

CONTROLLED SUBSTANCE MONITORING DATABASE ADVISORY
COMMITTEE MEETING
APRIL 16, 2013
227 FRENCH LANDING, IRIS ROOM
NASHVILLE, TN
MINUTES

Members Present

Dr. Richard Orgain, Board of Optometry
Dr. Michael Baron, Board of Medical Examiners
Dr. Terry Grinder, Interim Executive Director, Board of Pharmacy
Dr. Jason Kizer, Board of Pharmacy
Dr. Forest Reynolds, Board of Veterinary Medical Examiners
Dr. Lawrence Hsia, Board of Dentistry
Ms. Rosemarie Otto, Director, Health Related Boards/ Executive Director, Board of Medical Examiner
Ms. Patricia Eller, Board of Medical Examiners
Ms. Joyce McDaniel, Board of Pharmacy
Mr. Donald Bell, APN, Board of Nursing

Members Absent

Dr. Don Polk, Board of Osteopathic Examination, Chairperson
Mr. Jonnie Presley, Board of Physician Assistants
Dr. Paul Somers, Jr., D.P.M., Board of Podiatric Medical Examiners

Staff Present

Dr. Andrew Holt, Board of Pharmacy
Stefan Cange, Assistant General Counsel
Jane Young, Chief General Counsel
Sheila Bush, Administrative Manager
Dr. Mitchell Mutter, Medical Director of Special Projects

The Controlled Substance Monitoring Database Advisory Committee convened on Tuesday, April 16, 2013 in the Iris Room, 227 French Landing, Nashville, TN. Ms. Rosemarie Otto; Director of Health Related Board opened the meeting and requested that each member introduce themselves. Ms. Otto determined that a quorum to be present.

Election

Ms. Eller made the motion to nominate Dr. Michael Baron to be vice chairperson. Ms. McDaniel seconded the motion. The motion carried.

Minutes

Ms. McDaniel made the motion to accept the minutes as amended. Ms. Eller seconded the motion. The motion carried. Dr. Grinder abstained.

Director's Report

Dr. Holt stated that as of April 11, 2013 there are 29,357 registrants and 948,741 request for patient profiles. As of December 2012, the number of registrants was 22,192 and the number of request for patient profiles was 1,861,485.

Dr. Holt stated that there have been an overwhelming number of calls and emails concerning passwords, usernames, lock outs and the prescription safety acts requirements.

Dr. Holt informed the committee that he has sent out a survey concerning user statisification and should have the results at the next meeting. Dr. Baron asked Dr. Holt if it was a good idea to send out the survey at this time since the prescription safety act requirements just went into effect on April 1, 2013 and there have been a lot of complaints concerning the database. Dr. Baron suggested waiting at least six months to give the user time to get use to the database. Ms. McDaniel suggested waiting at least three months before sending out the survey. Dr. Holt stated that he will take the concerns of the committee to the Department.

Dr. Holt presented to the committee a draft of the enhancements that he is looking into to improve the database. He is looking into grants or intradepartmental grants for funding. Dr. Kizer asked if the enhancement will include adding supervising physician. Dr. Holt stated that he has requested and received a partial list of supervising physicians of those professions that are required to have one and looking at the data to see if they need to make adjustment to the request so that it is easier to manage and cross reference with the database. Ms. Eller asked if this procedure will be the only checks and balances that they will use. Ms. Eller stated that this is where most of the issue will be concerning Nurse Practitioners and Physician Assistants move around a lot and they change supervising physician. Dr. Holt stated that the list is the information received from the advanced practice nurse and physician assistants stating who their supervisors are. Ms. Eller asked if the supervisor physician would be responsible for those

prescriptions written by the advanced practice nurse and physician assistants. Dr. Holt stated that the committee can advise on how to handle this issue but typically that information would be analyzed and then provided to the next group to check and then it may go to investigation. Dr. Kizer stated that he thinks it should be part of the investigation not to start an investigation. Ms. Eller asked who will be the ones who will establish the thresholds listed in the report. Dr. Holt stated that it could be committee driven but also the committee working with the commissioner. Dr. Baron asked if there is a method to disseminate the law to all the different profession so they can disseminate to all licensees in that profession. Dr. Holt stated that a letter was sent to all licensees in December 2012 and that they do capture email address in the database.

Presentation

Dr. David Reagan, Chief Medical Officer, Department of Health presented to the committee information from a study that was done by Dr. Jane Baumblatt concerning data from the CSMD and the number of overdose deaths in Tennessee in 2010. Dr. Reagan stated that Dr. Baumblatt's study objective was to describe the epidemiology of prescription opioid abuse, to describe patterns of high risk for opioid abuse and to assess the risk of unintentional opioid related deaths. Dr. Baron stated that generally opioids are lethal but much more so when they are combined with other drugs or substance and wanted to know what they are being mixed with. Dr. Reagan stated the benzodiazepene is part of the mix and this study didn't quantify that. That would be something that could possibly be quantified in the future. Dr. Orgain asked if being able to receive data from the people living near border states and the possibility that they are going to those states to receive their prescription would the numbers go up. Dr. Reagan stated that the numbers would increase. Dr. Hsia asked if did they do a correlation between people who had prescription whether they paid through insurance or not and if there is a high correlation between the two would insurance data be helpful. Dr. Reagan stated that they did not and that the insurance data is another database that they may look into in the future. Dr. Kizer asked about when CSMD will be able to interconnect with other bordering states that have a prescription monitoring database. Dr. Holt stated that they will start testing within the next couple of weeks and the first state will be South Carolina. If the testing works well with South Carolina then they will add other states through NABP Interconnect. Dr. Baron stated what really surprises him is that according to the data collected 97% of the people are white and 2.7% are black that end up in the morgue and wanted to know if this was being underreported within racial groups. Dr. Reagan stated that there are inconsistencies in the reporting the data to vital records from doctor's office and that the death certificate may be filled out differently from one jurisdiction to other. Dr. Reagan stated that this does not include accidental deaths. Ms. McDaniel asked how are patients able to get multiple prescriptions if the doctors are checking the database. Dr. Mitchell Mutter, Medical Director of Special Projects, stated that there are really two types of over prescribers one being the criminal element and the other is the codependent element. Most

physicians want to help and relieve pain and are not really aware but he thinks that once they write the treatment guidelines it will help the physicians who are codependent. Dr. Baron stated that in the primary care model it is easier to write a prescription than to get someone off the prescription. He stated that it is a matter of effort and education by the physicians. Dr. Orgain asked if purposeful overdoses are listed separately in the data collect. Dr. Reagan stated that it is not and that most of the deaths are accidental overdose deaths not intentional.

Michelle Long, Assistant Commissioner, Department of Health introduced Dr. Chin who will be the epidemiologist who will continue to mine the data previously done by Dr. Baumblatt. Dr. Baumblatt was on loan to the department and has since left. There have been two new employees added to the CSMD staff that is being paid through the Prescription Safety Act. Debra Sanford is on loan to the committee through the Department of Health IT Department and she is the liaison with our vendor. Ms. Sanford is working on the enhancements and working with the vendor to make sure that they are doing the work required. Ms. Long stated that the statute the leadership for the CSMD was tied to the executive director of the Board of Pharmacy. The executive director has been working in that dual capacity for quite some time. In a recent meeting of the Board of Pharmacy the board became aware when the fungal meningitis outbreak occurred that the 50% of the executive director's time was being spent dealing with the CSMD issued. The board addressed Ms. Long and asked what she going to do about this issue. Ms. Long present the committee with two options, one being that the committee could continue as it has always functioned or create a new position and have it funded, as Dr. Chin is, by the nine boards that contribute to the CMSD. After discussion, Ms. Otto made the motion to add a director's position separate from the Board of Pharmacy for the CSMD. Ms. McDaniel seconded the motion. The motion carried.

Financial Report

Lisa Tittle spoke to the committee about the way the finances are distributed to the committee. The committee has its own cost center and the cost of the expenses is attached to that cost center. Ms. McDaniel asked what the professional services cost was. Ms. Tittle explained that in 2013 it is the cost to Optimum. Optimum is the vendor for the CSMD database. The equipment cost is attached to the Prescription Safety Act. Ms. McDaniel asked if grants are available. Dr. Holt stated that grants are available but most are for specific needs. Ms. Tittle stated that the committee projections for fiscal year 2013 are \$644,191.88.

Office of General Counsel Report

Stefan Cange, Attorney, informed the committee that there are nine cases in RBS which list CSMD as the complainant. Of those nine cases, 1 case has been closed, 5 are currently being investigated and 3 have been investigated and are waiting for a second review by their respective boards' attorneys. By profession the nine cases would be listed as 5 physicians, 3 advanced practice nurses and 1 osteopathic physician.

Ms. Young introduced Mollie Gass to the committee. Ms. Gass will be working with over prescribing cases.

Mr. Cange informed the committee that the final version of the CSMD rules was filed with the Department of State on April 2, 2013 and will become effective on July 1, 2013.

Mr. Cange informed the committee about Senate Bill 529 would require some additional reporting of specific data and analyses from the database to the legislature. Mr. Cange stated that he has since been told that this amendment has been taken out of Senate Bill 529. Senate Bill 676 has some changes to the Prescription Safety Act.

Mr. Cange informed the committee that the Department has begun receiving requests for the Committee to designate certain medical specialties as exempt from checking the database in accordance with Tenn. Code Ann. §53-10-310(3)(5)(B). Mr. Cange stated that he is in the process of developing policies and procedures to implement this portion of the law.

Ms. Eller asked if the patient profile would be added to the medical records. Ms. Young stated that there have not been any changes in the law. The issue is that there are only three instances (patient, law enforcement and another treating physician) to whom the records can be released. Ms. Young stated that she believes that it is the risk management of physician who are advising physician not to add the patient profile to the medical record. Dr. Hsia asked how you would know in the medical record if the database has been checked. Ms. Young stated that there is no prohibition to marking in the record that the database has been checked.

Chris German, Counsel for the Tennessee Health Care Association, appeared before the committee to ask for consideration modification to or removal of the requirement for prescribers to check the database for medications prescribed and provided to patients in nursing homes. Allison Rainey, Nurse Practitioner and Clinical Coordinator for National Health Care Corporation, and explained what she has seen in practice in reference to T.C.A. §53-10-310 (e) (5) (b). Dr. Baron asked how a facility can get an exemption when facilities don't prescribe. Mr. Cange stated that under the current law the exemption can only be given to a medical specialty

which does not refer to a practice site but refers to the training of a licensed health professional. Mr. Cange also stated that absence from a legislative change he is not sure that there is a way to grant a waiver for a facility. If the legislation that grants the waiver does not pass then the committee could sit down with the stakeholders and try to find a solution. Dr. Orgain asked if they were receiving pressure from physicians to come see the patients. Ms. Rainey stated that prescribers are changing their practices and will only write covered controlled substance requirements for the seven day requirement and avoid checking the database or asking licensed personnel at the facility to check the database for them. Dr. Orgain stated that it is in the statute that it is the physician duty to check the database. Ms. Eller stated that she thinks that they should approach the legislation to change the law. After discussion, Ms. McDaniel made the motion to accept the current legislation with the change effective immediately. Dr. Kizer seconded the motion. A roll call vote was taken. Dr. Kizer, Ms. McDaniel and Dr. Grinder voted yes and Dr. Baron, Dr. Bell, Ms. Eller, Dr. Orgain, Dr. Reynolds, Dr. Hsia and Ms. Otto voted no.

Reports

Dr. Mutter informed the board that there are 293 pain clinics in Tennessee as of March 2013. Dr. Mutter stated that they will be looking at the population per county per pain clinics. Dr. Mutter and Andrea Huddleston, Deputy General Counsel will be attending a meeting in Washington, D.C. with the Center for Disease Control to discuss what Tennessee is doing with the prescription monitoring database.

Dr. Mutter stated that they are looking into creating a CSMD newsletter to help educate users about the database. Dr. Mutter also explained to the committee about sending out letters concerning the top 50 prescribers and that they are making progress. In 2012, there were 80 complaints in the Board of Medical Examiners, 28 complaints against APN's and 14 complaints against physician assistants for overprescribing. Some of these complaints were generated from the top 50 prescribers.

Dr. Mutter stated that the audit for pain clinics have not been started due to staffing issues. They are in the process of hiring new investigator's to help audit the pain clinics.

Exemptions

Dr. Orgain made the motion to approve the following requests for exemptions from electronic reporting to the controlled substance monitoring database. Ms. Eller seconded the motion. The motion carried.

Controlled Substance Monitoring Database Advisory
 Committee Meeting
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|-------------------|-------------------------------------|
| Laura Dougherty | BET Pharm, LLC |
| Brad Stoltz | Cardinal Health 414, LLC |
| William Frederick | Cardinal Health 414, LLC |
| Howard Edwards | Anovo RX Group, LLC |
| John Nigara | Simfa Rose Pharmacy |
| Adam DeBruin Sr. | Embrace Pharmacy |
| Lisa Dimick | PCM Venture I, LLC |
| Bhavesh Patel | Carepoint Pharmacy |
| Bhavesh Desai | California Specialty Pharmacy |
| Rita Storie | Trevecca Nazarene University |
| Lisa Dimick | Bella Brands, LLC |
| Allison Gilmore | Home Care Solutions, Inc. |
| Mark Zilner | Diamond Pharmacy Services |
| Phillip Moss | Baxter Healthcare Corp. |
| Tommy Phillips | Senderra Rx Partners |
| Arlene Nakata | BioFusion |

Waivers

Dr. Orgain made the motion to approve the following requests for waivers from electronic reporting to the controlled substance monitoring database. Dr. Kizer seconded the motion. The motion carried.

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|------------------|-----------------|
| Billie Stidam | |
| Shari Marshall | RX Alternatives |
| Barbara A. Reeve | Jackson Square |

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|------------------------|---------------|
| | Animal Clinic |
| Ronald L. Rimer, MD | |

Correspondence

Dr. Holt presented to the board a written request from Norman A. Desbiens, M.D., Medical Director for Program of All-Inclusive Care of the Elderly (PACE) asking to be exempt from checking the database. The committee deferred the request since this request is part of a bill that is in the legislation.

Dr. Holt presented a request from Traci Green, Ph.D. requesting de-identified data from the CSMD database to evaluate the health impact on PMP utilization by prescribers and pharmacists as a means of preventing unintentional prescription drug overdoses in the adolescent and adult population. Dr. Holt presented a request from Meharry General Hospital requesting de-identified data from the CSMD database at a county level to correlate with the poison control center to establish calls between poison control centers and prescription drug use. Dr. Baron asked if the committee was authorized to release this information. Mr. Cange stated that under the current law the committee cannot release this information to anyone other than government personnel, law enforcement and practitioners.

Ms. Eller made the motion to adjourn at 12:05 p.m. Dr. Orgain seconded the motion. The motion carried.

The minutes were ratified at the August 20, 2013 committee meeting.