



Controlled Substance Monitoring Database (CSMD)
Committee Meeting Minutes
June 7, 2016

MEMBERS PRESENT

Dr. Michael Baron, Board of Medical Examiners,
Chairperson
Dr. Debra Wilson, Board of Pharmacy
Ms. Patricia Eller, Board of Medical Examiners
Mr. Brent Earwood, Board of
Nursing
Dr. Brad Lindsay, Board of
Optometry
Dr. Shant Garabedian, Osteopathic
Board
Dr. Sheila Schuler, Podiatry Board

MEMBERS ABSENT

Vacant, Board of Optometry
Dr. Kim Johnson, Board of Veterinary Medicine

Mr. Omar Nava, Committee on Physician Assistants
Dr. Katherine Hall, Board of Dentistry
Ms. Joyce McDaniel, Board of Pharmacy

STAFF PRESENT

Dr. D. Todd Bess, Director of Controlled Substance
Monitoring Database
Dr. Mitchell Mutter, Medical Director for Special
Projects
Ms. Tracy Bacchus, Administrative Assistant
Mr. Andrew Coffman, Attorney, Office of General
Counsel
Ms. Debora Sanford, Project Manager
Ms. Antoinette Welch, New Director, Office of
Investigations
Mr. Jerud Colbert, Project Manager

The CSMD Committee convened on Tuesday, June 7, 2016, in the Iris Room, 665 Mainstream, Nashville, TN. Dr. Baron called the meeting to order at 9:00 a.m. and requested that members introduce themselves.

Dr. Baron mention to the group that we are live streaming so please make sure the green light is on and speak into microphone.

Minutes

Dr. Baron asked had everyone read the minutes from the last meeting, and if so can the committee have a motion to approve the minutes. Dr. Debra Wilson made the motion to accept the minutes from the January 25, 2016 and March 22, 2016 committee meetings. Dr. Brad Lindsay seconded the motion; move by acclimation the minutes were approved.

Office of General Counsel

- Mr. Coffman discussed that 53-10-311 has created an Operations Committee, and that Dr. Reginald Dilliard is on that committee. A member from the CSDM would be a member on the Operations Committee. Dr. Baron asked would the CSMD committee need to vote, and Mr. Coffman stated that that is not necessary unless they wanted to vote. Ms. Eller recommends that the Chairman sit on the Operations Committee.
- Mr. Coffman updated the committee on the rule making process stating the rules are still with the Attorney General Office. The new law has created the needs for new rules, which will be presented at the next committee meeting.
- Mr. Coffman requested the committee to approve travel for two people from OGC to attend the NASCSA Conference in New Orleans, LA. Dr. Brad Lindsay motion to approve travel and Dr. Shant Garabedian second the motion; move by acclimation to approve travel to attend NASCSA Conference.

Legislative Updates

- Ben Simpson updated the committee on the Prescription Safety Act 2016 that it removed the sunset from the original act that will be effective April 27, 2016. This act also created an Operations

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Committee and this committee will consist of a member of the CSMD Committee and four other members. The CSMD Committee will still have the authority to set fees and policies. Mr. Simpson also mentioned that the CSMD Committee is responsible for going back to the individual boards to update their board. Dr. Mutter asked are you referring to the fees that the regulatory boards pay to run the CSMD? Mr. Simpson states that any time the CSMD Director ask for an analysis or expansion of duty it needs to come to the CSMD Committee before it can go to the Commissioner for approval. Ms. Eller asked Mr. Simpson to explain the rule making authority piece again. Mr. Simpson stated that the Commissioner has the authority to promulgate rules according to the Uniform Administrative Procedures Act (UAPA). There are four specific things that the Commissioner is given power and the specifics are establishing and maintain the operation of the database, access to the database and how the data is obtained, controlled and dissemination of data in the database, and the control and sharing of data in the database with other states and entities acting on behalf of the state. The CSMD committee shall advise the commissioner of any rules made under this part and CSMD committee is the only one charged with this responsibility. Dr. Baron asked who approves the legislative report and Mr. Simpson said that the committee would still approve the legislative report. This new law gives the Director of the CSMD more time to prepare the legislative report.

- Dr. Mutter asked Mr. Simpson to discuss Public Chapter 1033.
 - Mr. Simpson stated that by July 1, 2016 every pain management clinic registered with the state needs to have a pain management specialist listed as the medical director. The medical director of a pain management clinic would be the licensee on the certificate effective January 1, 2017. Dr. Mutter also communicated that the license for the pain management clinic goes with the medical director and not the pain management clinic. So how long does the clinic have to get a new medical director and a new licensee was asked and it is still 10 business days and Mr. Simpson stated it is still 10 business days.

- Mr. Simpson discussed Public Chapter 959.
 - This bill authorizes the commissioner of health or the commissioner's designee to obtain records maintained by any licensed facility licensed to facilitate investigations and inquiries concerning opioid drug abuse, opioid drug overdoses, and opioid overdose deaths. Such facilities must provide records in the most efficient and expedient means possible. To determine these means, the department must:
 - Consult with stakeholders to develop data reporting elements and a short-term mechanism for near real-time electronic access to these data elements by July 1, 2016.
 - Implement the short-term reporting system by October 1, 2016.
 - Consult with stakeholders to develop a long-term electronic real-time data-reporting plan utilizing electronic processes for opioid drug abuse, overdoses, and overdose deaths by January 1, 2017. This legislation took effect on April 27, 2016

- Mr. Coffman asked if he would elaborate on being a pain management specialist.
 - Mr. Simpson said that there is a clinic designation; you can be certified by the ABPM (American Board of Pain Management); ABIPP you will need to have passed exam 1 and 2 portion of the test; and ABMS (American Board of Medical Specialty).

- Mr. Coffman asked to elaborate more on Public Chapter 973.
 - Mr. Simpson states that this act establishes requirements for the dispensing of opioids and benzodiazepines by physicians and other healthcare providers. This mean dispenses opioids and benzodiazepines, as directed by the patient's prescription, in safety-sealed, prepackaged containers stamped with the manufacturer's national drug code (NOC) number.



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- Administers and records pill-counts for opioids or benzodiazepines in order to ensure patient compliance with the prescription.
- Dispenses non-controlled substances, which amount to at least fifty percent (50%) of the prescriptions filled annually from the practice.
- Submits controlled substance dispensing information to the controlled substances monitoring database under title 53, chapter 10, part 3, according to the requirements of state law. This act took effect on April 27, 2016.
- Dr. Mutter asked Mr. Simpson to elaborate more on Public Chapter 912.
 - Public Chapter 912 creates a non-residential office base opioid treatment facility that puts them under the Department of Health. The definition of this is prescribing buprenorphine or products containing buprenorphine to fifty percent or more of their patients to 150 patients or more.

Axial Healthcare

Kevin Kirkpatrick gave the committee a little bit of history on Axial Healthcare. Some things you should know about us; they are a Tennessee-based Company - 4 years in R&D

- A team of physicians, scientists, pharmacists, technologists, and health plan operators,
- Presiding over nation's largest structured database of patients in pain and opioid users,
- Maintaining the most extensive compendium of pain treatment and medication EB literature,
- Collaborating with the Center for Medicare & Medicaid Innovation (CMMI) on "payment for value" chronic pain episodic development,
- Deploying our solutions with large health insurers, ACOs and IDNs nationwide. Supporting Practitioners, Enhancing Pain Care, Minimizing Opioid Misuse

Axial has worked extensively with respected academic centers and its national scientific advisory board to develop evidence based protocols for treating the more common pain complaints that drive patients to seek medical care. These pathways are to be used as clinical guides only with the understanding that specific clinical circumstances should supersede these algorithms. Shant Garabedin asked if this is a service that health care providers would have to pay? Kevin responded that it is not because Axial clients are the health plans that pay for the services.

CSMD Director's Report

Updates:

- Dr. Bess introduced Dr. Melissa McPheeters to the CSMD Committee.
- Updated the committee on the Public Health Approach to the Opioid Abuse Strategic Map of 2016.
- Updated the committee that the CSMD applied for a Harold Roger Grant.
- Went to Atlanta in May to update the CDC Grant group on the TennCare Lock-In Program. TennCare, and the CSMD will partner together to have a new CSMD Clinical Risk indicator related to this TennCare Lock in Program added to the indicator to the CSMD patient report.
 - Dr. Baron asked if the patient decides not to use their insurance benefits and go outside of the lock-in pharmacy, and Dr. Bess said they could, but TennCare expects the patient to stay at the same pharmacy.
- Dr. Garabedin asked if a CII can be e-prescribed, and Dr. Dilliard stated that e-prescribing is allowed for CII and the software of the prescriber and dispenser have to comply with DEA requirements.



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- Working on the Top 50 and Top 10 for small counties. We had an 11.2 percent decline in the Top 50 MME for 2016 compared to 2015.

Dr. Bess and Dr. Reginald Dilliard traveled throughout the state updating pharmacists on the prescription drug crisis and the CSMD Program in the first half of 2016. They had about 1200 individuals attend their sessions. He communicated that the CSMD was in the NY Times Article on May 20, 2016 and quoted: "Tennessee tried hard to get doctors to consult the database it set up in 2006, to no avail — the number of doses prescribed rose by 12 percent from 2010 to 2012, state officials said. So in 2013, the state made checking the database mandatory, and the number of doses declined by 14 percent from 2012 to 2015."

Dr. Bess updated the committee that TDH was working on the final draft of the NABP contract and it is being sent to NABP for signature. TDH's Appriss contract will expire in September 2016, and TDH has decided to do a one-year contract. This will give TDH more time to work on a high quality long-term vendor contract next year.

Mr. Coffman has been working very hard on the doctor shoppers' project with the Kentucky. Mr. Coffman stated that he tentatively promised to have that contract in place before his vacation.

Dr. Bess ask the committee to approve travel for:

- Debora Sanford to attend the NABP Steering Committee Meeting, in Northbrook, IL in July
- Dr. Bess, Debora Sanford, and Zhi Chen to attend the NASCSA Conference in New Orleans in October, 2016

Debora Wilson made the motion and Ms. Patricia Eller second the motion, and move by acclamation the traveled was approved.

Dr. Bess asked the committee to grant him permission to approve travel related to the CSMD. Debora Wilson made the motion to grant Dr. Bess permission to approve travel and report back to the committee during the annual budget report; Dr. Lindsay seconds the motion; the motion was approved to grant Dr. Bess permission to approve travel.

Dr. Bess proposed to the committee to grant him permission to approve the waivers and exemptions. Dr. Lindsay made the motion to grant Dr. Bess permission to approve the waivers and exemption and bring the ones to the CSMD Committee that posed an issue; Mr. Earwood seconded the motion; and the motion carried to grant Dr. Bess permission to approve the waivers and exemptions.

Exemptions/Waivers

Debora Wilson made the motion to approve the waivers and exemptions as they are presented, Dr. Lindsay second the motion; and the motion carried to approve d waiver and exemptions.

Name	Business	No DEA	No Dispensing	Exempt By Statute	Waiver from electronic reporting	Approved
Lisa Dimick	Bella Brands, LLC	x				X
Pamela S. Smith	Care Services On Call	x			x	X



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Name	Business	No DEA	No Dispensing	Exempt By Statute	Waiver from electronic reporting	Approved
Johnny Ray J. Garcia	Caremark Florida Mall Pharmacy, LLC dba CVS Caremark	x				X
John M. Belobraydic	Convergys Corporation	x				X
An Tran	Darsalud Pharmacy	x				x
Andrea Erb	ETSU Charitable Pharmacy	x				x
Mary Theresa Rossetti	Express Pharmacy Services of PA, LLC. Db a CVS Caremark #1638	x			x	x
Kathryn P. Cartwright	FarmVet.com	x				x
Humphrey Kem-Bumbala	Henry Schein Animal Health	x				x
Cramartie Nickerson	Jefferson Pharmacy, LLC	x				x
Jessica Lisa	Medex BioCare Pharmacy	x				x
Jennifer Mooney-Thompson	Mint Pharmacy and Skin Clinic	x				x
Mitesh G. Prajapati	Mylan Health Management	x				x
Angela Ballon	Performance Animal Health	x				x
Milton L. Hagan	PetNet Solutions, Inc.	x				x
Paul Stroud	PetNet Solutions, Inc.	x				x
Martin James Farrell	Rapid Equine Solutions, LLC	x				x



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Name	Business	No DEA	No Dispensing	Exempt By Statute	Waiver from electronic reporting	Approved
Susan O. Smith	Shared Solutions Pharmacy	x				x
Walter Guice	Triade Isotopes Chattanooga	x				x
Michael Arrowwood	Veterinary Internet Company Pharmacy	x				x
Alan Kanning	Walgreens Specialty Pharmacy	x				x
Jennifer A. Ondrus-Otto	American Services Product		x			x
Brian Rutherford, D.V.M.	Animal Emergency & Specialty Center				x	x
Kelli E. Lewis	AnovoRx Group, LLC		x			x
Michael E. Lonczynski	Apria Healthcare LLC dba Apria Pharmacy Network		x			x
Arlene K. Nakata	BioFusion, LLC		x			x
Gregory Wolfe	Biologics, Inc		x			x
William H. Graybeal, Pharm.D.	BioPlus Specialty Pharmacy Services, Inc.		x			x
Carrie Belsom	Brand Direct Health Pharmacy, LLC		x			x
Melissa Anderson	Brioval Rx		x			x
Larry Todd Roberts	Brioval Rx of Texas		x			x
Denise Gleeson	Bryan's Family Pharmacy		x			x



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Cristina Escobedo	Caprock Pharmacy		x			x
Jennifer Almon	Cardinal Health 128, LLC dba MMS Solutions		x			x
Sara L. Collins	Caremark Illinois Mail Pharmacy, LLC dba CVS Caremark		x			x
Robert L. Marx, Pharm.D.	Cystic Fibrosis Pharmacy, Inc.		x			x
Arash Raei, Pharm.D.	Deliver Care Rx Pharmacy, LLC		x			x
Noureen Wadhwanian	Distinguished Pharmaceuticals		x			x
Rodney Ford	Eagle Pharmacy, LLC		x			x
Gleb Chemerisov	Empire Specialty Pharmacy Corporation		x			x
Tiffany Hoose	Erlanger Bledsoe Medical Center Pharmacy			X		x
Thomas Edinger	Express Scripts		x			x
Chacko Varghese	Family Pharmacy, LLC		x			x
David Armstrong	Fresenius Care, Rx, LLC		x			x
Beth Sweeney	Fresenius Medical Care Pharmacy, Inc.		x			x
Laura Brunner Crow	Gateway Medical Center			X		x



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Scott Keith	Gateway Pharmaceuticals		x			x
Stephen Seiden	Glen Rock Medical Pharmacy		x			x
Grady Jerome Broome	HealthSouth Chattanooga Rehabilitation Hospital			X		x
Matthew L. Farmer	Heartland Home Infusions, Inc. dba HHI Infusion Services		x			x
Robert L. Marx, Pharm.D.	HHCS Pharmacy, Inc. dba Freedom Pharmacy		x		x	x
Marisol Limehouse	InTouch Pharmacy, LLC		x			x
Amy Ruth Gostomski	JHSMH Pharmacy Specialty dba Plus		x			x
Adam Walters	Lantana Pharmacy Inc.		x			x
Shanna Nyberg	LLC Patient Services		x			x
Ira Schylman	LMC Medical Supplies Inc. dba LMC Pharmacy		x			x
Elizabeth Cherry	Medicine Shoppe of Somerset		x			x
Erica Yelton	Med Scripts Medical Pharmacy		x			x
John E. Brunner, D.V.M.	Noah Friend Inc.			X		x



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Deppali Chachare	Northmark Pharmacy		x			x
Emily Williamson	Nutritional Parenteral Home Care of Huntsville, Inc.		x		x	x
Lucas Dominick	OpiMed Speciality Pharmacy		x			x
Yong Lee	Optum Rx Home Delivery of Illinois, LLC dba Optum Rx of Illinois		x			x
Yong Lee	OptumRx of Illinois		x			x
Kimberly Feckley	OptumRx of Ohio		x			x
Samantha Ashley	Opus Rx		x			x
Masum Patel Amin	Peterson Pharmacy, LLC		x		x	x
Viroopaksha Velishala	Pharmacy Depot		x			x
Barbara Petronzio	Pinnacle Pharmacy		x			x
Richard Nguyen	PX Drug Store		x			x
Vishal Gandhi	Red Chip of Nevada		x			x
Marlia Burke	Reliable Pharmacy		x			x
Gwendolyn S. Washington	Reliant Pharmacy Services		x			x
Joey Donoho, Pharm.D.	Riverview Regional Medical Center			X		x
Noureen Wadhwanian	Rx Compounding Solutions, LLC dba Pharma Care Plu		x			x



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Name	Business	No DEA	No Dispensing	Exempt By Statute	Waiver from electronic reporting	Approved
Connie Stroud	Rx Direct, Inc.		x			x
Kenneth Zielinski	Sentrix Pharmacy and Discount, LLC		x			x
Kristen Duncan	The Drug Store, Inc.			X		x
Randolph Baez	TLC Rx, LLC					x
Mark Landry	Total Life Care Rx Pharmacy, LLC		x			x
Gregg M. Smith	Transition Pharmacy		x			x
Sheeba Thomas	Twin Lakes Pharmacy, LLC		x		x	x
Cristina Lorenzo	Walgreens #1219-2		x			x
William R. Kitson	Walgreens #13873		x			x

Dr. Bess ask the committee to approve the attestations from ARCOS reporting. Mr. Earwood made the motion to approve the waivers from ARCOS reporting; Dr. Lindsay seconds the motion; and the motion carried to approve attestations from ARCOS reporting.

License Number	Company Name	Date	Responsible Person
4292	TheraCom, LLC 2	2/10/2016	Anthony Holben
4294	ASD Specialty Healthcare, Inc. 2	2/10/2016	Anthony Holben
2078	Accredo Health Group, Inc.	2/25/2016	Jack Beck
3123	Vanderbilt University Medical Center	4/13/2016	Jimmy Hayman
3834	Vanderbilt University Medical Center	4/13/2016	Jimmy Hayman
4387	Transcript Pharmacy, Inc.	5/17/2016	Clifton Osbon



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Medical Director for Special Projects – Dr. Mutter

- Reminded the committee of the symposia held around the state in Johnson City, Knoxville, Jackson, Upper Cumberland, and the addition of trying to target smaller cities this year.
- Updated the committee on the IMS data, and that this is prescription based and not morphine milligram equivalent based. Tennessee is still number two for number of prescriptions per capita in 2015.
- In the Top 50 this year: 29 APN's, 15 M.D.'s, 1 D.O., and 5 PA's
- Currently have 261 pain management clinics registered in the state and he expects that number will decline between now and July 1, 2016.
- Currently we still have about 30 percent of patients that were above 90 morphine **milligram equivalents**. Reiterated as of July 1, 2016 in order to be a pain management specialist you will have to have passed ABIPP 1 and 2.
- Final version of the pain clinic guidelines will be January 1, 2017, and it has to be sent for rule making before it is completed.
- Surgeon General will be in Knoxville on June 21, 2016.

BIV Report – Antoinette Welch

- Informed the committee that she has trained all twenty-one of her investigators to do pain clinic audits
- Created a group called Team 6, which is specialty, trained to do the audits for pill mill clinics.
- Invited the CSMD Committee to ride along with the investigators when doing an audit.
- Six audits completed and thirty-four year to date; one closed with no violation; two letter of warning; one was referred to OGC; and twenty-six was closed year to date.
- In May they had one new complaint, and they carried over twenty-three complaints and right now they have thirty-one complaints.

The meeting was adjourned at 11:45 a.m.