

CONTROLLED SUBSTANCE MONITORING DATABASE  
COMMITTEE MEETING  
AUGUST 20, 2013  
227 FRENCH LANDING, IRIS ROOM  
NASHVILLE, TN  
MINUTES

**MEMBERS PRESENT**

Dr. Don Polk, Board of Osteopathic Examiners, Chairperson  
Dr. Richard Orgain, Board of Optometry  
Dr. Michael Baron, Board of Medical Examiners  
Dr. Forest Reynolds, Board of Veterinary Medical Examiners  
Ms. Rosemarie Otto, Director, Health Related Boards/Executive Director,  
Board of Medical Examiners  
Ms. Patricia Eller, Board of Medical Examiners  
Dr. Reginald Dillard, Executive Director Board of Pharmacy  
Ms. Joyce McDaniel, Board of Pharmacy  
Mr. Brent Earwood, Board of Nursing

**MEMBERS ABSENT**

Dr. Jason Kizer, Board of Pharmacy  
Dr. Lawrence Hsia, Board of Dentistry  
Mr. Johnnie Presley, Board of Physician Assistant  
Dr. Paul Somers, Jr., Board of Podiatric Medical Examiners

**STAFF PRESENT**

Dr. Andrew Holt, Director, Controlled Substance Monitoring Database  
Stefan Cange, Assistant General Counsel  
Jane Young, Chief General Counsel  
Dr. Mitchell Mutter, Medical Director of Special Projects  
Dr. David Reagan, Chief Medical Officer, Department of Health  
Michelle Long, JD., Assistant Commissioner, Department of Health  
Sheila Bush, Administrative Manager

The Controlled Substance Monitoring Database Advisory Committee convened on Tuesday, August 20, 2013 in the Iris Room, 227 French Landing, Nashville, TN. Dr. Polk, Chairperson opened the meeting and requested that each member introduce themselves. Ms. Otto determined that a quorum to be present.

## **Minutes**

Dr. Baron made the motion to accept the minutes as presented. Dr. Reynolds seconded the motion. The motion carried.

## **Presentation**

Dr. Reagan expressed his appreciation to the committee for their hard work and dedicated service.

## **Director's Report**

Dr. Holt informed the committee that several enhancements are scheduled for the database with Phase I to production by September 30, 2013 and Phase II to production by December 31, 2013. Some of the enhancements to the database will be automated username retrieval, administrative search feature via email, multiple practice locations per user, enhanced linking of extenders to supervisors, reports that the supervisor can use on extenders and extenders running reports for the supervisor. Dr. Holt also stated that clinical notifications solicited or unsolicited reports and a morphine calculator will be added to the database. The push notifications (unsolicited) will be sent to the practitioner when a patient has exceeded the threshold of the number of pharmacies, number of practitioners or the morphine equivalent set by the committee. With the solicited report a practitioner will be able to look up a patient and receive a report that will show whether the patient has been to several different pharmacies, practitioners or if they have exceeded the morphine equivalent threshold set by the committee. The morphine calculator will allow the practitioner to see the patient's active average morphine equivalents per day. This will work by taking all the patients active prescriptions calculated from day supply added together and averaged by day. Dr. Holt stated that on the data collection side of the database the enhancements will include adding the waivers and exemptions which will help identify delinquent pharmacies and an indication of prescribers who dispense. Dr. Holt informed the committee of future enhancement that he is looking into and he will be looking for grant money to fund those enhancements. Ms. Eller asked how the report will be given to the extenders or practitioners. Dr. Holt stated that the reports are usually given in a pdf format. Dr. Baron asked what variable will be used as the morphine equivalent and if there will be a warning if the threshold has been exceed. Dr. Holt stated that the threshold would need to be set by the committee today and that a warning will be sent to the prescriber. Dr. Holt asked the committee to decide what the clinical threshold variable would be for the number of prescribers, number of pharmacies, number of morphine equivalents and the number per day. The notifications alerts will be designated by the colors red or yellow. The yellow alert could be that the report deserves a look and red alert would mean that there is significant evidence and would require another look. After discussion, Dr. Orgain made the motion for yellow alert to be sixty (60) days and the red alert to be one hundred and twenty (120) days. Ms. McDaniel seconded the motion. The motion carried. Mr. Earwood made the motion to use three (3) pharmacies for the sixty (60) day threshold and four (4) or greater pharmacies for the one hundred and twenty (120) day threshold. Dr. Orgain seconded the motion. The motion carried. Dr. Baron made the motion to use three (3) prescribers for the sixty (60) day threshold and four (4) or greater prescribers for the one hundred

and twenty (120) day threshold. Dr. Orgain seconded the motion. The motion carried. Dr. Baron made the motion to use sixty (60) for the morphine equivalent and one hundred (100) for the morphine equivalent. Ms. Eller seconded the motion. The motion carried.

Dr. Holt informed the committee about Public Chapter 430 which will require CSMD to collect data from wholesaler/distributor when they distribute controlled substance. The data will be collected in a system that is similar to the ARCOS system used by the DEA.

Dr. Holt informed the committee that the CSMD started interstate data sharing with Michigan and South Carolina on July 31, 2013 and will add Virginia on August 8, 2013.

Dr. Holt asked the committee for approval to purchase a secure file transfer protocol (SFTP) or a mirrored copy transfer which provides a secure way to transfer files from the vendor to the CSMD so that the epidemiologist can have updated information for reporting purposes. The SFTP has high labor cost and is not as current as a mirrored copy and the mirror copy has low labor cost and is updated daily but the mirrored copy has a high up front cost. The cost for the SFTP is \$5000.00 monthly and the mirror copy is \$5000.00 monthly and \$20,000.00 for the server. After discussion, Dr. Orgain made the motion to purchase both the SFTP and the mirror file transfer. Ms. McDaniel seconded the motion. The motion carried.

Dr. Holt informed the committee that by statute TennCare, Medicaid Fraud and Mental Health and Substance Abuse Services have access to the data reported to the CSMD. Dr. Holt also stated that Legislators can request aggregate and deidentified data as well. Dr. Baron asked if the agencies listed have to request the data or can they access the data themselves. Dr. Holt stated that the agencies are able to log in to the database themselves.

Dr. Holt asked the committee for approval to purchase GSI mapping software which will allow us to take data from the database to use in map. After discussion, Ms. McDaniel made the motion to allow Dr. Holt and staff to decide which GSI mapping software to purchase. Dr. Orgain seconded the motion. The motion carried.

Dr. Holt informed the committee that the educational project/webinar is nearing completion and should be up and running soon. Dr. Holt also stated that he has been invited to speak at the University of Tennessee Fall Therapeutics Seminars which is scheduled around the state, the 2013 Harold Rodgers National Meeting in Washington, DC on September 25-27, 2013 and Southeast Addiction Technology Transfer Center in Chattanooga, TN on September 20, 2013. Dr. Holt asked for travel authorization to attend the National Association of States Controlled Substances Authorities (NASCSA) Annual Meeting in Kansas City, MO on October 22-25, 2013. After discussion, Ms. Otto made the motion authorizing travel for Dr. Holt and Dr. Zhi Chen to attend NASCSA Annual Meeting in Kansas City, MO on October 22-25, 2013. Dr. Orgain seconded the motion. The motion carried.

Dr. Holt asked the committee to consider meeting more frequently due to responsibility changes listed in Public Chapter 430 related to top prescribers. Dr. Orgain made the motion made the motion to meet more frequently. Ms. McDaniel seconded the motion. The motion carried.

### **Report from Director of Special Projects**

Dr. Mutter stated that the top fifty (50) prescriber letters were sent registered mail at the end of July 2013 and they have fifteen (15) days to respond per statute. The letter contained information concerning a significant number of controlled substances, number of patients and morphine equivalents prescribed.

Dr. Mutter informed the committee that Public Chapter 430 states that all dispensers may only dispense controlled substances scheduled II-IV for thirty (30) days at a time and it is non-refillable. Also included is the requirements is that the chronic pain guidelines to be written by January 1, 2014 and all prescribers with DEA must complete two (2) hours of continuing medical education every two (2) years.

Dr. Mutter informed the committee there are 313 certified pain clinics in Tennessee as of July 2013. The Bureau of Investigations has conducted twelve (12) audits and there are five (5) active investigations.

Dr. Mutter stated that they will be conducting a several risks models using patient risk, prescribers risk and pharmacy risk. Ms. Eller asked if the NAS data being accurately reported. Dr. Mutter stated that it is not. Dr. Mutter stated that he will bring it to attention at the next NAS Task Meeting. Ms. Otto asked who is responsible for the report. Dr. Mutter stated that it is reported by the hospitals to the Health Department. After further discussion, Ms. Eller made the motion to send a recommendation to the NAS Task Force to retrieve more timely and accurate NAS reports from Health Facilities. Ms. Otto seconded the motion. The motion carried.

### **Office of General Counsel Report**

Mr. Cange informed the committee that the current changes to the rules that pertain to veterinarians are in the Attorney General's office for review.

Mr. Cange explained to the committee that Public Chapter 430 amended some of the controlled substance monitoring database statutes. Some of the changes include the definition of health care practitioner extender was modified and definitions for manufacturer and wholesaler was added. Mr. Cange stated that wholesalers and manufacturers of controlled substances will be required to report sales of controlled substances to the Department using the ARCOS format currently required for federal reporting. Also, a provision was added that exempts prescribers from having to query the database before issuing a prescription when the controlled substance is to be administered during the course of inpatient or residential treatment in a hospital or nursing home licensed under Title 68 or a mental health hospital licensed under Title 33.

Mr. Cange informed the committee that the Department of Health has drafted a policy statement concerning the access and dissemination from the database by authorized personnel.

## Exemptions

Ms. McDaniel made the motion to approve the following request for exemptions from electronic reporting to the controlled substance monitoring database. Mr. Earwood seconded the motion. The motion carried.

Enrique Hernandez	All Med Services of Florida Inc. Univita
Odell Glenn Jr	Eiris Health Services #6012
John Scott Borland	Accredo Health Group, Inc.
G. Scott Rye	Franklin Pharmacy
Justin Mills	Pet360 Inc. dba Petscriptions
Patricia Moneyham	Alliance Allergy Solutions, Inc.
William Bucy	Medicine Arts Pharmacy
Nathan Hughes	Manifest Pharmacy
Kenneth Zielinski	Liberty Medical Supply Pharmacy
Steven Getz	Accredo Health Group, Inc.
Andrea P. Wright	Atlantic Medical LLC
Susan Smith	Shared Solutions Pharmacy
Nicole Balarezo	Goodlife Pharmacy
Penny Thompson	Franklin Professional Pharmacy
Allen F. Scorsatto	Community Healthcare Services, Inc.
David Diehl	Everest Pharmacy, LLC
Spencer Brown	Pet's Choice Pharmacy LLC
Wendy Blackston	Rite Aid Specialty Pharmacy, LLC
Brian Buford	Anovo RX Group, LLC
David Armstrong	Fresenius Medical Care Rx
Benji Post	Fresenius USA Manufacturing dba Fresenius Meci. Care North
Betty Jones	Fresenius USA Manufacturing dba Fresenius Meci. Care North
Sherry Mauldin	Fresenius USA Manufacturing dba Fresenius Meci. Care North
Paul Mahan	Petnet Solutions
Scott Angus	QPharxMacy, Inc.

Ms. McDaniel made the motion to deny the following request for exemptions from electronic reporting to the controlled substance monitoring database. Dr. Orgain seconded the motion. The motion carried.

Lisa P. Timberlane	Southmed Pharmacy
John Scott Borland	Accredo Health Group, Inc.
William T. Rye	

### **Waivers**

Ms. Eller made the motion to approve the following request for waivers from electronic reporting to the controlled substance monitoring database and to defer the request from Kenneth Salhany, Murfreesboro, TN and Kenneth Salhany, Manchester, TN until additional information has been received. Dr. Orgain seconded the motion. The motion carried. Dr. Barron was recused.

Frank La Corte	Miami Executive Pharmacy
Kathryn J. Simpson	Kingston Animal Hospital, PC
	Kenneth Salhany, DO
	Kenneth Salhany, DO
Connie S. Ewald	Rx Direct
J. Neil Utkov	Pet Health Center

### **General**

Dr. Polk announced his wishes to step aside as chairperson of the committee and remain an active member. Elections will take place at the next committee meeting.

**The minutes were approved and ratified at the October 8, 2013 committee meeting.**