AGENDA

Florida Board of Pharmacy
Controlled Substance Standards Committee Meeting

April 2, 2018 – 3:00 p.m.

Residence Inn Tallahassee Universities at the Capitol,
600 West Gaines Street, Tallahassee, Florida 32304, 850-329-9080

Committee Members:
Gavin Meshad, Chair
David Bisaillon
Jeffrey Mesaros, PharmD, JD
Richard Montgomery, BPharm, MBA
Jeenu Philip, BPharm

Board Staff
C. Erica White, MBA, JD - Executive Director
Savada Knight, Regulatory Supervisor

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. **64B16-27.831 – Standard of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education (pg. 4)**
   a. Comprehensive Review Related to Mandatory Continuing Education
   b. Review JAPC Correspondence to Pending Notice of Proposed Rule
   c. Review Recommended Changes Based on JAPC

2. **64B16-27.831 – Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education (pg. 10)**
   a. Comprehensive Review for Necessary Changes and Updates
   b. Review and Discussion of Adding Proposed Mandatory Counseling for Opioid Naive Patients.

3. **64B16-27.810 - Prospective Drug Use Review (pg. 12)**
   a. Comprehensive Review for Necessary Changes and Updates
   b. Review and Discussion of Proposed Changes

4. **64B16-27.820 - Patient Counseling (pg. 14)**
   a. Comprehensive Review for Necessary Changes and Updates
   b. Review and Discussion of Proposed Changes

5. **Policy and Procedures Related to Dispensing of Opioid Prescriptions**

6. **2018 Legislation Impacting or Relating to Controlled Substances**

7. **Old Business / New Business**

6. **Public Comment**

7. **Adjourn**

TAB #1

THE FULL TEXT OF THE PROPOSED RULE IS:

The underlined and struck through text in black represents the approved changes at the February board meeting. The red underlined and struck though text represents additional recommended changes based on further review and JAPC comments.

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) through (5) No change.

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

(a) through (c) No change.

(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.~~

(f) Proper disposal of unused controlled substances;

(g) Protocols for addressing and resolving problems recognized during the drug utilization review to include but not limited to the following:

1. drug /drug interactions;

2. side effects; and

3. high dose/low dose guidelines.~~; and~~

~~4. section 381.887, F.S., Emergency treatment for suspected opioid overdoses and the State Surgeon General's Statewide Standing Order for Naloxone~~.

(h) Education on the provision of section 381.887, F.S., Emergency treatment for suspected opioid overdoses and on the State Surgeon General's Statewide Standing Order for Naloxone (eff. May 19, 2017).

(i)~~(h)~~ Pharmacist initiated counseling of patients with opioid prescriptions; and

(j)~~(i)~~ Available treatment resources for opioid physical dependence, addiction, misuse, or abuse.

(7) All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2019. 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. A licensee who completed the mandated Validation of Prescription for Controlled Substances course between October 1, 2017 and May 1, 2018, shall be deemed to have complied with this subsection for the biennium ending on September 30, 2019.

(8)~~(7)~~ No change.

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,_____.

JOE NEGRON
President

RICHARD CORCORAN
Speaker

THE FLORIDA LEGISLATURE

JOINT ADMINISTRATIVE PROCEDURES COMMITTEE

Senator Kevin Rader, Chair
Representative George R. Moraitis, Jr., Vice Chair
Senator Daphne Campbell
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Representative Amy Mercado
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March 6, 2018

Mr. David Flynn
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

Re: Department of Health: Board of Pharmacy
Proposed Rule 64B16-27.831

Dear Mr. Flynn:

I have reviewed proposed rule 64B16-27.831, "Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education," which was advertised in the Florida Administrative Register on February 19, 2018. I have the following comments.

64B16-27.831(6)(g)4.: The two hour continuing education course on the Validation and Counseling of Prescriptions for Controlled Substances and Opioids must include protocols for addressing and resolving problems recognized during the drug utilization review to include: section 381.887, emergency treatment for suspected opioid overdoses and the State Surgeon General's Statewide Standing Order for Naloxone.

Please provide a copy of the "State Surgeon General's Statewide Standing Order for Naloxone" to the committee for review. Further, it appears the board is requiring the mandatory continuing education course to include a protocol addressing this order, and therefore it appears this document should be specifically incorporated by reference in the rule text. As with all incorporated material, the board should comply with the requirements of section 120.54(1)(i) and rule 1-1.013. Please specifically incorporate the State Surgeon General's Statewide

Standing Order for Naloxone by reference in the rule text or explain why this is not required. *See* § 120.545(1)(i), Fla. Stat.

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General
Mr. Lawrence Harris, Assistant Attorney General

MH :DF WORD/MARJORIE/64B16_27.831LS030618_164324

STATE OF FLORIDA

OFFICE OF THE GOVERNOR
EXECUTIVE ORDER NUMBER 18-47
(Opioid Epidemic Extension)

WHEREAS, the Centers for Disease Control and Prevention has declared a national opioid epidemic which poses a severe threat to the State of Florida and requires that measures are taken to protect the communities and the general welfare of this State; and

WHEREAS, on May 3, 2017, I issued executive order 17-146 declaring that the opioid epidemic threatens the State of Florida with an emergency, and as a consequence of this danger a state of emergency exists in the State of Florida; and

WHEREAS, I have subsequently issued executive orders 17-177, 17-178, 17-230, 17-285, and 17-329 extending the state of emergency through February 20, 2018; and

WHEREAS, no state of emergency declared pursuant to the Florida Emergency Management Act may continue for more than 60 days unless renewed by the Governor; and

WHEREAS, the opioid epidemic continues to pose an immediate threat to the health, safety, and welfare of the State of Florida and its residents.

NOW, THEREFORE, I, RICK SCOTT, as Governor of Florida, by virtue of the authority vested in me by Article IV, Section 1 (a) of the Florida Constitution and by the Public Health Act, and all other applicable laws, promulgate the following Executive Order, to take immediate effect:

Section 1. The state of emergency declared in Executive Order 17-146 on May 3, 2017 and extended by executive orders 17-177, 17-178, 17-230, 17-285, and 17-329 will be extended for 60 days following the issuance of this order.

Section 2. Except as amended herein, Executive Orders 17-177, 17-178, 17-230, 17-285, and 17-329 are ratified and reaffirmed.

Section 3. This Executive Order will expire 60 days from this date unless extended within that time.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Florida to be affixed, at Tallahassee, this 19th day of February 2018.

GOVERNOR

ATTEST:

SECRETARY OF STATE

FILED
2018 FEB 19 AM 11:43
DEPARTMENT OF STATE
TALLAHASSEE, FLORIDA

STATE OF FLORIDA
SECOND AMENDED
DEPARTMENT OF HEALTH
DECLARATION OF PUBLIC HEALTH EMERGENCY
AND STATEWIDE STANDING ORDER FOR NALOXONE

WHEREAS, on May 19, 2017, Governor Rick Scott declared that the opioid epidemic threatens the State of Florida with an emergency, and that as a consequence of this danger a state of emergency exists in the State of Florida; and

WHEREAS, the Centers for Disease Control and Prevention has declared a national opioid epidemic which poses a severe threat to the State of Florida and requires that measures are taken to protect the communities and the general welfare of this State; and

WHEREAS, in 2015, opioids were responsible for nearly 3,900 deaths in Florida; and

WHEREAS, opioid abuse has required additional resources from local first responders such as law enforcement, firefighters, and emergency medical services; and

WHEREAS, in 2016, Florida enacted the "Emergency Treatment and Recovery Act" which authorized health care practitioners to prescribe and dispense opioid antagonists to patients, caregivers and first responders pursuant to a non-patient-specific standing order for the emergency treatment of known or suspected opioid overdoses occurring when a health care practitioner is not available; and

WHEREAS, pharmacists are authorized to dispense an appropriately labeled opioid antagonist based on a non-patient-specific standing order for an autoinjection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use; and

WHEREAS, the Act authorizes emergency responders, including but not limited to, law enforcement officers, paramedics and emergency medical technicians, to possess, store and administer emergency opioid antagonists as clinically indicated; and

WHEREAS, immunity from civil liability is provided under section 768.13, Florida Statutes, the Good Samaritan Act, to any person, including health care practitioners and emergency responders, who possess, administer or store an approved opioid antagonist in accordance with the Act. A health care practitioner acting in good faith and exercising reasonable care is not subject to discipline under the applicable professional licensure statute and is also immune from civil or criminal liability for prescribing or dispensing an opioid antagonist in accordance with the Act.

NOW, THEREFORE, I, Celeste Philip, MD, MPH, Surgeon General of Florida and State Health Officer, by virtue of Executive Order Number 17-146 issued by Governor Rick Scott and the authority vested in me by section 381.00315, Florida Statutes, do hereby declare the following:

Section 1: A Public Health Emergency is declared statewide.

Section 2: As directed by Executive Order Number 17-146, the following Florida standing order for Naloxone is issued.

Naloxone Standing Order

This order authorizes pharmacists who maintain a current active license practicing in a pharmacy located in Florida that maintains a current active pharmacy permit to dispense one of the following naloxone formulations to emergency responders for administration to persons exhibiting signs of opioid overdose. Emergency responders include law enforcement officers, firefighters, paramedics and emergency medical technicians.

The pharmacy must maintain a copy of the naloxone Standing Order if dispensing naloxone pursuant to the order.

Incorporated in this Naloxone Standing Order is the expectation that the SAMHSA Opioid Overdose Prevention Toolkit Five Essential Steps for First Responders be followed.

Approved Options for Intranasal or Auto-Injector Administration:

Intranasal	Auto-Injector	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 0.4 mg **or** 2mg #1 twin pack SIG: Inject one auto-injector into the outer thigh (through clothing if necessary) upon signs of opioid overdose Call 911 May repeat x 1 in 2 to 3 minutes No kit is required. Product is commercially available	Narcan Nasal Spray 4mg, #2 SIG: Administer a single spray intranasally into one nostril. Call 911. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. No kit is required. Product is commercially available.

Executed this 19th day of May, 2017, in Department of Health Offices, Tallahassee, Leon County, Florida.

Celeste Philip, MD, MPH
Surgeon General and Secretary

TAB #2

Proposed Language for Discussion
Mandatory Counseling of Opioid Naïve Patients

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Mandatory Counseling; 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) through (c) NO CHANGE

(d) Opioid Naïve Patient. An opioid naïve patient is a patient that has not filled a prescription for a Schedule II or Schedule III opioid, as defined in s. 893.03, F.S., within the last 180 days.

(2) NO CHANGE

(3) Mandatory Counseling for Schedule II or Schedule III Opioid Prescriptions: Prior to dispensing any opioid prescription for a Scheduled II or Schedule III controlled substance to an opioid naïve patient, the dispensing pharmacist shall conduct a mandatory counseling session with the patient or the patient's agent.

(a) The counseling session shall include, but is not limited to, the following:

1. Proper use of the controlled substance as prescribed;
2. Alternative non-opioid options for managing pain;
3. Drug/Drug Interactions;
4. Side effects;
5. Proper disposal of unused medication;
6. Warning signs of abuse;
7. Emergency treatment for suspected opioid overdose; and
8. Available treatment resources for opioid physical dependence, addiction, misuse, or abuse.

(b) The counseling session shall be provided by in one of the following ways:

1. In person;

2 Via telephonic communication; or

2. In an interactive digital image format.

(c) If the patient or the patient's agent refuses the counseling session the prescription shall not be dispensed.

(4)~~(3)~~ through (8) ~~(7)~~ NO CHANGE

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.

TAB #3

Proposed Recommended Changes for Discussion

64B16-27.810 Prospective Drug Use Review.

(1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contraindications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or duration of drug treatment;

(f) Drug-allergy interactions;

(g) Physical dependence , addiction, misuse, or abuse. ~~Clinical abuse/misuse~~

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber or mandatory patient counseling.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.810, 61F10-27.810, 59X-27.810.

TAB #4

64B16-27.820 Patient Counseling.

(1) Upon receipt of a new or refill prescription, the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present. If the delivery of the drugs to the patient or the patient's agent is not made at the pharmacy the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. If the patient does not refuse such counseling, the pharmacist, or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist, shall review the patient's record and personally discuss matters which will enhance or optimize drug therapy with each patient or agent of such patient. Such discussion shall be in person, whenever practicable, ~~or~~ by toll-free telephonic communication, or by an interactive digital image format, and shall include appropriate elements of patient counseling. Such elements may include, in the professional judgment of the pharmacist, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) Intended use of the drug and expected action (if indicated by the prescribing health care practitioner);

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage;

(h) Prescription refill information;

(i) Action to be taken in the event of a missed dose; ~~and,~~

(j) The potential for physical dependence, addiction, misuse, or abuse; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Patient counseling as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

(3) With respect to controlled substance prescriptions, particularly opioids, licensees shall take extra care in determining whether patient counseling and education is warranted and necessary. Accordingly, for each new or refill prescription for controlled substances, a pharmacist shall, in addition to the requirements of Rules 64B16-27.810, F.A.C., determine whether mandatory patient counseling is required before a prescription for a controlled substance is dispensed.

(4) ~~(3)~~ A pharmacist shall not be required to counsel a patient or a patient's agent when the patient or patient's agent refuses such consultation. In the case of a controlled substance, if the pharmacist determines that mandatory patient counseling is required and the patient refuses such counseling, the pharmacist shall document such refusal in the patient's record and shall refuse to dispense the prescription.

(5) When a pharmacist is filling and dispensing a Schedule II or III opioid prescription for an opioid naïve patient, the mandatory counseling provision in rule 64B16-27.831, F.A.C., shall control.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.820, 61F10-27.820, 59X-27.820