MEMBERS PRESENT

Dr. Melanie Blake, Board of Medical Examiners, Chair Dr. Robert Simpson, Board of Veterinary Medicine, Vice Chair Dr. Bhekumuzi Khumalo, Podiatry Board Ms. Amber Wyatt, Board of Nursing 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 Dr. Tonya Reynoldson, Board of Optometry

STAFF PRESENT

Dr. D. Todd Bess, Director of Controlled Substance Monitoring Database
Mr. Andrew Coffman, Attorney, Office of General Counsel (OGC)
Ms. Debora Sanford, Clinical Application Coordinator
Ms. Tracy Bacchus, Administrative Assistant
Ms. Sonya Moten, Project Manager
Ms. Jaime Byerly, Director, Office of Investigation (OIV)
Mr. David Silvus, Attorney, Office of General Counsel
Ms. Jennifer Putnam, Deputy Director, Division of Health Licensure and Regulation
Ms. Alicia Grice, Office of Finance
Dr. Wesley Geminn, Mental Health and Substance Abuse
Dr. Reginald Dilliard, Executive Director of Board of Pharmacy

MEMBERS ABSENT

Vacant Public Member, Board of Pharmacy Dr. Shant Garabedian, Osteopathic Board

STAFF ABSENT

Dr. Mitchell Mutter, Medical Director for Special Projects

The Controlled Substance Monitoring Database (CSMD) Committee convened via WebEx on Tuesday, October 6, 2020, in the Iris Room, 665 Mainstream, Nashville, TN. Ms. Bacchus made opening remarks to the Committee and provided an overview of the requirements for a special electronic meeting. All of the requirements were satisfied. Mr. Robert Ellis made the motion for approval to conduct the meeting electronically for this purpose and Mr. Simpson seconded the motion. A roll call vote was taken, and it passed. The teleconference was then turned over to the Chair of the Committee, Dr. Melanie Blake.

Dr. Blake called the meeting to order at 9:05 a.m., and the members introduced themselves.

Minutes

Dr. Blake asked if everyone had read the minutes from the meeting on June 23, 2020, and if so, could the committee have a motion to approve the minutes?

• Dr. Robert Simpson made the motion to accept the minutes from the June 23, 2020



committee meetings, and Mr. Robert Ellis seconded the motion.

• A roll call vote was taken, and the minutes were approved.

Office of Finance – Alicia Grice

- Total direct expenditures for FY2020 was just over 1.6 million.
- Alicia Grice presented a breakdown to the committee the portion that each board pays related to the CSMD. She then provided the committee a comparison for changes in expenditures over the last three years.

Legislative Update – Patrick Powell

Mr. Powell updated the committee on the 2020 legislative changes that would be of interest to the CSMD Committee members which included:

- 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 act 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 on March 20, 2020.
- <u>Public Chapter 738</u>: This act prohibits a governmental entity from authorizing destruction of public records if the governmental entity knows the records are subject to a pending public record request. Prior to authorizing destruction of public records, an entity must contact the public record request coordinator to ensure the records are not subject to any pending public record requests. Records may still be disposed of in accordance with an established records retention schedule/policy as part of an ordinary course of business, as long as the records custodian is without knowledge the records are subject to a pending request. This act took effect on June 22, 2020.
- Public Chapter 761: This act allows certain mid-level practitioners to prescribe buprenorphine when employed in a community mental health center (CMHC) or a federally qualified health center (FQHC). To be eligible under this law, the practitioner must be licensed, and practice as, a family, adult, or psychiatric nurse practitioner or physician assistant. They also must have a DATA waiver issued by SAMHSA/DEA. There can be no limitations or conditions imposed on the provider's license within the previous three (3) years. Prescriptions by the practitioner must not exceed a sixteen (16) milligram daily equivalent. The provider may only prescribe buprenorphine products to patients treated through the organization that employs the provider. Prescriptions can only be dispensed by a licensed pharmacy to ensure entry into the CSMD. The provider has a cap of fifty (50) patients at any given time. The law also requires the provider to initiate and

lead a discussion regarding patient readiness to taper off medications in their treatment at any time upon the patient's request, but no later than one (1) year after initiating treatment, and then every six (6) months thereafter.

The facility must employ one or more physicians and have adopted clinical protocols for medication assisted treatment (MAT). The midlevel's collaborating physician must hold an active DATA waiver and be treating patients with buprenorphine at the same facility. The facility must employ providers that accept TennCare and are accepting new TennCare patients. The facility must verify identification of patients. The collaborating physician must review 100% of the charts of patients being prescribed a buprenorphine product and can only collaborate/supervise four (4) nurse practitioners or physician assistants. This act took effect on July 1, 2020.

• Public Chapter 771: This act allows certain midlevel practitioners to prescribe buprenorphine when employed in a non-residential office-based opiate treatment facility (OBOT) licensed by the Department of Mental Health and Substance Abuse Services (MHSAS). To be eligible under this law, the practitioner must be licensed, and practice as, a family, adult, or psychiatric nurse practitioner or physician assistant. They also must have a DATA waiver issued by SAMHSA/DEA. Prescriptions by midlevel providers under this statute are capped at a sixteen (16) milligram daily dose and must not be for a mono-product or buprenorphine without naloxone, except when utilizing injectable or implantable buprenorphine products. Midlevel providers under this statute are capped at 100 patients.

The OBOT in these situations must employ the midlevel's collaborating physician (who also must hold an active DATA waiver and be treating patients with buprenorphine at the same OBOT), and the OBOT must not have the authority to dispense buprenorphine products. The collaborating/supervising physician under this statute cannot supervise more than two (2) midlevel practitioners.

The OBOT also must employ providers that are credentialed and contracted to accept TennCare patients and bill TennCare for services for treatment of opioid use disorder with buprenorphine. Finally, the OBOT must be accepting new TennCare patients. This act took effect on August 1, 2020.

• Dr. Geminn's reported that the State of Tennessee has about 130 license Office Based Opioid Treatment Program (OBOT) with about 80% are in middle and east Tennessee.

Office of General Counsel - Andrew Coffman

- Reported prescribing cases for May 2020 through August 2020, including:
 - o Three BME cases
 - One Podiatry case
 - Three 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.
- Mr. Coffman stated there were many changes to the CSMD rules since last discussed. There were two things that Mr. Coffman wanted to bring to this committee's attention:
 - Reporting patient gender.
 - Definitions section of CSMD rules where consensus is needed related to discount pharmacy card
 - 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, and the Tennessee Chronic Pain Guidelines Committee.
 - OGC will take the discount card issue to the next Board of Pharmacy meeting.

Office of Investigation (OIV) – Jaime Byerly

- Pain Management Clinics
 - \circ Number of Pain Management Clinics currently licensed: 118 as of September 2020
 - There are two pending applications.
 - The executive order that suspended pain clinic inspections expired in early September.
 - There were 56 inspections that were suspended due to COVID-19. Since the order lifted, OIV has completed 17. OIV is prioritizing those with conditional licenses and those requiring follow-up inspections.
 - Year to date, one complaint has been opened on a pain management clinic for fraud/false billing.
- Overprescribing MD/DO to date in 2020
 - Pending first review: 3
 - Currently being investigated: 7
 - Pending second review: 21
 - Pending expert review: 1
 - o Osteopathic Physician pending second review: 2

• Overprescribing APRN to date in 2020

- Pending first review: 3
- Currently being investigated: 3
- Pending second review: 4
- There are no open complaints for dentists, podiatrists, or veterinarians.



• Office of Investigations General Updates

- Over the past few months, the OIV has implemented online complaints and can now receive complaints electronically.
- OIV is implementing new technology to become a more paperless office. OIV is in the building phase of implementing a SAS Visual Investigator tool, which will help with data analysis and investigation management.

Office of Informatics and Analytics – Ben Tyndall, Ph.D.

- The number of opioid prescriptions for pain has declined between 2015 and 2019.
 - At the highest in Q3 of 2015, 2.04 million prescriptions of opioids for pain were filled, representing a rate of 309 prescriptions per 1,000 residents.
 - Since this peak, opioid prescriptions for pain have fallen to 1.28 million filled in Q4 of 2019, representing a rate of 189 prescriptions per 1,000 residents. This represents a decrease of 37.3%.
 - Benzodiazepines are prescribed about half as often as opioids for pain and have followed a trend similar to opioids.
 - Benzodiazepine prescriptions peaked in Q3 of 2015 at 1.04 million prescriptions filled (157 per 1,000 residents) and have decreased to 652,000 filled prescriptions in Q4 of 2019 (96 per 1,000 residents), representing a 37.5% decrease.
 - Gabapentin prescriptions were first required to be reported to the CSMD on July 1, 2018, and gabapentin data are only presented from Q3 of 2018 forward.
 - Over this period, around 500,000 gabapentin prescriptions were filled in each quarter. In Q4 of 2019, there were 517,000 gabapentin prescriptions filled, representing 78 prescriptions per 1,000 residents.
 - Overdose deaths in Tennessee by Drug Type, 2015-2019:
 - Opioids still confirmed in about 74% of all overdose deaths.
 - "Pain Relievers" (opioids typically obtained through a prescription) are still declining for third year in a row.
 - Illicit opioids (particularly illicit fentanyl) are accelerating and driving growth in overdose deaths.
 - Stimulant Overdose Death in Tennessee, 2015-2019:
 - Stimulant-involved ODs are also increasing rapidly.
 - Stimulants were involved in 44% of OD deaths in 2019, which is up from 21% in 2015.
 - Other than cocaine, stimulant-involved OD deaths primarily involve methamphetamine."28% of OD deaths confirmed involvement of both an opioid and a stimulant. It is important to note that most overdose deaths involve more than one substance (polydrug).
 - All drug overdose death by sex, 2015-2019:
 - In 2019, nearly two times as many men died of an overdose as women.
 - The number of women dying of overdose has stayed relatively consistent the past several years, and the gap between men and women has grown considerably in that time.
 - All drug overdose deaths by race, 2015-2019:
 - o In 2019, White Tennesseans accounted for 84% of OD deaths, while Black Tennesseans



accounted for about 15%.

• This is a 66% increase in overdose deaths of Black Tennesseans from 2018 to 2019.

- All overdose deaths by age, 2015-2019:
 - All age groups between 25-54 years old have high numbers of opioid deaths.
 - Younger age groups, particularly those 25-44, have experienced sharp increases.
 - Although OD deaths are still relatively low among the oldest and youngest groups, the 15-24 and 65-74-year-old groups are increasing.
- Pain reliever overdose deaths by sex, race and age, 2015-2019:
 - In a reversal of overall trends, women are more likely than men to have a fatal overdose involving pain relievers, and the gap between women and men appears to be growing.
 - The number of White Tennesseans overdosing with pain relievers is decreasing, while that of Black Tennesseans is remaining relatively consistent.
 - There has been a sharp drop in the 45-54 age group (and 35-44 to a lesser extent).
- Percent who filled <u>any</u> prescription in the Tennessee CSMD within <u>60 days</u> of death by type of overdose death among all individuals who died by year, 2015-2019:
 - Of the 8,765 overdose deaths between 2015 and 2019, we were able to link 87% to records in the CSMD to conduct this analysis.
 - The proportion of decedents with *any* Rx in the CSMD in the 60 days before OD death has decreased steadily for most OD types (57% in 2015 decreased to 36% in 2019), but particularly among those with an OD involving "Pain Relievers" (opioids typically obtained through a prescription).
- Percent who filled a prescription for <u>an opioid or benzodiazepine</u> in the Tennessee CSMD within <u>60 days</u> of death by type of overdose death among all individuals who died by year, 2015-2019:
 - Only 23% of deaths involving opioids had opioid Rx in the 60 days prior to death (37% for deaths involving "Pain Relievers"). That's down from 51% in 2015 (59% for "Pain Relievers").
 - Similarly, the percentage of decedents with a benzodiazepine Rx in the 60 days before death involving benzodiazepine dropped from 55% to 39%.
 - A decrease in fentanyl deaths with an opioid Rx is also notable.
- Key Takeaways:
 - Drug overdose deaths are increasing despite success in limiting opioid and benzodiazepine prescribing;
 - Overdose increase driven by illicit fentanyl and stimulants;
 - Demographics of overdose are changing; and
 - Many decedents still encounter the healthcare system before death.
- More Information
 - Questions for OIA: <u>TDH.Analytics@TN.gov</u>
 - Reports and Infographics<u>https://www.tn.gov/health/health-program-areas/pdo/pdo/facts-figures.html</u>
 - New Drug Overdose Dashboard: <u>https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html</u>

Director of Special Projects Updates – Jennifer Putnam

Ms. Putnam thanked Ben Tyndall and his team for the work done on the Top 50, 10 and 20:

- Legislature passed a statue in 2017 that required the department to identify high-risk prescribers and do the following:
 - o Notify the high-risk prescribers via letter
 - Require the identified high-risk prescribers to participate in a continuing education course that covers the risk, complications, and consequences of opioid addiction due to their high prescribing
 - Letters go out to those prescribers by July 31st of each year
 - They must respond to why they feel their prescribing is justified
 - They may obtain legal counsel
 - The Department then reviews response
 - Choose to close
 - Open a complaint in Office of Investigation (OIV)
 - The high-risk prescriber would have to produce medical records to show additional documentation then another review will be conducted by the overprescribing team
 - The team will determine if OIV can close with a letter or warning, letter of concern if formal discipline is not warranted
 - If formal discipline is warranted, the case is assigned to the Office of General Counsel to add with an active case or open a new case
 - Ms. Wilkins stated that the Department of Health as it relates to the Top 50 prescribers
 - No action was taken on 33
 - 3 was combine with OIV complaint
 - o 8 was combine with OGC cases
 - 8 new complaints opened in OIV

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

- Gateway Update
 - Updates are being provided to the boards related to progress of the Gateway project.
 - Currently, there are 500 plus entities that have expressed interest to Appriss.
 - Towards the end of September, greater than 60 sites were live.
 - Contact CSMD office if you know of an entity interested in Gateway, and CSMD will facilitate connecting with Appriss resources to get the process started; or go to <u>http://www.tn.gov/health/csmd</u> and navigate to the integration section to get started.
- CSMD Enhancement
 - \circ $\;$ Drug Court Judges were added as a role that can register to the CSMD application.
 - Several improvements to Data Collection:
 - Improved communication functionality to allow central reporters and/or software reporters to add an email contact for each dispensing site so that any error and future warning communications are sent to both the reporter and the contact at the dispensing site at the same time.
 - All roles in Data Collection are receiving a pop-up to prompt the user to add dispensing site information to ensure both the reporter and the contact at the



dispensing site would receive important communications from the CSMD regarding Data Collection.

- Several improvements to CSMD:
 - CSMD roles that potentially have an NPI are receiving a pop-up box at login to collect NPI and provides the opportunity to update their email address. If any other required information is missing from the user profile, those fields will also appear on the pop-up.
 - This enhancement will improve the success of Gateway implementations and improve the ability for users to receive important communications from the CSMD.
- TN E-Prescribing Progress
 - As of August 2020, approximately 37% of new controlled prescriptions dispensed by pharmacies in TN were E-Prescribed.
- Department of Veterans Affairs
 - The Department of Veterans Affairs (VA) intends to pursue rulemaking to implement 38 U.S.C. § 1730B, Access to State prescription drug monitoring programs (PDMP).
 - Office of General Counsel is working with the Controlled Substance Monitoring Database to move toward compliance with these federal initiatives.
- 2020 Interstate Data Sharing
 - o February 2020
 - Massachusetts
 - Role discussion held with Tennessee in September 2020
 - Arizona
 - Nevada
 - Role discussion scheduled with Tennessee in October 2020
 - Wisconsin
 - Future role discussion with Tennessee
 - South Dakota
 - Vermont discussion on hold due to Covid19
- The Proposed Meeting for 2021 CSMD Committee is:
 - February 2, 2021
 - o April 13, 2021
 - o June 22, 2021
 - o October 12, 2021
 - \circ $\,$ Members were requested to notify Tracy Bacchus if they had a conflict with any of the dates.

The meeting adjourned at 12:15 p.m.