

## **MEMBERS PRESENT**

Dr. Melanie Blake, Board of Medical Examiners, Chairperson  
Dr. Bhekumuzi Khumalo, Podiatry Board  
Dr. Robert Simpson, Board of Veterinary Medicine  
Mr. Mark Young, Board of Nursing  
Dr. Shant Garabedian, Osteopathic Board  
Mr. Robert Ellis, Board of Medical Examiners  
Dr. Adam Rodgers, Board of Pharmacy  
Mr. Brett Reeves, Committee on Physician Assistants  
Dr. Thomas Williams, Board of Dentistry

## **STAFF PRESENT**

Dr. D. Todd Bess, Director of Controlled Substance Monitoring Database  
Dr. Mitchell Mutter, Medical Director for Special Projects  
Mr. Andrew Coffman, Attorney, Office of General Counsel  
Ms. Debora Sanford, Clinical Application Coordinator  
Ms. Tracy Bacchus, Administrative Assistant  
Ms. Sonya Moten, Project Manager  
Ms. Jaime Byerly, Office of Investigation

## **MEMBERS ABSENT**

Vacant Public Member, Board of Pharmacy  
Dr. Linda Tharpe, Board of Optometry

The Controlled Substance Monitoring Database (CSMD) Committee convened via WebEx on Tuesday, June 23, 2020, 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 had everyone read the minutes from the meeting on February 3, 2020, and if so could the committee have a motion to approve the minutes.

- Dr. Bhekumuzi Khumalo made the motion to accept the minutes from the February 3, 2020 committee meetings, and Dr. Robert Simpson seconded the motion,
- Move by acclamation the minutes were approved

## **Office of TennCare – Dr. Victor Wu**

Dr. Victor Wu, TennCare Chief Medical Officer, and others from TennCare (Chief Data Officer Andrei Dumitrescu, Chief Privacy Officer Sarah Raybin, and Director of Health Policy & Strategy Sarah Mansouri) provided the annual update to the committee as requested. TennCare reported back to the Committee several analyses of the of the prescription data for its enrollees. The presentation started with a review of the TDH TennCare Data Partnership which included the following:

- Dr. Wu presentation to the CSMD Committee highlighting the necessity of the CSMD data to combat the opioid epidemic (April 10, 2018)
- CSMD Committee formally approves TDH/TennCare Interagency Agreement that outlines data sharing processes (July 2018)
- Initial Interagency Agreement between TDH and TennCare was signed and executed (July 2018)
- Dr. Wu presented key successes from CSMD data usage to the CSMD Committee leading to CSMD Committee approval of 5-yr extension of CSMD partnership with required annual report back to the committee (July 2019)
- Interagency Agreement amendment (5-year) between TDH and TennCare was signed and executed (September 2019)

Dr. Wu presentation stated that through the partnership the committee has been able to significantly improve the care of TennCare enrollees especially those that suffer from substance use disorder or are at risk of Neonatal Abstinence Syndrome (NAS). Highlights of the presentation include the following:

- Case presentations of CSMD data driven improvements in patient care due to CSMD data enhancing the managed care opportunities for TennCare and their MCOs
- Described how the CSMD data partnership supports decision making processes for providers and prescribers
- Provided examples of increase patient engagement and improve access to clinical service delivery such as high quality Medication Assisted Treatment (MAT)
- Outlined the six clinical use cases for the CSMD providing TennCare a more comprehensive review
  - Support building TennCare high-quality MAT Provider Network
  - Identifying and engaging women of childbearing age with opioid use
  - Population Health Stratification (allows TennCare to identify more patients that could benefit for targeted managed care intervention)
  - Creating MAT Quality Metrics for Provider Education
  - Providing case managers with key prescription information (CSMD helps identify patients with certain substance use disorders when patients medical claims history fails to indicate patient may have need for such care)
  - Internal dashboards to track overall opioid utilization including benzodiazepines & stimulants

Dr. Wu reported to the Committee some analysis based on the use of CSMD data including:

- TennCare pharmacy claims suggest a 50% decline in new, acute opioid users since 2016
- TennCare reported to the committee that there were 205 fewer NAS births in 2018 and a 12.8% decrease since 2016 (Dr. Wu stated that CSMD data has contributed to driving these cases down)
- TennCare MAT provider network is required to check the CSMD
- Early data indicating that TennCare patients utilizing the TennCare MAT provider network are remaining in treatment at least 90 days somewhat better than those outside of the network

- Review of Data Privacy and Compliance Review that includes audit files of all users of CSMD data entrusted to TennCare by the CSMD Committee (presentation included details of protocol if a security breach occurred)
- Overview of Monthly Milestones related to CSMD data
  - TennCare receives from TDH updated CSMD data
  - TennCare prepares the data (TennCare fully integrates the CSMD data into claims data via use of Jaro-Winkler algorithm supplemented with TennCare paid claims) before securely transferring final data to the MCOs and PBM

Dr. Wu stated that goals for the upcoming year are to continue to improve quality of care for the MAT Provider Network, improve population health risk stratification with more accurate incorporation of controlled substances (e.g. chronic opioid users with multiple benzodiazepine usage), and prioritize prenatal and postpartum health for mothers engaged in opioid use disorder and substance use disorder. Dr. Blake shared with the committee and the TennCare team that this was an incredible presentation documenting tremendous progress. The committee shared with Dr. Wu that they desire to learn more about the provider's feedback TennCare is receiving related to TennCare interventions relevant to the CSMD Committee and TennCare partnership.

#### **Office of General Counsel - Andrew Coffman**

- Reported prescribing cases for December 2019 through April 2020
  - Six BME cases
  - One Dentistry case
  - One Nursing cases
- The minimum discipline for all boards or committee assesses shall include the following:
  - Reprimand
  - Successful completion of a board or committee approved intensive continuing education course or program regarding treatment of opioids;
  - A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;
  - One or more Type A civil penalties;
  - Proof of the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and
  - Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.
- [Public Chapter 573](#) This act amends the Tennessee Together statutes. It expands the definition of "alternative treatments" by adding "non-opioid medicinal drugs or drug products, occupational therapy, and interventional procedures or treatments." This is primarily relevant to the treatments that must be disclosed and explained by a healthcare practitioner to a patient or the patient's legal representative as a prerequisite to obtaining informed consent to treatment with an opioid. This act took effect on March 19, 2020.
- [Public Chapter 594](#) This act was the Department of Health's Licensure Accountability Act. The bill allows all health related boards to take action against a licensee that has been disciplined by another state for any acts or omissions that would constitute grounds for

discipline in Tennessee. The law also expands available emergency actions, allowing actions beyond simply a summary suspension. Finally, the act establishes that the notification of law changes to health practitioners can be satisfied by the online posting of law changes by the respective boards. Notice must be maintained online for at least 2 years following the change. This act took effect March 20, 2020.

- Mr. Coffman stated there was a lot of changes to the CSMD rules since we last discussed the rules. There is two things that he wanted to bring to this committee's attention:
  - Reporting patients gender
  - Definitions section of CSMD rules and we haven't reach a good consensus
    - Discount pharmacy card and current rules says they can be reported separately
- These rules have been distributed to the Tennessee Hospital Association, Tennessee Pharmacy Association, Tennessee Medical Associations, Tennessee Medical Foundation, and Tennessee Podiatric Medical Association, Tennessee Academy of Physician Assistant, Tennessee Nurses Association, and Tennessee Osteopathic Medical Association, Tennessee Dental Association, Tennessee Chronic Pain Guidelines Committee
- Will take the discount card issue to the Board of Pharmacy next

### **Office of Investigation – Jaime Byerly**

- **Pain Management Clinics**
  - Number of Pain Management Clinics currently licensed: 122
  - In 2019, 67 Pain Management Inspections were completed, which included new clinics, change in medical director, and biennial inspections. Fourteen inspections have been completed in 2020.
  - Executive orders due to COVID-19 limited pain clinic inspections. This affected 27 inspections: 14 biennials have been delayed, 10 applications were approved and are awaiting inspection, and 3 need re-inspection. The inspections will be completed when the order expires or is otherwise extended or modified.
  - There are 12 pending applications for Pain Management Clinics
  - Disciplinary action:
    - Zero pain clinics revoked in 2019 or 2020
    - In 2019, three pain clinics were issued conditional licenses. One conditional license was issued so far in 2020.
    - In 2019, one pain clinic was ordered to pay civil penalties. No clinics have been ordered to pay civil penalties in 2020.
- In 2020, there have been no complaints opened on Pain Management Clinics. In 2019, there were 10 complaints opened. Of those 10:
  - Three are being investigated, six were closed, and one was sent to OGC for discipline.
  - The allegations against the clinics were for unprofessional conduct (5), fraud/false billing (1), unlicensed practice (2), or were outside the investigative scope (2).
- **Over-Prescribing Investigations**
  - In 2020 year-to-date, fourteen over-prescribing complaints have been opened in OIV. Of these 14:
    - Two are pending first review, nine are being investigated, and two are pending second review.
    - Ten of the complaints are open on medical doctors, and four are open on advanced practice registered nurses.

- In 2019, 72 over-prescribing complaints were opened in OIV. Of the 72:
  - Four complaints are being investigated, 28 are pending second review, 24 were closed, 11 were sent to OGC for discipline, 1 is out for further investigation, and 4 are pending third party action.
- Other updates:
  - OIV, OGC, and the PMC administrative team are working together on updating policies and procedures for Pain Management Clinics.

### **Medical Director for Special Projects – Dr. Mitchell Mutter**

#### **Dr. Mutter’s presentation to the committee included the following:**

- Tennessee Code Annotated, Section 63-1-160 (d), on or after January 1, 2021, any prescription for a Schedule II, III, IV, or V controlled substance issued by a prescriber who is authorized by law to prescribe the drug must be issued as an electronic prescription from the person issuing the prescription to a pharmacy. The name, address, and telephone number of the collaborating physician of an advanced practice registered nurse or physician assistant must be included on electronic prescriptions issued by an advance practice registered nurse or physician assistant.
- Discussion on how to educate prescribers  
<https://publications.tnsosfiles.com/acts/111/pub/pc0124.pdf>
- Updated the committee on the Top 50 numbers across the state for 2014 vs 2019
- Presented Top 50 information by classification of APRN, PA, DO, and MD
- MME prescribed by rank in 2014 vs 2019
  - number 1 prescribed approximately 43,000,000 in 2014 vs 25,000,000 in 2019
  - number 25 prescribed approximately 22,000,000 in 2014 vs 12,000,000 in 2019
  - number 50 prescribed approximately 11,000,000 in 2014 vs 9,000,000 in 2019

### **CSMD Director’s Report – Dr. D. Todd Bess**

Dr. Bess updated the committee that he and Dr. Dilliard completed the 2020 University of Tennessee Pharmacy update programs. Two items emphasized were the Draft CSMD Rules and the January 2020 requirement for electronic prescribing of controlled substances. The CSMD Director’s report included the following:

- Gateway Update
  - TN’s strategy to offer statewide Electronic Health Record (EHR)/ Pharmacy Management software integration using Gateway Service shared during the outreach programs
  - Appriss is working with many Hospitals, Health Systems and Pharmacies to finalize legal agreements and begin the onboarding process
  - Covid-19 slowed interested sites’ legal review and technical teams development on this work
  - Committee members were advised to contact the CSMD office if they knew of an entity interested in Gateway so CSMD could facilitate connecting them with Appriss resources to get the process started
- Law Enforcement role enhancement for electronic access has been completed for the following roles:

- District Attorney General
- Law Enforcement officer
- TBI Director
- TBI Agent
- Drug Enforcement Assistant Special Agent in Charge
- Drug Enforcement Agent
- TN E-Prescribing Progress
  - As of May 2020, approximately 35% of new controlled prescriptions dispensed by pharmacies in TN were E-Prescribed
  - Committee members reported some prescribers are employees of health systems where the prescribing system has not progressed to allow controlled substance E-prescribing
- Committee was requested to discuss possible options for challenges with CSMD Data Collection Related to Clinical Trials with FDA approved controlled substances (Example such as a blinded, placebo controlled study design)
  - Andrew Coffman stated that the statute empowers this committee to create an exemption from reporting under certain circumstances
    - Someone would need to come to the committee to request the exemption from reporting
    - Some circumstances you would empower Dr. Bess to grant those exemptions from reporting

Dr. Bess asked the committee for parameters for making decisions on FDA clinical trials:

- Dr. Robert Simpson made the motion that Dr. Bess could make decisions on any FDA Clinical Trials with proper documentation, and Dr. Adam Rogers seconded the motion,
- The next CSMD Committee is scheduled for October 6, 2020
  - Members were requested to notify Tracy if they had a conflict with the date

#### **Office of Informatics and Analytics – Charlotte Cherry**

- **Charlotte Cherry**, MS, MPH is an Epidemiologist from the Office of Informatics and Analytics (OIA) to update the committee on the way that TDH is utilizing CSMD data to better inform and direct the best possible response to the drug epidemic. Highlights from the presentation included the following:
  - A description was provided on the types of data available to TDH
  - Described how linked data enhance surveillance or prioritization of resources
  - Provided an overview of how dynamic data visualization can add context to linked data
  - OIA has worked to build a robust data infrastructure that guides best practices for data sharing, interoperability, analysis, and reporting for the TDH
  - OIA consists of three units that work on specific aspects of the data lifecycle: Data Governance, Core Informatics, and Advanced Analytics and Visualization
  - Examples of work completed can be viewed at the TDH website <https://www.tn.gov/health/health-program-areas/pdo.html>
  - An overview of drug overdose in TN was provided, including Age-Adjusted Rates

- for Drug Overdose Deaths by Sex and Race in TN by Year for 2014-2018
- The number of filled opioid prescriptions for pain and filled benzodiazepine prescriptions have continued to decline between 2015 and 2019 demonstrating the great work accomplished in TN
- New linked data projects for OIA
  - Overdose risk modeling with Walsh Lab at Vanderbilt University Medical Center
  - Provider report cards
  - Dynamic prescriber and pharmacy investigation tools
- Data Dissemination Partners
  - External
    - Tennessee Bureau of Investigation- Dangerous Drugs Task Force
    - Tennessee Department of Mental Health and Substance Abuse Services- Office of Prevention
  - Internal
    - TDH- Overdose Response Coordinating Office (ORCO)
    - TDH- Communicable and Environmental Disease and Emergency Preparedness
    - Viral Hepatitis Program
    - HIV Prevention and Surveillance
    - Controlled Substance Monitoring Database Program
  - On the horizon
    - “End the Syndemic” to jointly address HIV, STIs, VH, and substance use disorder (SUD) in TN
- The presentation ended with a demo of a dynamic dashboard that has been created for TDH

The meeting adjourned at 12:15 p.m.