MEETING MINUTES

Florida Board of Pharmacy
Controlled Substances Standards Committee Meeting

October 5, 2015, 2 p.m.

Tampa Mariott Westshore
1001 N Westshore Blvd.
Tampa, Florida 33607

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
Joel Rose, D. O., Board of Osteopathic Medicine

Board Staff
Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

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.

Meeting called to order at 2 pm by Mr. Meshad.

Special Committee member Tom Davis was unable to attend. Mark Vernazza was present on his behalf.

Special Committee member Natasha Polster was unable to attend.

Special Committee member Mark Rubenstein was unable to attend.

Dr. Mesaros provided the committee with a recap of the September 21, 2015, sub-committee meeting that was held in Tallahassee. Dr. Mesaros stated the purpose of the sub-committee meeting was to work on proposed language for Rule 64B16-27.831, Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

Mr. Flynn provided the committee with proposed language that he and Ms. Dudley drafted at the direction of the subcommittee. Mr. Flynn suggested looking at the mandatory education section first. Mr. Meshad then read aloud the proposed mandatory education section. Mr. Flynn stated if the committee chooses not to go forward with proposed language of this rule, he would like to move forward with education in a different rule. The proposed education section read as follows:

Mandatory Continuing Education – All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:

- Ensuring access to controlled substances for all patients with a valid prescription;
- Use of the Prescription Drug Monitoring Database (PDMP);
- Assessment of prescriptions for appropriate therapeutic value;
- Detection of prescriptions not based on a legitimate medical purpose; and
- The laws and rules related to the prescribing and dispensing of controlled substances.

All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period.

After discussion, the committee voted to accept the proposed mandatory education section.

Motion: by Dr. Mesaros, to approve proposed education section. Motion carried.

Mr. Flynn suggested Ms. Dudley read off each section of the proposed rule language. After discussion, the committee agreed to the following language:

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. The Board recognizes that every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. The Board encourages pharmacists to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Valid Prescription - A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose. A prescription shall be deemed invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.

(2) Prescription Validation - Validating a prescription means the process and steps implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose. During the validation process, when the pharmacist is communicating with the patient or the prescriber, the pharmacist shall ensure that the communication cannot be overheard by others in the prescription dispensing area of the pharmacy. Neither a person nor a licensee shall interfere with the independent professional judgment of the pharmacist who is responsible for determining that the prescription is valid.

(3) Filling and Dispensing – When a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment through a prescription validation process deemed appropriate under the specific circumstances. If at any time during the validation process a pharmacist determines that in his or her independent professional judgment that the doubts or concerns about the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

(a) There are certain circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance. In the pharmacy community, these concerns

are often referred to as "red flags." A concern with the validity of a prescription does not mean the prescription shall not or cannot be filled. Rather, when a pharmacist has a concern with the validity of a prescription, a pharmacist shall attempt to resolve any concerns.

(b) Neither pharmacists nor pharmacies may refuse to fill a prescription for a controlled substance based ONLY on a concern or doubt about whether the prescription was issued for a legitimate medical purpose without first attempting to resolve the concerns and doubts through the following minimum validation process steps:

1. The pharmacist shall first verify or attempt to verify the identity of the person who presented the prescription to the pharmacy through proper identification issued by a state or the Federal Government that contains a photograph and a printed name with a signature or through a document as recognized in s. 893.055(14), Fla. Stat. (2015).

2. If the pharmacist has doubts or concerns about the validity of the prescription, the pharmacist may attempt to resolve concerns with the validity of the prescription by accessing the Prescription Drug Monitoring Database (PDMP).

3. If accessing the PDMP does not resolve the doubts or concerns with the validity of the prescription, the pharmacist must then attempt to validate the prescription with the prescriber or his or her agent prior to refusing to fill the prescription.

(4) Mandatory Continuing Education – All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:

(a) Ensuring access to controlled substances for all patients with a valid prescription;

(b) Use of the Prescription Drug Monitoring Database (PDMP);

(c) Assessment of prescriptions for appropriate therapeutic value;

(d) Detection of prescriptions not based on a legitimate medical purpose; and

(e) The laws and rules related to the prescribing and dispensing of controlled substances.

All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period.

(5) Electronic Prescriptions – All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of s.456.42(2), Fla. Stat. (2015), and pursuant to applicable federal law.

(6) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017, F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(7) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

Rulemaking Specific Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 456.072(1)(i), 465.0155, 465.003, 465.009, 465.016(1)(i), (s)(o), 465.017(2), 465.022(12), 893.04 FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

Mr. Meshad stated he liked how the Filling and Dispensing section did not list Red Flags, but instead gave steps to go through to validate a prescription. Pharmacists have just as much responsibility to follow through on their duties when they do a refusal as they do when filling a prescription.

Mr. Jackson stated that pharmacists are accessing the PDMP 90 percent of the time, amounting to 11 million checks.

Ms. Dudley said Board members have made it clear that the Board's interpretation of "written" includes electronically as federal law allows.

Dr. Mesaros said the rewrite provides balance. It doesn't say that pharmacists have to do all three steps and it doesn't say they should only do the three steps described.

The committee discussed possibly adding a documentation requirement, but decided it should be addressed during required education.

Motion: by Dr. Mesaros, to move proposed language to Full Board. Motion carried.

Motion: by Dr. Weizer, that proposed language changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Mr. Meshad then thanked the sub-committee members and advised there is no need for the sub-committee to continue meeting.

Gary Cacciatore with Cardinal Health was asked at the August 10, 2015, Controlled Substance Standards Committee to gather data from wholesaler perspective. He stated it was very difficult to find data but he believed Michael Jackson with FPA had surveyed his members. He then stated the GAO report included in the June committee materials reflects this problem and has become an industry standard. He stated he was able to look at his own company and verify the percentage of orders that were refused to ship. He stated Florida is no higher than other states. He made it clear to the committee he was only speaking for his company, Cardinal Health.

Mr. Cacciatore stated it would be helpful to the committee to hear from a broader industry. He then introduced Gary Riddle with HDMA. Mr. Riddle is the Vice President of State Government Affairs for Healthcare Distribution Management Association (HDMA). HDMA is the national association of representing primary pharmaceutical distributors who serve as vital link between nation's pharmaceutical manufacturers and healthcare providers.

Mr. Riddle stated HDMA is committed to lending their expertise in the delicate balance of legitimate access verses inappropriate use of prescription medicines when and wherever possible. He then stated the best way for the supply chain to strike the appropriate balance, in order to address both of these goals, is through more reliable and consistent communication.

Bob Parrado addressed the committee to discuss the validation and documentation of controlled substance prescriptions. Mr. Parrado stated the education program will be well received. He then stated he was happy the committee was working on these issues. Mr. Parrado stated documentation is essential and that having it in the rule may not be feasible, needs to be part of education.

Mr. Cacciatore recommended an article and chart he uses when teaching called "The Practitioner's Dilemma." He stated it would be a great resource when creating the educational program.

Please refer to the audio for the public comment portion:

http://floridaspharmacy.gov/meeting-information/past-meetings/

Motion: by Dr. Mesaros to ADJOURN at 4:18 pm.