MEETING MINUTES

Florida Board of Pharmacy
Controlled Substances Standards Committee Meeting

August 10, 2015, 2 p.m.

Double Tree by Hilton
100 Fairway Dr.
Deerfield Beach, FL 33441

Committee Members
Gavin Meshad, Committee Chair
Michele Weizer, PharmD, BCPS, Board Chair
Jeffrey Mesaros, PharmD, J.D.
Debra Glass, BPharm
Jeenu Philip, BPharm

Special Committee Members
Michael Jackson, BPharm, Florida Pharmacy Association
Gary Cacciatore, Cardinal Health
Mark Rubenstein, M.D., Florida Medical Association
Harold Dalton, D.O., Fla. Society for Interventional Pain Physicians
Natasha Polster, Walgreens
Tom Davis, CVS
Anna Hayden, D.O., Florida Board of Osteopathic Medicine
Nabil El Sanadi, M.D. Florida Board of Medicine

Board Counsel
David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

Participants in this public meeting should be aware that these proceeding are being recorded.

Monday, August 10, 2015 – 2 p.m.

Mr. Meshad called this meeting to order at 2 pm.

All members were present. Tom Davis with CVS arrived at 2:09 pm.

1. Introductions

Mr. Meshad introduced the newest members to the committee. The new members were Anna Hayden, D.O., with the Florida Board of Osteopathic Medicine, Nabil El Sanadi, M.D., with the Florida Board of Medicine and Tom Davis with CVS.

2. Committee member updates
    a. Gary Cacciatore – DDC workgroups

Mr. Cacciatore stated the Florida Drug Wholesale Council met in last week in Tallahassee. He explained that wholesalers are regulated by the Department of Business and Professional Regulation. The council is made up of industry representatives, which includes three primary wholesalers, one secondary wholesaler, one pharmaceutical manufacturer, one hospital pharmacist, one physician, one Board of Pharmacy member and one member from the medical gas industry. Mr. Cacciatore stated he advised the council that the committee requested they address the issue of access to controlled substances.

He asked the council what the concerns were with language in Florida Statute 499.0121(15)(b) which is the section that applies to wholesalers. The statute states a wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable.

Mr. Cacciatore stated the council was interested in language regarding 5,000 dosage units per month and concern that the language is not consistent with DEA regulations. Due to DEA requirements they have a system to identify suspicious orders. There was general agreement that additional guidance from DEA would be most helpful to assist wholesalers. The council felt communication between the wholesale customer and wholesale distributor would be most beneficial to ensure adequate supply for the customer.

Mr. Cacciatore stated he thought most distributors have limitations and thresholds which are required by the DEA. He then stated all enforcement actions have been in regards to excessive quantities. He said the obligation under the DEA regulation is to design a system to detect suspicious orders. Mr. Cacciatore stated unusual size and frequency brings up suspicion.

Mr. Cacciatore stated the DEA seems hesitant to offer more guidance. The industry is looking for better guidance. He stated that the interpretation of this regulation has changed over the years.

Mr. Meshad believed supply, the pharmacies and fear of making a mistake are issues.

Mr. Jackson stated the stakeholders are struggling to get the product. They do not know what the thresholds are or what would trigger a review of a suspicious order.

3. Susan Langston, DEA

Ms. Langston with the DEA read a statement to the committee. To hear the entire statement please refer to the audio. http://ww10.doh.state.fl.us/pub/bop/Audio/Compounding%20Rules%20Committee/2015/Sterile_Compounding_Committee_08112015.MP3

Ms. Langston stated the patients' voices are being heard. The goal is to ensure legitimate pain patients receive what medication they need. Ms. Langston stated the DEA recognizes that prescriptions are being written by well recognized doctors. She then explained that a patient should not have to do the "pharmacy crawl" to obtain medication. She stated this problem needs to stop now. The DEA cannot make a pharmacy fill a prescription.

Ms. Langston stated the pharmacists do not need to fear the DEA, they simply need to use good judgement and use common sense when filling a prescription. All patients should be assessed individually. The pharmacist needs to get to know the patient.

The DEA does not impose a quota or threshold on the number of prescriptions a pharmacy can fill or the amount of drugs a pharmacy can purchase. The DEA cannot provide suspicious order guidance. The DEA can't control or direct how a distributor conducts business.

Mr. Jackson asked Ms. Langston how many registrations were surrendered. Ms. Langston stated she did not have an exact number. She then stated the DEA will put together an educational program for pharmacists.

Dr. El Sanadi asked Ms. Langston if the DEA had a consumer hotline. Ms. Langston replied that the DEA does not have an actual consumer hotline, but the DEA receives lots of calls through different DEA offices.

Mr. Meshad explained that pharmacists are fearful and it would help if the DEA was a part of laying the foundation. If the DEA was a part of it, it would be a valuable collaboration.

Dr. Dalton thanked Ms. Langston for being present during the meeting. He then stated there is confusion with the distributors. Can the DEA give better clarification to the distributors as far as how they should proceed moving forward? Ms. Langston stated the policies are handed down from DEA headquarters, but DEA headquarters are aware of what the distributors are looking for.

Mr. Meshad stated we need the DEA's participation with educating pharmacists. Everyone needs to come together.

4. Discussion – Successes/Solutions

a. Bob Parrado

Mr. Parrado suggested mandating prescribers view and document the PDMP profile of each patient prior to prescribing an opioid. He then suggested encouraging collaboration between the prescribers and the dispensers so each understands the regulatory pressure being placed on both professions. Mr. Parrado then referred to Rule 64B16-27.831. He stated this rule needed to be readdressed. He suggested the red flags listed in rule 27.831 be worded so as not to be seen as reasons to not refill a prescription. He then suggested that FAQs be placed on the Board of Pharmacy, the Board of Medicine and the Board of Osteopathic Medicine websites discussing the state and federal requirements for the prescribing of controlled substances.

Ms. Dudley liked the idea of placing FAQs on the website. She stated the Board office receives calls on a weekly basis.

Mr. Meshad stated we need more communication and more calls to be made if questions are raised when filling a prescription.

Dr. El Sanadi stated there needs to be more collaboration between the pharmacy and the medical doctor.

Mr. Meshad stated we need to create a subcommittee.

Department of Health MQA Division Director Lucy Gee stated an educational program is exactly what is needed.

b. Florida Society for Health System Pharmacists

Ms. Brown thanked the Board for allowing them to be present at the meeting. She then read a statement. For the full statement please refer to the audio.
http://ww10.doh.state.fl.us/pub/bop/Audio/Compounding%20Rules%20Committee/2015/Sterile_Compounding_Committee_08112015.MP3

c. Rule 64B16-27.831, F.A.C.

Mr. Meshad recommended a subcommittee be created. Mr. Flynn stated we need to come together and come up with ideas, maybe do a workshop in Tallahassee before the next committee meeting. Ms. Dudley stated we are looking for volunteers for the subcommittee. The following members volunteered: Jeff Mesaros, Michael Jackson, Harold Dalton, Gary Cacciatore and Jeenu Philip. Dr. Rubenstein stated he will get someone from the Florida Medical Association to participate.

5. Discussion – Education opportunities

a. Dr. Joseph Cammilleri

Mr. Phillip suggested that Dr. Cammilleri address the committee. Dr. Cammilleri is a pharmacist from Shands hospital who works with pain management doctors. Dr. Cammilleri stated the biggest push should be education. He believed a guide for professional refusals for not refilling a prescription would be helpful. He then stated he would like to see the Board mandate pharmacist CE.

Dr. Cammilleri stated supply is an issue especially with the independent pharmacies verses the big chains. He offered to help with the subcommittee anyway he could.

Mr. Meshad suggested everyone email their ideas to Ms. Dudley and she could pass them on the subcommittee.

Dr. Rubenstein stated both himself and Dr. Dalton both have prescriptions that get denied. He stated the pharmacists and the doctors should have open dialogue and open communication.

Mr. David with CVS stated through NABP there is a stakeholders group and recently published a consensus document centering on red flags. Mr. Meshad stated the consensus document was provided at the June committee meeting.

b. Example from other states (Arizona Best Practices document)

The subcommittee will look at ideas from other states.

Public Comments:

Please refer to the audio for all the public comments.

http://ww10.doh.state.fl.us/pub/bop/Audio/Compounding%20Rules%20Committee/2015/Sterile_Compounding_Committee_08112015.MP3

Mr. Meshad closed the meeting by encouraging everyone to email their ideas to the Board office.

Ms. Dudley stated she anticipated a 2 p.m. committee meeting in conjunction with the October board meeting.

Meeting ADJOURNED at 4:46 pm.