AGENDA

Florida Board of Pharmacy
Controlled Substances Standards Committee Meeting

December 9, 2015, 2 p.m.

Residence Inn
600 W. Gaines St.
Tallahassee, Florida

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

Special Committee Members
Michael Jackson, BPharm, Florida Pharmacy Association
Gary Cacciatore, Cardinal Health
Harold Dalton, D.O., Fla. Society for Interventional Pain Physicians
Mark Rubenstein, M.D., Florida Medical Association
Natasha Polster, Walgreens
Mark Vernazza, CVS
Michelle Mendez, D.O., Board of Osteopathic Medicine

Board Counsel
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

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

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

Chair Gavin Meshad called the meeting to order at 2:01 p.m., Dec. 9, 2015.

1. Roll call

Harold Dalton and Mark Rubenstein were absent. FMA counsel Mary Thomas was in attendance for Dr. Rubenstein.

2. Update regarding Rule 64B16-27.831, Florida Administrative Code

Board Counsel David Flynn told committee members that the rule had been adopted Dec. 4 and would become effective Dec. 24, 2015. It covers the primary aspects that the committee identified as goals: education, guidelines for validating prescriptions, better communication and collaboration. The rule requires pharmacists to increase communication with patients and physicians and sets standards for refusing to fill a prescription.

Chair Gavin Meshad commended the board counsel and all involved, saying it was the fastest he had ever seen a rule go into effect. He also noted that he was pleased the rule referenced checking the PDMP, acknowledging one of the many tools pharmacists have available.

Executive Director Allison Dudley said continuing education requirements start with the current renewal biennium, meaning pharmacists must do the two hours for renewal in 2017. Companies and organizations who want to apply for qualifying courses need to use CE Broker and get approval from the Tripartite Committee.

Michael Jackson said feedback had so far been benign. Most people asked when the continuing education requirement would start and whether anything in 27.831 would be addressed during compliance checks. Ms. Dudley said it would not be a part of the inspection process.

Lucy Gee, division director for Medical Quality Assurance, the Department of Health division that oversees the Board of Pharmacy office, said the CE requirements will be a renewal requirement, but pharmacists will see the information in CE Broker.

Jeffrey Mesaros asked that the Board office put information on the website. Ms. Dudley said there will be a big announcement about the Dec. 24 effective date and relevant information.

3. Issues that may affect supply to pharmacies

- State and Federal Requirements for Wholesale Distributors
    - Section 499.0121(14), F.S. Storage and handling of prescription drugs; recordkeeping
    - 21 U.S.C. § 823(b), Registration Requirements
    - 21 CFR 1301.74(b), Registration of Manufacturers, Distributors and Dispensers of Controlled Substances
    - DEA presentation re Distributor Initiative

- Manufacturing Quotas
    - GAO Report

Mr. Meshad said issues that affect supply are more nebulous.

Ms. Dudley pointed committee members to state law in Chapter 499 and federal laws.

Gary Cacciatore said the most impact the Board of Pharmacy could have on the distribution side was to encourage pharmacists and pharmacies to communicate with wholesalers and suppliers. Know your customer requirements and respond when distributors send questionaires.

Mr. Cacciatore also serves on the Division and Drugs, Devices and Cosmetics' Drug Wholesale Distributor Advisory Council and said the council had discussed the 5,000 dosage number in state law again, once he advised them it was raised as an issue during the committee meetings. The council agreed to support any legislation to remove that language and make it consistent with DEA language, but currently none has been introduced for the 2016 session.

4. Other identifiable issues affecting access to controlled substances

Mr. Jackson said the committee talked about the prescription validation process. However, he also wanted discussion to continue on the issue of opioid abuse and misuse in Florida, which is still a problem. The Legislature just passed a measure that allows emergency responders to carry naloxone, an opioid antagonist used during an overdose situation.

Mr. Meshad said the committee was initially a committee brought together for that issue and, as a board member, he will continue to make sure it is part of the discussion.

5. Old Business/New Business

Mr. Meshad suggested the Board of Pharmacy share information with the Boards of Medicine and Osteopathic Medicine regarding the controlled substances issues discussed by the committee. Dr. Michelle Mendez said communication is essential and her board members have some concerns with what is being considered a valid prescription under the Pharmacy board's revised rule, that some pharmacists are overstepping their bounds.

Mr. Flynn said corresponding responsibility, under federal law, is more than just making sure the prescription was written by a licensed prescriber. Dr. Mendez said the osteopathic association should include information in its newsletter not to antagonize pharmacists when they call to better ensure that prescriptions are validated.

Ms. Dudley clarified that validation requirements to call the prescriber only address what needs to be done before a pharmacist denies filling a prescription, not in every situation.

FMA representative Mary Thomas said the association would discuss the rule during its January meeting.

Mr. Flynn stated that the committee seemed to be moving to the issue of communication and collaboration with patients and prescribers.

Ms. Gee said the Board of Medicine identified in its strategic planning meeting that it wanted to hold joint meetings with other boards, including Pharmacy. She said the controlled substance issue is a systemic one and suggested the boards coordinate schedules to hold a joint meeting. She committed the division to arranging for a joint meeting.

See the audio for public comments:
http://ww10.doh.state.fl.us/pub/bop/Audio/Controlled_Substance_Standards_Committee_06092015/Controlled_Substance_Committee_12092015.MP3

The meeting was adjourned at 3:36 p.m.