigator for clarification. Dr. Denaburg explained that when Airgas makes the oxygen, they are considered a manufacturer, when the wholesale the oxygen, selling to others, they are considered a wholesale/distributor. The oxygen supplier license when Airgas gets a medical order/prescription and dispenses the oxygen to a patient. Dr. Denaburg referenced board rule 1140-01-.01 (29) "Oxygen Supplier means any person who sells, delivers, distributes or wholesales medical gases which require a prescription or medical order prior to administration, dispensing or delivery and which are considered legend drugs pursuant to the federal Food, Drug, and Cosmetic Act to any person residing in this state". After discussion, Airgas would need a manufacturer license if they were manufacturing or transfilling medical gas or performing intracompany sales, an oxygen supplier license if they are distributing by prescription/medical order directly to a patient, and a wholesaler/distributor license if they are storing medical gas or dispensing to other facilities unless through intracompany sales. This would be absent any requirements that they may need through the Health Facilities Commission.

Director Report

Dr. Shell asked the board for approval for travel authorization for TPA Summer Meeting scheduled for June 22-25, 2023, in New Orleans, LA, NADDI Tennessee Training Conference Meeting scheduled for June 22, 2023, and NABP District III Meeting scheduled for September 10-13, 2023, .in Sarasota, FL. After discussion, Mr. Bynum made the motion to approve the request for travel for to the TPA Summer Meeting, NADDI Meeting and NABP District III Meeting. Dr. Blane seconded the motion. The motion carried.

Dr. Shell asked the board for guidance concerning storage of records. The office staff has had several questions on whether records and can stored electronically, specifically prescription records. After discussion, the board stated that electronic storage of pharmacy records to be readily retrievable is acceptable and encouragement of pharmacy staff to be trained on how to retrieve the electronic records.

Remote Order Entry Policy Dr. Rodgers volunteered to work with Dr. Shell to update the policy for Remote Order Entry and Centralized Prescription Processing.

Pharmacy Technician Vaccine Administration- Dr. Shell was granted the authority to grant waivers for pharmacy technician giving immunization that is referenced in the PREP Act. Dr. Shell stated that the Prep Act portion that pertains to pharmacy technician giving specific immunization may be extended and the waiver would not be necessary.

Dr. Grinder gave the investigator's report.

Dr. Shell informed the board that the pharmacist investigator's currently are using NABP Universal Inspection Form when conducting sterile inspections. Dr. Shell stated that NABP is in the process of updating the inspection form due to changes with the UPS guidelines and that the Board has received a

comment from some stakeholders that they were not able to opine on the changes that NABP is considering and have issues with the investigators using this form.

Dr. Shell introduced Shannon Kelly, D.Ph. as the new pharmacist investigator.

Dr. Shell presented language surrounding amended pharmacy technician rules to the Board, as well as a discussion around registering of pharmacy interns. After discussion, the Board asked for additional language to be considered around pharmacy support personnel, as well as a consistent and clear definition of the types of supervision for both technicians and interns. Dr. Shell will continue to work on the language and engage schools and colleges of pharmacy as it relates to interns in order to bring updated language back to the Board for consideration. The Board members also requested for updated language around what type of law book is required in pharmacies.

General Discussion

Mary Katherine Bratton, General Counsel for the Tennessee Department of Health appeared before the Board of Pharmacy after discussion around what information in complaints could be provided to the Board and at what time the information could be shared. Ms. Bratton oversees the Office of General Counsel. Ms. Bratton shared that when a consent order is presented to the Board, it only includes information that the respondent has agreed as facts of the case and is the only information that can be shared regarding the investigation as they have waived their confidentiality related to those facts. This is to ensure that the Board remains unbiased in the event that the complaint can not be settled in a consent order and needs to be contested, where the Board will then serve as the jury. If the Board does not agree with the discipline presented in a Consent Order, they have the opportunity to deny the Consent Order and provide the Office of General Counsel with discipline that they feel is more appropriate. If the Board does not feel as if the consent orders are being drafted with enough information or if there any concerns with services provided by the Office of General Counsel, Ms. Bratton indicated that her door was open, and she would be willing to discuss the matter with any Board member.

Office of General Counsel

Mr. Gibbs informed the board that there are currently 58 cases open for discipline within the Office of General Counsel. Of those 58 cases, 29 are eligible for a contested case hearing.

Notice:

The Tennessee Board of Pharmacy along with the Tennessee Department of Health has been named as two of the defendants contained in the master docket for the National Prescription Opiate Litigation. The Office of the Attorney General is aware of this litigation.

Rules:

There shall be ongoing discussion regarding other rulemaking projects.

Proposed legislation:

Pharmacy, Pharmacist- As introduced, authorizes as part of the practice of pharmacy the prescribing of dietary fluoride supplements, certain immunizations agents, opioid antagonists, and certain other drugs and products; makes various other changes to pharmacy practice.

Amends T.C.A. Title 33; Title 58; Title 63; Title 68; and Title 71. (HB0282)

- Assigned to Health subcommittee (House) and Senate Health and Welfare Committee

Sunset Laws-As introduced, extends the board of pharmacy to June 30, 2027.- Amends TCA Title 4, Chapter 29 and Title 63, Chapter 10. (SB0034)

- Submitted to the governor for signature

Health Care- As introduced, permits the services authorized in a collaborative pharmacy practice agreement to include weight management services; requires the bureau of TennCare to make available, or cause to be made available, anti-obesity medication to recipient if the medication is medically necessary-Amends TCA Title 63, Chapter 10 and Title 71, Chapter 5 (SB0674)

- Amended in Senate Health and Welfare Committee, referred to Finance, Ways and Means as amended.
- Taken off notice of the subcommittee of Finance, Ways, and Means Committee

Drug, Prescription- As introduced, makes various changes to the prescription drug donation repository program operated by the department of health- Amends TCA Title 56; Title 63 and Title 68. (SB675)

- Signed into law as Public Chapter 200

Pharmacy, Pharmacists- As introduced, vacates the board of pharmacy, adds an additional pharmacist and pharmacy technician members to the board, and make various other changes to the board's composition; authorizes the board to employ or retain general counsel- Amends TCA Title 4, Chapter 29; Title 63, Chapter1 and Title 63 Chapter 10, Part 3 (SB0753)

- Amendment signed by Speaker of the Senate on May 3, 2023

Consent Orders

Mr. Bynum made the motion to deny **CVS Pharmacy #5636** consent order. Dr. Blane seconded the motion. The motion carried. Dr. Rodgers was recused.

Mr. Bynum made the motion to accept **CVS Pharmacy #6355** consent order with a $150.00 civil penalty for violating board rule 1140-03-.14 (2) (a), (4), (5), (6) and (7). Dr. Blane seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **Donna Christian, RT** consent order with a $100.00 civil penalty for violating T.C.A §63-10-305 (8). Dr. Rodgers seconded the motion.

Mr. Bynum made the motion to accept **Matthew Hobbs, D.Ph**. consent order for license suspension for violating T.C.A §63-10-305 (4), (6) & (8). Dr. Blane seconded the motion. The motion carried.

Dr. McKinney made the motion to accept **Jennifer Walker, RT** consent order with a $100.00 civil penalty for violating T.C.A §63-10-305 (8). Mr. Bynum seconded the motion. The motion carried.

Dr. Rodgers made the motion to accept **Monica Belcher, RT** consent order to voluntary surrender her pharmacy technician registration for violating T.C.A §63-10-305 (4), (6) & (8). Mr. Bynum seconded the motion. The motion carried.

Dr. Bynum made the motion to accept **Madison Avenue Pharmacy** consent order with a license reprimand, a $1000.00 civil penalty and the license placed on 1 year probation for violating T.C.A §63-10-305 (4), (6) & (8). Mr. Bynum seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **Renee Huskey, D.Ph**. consent order with a license reprimand, 30 continuing education hours in non-sterile compounding and license on probation for 1 year for violating T.C.A §63-10-305 (4) & (8). Dr. McKinney seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **John Gibson, D.Ph.,** consent order with a license reprimand for violating T.C.A §63-10-305 (6) & (8). Dr. McKinney seconded the motion. The motion carried.

Dr. Blane made the motion to accept **Long & Gibson Pharmacy** consent order with a license reprimand and a $1000.00 civil penalty for violating T.C.A §63-10-305 (4), & (8). Dr. McKinney seconded the motion. The motion carried.

Dr. Rodgers made the motion to deny **Michal Richard, RT** consent order. Mr. Bynum seconded the motion. The motion carried.

Mr. Bynum made the motion to deny **Snapp Ferry Pharmacy** consent order. Dr. McKinney seconded the motion. The motion carried.

Mr. Bynum made the motion to deny **Jack Ward, D.Ph** consent order. Dr. Blane seconded the motion. The motion carried.

Dr. McKinney made the motion to accept **Walgreens Pharmacy #07808** consent order with a $100.00 civil penalty for violating T.C.A §63-10-305 (8). Mr. Bynum seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **Walgreens Pharmacy #6532** consent order with a $100.00 civil penalty for violating T.C.A §63-10-305 (8). Dr. McKinney seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **Guardian Pharmacy of TN One, LLC dba Middle TN Pharmacy** consent order with a license reprimand and $600.00 civil penalty for violating T.C.A §63-10-305 (8). Dr. McKinney seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **Shawnelle Wilson, RT** consent order to voluntary surrender her pharmacy technician registration for violating T.C.A §53-10-104 (a). Dr. Blane seconded the motion. The motion carried.

The meeting adjourned at 4:11 p.m.

May 10, 2023

A quorum of the members being present, the meeting was called to order at 9:02 a.m. with Dr. Breeden presiding.

Contested Cases
Christine Kozlowski, RT

Ms. Kozlowski was present but not represented by legal counsel. Mr. Richardson represented the State. Mr. Phillip Hilliard was the Administrative Law Judge. After discussion, Ms. Kozlowski asked for a continuance to retain an attorney.

Tosha Pugh, RT

Ms. Pugh was not present nor represented by legal counsel. Mr. Peters represented the State. Mr. Phillip Hilliard was the Administrative Law Judge. Mr. Peters asked to proceed in default. Dr. McKinney made the motion to proceed in default. Dr. Blane seconded the motion. The motion carried. Mr. Peters passed out the Notice of Charges. Ms. Pugh is charged with violating T.C.A. §63-10-305 (4), (6) and (8). After discussion, Mr. Bynum made the motion to revoke Ms. Pugh's registration as a pharmacy technician. Dr. Rodgers seconded the motion the motion. The motion carried. Dr. McKinney made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee and those visiting Tennessee. Dr. Blane seconded the motion. The motion carried.

Dr. McKinney made the motion to adjourn at 10:10 a.m. Dr. Blane seconded the motion. The motion carried.

The minutes were approved and ratified at the July18-19, 2023 board meeting.