



MEMBERS PRESENT

Dr. Melanie Blake, Board of Medical Examiners, Chairperson
Dr. Shant Garabedian, Osteopathic Board, Vice Chairperson
Dr. Montgomery McInturff, Board of Veterinary Medicine,
Dr. Bhekumuzi Khumalo, Podiatry Board
Dr. Robert Caldwell, Board of Dentistry
Dr. Kurt Steele, Board of Optometry
Mr. Robert White, Committee on Physician Assistants

STAFF PRESENT

Dr. D. Todd Bess, Director of Controlled Substance Monitoring Database
Mr. Jae Lim, Attorney, Office of General Counsel
Ms. Debora Sanford, Clinical Application Coordinator
Ms. Tracy Bacchus, Administrative Assistant
Ms. Jaime Byerly, Office of Investigation

MEMBERS ABSENT

Mr. Robert Ellis, Board of Medical Examiners
Dr. Adam Rodgers, Board of Pharmacy
Ms. Amber Wyatt, Board of Nursing
Mr. Jake Bynum, Board of Pharmacy Public Member

The Controlled Substance Monitoring Database (CSMD) Committee convened on Tuesday, February 15, 2022, 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 had read the minutes from the meeting on October 12, 2021, 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 October 12, 2021 committee meetings, and Mr. Robert White seconded the motion.
- Motion carried.

Action Item: Jae Lim and a CSMD committee member collaborate to create an example patient for the CSMD FAQ's to demonstrate the CSMD checking requirements.

Office of Investigations (OIV) Update – Jamie Byerly

- Heat map showing the pain clinics in Tennessee
- In 2021, 70 total inspections were completed
 - 35 biennial inspections
 - 35 new application inspections
- PMC Complaints for 2021
 - 6 new complaints
 - 11 closed
 - 4 closed insufficient evidence
 - 3 sent to Office of General Counsel

- 4 closed no violation
- Total OP Complaints for MD:
 - Pending first review: 13
 - Being investigated: 22
 - Pending second review: 22
 - Pending third party action: 9
- Total DO:
 - Pending first review: 0
 - Being investigated: 4
 - Pending second review: 2
 - Pending third party action: 3
- APRN
 - Pending first review: 2
 - Being investigated: 12
 - Pending second review: 10
 - Pending third party action: 1
- PA
 - Pending first review: 1
 - Being investigated: 2
 - Pending second review: 4
 - Further investigation: 0
 - Pending third party action: 2
- There are no open complaints for dentists, podiatrists, optometrists or veterinarians.
- Overall Overprescribing Complaints in 2021 Outcomes
 - 157 OP cases closed overall:
 - 23 closed – insufficient evidence
 - 42 closed – no violation
 - 2 closed with letter of concern
 - 26 closed with letter of warning
 - 64 closed to OGC

Office of General Counsel – Jae Lim

- Reported prescribing cases for September 2021 through January 2022
 - Ten BME cases
 - Four Board of Nursing cases
 - One Board of Dentistry case
 - One Pharmacy case
 - Four Physician Assistant cases
 - One Board of Veterinary case
 - One Occupational Therapist case
- **HB2171*/SB2421** – Controlled Substances – As introduced, makes various changes to the Controlled Substance Monitoring Database. – Amends TCA Title 53, Chapter 10, Part 3.
 - Note – This is the Department’s CSMD administration bill. Most important changes:
 - this bill would require the reporting of all methadone dispensed in Tennessee;
 - under this bill, only drugs administered directly to a patient during inpatient or residential treatment would be exempt from the reporting requirements;
 - this bill would enhance the Commissioner’s ability to share CSMD data and

information by authorizing her to enter into agreements with “other governmental entities” (e.g., other Tennessee state government agencies or federal agencies) and expanding the scope of sharing to “patient care coordination”; and

- this bill would ensure compliance with federal privacy and confidentiality laws related to Part 2 programs and authorize the Commissioner to promulgate rules governing the additional reporting requirements.
- **SB2037*/HB2259** – Drugs, Prescription – As introduced, requires a practitioner to discuss with a patient the risks associated with a Schedule II controlled, dangerous substance or other opioid pain reliever prior to the initial prescription and prior to the third prescription. – Amends TCA Titles 39, 40, 53, 63, and 68, relative to prescriptions for Schedule II controlled substances.
 - Note – Practitioners are already required under Tenn. Code Ann. § 63-1-164 to have a similar discussion with patients before prescribing opioids. This bill extends that requirement to prescriptions of Schedule II non-opioid controlled substances and requires a follow-up discussion before the third prescription.
- **SB2240*/HB2335** – Controlled Substances – As introduced, requires the department of mental health and substance abuse services to study the effect of rules concerning the prescribing of buprenorphine products in nonresidential office-based opiate treatment facilities, nonresidential substitution-based treatment centers for opiate addiction, pharmacies, and hospitals for calendar years 2019, 2020, and 2021, including effects on patient access, prescriber availability, and the delivery of substance abuse treatment; requires the department to report findings and recommendations to health-related committees of the general assembly by February 1, 2023. – Amends TCA Titles 33, 53, 63, and 68, relative to the prescribing of buprenorphine.
- **SB1843*/HB1897** – Controlled Substances – As introduced, requires employers of healthcare prescribers to report to the TBI and local law enforcement authorities, as well as the Department of Health, prescribers that acquire or attempt to acquire controlled substances by misrepresentation, fraud, forgery, deception, or subterfuge. – Amends TCA Title 53, Chapters 10 and 11, Title 63, relative to controlled substances.
- **HB2715*/SB2540** – Opioids – As introduced, extends, from three years to five years, the period of time a nonresidential office-based opiate treatment facility must maintain billing records and bank deposits of cash payments for services. – Amends TCA Titles 4, 8, 9, 20, 33, 47, 53, 63, 68, and 71, relative to opioid treatment.
- Current version – All healthcare practitioners are required to check before prescribing an opioid or benzodiazepine to a human patient as a new episode of treatment and every six (6) months thereafter when said controlled substance remains a part of the treatment. A new episode of treatment means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous six (6) months. A new episode of treatment includes not only changes to specific drugs, but all changes to the strength of the drug prescribed, and the frequency with which the drug is taken.
- Proposed updates in red to the CSMD FAQ’s – All healthcare practitioners are required to check *the CSMD* before prescribing an opioid, benzodiazepine, or *Schedule II amphetamine* to a human patient *at the beginning of* a new episode of treatment, before the issuance of each new prescription for the first ninety (90) days, and every six (6) months thereafter when that controlled substance remains a part of the treatment. A new episode of treatment means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous six (6) months. A new episode of treatment includes not only

changes to specific drugs, but all changes to the strength of the drug prescribed, and the frequency with which the drug is taken.

- It was proposed by the committee that Jae Lim and a CSMD committee member collaborate to come up with an example patient for the CSMD FAQ's to demonstrate what is required.
- The committee decided to use the language below to update question 10 on the CSMD FAQ's.
 - All healthcare practitioners are required to check the CSMD before prescribing an opioid, benzodiazepine, or Schedule II amphetamine to a human patient:
 - at the beginning of a new episode of treatment; and
 - prior to each new prescription for the first 90 days of that treatment; and
 - every 6 months thereafter if that treatment is continued.
 - A new episode of treatment means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous 6 months. A new episode of treatment includes not only changes to specific drugs but also all changes to dosage and frequency.

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

- Dr. Bess provided the committee with the final draft of the CSMD 2022 Legislative report and shared the following:
 - Key findings comparing 2013-2021
 - Morphine Milligram Equivalents (MME) prescribed and dispensed to patients in TN has decreased by 60%.
 - Number of potential doctor shoppers has decreased by 93%.
 - Number of opioid prescriptions for pain has decreased by 46%
 - Key Highlights for CSMD in 2021
 - Since 2013, the number of controlled substance prescriptions reported to the CSMD has decreased 15%, note that gabapentin was added as a new controlled substance in 2018 and had just over 2 million prescriptions reported in 2021.
 - Response time for searches in the CSMD was less than one second if the request did not include data from another state.
 - Gateway Electronic Health Record (EHR)/Pharmacy Management System workflow integration has spread across the state to provide controlled substance prescribers and pharmacists the ability to integrate CSMD information into clinical workflow. In 2021, the CSMD was successfully connected to the RxCheck Hub, a federally supported PDMP data sharing system that supports interstate data sharing and EHR integration
- Dr. Blake asked the committee for a motion to approve the 2022 CSMD Legislative Report.
 - Dr. Bhekumuzi Khumalo made the motion to approve the 2022 CSMD Legislative Report with minor updates, and Dr. Richard Caldwell seconded the motion.
 - 2022 CSMD Legislative Report motion carried.
- Ms. Sanford communicated with the Committee regarding the lookback period in the CSMD. Most states have a limited lookback period from one year to three years. Discussion occurred among the Committee on the amount of data to make a clinical assessment. The Committee came to consensus that three years would be the appropriate amount of time needed.
 - Dr. Bhekumuzi Khumalo made the motion to make Tennessee lookback period three years, and Dr. Shant Garabedian seconded the motion.
 - The motion carried.
- Dr. Bess communicated to the Committee the challenges of allowing neighboring states to

utilize the Gateway HER integration without the Pick List Enhancement to pull TN data into the patient's medical record. Dr. Bess and Ms. Sanford outlined the pros and cons of a wide TN search logic vs narrow search utilized by other prescription monitoring programs. Each comes with its own issues with either false positives or false negatives. . With that discussion Dr. Bess explained that TN's search logic cast a wide net which could create false positives and other states do not have the functionality in their version of Gateway to remove those patients from their report. Given that knowledge Dr. Bess asked for a vote on allowing entities outside of TN to use the Gateway Service to query the CSMD.

- Dr. Bhukumuzi Khumalo asked when request come from out state to Tennessee if the search could be an exact match to narrow the results to an exact match only being returned from t the CSMD to the other states. Ms. Sanford communicated she did not know if this functionality was possible and would take the suggestion to Bamboo Health (TN's Vendor) to determine if this functionality was possible.
- Option one presented to the Committee for consideration is TN consider allowing entities from other states to use the Gateway Service if Bamboo Health was communicating to the state the option to enhance their Gateway service to include a picklist to provide the option to remove false positive(s); if the other state did not want to use the version of Gateway with the option to remove then Bamboo Health could present Option two.
- Option two presented by Bamboo Health only if other state rejects Option one is the other state would be required to include disclaimer language within the Gateway service communicating if patient information presented was not the patient searched in the Gateway then the user would need to perform the search in the home PMP
- Dr. Shant Garabedian made the motion to accept what Ms. Sanford presented; Dr. Bhukumuzi Khumalo seconded the motion;
- The motion carried.
- Dr. Bess communicated that the new clinical risk indicators discussed in the last Committee meeting were under development. At this time asking the committee for recommendation on inclusion on the patient report only or patient report and also include in the clinical risk indicators generated at the beginning of each week that appear on the CSMD User Dashboard.
 - Dr. Bhukumuzi Khumalo made the motion to put this on the patient report and the dashboard; Dr. Shant Garabedian seconded the motion
 - The motion carried.
- Dr. Bess communicated since the vote was to add the new CSMD Clinical Risk Indicators that he would like to get the Committee to discuss and determine the prioritization of the Clinical Risk Indicators as it related to the CSMD User Dashboard. After much discussion the committee decided to reprioritize the current dashboard and new CRIs as follows:
 - Multiple Practitioners ≥ 4
 - Multiple Dispensers ≥ 4
Two or more Combination drug classes with overlapping days (Benzodiazepines, opioids, and/or muscle relaxers)
 - Dr. Khumalo made a motion to consolidate the language and add combination drug to equal or greater than two, and the order be kept with the practitioner/dispenser and MME following below the drug combination CRIs; Dr. Steele seconded the motion
 - The motion carried.
- Dr. Bess asked the committee to approve travel for Dr. Zhi Chen and Debora Sanford to attend the 2022 National Drug Abuse Conference; and Debora Sanford to attend the 2022 ASAP Conference

- Dr. Shant Garabedian made the motion to approve travel for Debora Sanford and Zhi Chen; and Dr. Kurt Steele seconded the motion;
- Travel for Debora Sanford and Zhi Chen motion carried.
- Election for Chair and Vice Chair of the CSMD Committee
 - Dr. Bhekumuzi Khumalo nominated Dr. Melanie Blake as the Chair of the CSMD Committee, and Dr. Shant Garabedian seconded the motion,
 - Motion carried for Dr. Blake as the Chair of the CSMD Committee.
 - Dr. Melanie Blake nominated Dr. Shant Garabedian as the Vice-Chair of the CSMD Committee, and Mr. Robert White seconded the motion,
 - Motion carried for Dr. Shant Garabedian as the Vice-Chair of the CSMD Committee.

The meeting adjourned at 11:04 a.m.