

MEMBERS PRESENT

Dr. Melanie Blake, Board of Medical Examiners, Chairperson
Dr. Robert Simpson, Board of Veterinary Medicine, Vice Chairperson
Dr. Bhekumuzi Khumalo, Podiatry Board
Mr. Robert Ellis, Board of Medical Examiners
Dr. Adam Rodgers, Board of Pharmacy
Dr. Robert Caldwell, Board of Dentistry
Dr. Linda Tharp, Board of Optometry
Dr. Michael Wieting, Osteopathic Board

STAFF PRESENT

Dr. D. Todd Bess, Director of Controlled Substance Monitoring Database
Ms. Mary Bratton, Chief Deputy General Counsel
Ms. Debora Sanford, Clinical Application Coordinator
Ms. Tracy Bacchus, Administrative Assistant
Ms. Jaime Byerly, Office of Investigation
Dr. Reginald Dilliard, Executive Director of Board of Pharmacy
Mr. Patrick Powell, Assistant Commissioner of Legislative Affairs
Dr. Ben Tyndall, Director, Advance Analytics and Visualization
Ms. Hannah Griffith, Epidemiologist I

MEMBERS ABSENT

Mr. Brett Reeves, Committee on Physician Assistants
Ms. Amber Wyatt, Board of Nursing
Jake Bynum, Board of Pharmacy Public Member

STAFF ABSENT

Mr. David Silvus, Attorney, Office of General Counsel

The Controlled Substance Monitoring Database (CSMD) Committee convened on Tuesday, June 22, 2021, in the Iris Room, 665 Mainstream, Nashville, TN. Dr. Blake called the meeting to order at 9:00 a.m. and the members introduced themselves.

Minutes

Dr. Blake asked if everyone read the minutes from the meeting on February 2, 2021, and if so could the committee have a motion to approve the minutes.

- Mr. Robert Ellis made the motion to accept the minutes from the February 2, 2021 committee meetings, and Dr. Bhekumuzi Khumalo seconded the motion,
- Minutes were approved

Office of Informatics and Analytics – Hannah Griffith and Ben Tyndall

- Ms. Griffith updated the committee on Tennessee Enhanced Prescriber Reports proposed by the Office of Informatics and Analytics.
- She shared with the committee examples of prescriber reports from Kentucky, Washington, and Minnesota
- All drug overdose deaths in Tennessee increased 15% from 2018 to 2019.
- Patients Receiving Opioid, Benzodiazepine, and Gabapentin Prescriptions in TN by Quarter for 2016-2020

- The number of patients who have filled prescriptions for opioids for pain and benzodiazepines has declined between 2016 and 2020, with slight increase from Q2 2020 to Q3 2020
- The number of patients filling gabapentin prescriptions has remained consistent since reporting began in July 2018
- Patients Receiving Opioid Prescriptions for Pain by Days' Supply in TN by Quarter for 2016-2020
 - The most common length of opioid prescription from 2016 to 2020 was 21-30 days
 - The least common length of opioid prescription from 2016 to 2020 was 11-20 days
- The total MME of opioid prescriptions for pain has fallen from 2016 to the present. In Q1 2016, 1.859 million MME were dispensed and dropped to 956 million by Q4 2020, a 48.6% decrease
- Ms. Griffith shared three versions of what the prescriber report card could look like
- Enhanced Prescriber Reports will include a link to a full user guide that includes the following information:
 - How to use and interpret the report
 - Where the data for each measure comes from
 - Disclaimers regarding report contents, accuracy of data, and implications of nonfatal overdose information
 - A list of frequently asked questions (FAQ) along with contact information for additional questions or issues
- New reports will be generated each quarter and will include prescribing information from the previous two quarters (six months).
- A report will be generated for each prescriber in the state with at least one opioid prescription documented in the CSMD for the corresponding reporting period.
- Prescribers will access their Enhanced Prescriber Report by logging into the CSMD and clicking a link.
 - OIA has closely collaborated with both CSMD and a Strategic Technology Solutions (STS) team to make this possible.

Office of Legislative Affairs – Patrick Powell

- Mr. Powell updated the committee on the legislation that passed this legislative session:
 - [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 de-identified 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 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 enjoinder 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 be repealed 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 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 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 468**](#) This act adds a reporting requirement to the TN Together legislation that the department of health is issuing by November 1st 2021. In doing so, this act requires the report to include an analysis of the impact of the COVID-19 pandemic has had in Tennessee in the opioid crisis, and whether it has impacted the ability to measure its efforts through the 2018 legislation by July 1, 2023. This act took effect May 18, 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 non-substantive 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.

Office of Investigation – Jaime Byerly

- Several new overprescribing consultants were approved by the Board of Medical Examiners. We have on boarded and worked with three of them for routine Pain Management Clinic reviews and for Over Prescribing case reviews.
- Out of 56 Pain Management Clinic on-site inspections that were suspended due to COVID-19 Executive Orders, 54 have been completed since the orders were lifted in September.
- There are currently 110 active Pain Management Clinics and two pending new clinic applications.
- • There are currently five complaints open on Pain Management Clinics.
 - Three are pending first review
 - One is pending second review
 - One is pending third party action
- TDH has license 110 Pain Management Clinics as of June 2021
- Overprescribing Complaints 2021 to date:
 - MD
 - Pending first review: 46
 - Being investigated: 9
 - Pending second review: 18
 - Further investigation: 1
 - Pending third party action: 3
 - DO
 - Pending first review: 2
 - Being investigated: 2
 - Pending second review: 2
 - Further investigation: 0
 - Pending third party action: 3
 - APRN
 - Pending first review: 3
 - Being investigated: 11
 - Pending second review: 7
 - Further investigation: 0
 - Pending third party action: 3
 - PA
 - Pending first review: 1
 - Being investigated: 2
 - Pending second review: 1
 - Further investigation: 0
 - Pending third party action: 2
 - There are no open complaints for dentists, podiatrists, optometrists or veterinarians.

Office of General Counsel – Mary Bratton

- Reported prescribing cases for January 2021 through May 2021
 - Seven BME cases
 - One Physician Assistant case
 - Four Board of Nursing cases
- Notice of Rulemaking Hearing for the CSMD Database Proposed Rules
 - The rulemaking hearing will be held at 9:00 A.M on August 4, 2021, in the Iris Room.
 - **View the notice at:** https://publications.tnsosfiles.com/rules_filings/05-14-21.pdf
 - The rules will go to the Attorney General Office for approval
 - There will be a 90-day waiting period before the CSMD Rules are effective
 - The rules will then go to the Government Operation Committee. Ms. Bratton or Mr. Silvus would notify Dr. Blake of the date.

CSMD Director's Report – Dr. D. Todd Bess

The CSMD Director's report included the following:

- Notice of Rulemaking Hearing for the CSMD Database Proposed Rules
 - The rulemaking hearing will be held at 9:00 A.M on August 4, 2021, in the Iris Room.
 - View the notice at: https://publications.tnsosfiles.com/rules_filings/05-14-21.pdf
- Public Chapter 136
 - CSMD team has worked with OGC to review and update FAQs to address changes of PC 136.
 - CSMD Application has been updated to allow an unlimited number of unlicensed delegates associated to a prescriber
 - The Medical Examiner (ME) role in the CSMD has additional sub categories added to reflect all titles contained in PC 136
 - Since the MEs are now considered Healthcare Practitioners (HCPs) by PC 136, development will be required to create a delegate role specifically for Medical Examiners.
 - TN will write requirements for a new Medical Examiner Delegate role to allow Medical Examiners to have unlimited delegates in the CSMD.
 - Then development by the vendor will occur to create the role and the functionality for this new role
 - This new ME Delegate role is needed to prevent existing health care provider delegates from losing interstate data sharing access
 - This change was anticipated in the contract development process as a future change and high level development dollars were included in the current contract
- Department of Health has updated the CSMD Data Collection Manual
 - DEA sent a letter to the National Association of State Controlled Substances Authorities (NASCSA) requesting assistance (information) from prescription drug monitoring programs (PDMP)
 - DEA works to establish aggregate production quotas for certain controlled substances and values information that could be provided by PDMPs
 - A data request link was sent to NASCSA with a communication to share link with the DEA contact.
 - Using this TDH data request link will enable TDH to receive a detailed request form of what data the DEA would like to receive. Request made through this TDH data link go directly to the TDH, Office of Informatics and Analytics where a review of the request will occur to determine if the request can be fulfilled.
- Updated the committee on the next CSMD Committee dates:
 - October 12, 2021
 - February 15, 2022
 - June 21, 2022
 - October 18, 2022

TennCare Project Update – Dr. Victor Wu, Andrei Dumitrescu, Sarah Mansouri

Dr. Wu gave a brief patient story on how TennCare is using the CSMD data:

- 31-year-old male with multiple medical comorbidities, Opioid use disorder, Bipolar II disorder, PTSD, in recovery for two years, but was experience social stress and didn't want

- to relapse.
- The patient was needing to be transitioned from one facility to a new facility providing MAT
- The patient was extremely hesitant about the transition. The MCO care manager spoke to the patient for over 2 hours
- The patient was scheduled for an appointment within 48 hours and a Lyft was scheduled to get him there
- The care manager closely followed the member (e.g., texting) and verified that he actually showed up to the appointment!
- The member successfully transitioned to the new facility without relapsing

Andrei Dumitrescu discussed how TDH and TennCare CSMD Data Partnership began and the mission:

- Began with discussions in 2017 about the significant number of TennCare members that suffer from substance use disorder and are in need of counseling, care, and support.
- To increase the quality of patient care by giving healthcare organizations timely and accurate information to identify and deploy resources to patients who are obtaining controlled substances and may be either suffering from or at risk for substance use disorders.
- On September 14, 2019, 5-year Interagency Agreement amendment between TDH and TennCare to share CSMD data was signed and executed
- TennCare and its partner MCCs have developed use cases in accordance with the outlined agreement
TennCare is currently in the 2nd year of the agreement and has deeply integrated the CSMD into member and provider quality strategies

Sarah Mansouri discussed how TennCare is securing CSMD Data and how the Manage Care Contractors use the CSMD Data:

- Department of Health (Office of Informatics and Analytics) transmits the CSMD data to TennCare
- TennCare transmits CSMD data to Manage Care Contractors (MCCs)
- MCCs store CSMD data isolated from other data
- MCCs access & integrate CSMD data
 - For each step of the data pathway, there are robust data security and protections in place
- MCO use the CSMD data to identify individuals paying out of pocket for buprenorphine containing prescription
- Individuals receiving medication assisted treatment (MAT) services from providers without a TennCare Medicaid ID are identified for outreach and education.
- Members are offered a warm transition and care coordination support to TennCare BESMART providers for MAT
- BESMART providers work collaboratively with MCOs for any members seeing multiple buprenorphine providers to ensure optimal treatment
- The CSMD is deeply integrated into TennCare's opioid strategy (TennCare shared with the committee the eight different use cases).

The meeting adjourned at 11:10 a.m.