TENNESSEE BOARD OF PHARMACY
665 Mainstream Dr.
Nashville, TN 37243

BOARD MEMBER PRESENT
Katy Wright, D. Ph President
Adam Rodgers, D.Ph., Vice President
Melissa McCall, D. Ph
Richard Breeden, D.Ph.
Rissa Pryse, D.Ph.
Jake Bynum, Consumer Member

BOARD MEMBER ABSENT
Shanea McKinney, D.Ph.

STAFF PRESENT
Terry Grinder, Interim Executive Director
Matthew Gibbs, Associate General Counsel
Mark Cole, Associate General Counsel
Rebecca Moak, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Richard Hadden, Pharmacy Investigator
Larry Hill, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Derek Johnston, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Rita Golden, Pharmacy Investigator
Patricia Beckham, Pharmacy Investigator
Sheila Bush, Administrator Director

The Tennessee Board of Pharmacy convened on Tuesday September 14, 2021, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present by the meeting was called to order at 9:01 a.m. with Dr. Wright presiding. Dr. Wright welcomed students from Lipscomb University, University of Tennessee, Belmont University and South College.

Rulemaking Hearing
Mr. Gibbs present the Notice of Rulemaking Hearing, statement of impact to small business and a regulatory flexibility analysis financial responsibility to the board.

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Sequence Number: _____
Notice ID(s): _____
File Date: _____

Notice of Rulemaking Hearing

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

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

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

ADA Contact:	ADA Coordinator
Address:	710 James Robertson Parkway, Andrew Johnson Building, 5th Floor, Nashville, Tennessee 37243
Phone:	(615) 741-6350
Email:	Tina.M.Harris2@tn.gov

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

Address 1:	Metro Center	
Address 2:	665 Mainstream Drive, ------ Conference Room	
City:	Nashville	
Zip:	37228	
Hearing Date :	September 14, 2021	
Hearing Time:	9:00 a.m.	_**X**_CST/CDT ___EST/EDT

Additional Hearing Information:

Revision Type (check all that apply):

___ Amendment
_X_ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
1140-09	Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesalers/Distributors
Rule Number	**Rule Title**
1140-09-.07	Inspections of manufacturers and distributors of medical devices

Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter 1140-09
Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesalers/Distributors
New Rule Section

Table of Contents

Authority: T.C.A. §§ 63-10-304(b)(1); 63-10-306(f); 63-10-311

Rule 1140-09-.07. Inspections of manufacturers and distributors of medical devices.

(1) Manufacturers and distributers of a medical device shall submit either:

(a) A Form 482 issued by the United States Food and Drug Administration ("FDA") as evidence of a facility inspection, and, if applicable, a response letter, as documented on a Form 483, from the FDA that indicates responses to the most recent inspection findings and demonstrates no further action is warranted by the manufacturer, distributor or FDA; or

(b) Documented evidence, such as International Organization for Standardization ("ISO") 13485 certification number, date of visit and expiration date of certificate, from a Notified Body that the firm is in good standing and their ISO 13485 certification is valid. Responses may include dates of Phase 1 and Phase 2 assessments from a Notified Body/Registrar in the certification process; or

(c) Evidence of successful Medical Device Single Audit Program certification. Alternatively, a report including corrective action plans for a Medical Device Single Audit Program certification and approval.

between December 1 and December 31 of each calendar year. Submission of documents referenced in paragraphs 1(a) – (c), above, which demonstrate immediate and continuous compliance with any and all federal and state laws and regulations, shall serve in lieu of a physical, on-site inspection conducted by the Board, subject to paragraph 3, below.

(2) Failure to submit documents referenced in paragraphs 1(a) – (c), above, or submission of a self-audit which does not demonstrate immediate and continuous compliance with any and all federal and state laws and regulations may result in a request from the Board for the production of any and all corresponding documents related to any mandatory reporting or compliance requirements directed by the federal government or its agencies, the International Standards Organization or the Medical Device Single Audit Program.

(3) Notwithstanding any rule provision to the contrary, the Board retains authority to conduct any inspection or investigation of a manufacturer or distributer of a medical device when, in the Board's sole determination, public health, safety, and welfare necessitates such an inspection or investigation.

Authority: T.C.A. §§ 63-10-304(b)(1); 63-10-306(f); 63-10-311

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

Date: _____

Signature: _____

Name of Officer: Matt Gibbs

Title of Officer: Senior Associate General Counsel
Department of Health

Subscribed and sworn to before me on: _____

Notary Public Signature: _____

My commission expires on: _____

Department of State Use Only

Filed with the Department of State on: _____

_____
Tre Hargett
Secretary of State

The rulemaking hearing adjourned at 9:20 a.m.

Minutes

Dr. McCall made the motion to accept the July 13, 2021 minutes as presented. Dr. Breeden seconded the motion. The motion carried.

Presentation
Tennessee Pharmacist Association

Anthony Pudlo Pharm.D., Executive Director of Tennessee Pharmacist Association. Dr. Pudlo spoke to the board about Public Chapter 569 and that the TPA has been receiving telephone calls concerning about the national guidance and how it aligns with the state response to COVID19 from pharmacist and pharmacy technicians about their roles with testing, immunization, booster shots, injectables products with the Prep Act. TPA will be conducting a webinar concerning COVID19 and to allow pharmacists and pharmacy technicians to discuss their concern.

Dr. Pudlo spoke to the board about Public Chapter 569as it relates to pharmacy benefits reform and ensuring access to a pharmacy of the patient choosing. TPA has been speaking with the TN Department of Commerce and Insurance about this issue and will conduct webinars to help educate pharmacists how to properly work with their PBM and filing appeals.

Dr. Pudlo stated that he understands that there has been discussion with TPA and the board working together in modernizing some of the rules and regulations. Dr. Pudlo stated that TPA is committed to helping the board. TPA is still working with about 30 pharmacies using the technician product verification pilot program.

Appearance
Jennifer Putnam, Esq., Assistant Commissioner, Department of Health, Division of Health Licensure and Regulations, spoke to the board about the Executive Director position and asked that they submit names to her of pharmacist that may be interested in the position. Ms. Putnam asked the board to nominate a member to participate in the hiring process. After discussion, Dr. Pryse nominated Dr. Rodgers to participate in the hiring process. Dr. Breeden seconded the motion. The motion carried.

Walgreens
Gene Hoover, Regional Healthcare Director and Nicole Culver, Director Pharmacy of Affairs, appeared before the board to ask about the pharmacist to technician ratio increases. Dr. Culver stated that Walgreens will not be able to have the pharmacy technicians national certified in a timely manner and is asking for enforcement discretion concerning board rule 1140-02-.07(13). Mr. Gibbs stated this issue would need to be for all pharmacies and that a preliminary approval be given and full ratification at the November 16-17, 2021 board meeting. Pharmacies will also need to be aware that if the board does not ratify these requests, they must stop immediately. After discussion, Mr. Bynum made the motion for Dr. Wright, Dr. McCall and Dr. Breeden, review and give preliminary approval of the pharmacist to pharmacy technician ratio affidavits if there are problems or concerns. Dr. Rodgers seconded the motion. The motion carried. After further discussion, Dr. Rodgers made the motion that an Accreditation Council for Pharmacy Education (ACPE) immunization certified pharmacy technician would be counted as a certified technician in the pharmacist-to-technician ratio for the purposes of giving vaccines but does **NOT** allow for additional duties of a certified technician. Dr. Breeden seconded the motion. The motion carried.

Waivers
Board rule 1140-01-.07(3) (c)5

Dr. Breeden made the motion to grant **Brittany Scott, D.Ph**. request to waive the one hundred and sixty (160) internship hours. Mr. Bynum seconded the motion. The motion carried. Dr. Hester must successfully take and pass the MPJE.

General Discussion

Mr. Gibbs stated that the Prep Act was amended on September 10, 2021 to allow pharmacies to order and administer remedies associated with COVID. It also allows pharmacy technicians to administer the same. The criteria listed in the Prep Act must be met. Dr. Calita Richards, Director of the Office of Pharmacy, Department of Health spoke to the board about the distribution of the medications.

Reinstatement
Randall S Jenkins, D.Ph.

Dr. Jenkins requested to have his licensed reinstated. Dr. Jenkins' license was revoked on 03/09/2021. After discussion, Dr. Rodgers made the motion to reinstate Dr. Jenkins' license. Dr. Jenkins' license will run

concurrent with his TPRN contract once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Breeden seconded the motion. The motion carried.

(a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in;
(b) The Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, except in the case of an emergency or upon proper referral from the Respondent's primary physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;
(c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing same from the physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;
(d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;
(e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
(f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacist Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;
(g) The Respondent shall successfully complete the Multistate Pharmacy Jurisprudence Examination
(h) The Respondent shall not serve as pharmacist-in-charge the respondent's pharmacist-in-charge shall submit to the Board quarterly reports detailing Respondent's work performance for a period of three (3) years from the state date of Probation; the Respondent may not work more than 40 hours over a 5 day period, however, the Respondent may petition the Board for a modification of this time limitation after (2) years from the start date of Probation;
(i) Respondent shall not work as a "floater" for a period of three (3) years from the start of Probation, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;
(j) Respondent shall satisfy all past due continuing pharmaceutical education, successfully complete the Multi-State Pharmacy Jurisprudence Examination (MPJE), pay all cumulative license renewal fees and any applicable penalties; complete a period of pharmacy internship for a minimum of one hundred and sixty (160) hours and must be completed within ninety (90) consecutive days.

Presentation
Vanderbilt University Medical Center
Bedside Delivery

Rusty Catlin, Director of Outpatient Pharmacy, Vanderbilt University Medical Center, appeared before the board concerning the Bedside Delivery Attestation form section 3 which states" Delivery must occur by certified pharmacy technician, pharmacist or pharmacy intern". Dr. Catlin asked if non-certified pharmacy technicians can assist with bedside delivery due to the challenges of employing certified pharmacy technicians and needing the certified pharmacy technicians at a higher level. After discussion, Dr. Breeden made the motion to change section 3 of the Bedside Delivery Attestation form from certified to registered pharmacy technicians. Dr. McCall seconded the motion. The motion carried.

OGC/Investigative Report

Mr. Gibbs informed the board that there are currently 40 cases open for discipline within the Office of General Counsel. Of those 40 cases, 5 are eligible for a contested case hearing.

Mr. Gibbs informed the board that 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.

Mr. Gibbs informed the board that in response to Public Chapter 149, regarding inspection and oversight of compounding pharmacies, shall begin internal review following this meeting. Mr. Gibbs stated that the rules that have been drafted does not cover the beyond use dates. Dr. Denaburg spoke to the board concerning the changes to USP 825, 800, 700 and how there are conflicts. Mr. Gibbs stated that the board can decide on how they want to proceed. Dr. Wright will work with the committee to work on the compounding rules.

Mr. Gibbs asked the board for approval to not investigate a complaint if the allegation is not against the practice act. After discussion, Dr. Breeden made the motion that complaints received and that are not against the pharmacy practice act, that no investigation is needed. Dr. McCall seconded the motion. The number of complaints received and are not against the pharmacy practice act, will still be reported on the investigative report.

Mr. Gibbs stated that the Complaint Committee has reviewed 35 complaints.

Mr. Gibbs explained to the board that the FDA has decided to pause enforcement of interstate distribution of compounding drugs until October 2022. After the board voted to pursue legislation, the Department of Health has decided to not take it to the General Assembly, but the board members can ask TPA or their legislator, individually not representing the board, to carry the legislation.

Mr. Gibbs explained that the board does not have statutory authority to require the pharmacy technician to be certified. The definition in the pharmacy practice act, statutorily, states that certification is voluntary. The drafted rules required that all pharmacy technicians must be certified by their next renewal cycle. Also, there is delignated list of things and individuals that the board can license and at the end of that list it states, "anything that is under federal law that requires a license". The board does not have the ability to create a licensing category for pharmacy interns per statute. Mr. Gibbs stated that the pharmacist to pharmacy technician ratio rules can go forward if the board chooses. Dr. Wright nominated Dr. McCall to

work with Mr. Gibbs for language concerning the pharmacist to pharmacy technician ratio. After discussion, Dr. Rodgers made the motion to change the pharmacist to pharmacy technician ratio to 6:1 and an unlimited number if they are certified. Dr. Breeden seconded the motion. The motion carried.

Consent Orders

Dr. Rodgers made the motion to accept **Lowell Grizzle, D.Ph**. agreed order to permanently voluntarily retired his pharmacist license. Dr. Grizzle violated §T.C.A. 63-10-305 (8). Dr. McCall seconded the motion. The motion carried.

Dr. Pryse made the motion to accept **Christina Ivester, RT**, consent order to revoke her pharmacy technician. Ms. Ivester violated §T.C.A. 63-10-305 (4). Mr. Bynum seconded the motion. The motion carried. Dr. Breeden was absent.

Dr. Pryse made the motion to accept **Jessica Waldman, RT**, consent order to voluntarily surrendered her pharmacy technician. Ms. Waldman violated §T.C.A. 63-10-305. Dr. McCall seconded the motion. The motion carried. Dr. Breeden was absent.

Dr. Rodgers made the motion to accept **Sheri G Simeon, D.Ph**., consent order to suspend Dr. Simeon's pharmacist license. The suspension stayed and her license place on probation to run concurrent with her TPRN contract. Dr. Simeon violated §T.C.A. 63-10-305. Dr. McCall seconded the motion. The motion carried. Dr. Breeden was absent.

Mr. Bynum made the motion to accept **Justin Kickliter, D.Ph**., consent order to suspend his license for 180 days, the suspension stayed with a $2700.00 civil penalty. Dr. Kickliter violated §T.C.A. 63-10-305 (4). Dr. Breeden seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **Broadway & Main Pharmacy**, consent order for a 2year probation. Broadway & Main Pharmacy violated §T.C.A. 63-10-305 (4). Dr. Breeden seconded the motion. The motion carried.

Dr. Breeden made the motion to accept **Mary Kathleen Kudrey, RT**, consent order to suspend her pharmacy technician registration. Ms. Kudrey violated §T.C.A. 63-10-305 (6). Dr. McCall seconded the motion. The motion carried.

Dr. Breeden made the motion to accept **Anthony A Okonkwo, D.Ph.**, consent order to suspend his license for 1 year. Dr. Okonkwo violated §T.C.A. 53-11-401 (a) (1). Mr. Bynum seconded the motion. The motion carried. Dr. Wright was recused.

The meeting adjourned at 3:17 p.m.

The minutes were approved and ratified at the November 16, 2021 board meeting.