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. Shanae McKinney, D.Ph. Rissa Pryse, D.Ph. Jake Bynum, Consumer Member

STAFF PRESENT

Terry Grinder, Interim Executive Director Matthew Gibbs, 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 July 13, 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 9:04 a.m. with Dr. Wright presiding.

Minutes

Dr. Bynum made the motion to accept the minutes as presented. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

Legislative Updates

Public Chapter 37

This act prohibits agencies subject to sunset review from promulgating rules or adopting policies to exempt members solely by virtue of their status as members.

This act took effect March 23, 2021.

Public Chapter 136

This act was one of the Department of Health's legislative initiatives, relative to the Controlled Substance Monitoring Database (CSMD). First, the act authorizes the state's chief medical examiner, or county medical examiner, to allow designees to approve death investigations. Next, this act allows deidentified CSMD data, rather than only aggregate, to be shared, with the intent of improving information access. Additionally, this act allows for CSMD data to be shared with additional state, county, or federal agencies outside of Tennessee. Lastly, this act decreases the quorum requirements of the CSMD committee by one member, but still have a majority of members present to conduct regular committee business (6).

This act took effect April 13, 2021.

Public Chapter 149

This act makes changes in the process of regulating compounding pharmacies. First, this act requires that prior to renewing or applying for their license in Tennessee, an out-of-state pharmacy practice site must submit to the Tennessee board of pharmacy its most recent inspection by the regulatory agency of their respective state, conducted within the past year. It also authorizes the Tennessee board of pharmacy to request more information if needed. Second, it requires the out-of-state pharmacy to notify the board within fourteen (14) business days of receipt of any order or decision by any regulatory agency in their state, rather than simply their in-state licensing entity. Lastly, rather than a quarterly report on the quality of products dispensed, this act requires out-of-state pharmacies who engage in sterile compounding make this information available to the board of pharmacy upon request and in a timely manner as defined by the board. A pharmacy that engages in sterile compounding, except hospital pharmacies compounding for inpatients of a hospital, shall make the quantity of sterile compounded products available to the board of pharmacy upon request. However, the executive director of the board of pharmacy may request the information from a hospital pharmacy for cause.

This act took effect April 13, 2021.

Public Chapter 179

This act authorizes unlicensed graduates of certain medical training programs to provide telehealth services, provided they maintain the same existing standards for telehealth that licensed providers must meet.

This act took effect April 20, 2021.

Public Chapter 230

This act revises the definition of marijuana to clarify that it does not include a product approved as a prescription by the Food and Drug Administration (FDA).

This act took effect April 22, 2021.

Public Chapter 242

This act authorizes records custodians to petition a court for injunctive relief from individuals making frequent public records requests with the intent of disrupting government operations, following a fifth (5th) public records request. A records custodian can only petition a court if they notify the person in writing stating the specific conduct may constitute intent to disrupt government operations, and that the person continues to do so. The individual upon a court enjoinment would not be able to make public requests at the agency for up to one (1) year.

This chapter took effect April 28th, 2021 and will sunset July 1, 2025.

Public Chapter 291

This act requires the attorney general and reporter to not approve an emergency rule if the emergency rule does not meet the statutory criteria for adoption of the rule.

This act took effect July 1, 2021.

Public Chapter 328

This act requires that starting December 1, 2023, state agencies submit a report of their effective rules to the chairs of the government operations committee every eight (8) years. The report is required to include a brief description of the department's operations that each chapter affects, as well as each rule and its administrative history, which would include the original promulgated date and the dates the rule was last amended, if applicable. Additionally, the report would include a determination of each rule on whether it is adheres to current state or federal law or court rulings, should be amended or repealed, reviewed further, or continue in effect without amendment. Lastly, if there are any intentionally false statements in the report, the government operations committee would have the ability to vote to request the general assembly to remove a rule or suspend the department's rulemaking authority for any reasonable period of time.

This act took effect July 1, 2021.

Public Chapter 346

This act was one of the Division of TennCare's legislative initiatives, relative to collaborative pharmacy practice agreements. In doing so, it authorizes the Chief Medical Officer of the department of health to implement a statewide collaborative pharmacy practice agreement specific to the distribution and administering of COVID-19 vaccine, to be reimbursed through TennCare. This act requires pharmacists to maintain copies of the agreement and documentation of the vaccine administration training program on file and make them available to the department of health on request.

This act took effect May 6, 2021.

Public Chapter 453

This act requires public or private entities or businesses that operate a building open to the general public to post signage regarding public restroom access in certain situations. Specifically, this applies to entities or businesses that have restroom policies allowing either biological sex to use any public restroom within their building. The act includes requirements for language, size, location, and even color for the signage. The act excludes unisex, single occupant restrooms or family restrooms intended for use by either sex.

This act took effect July 1, 2021.

Public Chapter 461

This act requires TDH licensing authorities, upon learning a healthcare prescriber was indicted of certain criminal offenses (controlled substance violations or sexual offenses), to automatically restrict the prescriber's ability to prescribe Schedule II controlled substances until the case reaches a final disposition. The restriction shall be removed upon sufficient proof of acquittal or dismissal/nolle prosequi. The act further requires licensing authorities to automatically revoke the license of a practitioner that is convicted of those same criminal offenses. A new license shall be granted if the conviction is overturned or reversed (but shall be restricted related to prescribing if the case has not reached final disposition). In addition, the act requires the licensing authority to suspend the license of midlevel practitioner (APRN/PA) upon finding the healthcare professional failed to comply with physician collaboration requirements. Finally, this act requires facility administrators to report certain disciplinary actions concerning licensed personnel to the professionals' respective boards.

This act took effect May 18, 2021.

Public Chapter 513

This act prohibits the Governor from issuing an executive order and a state agency, department or political subdivision from promulgating, adopting, or enforcing an ordinance or resolution that requires a person to receive an immunization, vaccination, or injection for the SARS-CoV-2 virus or any variant of the SARS-CoV-2 virus. It also deletes the previous override during an epidemic or immediate threat of an epidemic of an objection against vaccination that was made on the basis of religious tenets. The law prohibits requiring the COVID-19 vaccine to attend k-12 schools. The prohibition against requiring vaccines does not apply to governmental entities subject to federal or state statute or rule that prohibits the entity from requiring medical treatment for those who object on religious grounds or right of conscience. The law also does not apply to students of a public institution of higher education delivering healthcare services when the student is participating in/fulfilling requirements of a program in medicine, dentistry, pharmacy, or another healthcare profession.

This act took effect May 25, 2021.

Public Chapter 531

This act limits an agency's authority to promulgate rules without a public hearing. There are exceptions to the public hearing requirement. These exceptions include emergency rules, rules that are nonsubstantive modifications to existing rules (like clerical updates), rules that repeal existing rule, or rules that eliminate or reduce a fee described by an existing rule.

This act took effect July 1, 2021.

Public Chapter 532

This act authorizes the joint government operations committee to stay an agency's rule from going into effect for a period of time not to exceed ninety (90) days. If the government operations committee determines that subsequent stays are necessary, then the joint committee may issue consecutive stays, each for an additional ninety (90) day period, so long as such stays do not extend beyond the fifth legislative day of the year following the year in which the rule is filed with the secretary of state. The initial stay may be done by either the house or senate government operations committee, but subsequent stays must be by agreement by the committees of both chambers. A stay is effective when the respective committee files written notice with the secretary of state, and the respective committee shall specify the length of effectiveness of the stay.

This act took effect May 25, 2021.

Public Chapter 577

This public chapter establishes the medical cannabis commission which is administratively attached to the department of health for purposes of budgeting, audit, use of IT systems, HR support, clerical assistance and administrative support. The commission is composed of 9 members. The Governor appoints 3 members (1 from each grand division), the Lt. Governor appoints 3 members (1 must be a physician and 1 a pharmacist), and the Speaker of the House appoints 3 members (1 must be a physician and 1 a pharmacist). The commission must be impaneled and hold its first meeting by October 1, 2021. The

commission is required to meet at least once every two months prior to March 2023. The commission shall appoint an executive director.

The commission is to examine federal laws and other states' laws regarding medical use of cannabis, including issues relating to patient qualification, patient registration, role of practitioners in recommending/prescribing, establishing guidelines for acceptable medical uses, development of a standard of care, etc.

This act took effect May 27, 2021.

These are general summaries of legislation. For more detailed information and all specifics/requirements, please review the links to each public chapter

OGC

Mr. Gibbs informed the board that there are currently 43 cases open for discipline within the Office of General Counsel. Of those 43 cases, 2 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 the rules pertaining to pharmacy interns, pharmacy technicians and medical devices are currently in internal review. The medical device rules are scheduled for a rulemaking hearing on September 15, 2021. Mr. Gibbs also stated that rules in response to Public Chapter 149, regarding inspection and oversight of compounding pharmacies, shall begin internal review prior to September 2021.

Investigative Report

Mr. Gibbs stated that the Complaint Committee has reviewed 73 complaints.

Consent Order

Dr. Pryse made the motion to accept **Kulsoom Abidi, D.Ph.**, consent order with a \$300.00 civil penalty. Dr. Abidi violated board rule 1140-02-.02(3). Dr. McCall seconded the motion. The motion carried.

Dr. Rodgers made the motion to accept **Ujwalkmuar Panhalkar**, **D.Ph**. consent order with a \$100.00 civil penalty. Dr. Panhalkar violated board rule 1140-02-.02 (3). Dr. Breeden seconded the motion. The motion carried.

Dr. Breeden made the motion to accept **Marisa Jordan**, **RT**, consent order with a \$100.00 civil penalty. Ms. Jordan violated board rule 1140-01-.10 (4). Dr. McCall seconded the motion. The motion carried.

Dr. Rodgers made the motion to reject **Walgreens Pharmacy #9208** consent order as presented and to issue a Letter of Warning with a root cause analysis. Dr. McCall seconded the motion. The motion carried.

Dr. Breeden made the motion accept **CVS Pharmacy** #3762 consent order with a \$50.00 civil penalty. CVS Pharmacy # 3762 violated board rule 1140-03-.14 (2)(a) & (b). Dr. McKinney seconded the motion. The motion carried.

Dr. Breeden made the motion to accept **Joseph Mill, RT** consent order for revocation. Mr. Mills violated T.C.A. §53-11-402 (a)(3). Dr. McKinney seconded the motion. The motion carried.

Dr. Rodgers made the motion to reject **Sheri Simeon**, **D.Ph**. consent order. Dr. McCall seconded the motion. The motion carried.

Dr. McKinney made the motion to accept **Michael H Lingerfelt, D.Ph**. consent order for 30 days suspension of his pharmacist license and a \$1600.00 civil penalty. Dr. Lingerfelt violated T.C.A § 53-1-108 (1)(B). Mr. Bynum seconded the motion. The motion carried.

Dr. Breeden made the motion to accept **Kristy L Hensley**, **RT** consent order to voluntarily surrender her registration (same as revocation). Ms. Hensley violated board T.C.A. §53-10-104(1). Dr. Rodgers seconded the motion. The motion carried.

Mr. Bynum made the motion to accept **Dunlap Pharmacy** consent order with the license being placed on probation for 2 years. Dr. Breeden seconded the motion. Dunlap Pharmacy violated T.C.A. §53-10-401 (a)(1). The motion carried.

Dr. Breeden made the motion to accept **Srinivasulu Kandipati**, **D.Ph**. consent order. Dr. Kandipati's pharmacist license will be placed on probation or 2 years. Dr. Kandipati violated board rule T.C.A. §53-10-401 (a)(1). Dr. McKinney seconded the motion. The motion carried.

Appearance Sara Foster, RT

Ms. Foster 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 and "Have you ever held or applied for a license, privilege, registration or certificate to practice as a pharmacy technician in any state, country, or province that has been or was ever denied, reprimanded, suspended, restricted, revoked, otherwise disciplined, curtailed, or voluntarily surrendered under threat of investigation or disciplinary action. 10/24/2017 case shows dismissed. After discussion, Dr. Rodgers made the motion to approve Ms. Fosters application for registration as a pharmacy technician. Dr. McKinney seconded the motion. The motion carried.

Waivers

Board rule 1140-01-14 (12)

Dr. McCall made the motion to grant **Kevin Sykes, D.Ph**. request to be pharmacist in charge at NPS retail pharmacy and NPS mail order pharmacy. Dr. Breeden seconded the motion. The motion carried.

Board rule 1140-01-.07(3)(b)

Dr. Rodgers made the motion to grant **Ashley Pendergrass, D.Ph**. request to waive three hundred and twenty (320) internship hours and the NAPLEX. Dr. McCall seconded the motion. The motion carried. Dr. Pendergrass must successfully take and pass the MPJE.

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

Board rule 1140-01-.04 (6)

Dr. Pryse made the motion to grant **Stephanie Daughters, D.Ph.**, request to waive the NAPLEX as a requirement for license by reciprocity. Dr. Daughters is licensed by the CA Board of Pharmacy before 2004 when the requirements changed. Dr. Bynum seconded the motion. The motion carried. Dr. Rodgers voted no.

Presentation

Dr. Vandenberg, owner of Tennessee Vaccination Services, appeared before the board to request a waiver of the regulations concerning dispensing medication in patient's homes. After discussion, Dr. Breeden denied the request with the documentation that was submitted. Dr. McKinney seconded the motion. The motion carried. A pilot program was suggested. The board recommend that Dr. Vandenberg contact the Tennessee Pharmacist Association for guidance for presenting the pilot program.

General Discussion

Dr. Grinder asked the board if they want him to continue processing and approving the pharmacist to technician ratio evaluations. Dr. Grinder stated that the pharmacist in charge that is submitting the forms are not filling them out correctly. After discussion, Dr. Breeden made the motion to grant Dr. Grinder authority to approve the pharmacist to technician ration evaluations that are filled out correctly and justify need, to bring forms that are deficient to the board and to deny the forms that are not filled out correct. A disclaimer will be added to the website stating, "Failure to successfully complete the form and each required section will result in the form not being reviewed for approval". Dr. McKinney seconded the motion. The motion carried.

Dr. Grinder asked the board to authorize travel to NABP/District III meeting scheduled for October 3-6, 2021 in Hilton Head, SC. Dr. Breeden made a motion to authorize travel to the NABP/District III meeting for board members and investigators. Dr. McKinney seconded the motion. The motion carried.

The meeting adjourned at 12:05 p.m.

July 14, 2021

The Tennessee Board of Pharmacy convened on Wednesday July 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 9:02 a.m. with Dr. Wright presiding. Mr. Bynum, Dr. Hill, and Dr. Hadden were absent.

Contested Case Jessica Hayes, RT

Ms. Hayes was not present nor represented by legal counsel. Mr. Gibbs represented the State. Ms. Claudia Platfield was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. McCall made the motion to proceed in default. Dr. Breeden seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Ms. Hayes is charged with violated T.C.A § 63-10-305 (4). After discussion, Dr. McCall made the motion to assess a \$100.00 civil penalty and case cost. Dr. Breeden seconded the motion. The motion carried. Dr. McCall made the motion that the action taken was to protect,

promote and improve the health and prosperity of people in Tennessee. Dr. Breeden seconded the motion. The motion carried.

General Discussion

Dr. Grinder asked the board to authorize travel to MALTAGON meeting scheduled for October 17-20, 2021in Gulf Shores, AL Dr. McCall made a motion to authorize travel to the MALTAGON meeting for board members and investigators. Dr. Breeden seconded the motion. The motion carried.

The meeting adjourned at 9: 40 a.m.

The minutes were approved and ratified at the September 14, 2021 board meeting.