AGENDA

Florida Board of Pharmacy
Controlled Substance Standards Committee Meeting
October 3, 2017 – 8:00 a.m.

Rosen Plaza Hotel * 9700 International Drive
Orlando, FL 32819 * (407)996-9700

Committee Members:
Gavin Meshad, Chair
Debra Glass, BPharm
Jeenu Philip, BPharm
Michele Weizer, PharmD

Board Staff
C. Erica White, MBA, JD - Executive Director
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth – Gov. Analyst II

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

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. **August 2017 Committee Meeting – assignment updates**

2. **Presentations / Remarks/ Comments:**

   a. **Gary White, MPH, CPH**
   Associate Director, Hillsborough County Anti-Drug Alliance

   b. **Drew Winters, Esq.**
   Director, Division of Drugs, Devices and Cosmetics
   Department of Business & Professional Regulation

   c. **Rebecca R, Poston, BPharm, MHL, FCCM**
   Program Director , E-FORCSE - Florida's Prescription Drug Monitoring Program

3. **Rule 64B16-27.831 – The Standards of Practice for the Filing of Controlled Substances Prescriptions; Electronic Prescribing; Mandatory Education.**

4. **Old Business / New Business**

5. **Public Comment**

6. **Adjourn**

Controlled Substance Standards Committee Meeting
Research Assignments

PHYSICIAN ASKS: *(researched by Ms. Glass)*

1. Limiting physician prescribing through DEA restrictions.
2. Ensuring physicians follow CDC guidelines for the process in prescribing through FL adoption or adaptation.
3. Updating the mandatory Continuing Education (CE) for prescribers with the goal of more effective learning.
4. Limiting initial fills.

MANUFACTURER:

1. REMS aspect of pharmaceutical responsibility regarding manufacturing (*researched by Dr. Mesaros*)
2. Legal concerns and liability of pharmaceutical responsibility regarding manufacturing (*researched by Mr. Bisaillon*)

BETTER USE OF PDMP:

1. Better use of PDMP, including mandatory checking of PDMP, funding of PDMP, and sharing PDMP data across state lines (*researched by Dr. Mikhael*)
2. Current balance of MQA Pharmacy trust-fund and how it can be utilized for the PDMP (*trust fund aspect researched by Ms. White*)

MANDATORY COUNSELING:

1. Mandatory counseling by pharmacists of all patients prescribed opiates, including facilitation of take-back or disposal of unused medication (*researched by Dr. Alvarez*)
2. Mandatory Escribe for controlled substances (*researched by Mr. Philip*)

BETTER ACCESS TO REHAB:

1. Raising awareness and access to rehab for addicts, increasing qualified/certified providers of rehabilitation (*researched by Dr. Weizer*)

PHARMACY CS MANDATORY CE (*researched by Mr. Meshad and Mr. Flynn*)

1. Mandatory CE for pharmacy controlled substances, making this CE a "live" requirement and part of initial licensure.
2. Letters to the Deans of Florida Schools/Colleges of Pharmacy and Medicine.

499 DISPOSALS OF MEDICATION:

1. 499 drug take-back or disposal of unused medication (*researched by Mr. Philip*)

DEA Changes:

1. Research DEA rules for updates / changes (*researched by Dr. Mesaros*)

last updated August 26, 2017

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

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 regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Definitions: For purposes of this rule the following definitions shall apply:

(a) 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.

(b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.

(c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.

(2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, 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.

(a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

(b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

(c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

(3) Minimum Standards Before Refusing to Fill a Prescription.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;

2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

(5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of Section 456.42(2), F.S. (2015), and pursuant to applicable federal law. For more information related to the federal requirements, access http://www.deadiversion.usdoj.gov/ecomm/index.html.

(6) 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 Program's Database;

(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.

(7) Summary Record: 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 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History–New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.

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(1) Through (5) NO CHANGE

(6) Mandatory Continuing Education:

(a) All pharmacists shall complete a Board-approved 2-hour continuing education course on the **Validation of Prescriptions for 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. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period. After the biennium ending on September 30, 2017, the continuing education course must be taken through an in-person seminar or a live interactive video teleconference. The course content shall include the following:

1. Ensuring access to controlled substances for all patients with a valid prescription;
2. Use of the Prescription Drug Monitoring Program's Database;
3. Assessment of prescriptions for appropriate therapeutic value;
4. Detection of prescriptions not based on a legitimate medical purpose; and,
5. The laws and rules related to the prescribing and dispensing of controlled.

(b) All pharmacists shall complete a Board-approved 1-hour continuing education course on **Opioid Addiction Prevention**. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2019. A 1-hour course shall be taken every biennium thereafter. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period. The continuing education course must be taken through an in-person seminar or a live interactive video teleconference. The course content shall include the following:

1. Counseling of patients who have opioid prescriptions;
2. _____;
3. _____;
4. _____; and
5. _____.

(c) An applicant for licensure as a pharmacist shall be awarded credit for the continuing education mandated by paragraphs (a) and (b) if the applicant took the course(s) as a student at an accredited pharmacy school. To receive credit, the course(s) must have been taken during the applicant's final year of pharmacy school and the application for licensure must be received no later than 1-year following graduation.

(d) The continuing education required by paragraphs (a) and (b) shall count towards the required 30 hours of CE necessary for licensure renewal, and the 10 hours of "live" CE mandated by rule 64B16-26.103(1)(m).

(7) Summary Record: 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 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History–New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.